

The LINC logo features a stylized graphic of three curved lines in red, orange, and yellow, resembling a flame or a dynamic shape, positioned to the left of the text 'LINC'.The TOBA II BTK logo consists of the text 'TOBA II BTK' in a bold, blue, sans-serif font. The 'O' in 'TOBA' is replaced by a blue circle with a green arrow pointing clockwise. Below the main text, the words 'TACK OPTIMIZED BALLOON ANGIOPLASTY' are written in a smaller, white, sans-serif font, with each word underlined.

Repairing BTK dissection: Results from the TOBA II BTK pivotal study

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Disclosure

George Adams

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Critical Limb Ischemia

CLI currently afflicts 2-3.4 million in the US¹

- Forecast to exceed 4 million by 2030¹

Plain angioplasty is standard therapy

- Historically suboptimal results
- 30.7% dissection rate^{2,3}
- Underestimated: medial calcium, bone interference and small RVD⁴
 - Predictor for infrapopliteal restenosis⁵

No approved implant for BTK in the US



¹Yost, The Sage Group 2016

²Zeller, *J Am Coll Cardiol* 2014

³Fanelli, *J Cardiovasc Surg* 2014

⁴Razavi, *J Vasc Interv Radiol* 2014

⁵Schillinger, *Radiology* 2002

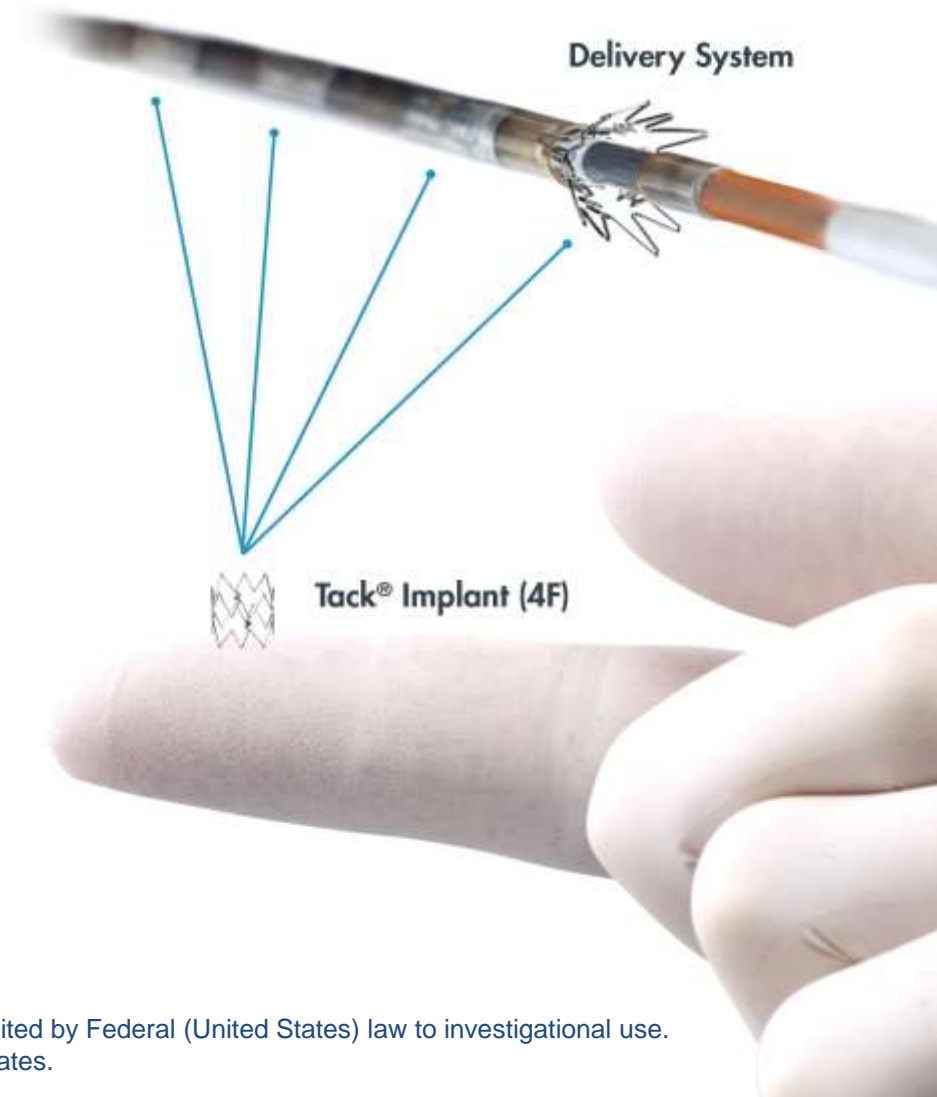
Tack Endovascular System®

Tack® Implants

