

# 24-Month Outcomes From The Pivotal VISION Trial for OCT-Guided Directional Atherectomy



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THE PERIPHERAL EVENT OF THE YEAR

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# Disclosures

## **Speaker's Bureau:**

- Penumbra
- W. L. Gore
- Avinger

## **Honorarium:**

- Penumbra
- W.L. Gore
- Cook inc

## **Stockholder:**

- Penumbra
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## **Medical/Scientific Boards:**

- Abbott
- Boston Scientific

# Image-Guided Directional Atherectomy



## Pantheris

110 cm working length  
.014" guidewire compatible  
Cutter rotation = 1,000 RPM  
OCT – frequency domain

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# VISION TRIAL OVERVIEW

## VISION TRIAL DESIGN

- Prospective, single arm, global trial
- 19 U.S. sites
- 1 German site

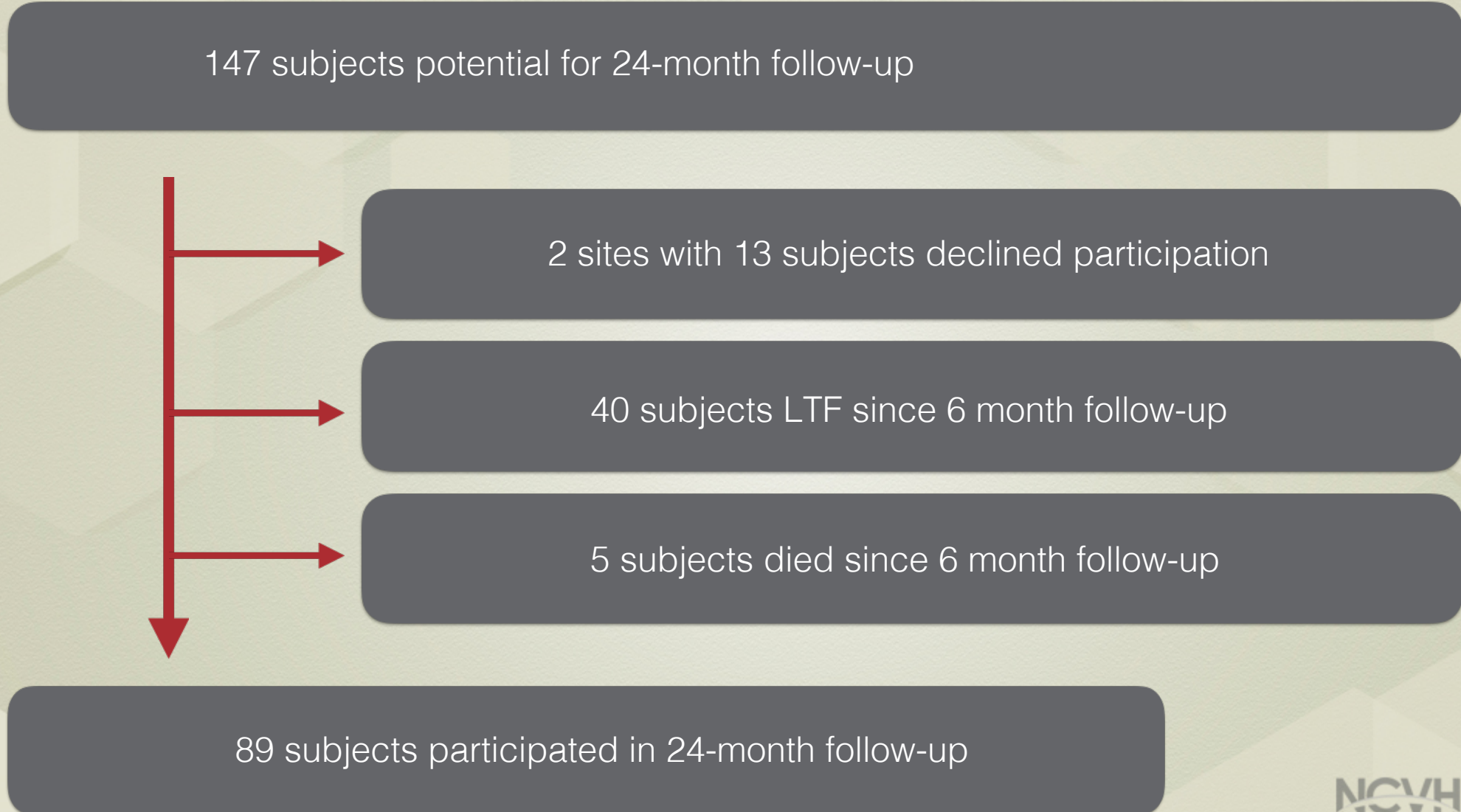
## MAJOR INCLUSION CRITERIA

- RVD  $\geq 3.0\text{mm}$  and  $\leq 7.0\text{mm}$  by visual estimation
- $\geq 70\%$  *de novo* lesion
- Rutherford classification 2-5
- $\leq 15\text{cm}$  lesion length
- $\geq 1$  patent runoff vessel
- Patient is  $\geq 18$  years old
- Patient is candidate for percutaneous intervention for PAD

## MAJOR EXCLUSION CRITERIA

- In-stent restenosis within the target lesion
- Target lesion stenosis  $<70\%$
- Target lesion within a graft or iliac artery
- Moderate-severe calcification
- Acute ischemia/thrombosis