- Four pre-loaded nitinol implants
- 6mm deployed length
- Each implant self-sizes to tapering BTK anatomy
 - 1.5 – 4.5mm RVD

OTW Delivery System

- 4F / .014"
- 150cm working length
- Accurate ($\leq 1\text{mm}$) deployment



TOBA Dissection Repair Trials (N=820)

ATK	TOBA (N=138)	Prospective, single arm 13 European sites	<i>Journal of Vascular Surgery</i> ¹	
			89.5% 12m K-M Freedom from CD-TLR 76.4% 12m K-M patency rate	98.5% Technical success rate
	TOBA II (N=213) <i>Pivotal IDE</i>	Prospective, single arm 33 US/European sites POBA or Lutonix® DCB	<i>JACC: Cardiovascular Interventions</i> ²	
		86.5% 12m K-M Freedom from CD-TLR 79.3% K-M Patency rate	0.5% Bail out stent rate 92.1% Dissection resolution	
	TOBA III (N=201)	Prospective, single arm 14 European sites IN.PACT™ Admiral™	12m data presented at TCT 2019*	
			97.5% 12m K-M Freedom from CD-TLR 95.0% K-M Patency rate	0.6% Bail out stent rate 97.7% Dissection resolution
BTK	TOBA BTK (N=35)	Prospective, single arm 6 European/New Zealand sites	<i>Catheterization and Cardiovascular Intervention</i> ³	
			93.5% 12m K-M Freedom from CD-TLR 84.5% 12m Amputation-free survival	78.4% K-M Patency rate
	TOBA II BTK (N=233) <i>Pivotal IDE</i>	Prospective, single arm 41 US/international sites	First presentation of 6m pivotal data in Europe at LINC 2020	

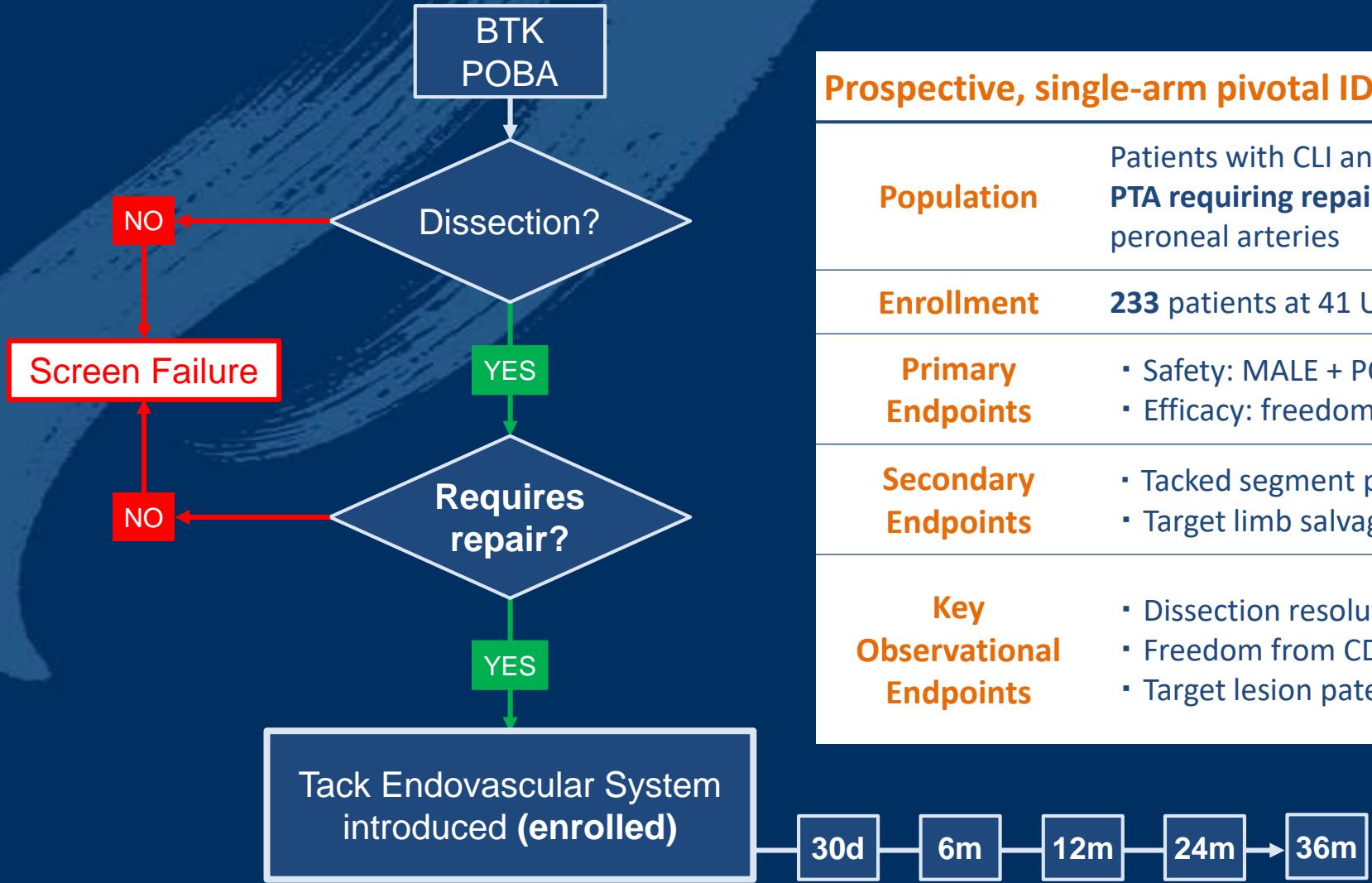
*12m results from standard lesion group (n =169); an additional 32 patients with long lesions (>15 - ≤25cm) were enrolled and analyzed separately

¹Bosiers, *J Vasc Surg* 2016

²Gray, *J Am Coll Cardiol: Cardiovasc Interv* 2019

³Brodmann, *Cathet Cardiovasc Interv* 2018

TOBA II BTK Study Design and Endpoints



Prospective, single-arm pivotal IDE study	
Population	Patients with CLI and angiographic evidence of a dissection post-PTA requiring repair in the mid/distal popliteal, tibial and/or peroneal arteries
Enrollment	233 patients at 41 US, international sites
Primary Endpoints	<ul style="list-style-type: none"> Safety: MALE + POD at 30d Efficacy: freedom from MALE at 6m + POD at 30d
Secondary Endpoints	<ul style="list-style-type: none"> Tacked segment patency at 6 months (DUS flow/no flow) Target limb salvage at 6 months
Key Observational Endpoints	<ul style="list-style-type: none"> Dissection resolution Freedom from CD-TLR Target lesion patency Changes from baseline: <ul style="list-style-type: none"> -Rutherford -Wound status -Quality of life

MALE + POD: composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis

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Duplex Ultrasound Core Lab: VasCore (Boston, MA)