# FOLLOW-UP AT 24 MONTHS POST-PROCEDURE



# BASELINE DEMOGRAPHICS & CO-MORBIDITIES

Demographics <sup>1</sup>	All Treated Cohort (N=152 Subjects)
Age (yrs)	
Mean ± Stdev	67 ± 10.5
Sex % (m/N)	
Male	55 %
Female	45 %
BMI	
Mean ± Stdev	28 ± 6.2

Co-morbidities <sup>1</sup>	All Treated Cohort (N=152 Subjects)
History of :	% (m/N)
Smoking	87.5% (133/152)
Diabetes requiring therapy	45.4% (69/152)
Hypertension requiring intervention	94.7% (144/152)
Coronary artery disease	62.5% (95/152)
Other vascular disease	88.8% (135/152)

<sup>1</sup> Site reported data.

# BASELINE LESION CHARACTERISTICS

Baseline Lesion Characteristics	All Treated Cohort (N=198 Lesions) <sup>3</sup>
Lesion Location <sup>1</sup> , % (m/N)	
SFA	80.8% (160/198)
Proximal	18.2% (36/198)
Mid	38.9% (77/198)
Distal	23.7% (47/198)
SFA/Popliteal	6.1% (12/198)
Popliteal	13.1% (26/198)
TASC <sup>1</sup> , % (m/N)	
A	76.5% (150/196)
B	20.4% (40/196)
C	3.1% (6/196)
Califications <sup>2</sup> , % (m/N)	
None	21.7% (43/198)
Mild	77.3% (153/198)
Moderate	0.5% (1/198)
Lesions Type <sup>2</sup> , % (m/N)	
De Novo	99.5% (197/198)
Restenotic	0.5% (1/198)
Lesion Length <sup>1</sup> , (cm)	
Mean ± Stdev (N)	7.2 ± 4.2 (198)
CTOSubgroup, Mean ± Stdev (N)	10.7 ± 4.5 (40)
Mean Reference Vessel Diameter <sup>1</sup> , (mm)	
Mean ± Stdev (N)	4.7 ± 0.8 (196)
Percent Pre-Procedure Stenosis <sup>1</sup> , (%)	
Mean ± Stdev (N)	78.7 ± 15.1 (196)

<sup>1</sup> Assessed by Imaging Core lab. <sup>2</sup> Site reported. <sup>3</sup> Denominators <198 lesions reflect missing data.

# MAJOR ADVERSE EVENTS THROUGH 6 MONTHS

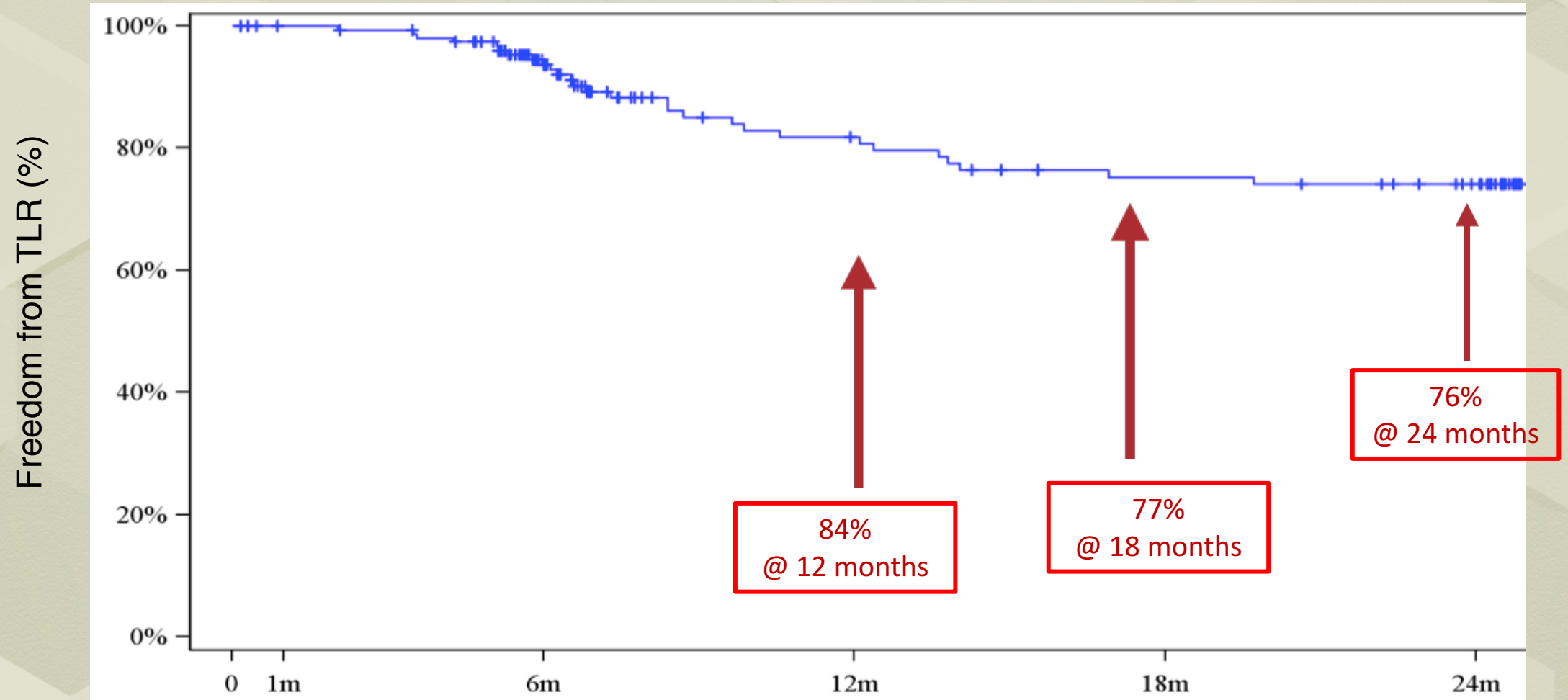
6 Month MAE <sup>1</sup>	All Treated Cohort (N=152 patients <sup>2</sup> )	
Overall MAEs	16.4% (25/152)	
Cardiovascular-related death	2.6% (4/152)	
Unplanned, major index limb amputation	0% (0/152)	
Target lesion revascularization (TLR)	7.9% (12/152)	
Myocardial infarction	2.0% (3/152)	
Device-related events	4.0% (6/152)	
	Pantheris Related	Occlusion Sheath Related
Clinically significant perforation	0.0% (0/152)	0.0% (0/152)
Clinically significant dissection	0.6% (1/152)	0.6% (1/152)
Clinically significant embolus	2.6% (4/152)	0.0% (0/152)
Pseudoaneurysm	0.0% (0/152)	0.6% (1/152)

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<sup>1</sup> Adjudicated by independent Clinical Events Committee (CEC). <sup>2</sup> Excludes 7 subjects who were not followed through 6 months.