TOBA II BTK Key Eligibility Criteria

Key Inclusion

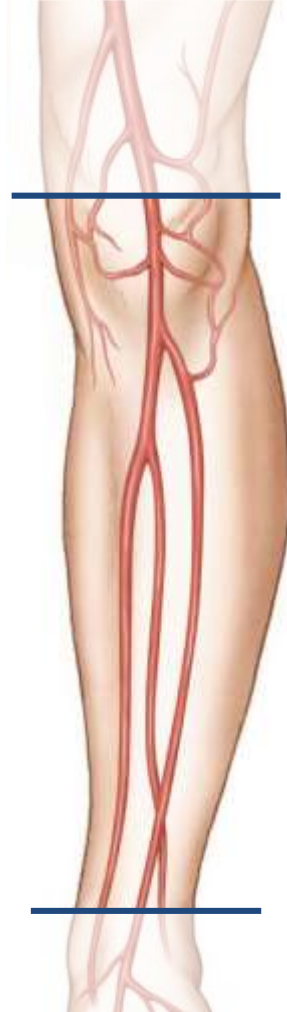
Rutherford 3-5*

RVD 1.5 – 4.5mm, inclusive

P2 to ≥ 1 cm above tibiotalar joint

Post-PTA residual DS $< 30\%$, and

≥ 1 dissection the investigator would otherwise treat (i.e., PTA / stenting)



Key Exclusion

WIFI wound / infection score > 2

Acute / sub-acute thrombosis and / or occlusion

Previous bypass / stent in target limb

Severe calcium (visual estimate)

TOBA II BTK Baseline Patient Characteristics (ITT population)

	Mean ± SD (N) or % (n/N)
Age (y)	74.4 ± 10.0 (233)
Gender	
Male	67.4% (157/233)
BMI	28.8 ± 5.6 (231)
BMI ≥ 30	37.2% (86/231)
TBI target limb	0.43 ± 0.23 (117)
Rutherford Class	
3	16.3% (38/233)
4	33.5% (78/233)
5	50.2% (117/233)

	% (n/N)
Smoking History	
Current/Former	62.2% (145/233)
Never	37.8% (88/233)
Diabetes mellitus	65.7% (153/233)
Arterial hypertension	93.6% (218/233)
Coronary artery disease	56.1% (129/230)
MI	22.0% (51/232)
PCI / CABG	43.9% (101/230)
Chronic renal insufficiency	24.1% (56/232)
History of previous peripheral intervention	50.2% (117/233)

TOBA II BTK Baseline Lesion Characteristics

(Core lab adjudicated; ITT population)

	Mean ± SD (N) or % (n/N)
Lesion type (site reported)	
De novo	93.8% (257/274)
RVD (mm)*	
Proximal	3.5 ± 1.0 (248)
Distal	2.6 ± 0.7 (248)
Pre-PTA DS %	85 ± 17 (248)
CTO	47.6% (118/248)
Calcification (PARC)	
None / mild	64.1% (159/248)
Moderate	18.1% (45/248)
Severe	17.7% (44/248)

	Mean ± SD (N) or % (n/N)
Lesion length (mm)	
Target lesion length	80 ± 49 (248)
PTA treated length	154 ± 110 (238)
Most distal target lesion location	
P2	4.0% (10/248)
P3	1.2% (3/248)
Tibioperoneal trunk	10.1% (25/248)
Anterior tibial	41.1% (102/248)
Posterior tibial	22.6% (56/248)
Peroneal	21.0% (52/248)

*Protocol specified a balloon-to-vessel ratio of 1:1 (by visual estimate)

Tack Delivery

(Core lab adjudicated; ITT population)

Tack Deployment Site

Anterior tibial	44%
Peroneal	18%
Posterior tibial	17%
Tibioperoneal trunk	11%
Popliteal	10%

Tack Procedure

Device success* **96.5%** (303/314)

Bail out stent rate **1.3%** (3/233)