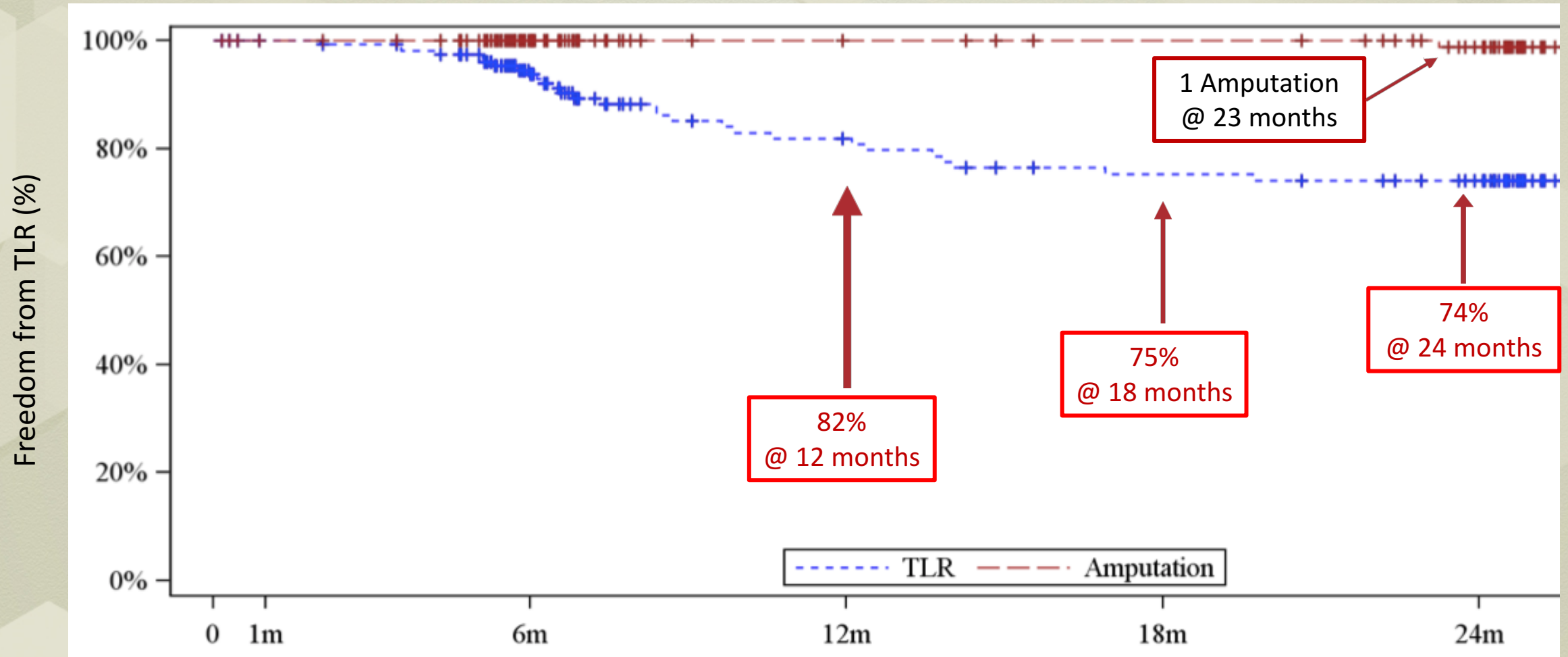
# 24 MONTH OUTCOMES FREEDOM FROM TLR BY LESION



Months since directional atherectomy with Pantheris catheter

# 24 MONTH OUTCOMES

## FREEDOM FROM TLR AND AMPUTATION BY PATIENT

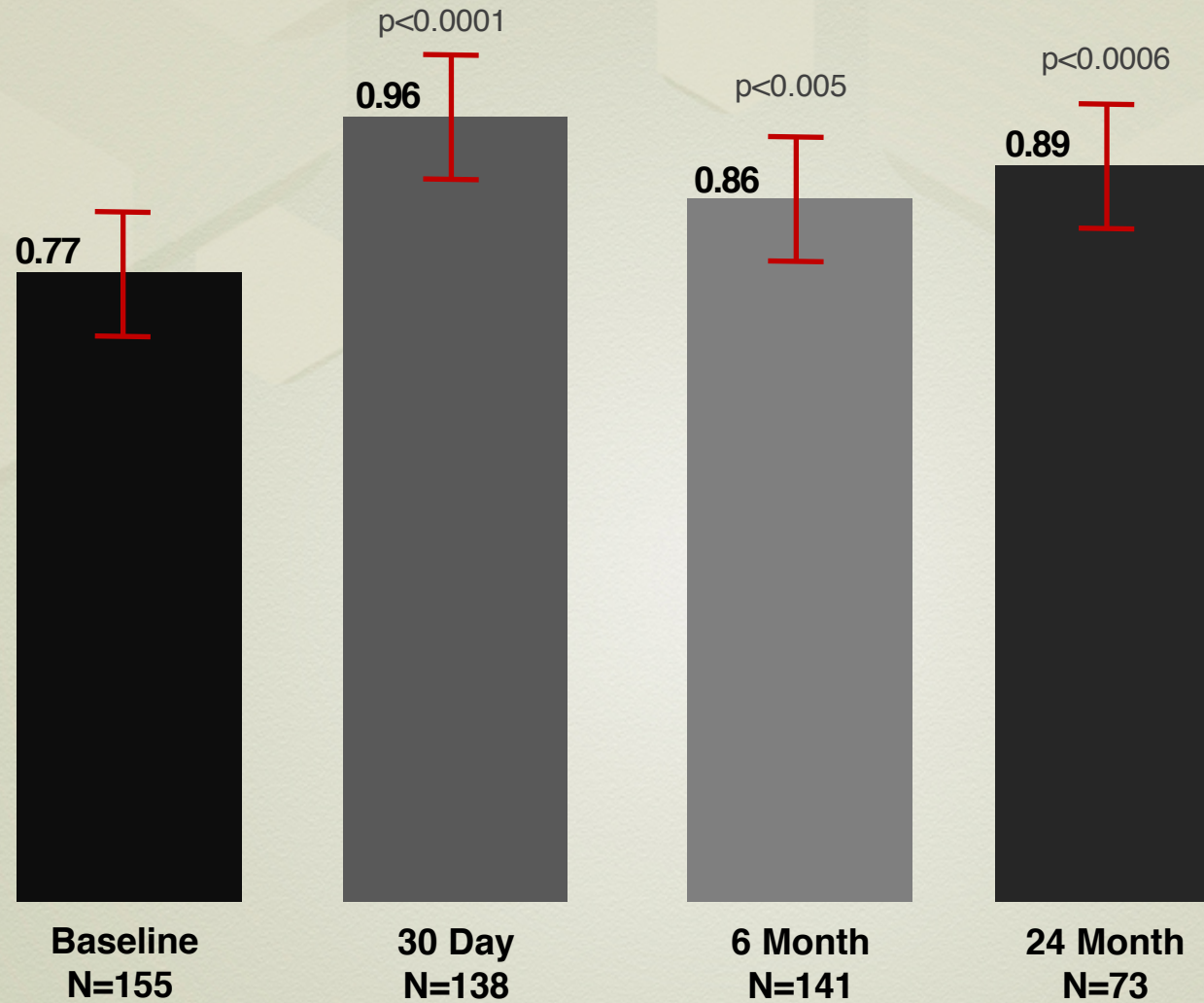


Months since directional atherectomy with Pantheris catheter

# RUTHERFORD CLASSIFICATION 30 DAYS, 6 MONTHS & 24 MONTHS

Rutherford Classification	Baseline (n=158)	30 Days (n=148) P<0.0001	6 Months (n=144) P<0.0001	24 Months (n=82) P<0.001
0 Asymptomatic	0% (0/158)	54.1% (80/148)	41.0% (59/144)	48% (40/82)
1 Mild Claudication	0% (0/158)	29.1% (43/148)	30.6% (44/144)	24.4% (20/82)
2 Moderate Claudication	29.1% (46/158)	11.5% (17/148)	13.2% (19/144)	12.2% (10/82)
3 Severe Claudication	54.4% (86/158)	4.7% (7/148)	10.4% (15/144)	9.8% (8/82)
4 Ischemic Rest	13.9% (22/158)	0% (0/148)	2.8% (4/144)	4.9% (4/82)
5 Minor Tissue Loss	2.5% (4/158)	0.7% (1/148)	2.1% (3/144)	0% (0/82)

# ANKLE BRACHIAL INDEX (ABI) 30 DAYS, 6 MONTHS & 24 MONTHS



# CHARACTERISTICS OF TLR OCCURRENCE BY LESION

Characteristic	TLR (N = 19)	No TLR (N=83)	
Mean Percentage of CTO prior to Atherectomy	41.2% (7/17)	18.1% (15/83)	p = 0.05
Lesion Length < 5 cm	35.3% (6/17)	62.7% (52/83)	p = 0.05
Lesion Length ≥ 5 cm	64.7% (11/17)	37.3% (31/83)	p = 0.05
Mean Percent Area of Thrombus	12.8% (19/19)	6.4% (82/83)	p = 0.02
Mean Percent Area of Adventitial Resection	4.9% (19/19)	3.4% (82/83)	p = 0.54

TLRs associated with CTOs, longer lesions, and double the area of thrombus.