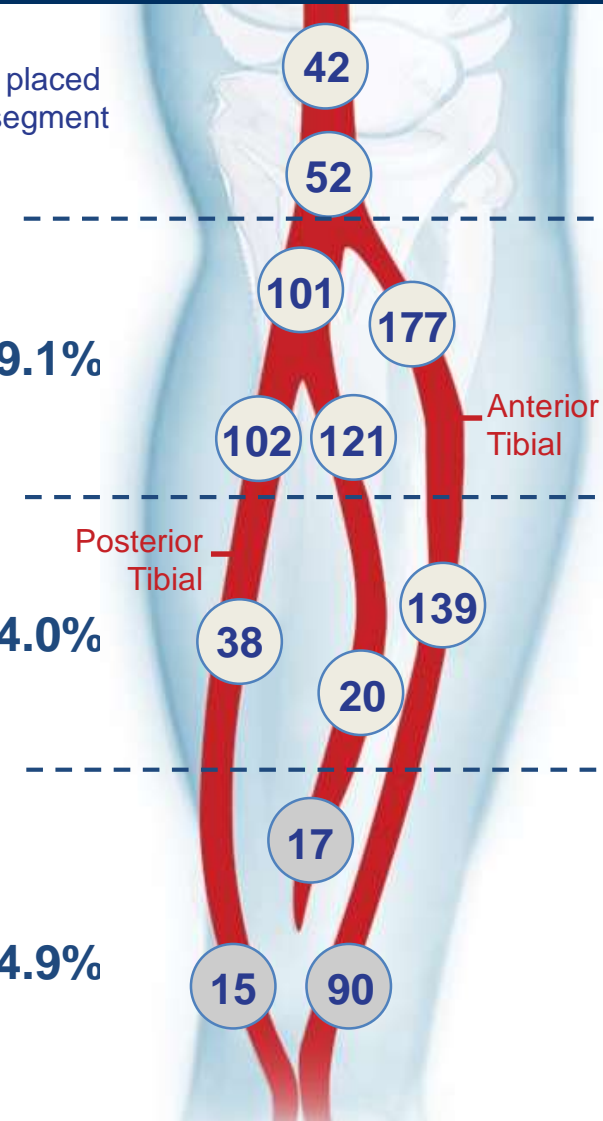
In Tacked segment **0.4%** (1/233)

of Tacks placed in vessel segment

Prox: **49.1%**

Mid: **24.0%**

Dist: **14.9%**

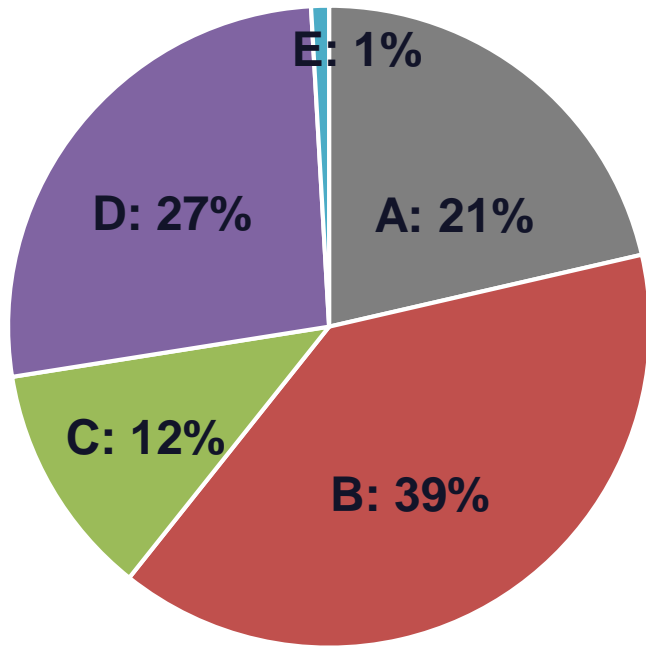


*successful deployment of the Tack(s) at the intended target site(s) and withdrawal of the delivery catheter from the introducer sheath (per device)

Dissection Resolution

(Core lab adjudicated; ITT population)

Pre-Tack



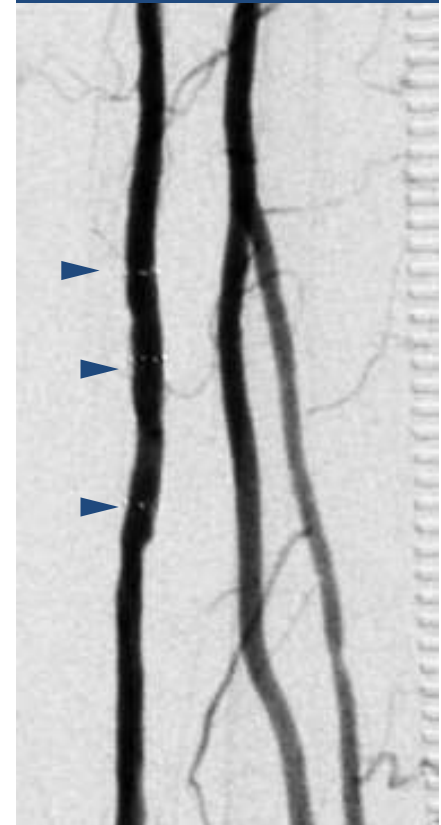
NHLBI Dissection Grade¹



100% of dissections were fully resolved with Tack placement

	Mean ± SD (N)
Dissections per patient	1.4 ± 0.6 (229)
Dissection length (mm)	24 ± 18 (341)
Tacks per patient	4.0 ± 2.8 (230)

Post



Primary Endpoints Met

Primary Safety		% (n/N) [97.5% CI]*	Performance Goal ¹	Endpoint	p-value*
MALE + POD at 30d	ITT	1.3% (3/228) [- , 3.8%]	12.0%	MET	<0.0001
Above-ankle amputation		0.9% (2/229)			
All-cause death		0.4% (1/229)			
Major reintervention to the target lesion		0.0% (0/229)			

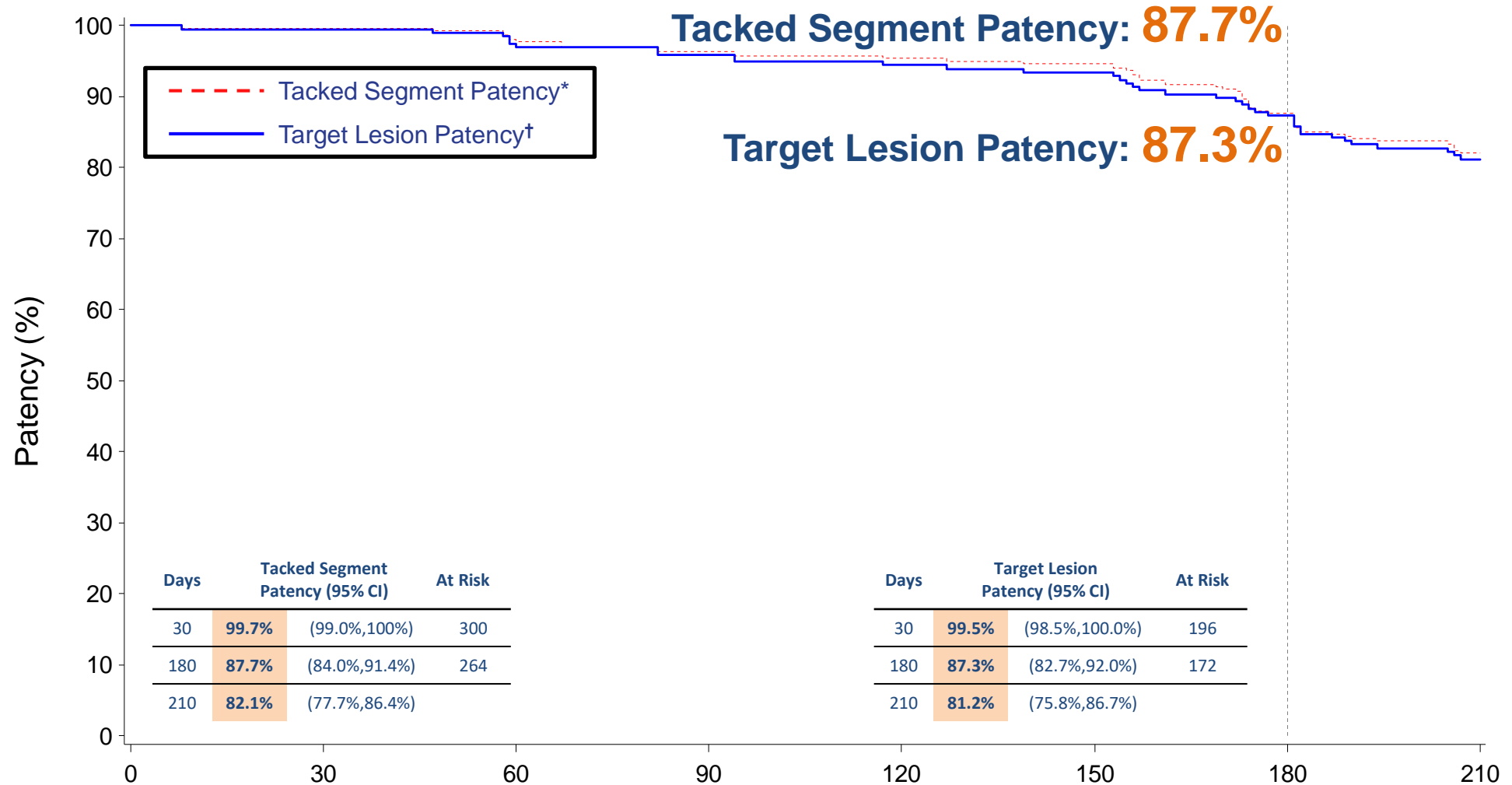
*Exact binomial test for one proportion. Confidence interval is the one-sided exact 97.5% upper bound.