# EXPERIENCE WITH PANTHERIS and CLINICAL USE

	≤ 2 uses	< 5 uses	≥ 5 uses	> 10 uses	Comparing ≤ 2 uses to > 10 uses
Mean number of excisions made	10.9 ± 5.3	11.2 ± 5.8	12.7 ± 9.2	15.1 ± 12.0	<i>p</i> = 0.04
Mean baseline lesion length	5.0 ± 3.6 cm	5.0 ± 3.7 cm	5.8 ± 4.5	7.9 ± 5.9	<i>p</i> = 0.01
Mean percent area adventitial resection	4.2 ± 10.6	3.5 ± 8.9	2.3 ± 4.5	0.49 ± 0.9	<i>p</i> = 0.01
Mean fluoro time used	32.8 ± 13.5 minutes	30.4 ± 13.5 minutes	28.1 ± 13.6 minutes	24.6 ± 11.9 minutes	<i>p</i> = 0.05

As surgeons gain experience with the Pantheris catheter, they tend to make more excisions, approach longer lesions, use less fluoro, and resect less adventitial tissue.

# CONCLUSIONS

- 1) Freedom from TLR:
  - 76% by lesion at 24 months
  - 74% by subject at 24 months
- 2) Only one amputation in 152 subjects, occurring at 23 months post-procedure
- 3) Statistically significant improvements in Rutherford and ABI noted at 6 months were maintained through 24 months
- 4) OCT-guided atherectomy results in effective and sustainable treatment of peripheral artery disease
  - >50% standalone atherectomy rate (104/198 lesions)
  - Low use of stents post-atherectomy - rate 5.1% (10/198 lesions)
  - Low use of drug-coated balloons post-atherectomy - rate 9.6% (19/198 lesions)

NOTE: Data in this presentation remain subject to adjustment based on final statistical analysis and review by the study's clinical events committee