Primary Efficacy		% (n/N) [97.5% CI]†	Performance Goal ¹	Endpoint	p-value†
Freedom from MALE at 6m + POD at 30d	ITT	95.6% (196/205) [91.8%, -]	74.0%	MET	<0.0001
	PP	95.8% (183/191) [91.8%, -]			

†Continuity corrected z-test for one proportion. One sided lower 97.5% confidence bound.

6M K-M Tacked Segment and Lesion Patency

(Core lab adjudicated; ITT population)

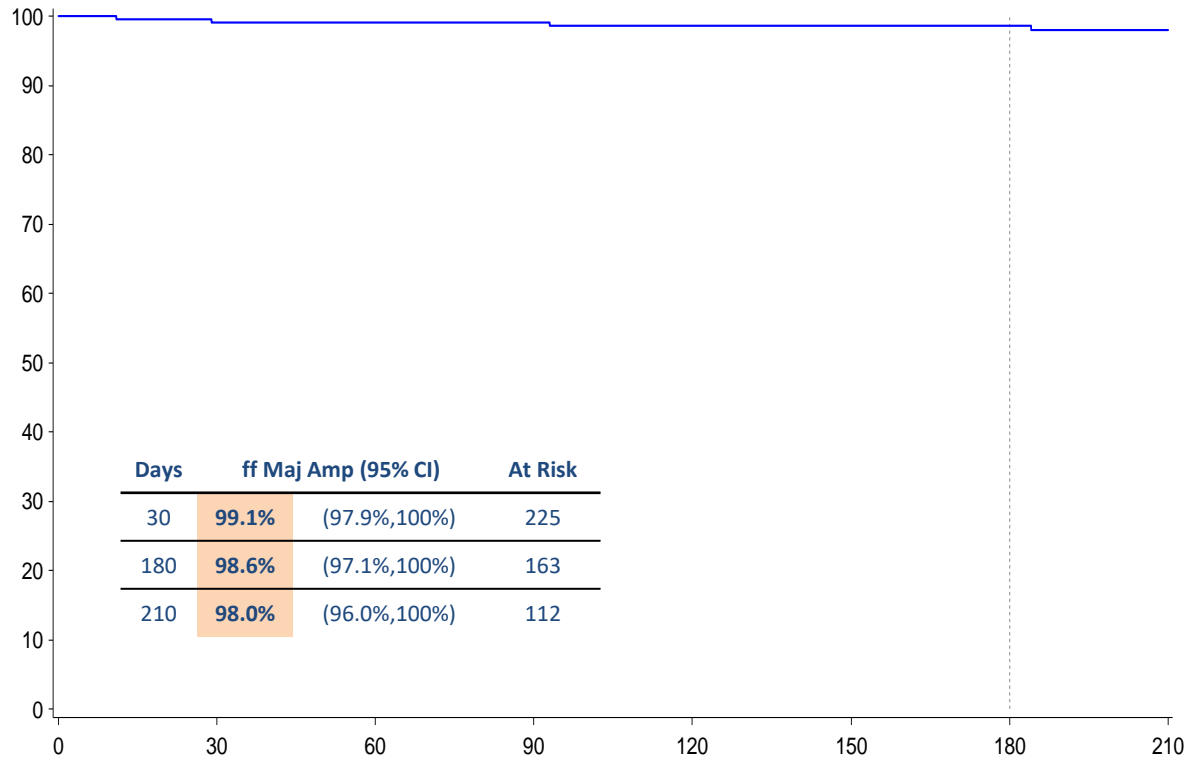


*DUS flow or no flow at 6m; Tacked segment: Tack implant + 5mm of artery proximal and distal; Tacks w/in 1cm are considered same segment

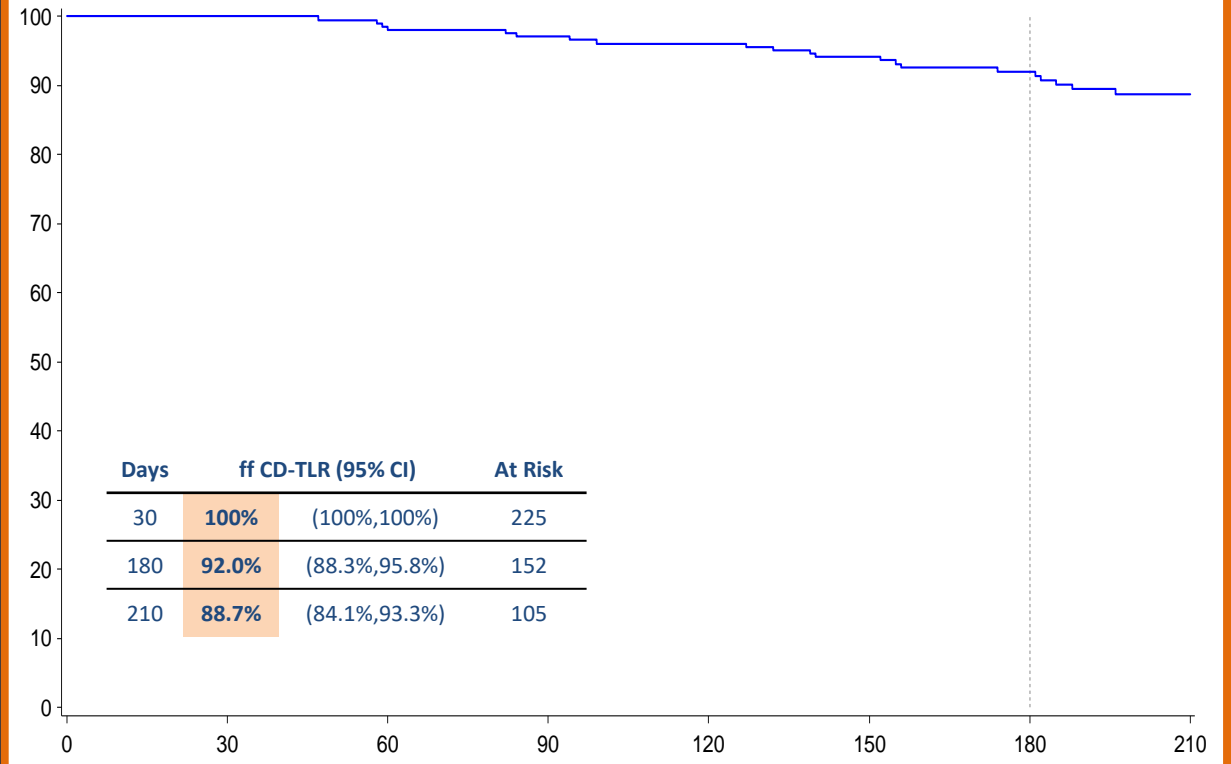
†DUS flow or no flow at 6m in PTA treated length

Limb Salvage and Freedom from CD-TLR (ITT population)

6m K-M Target Limb Salvage: **98.6%**

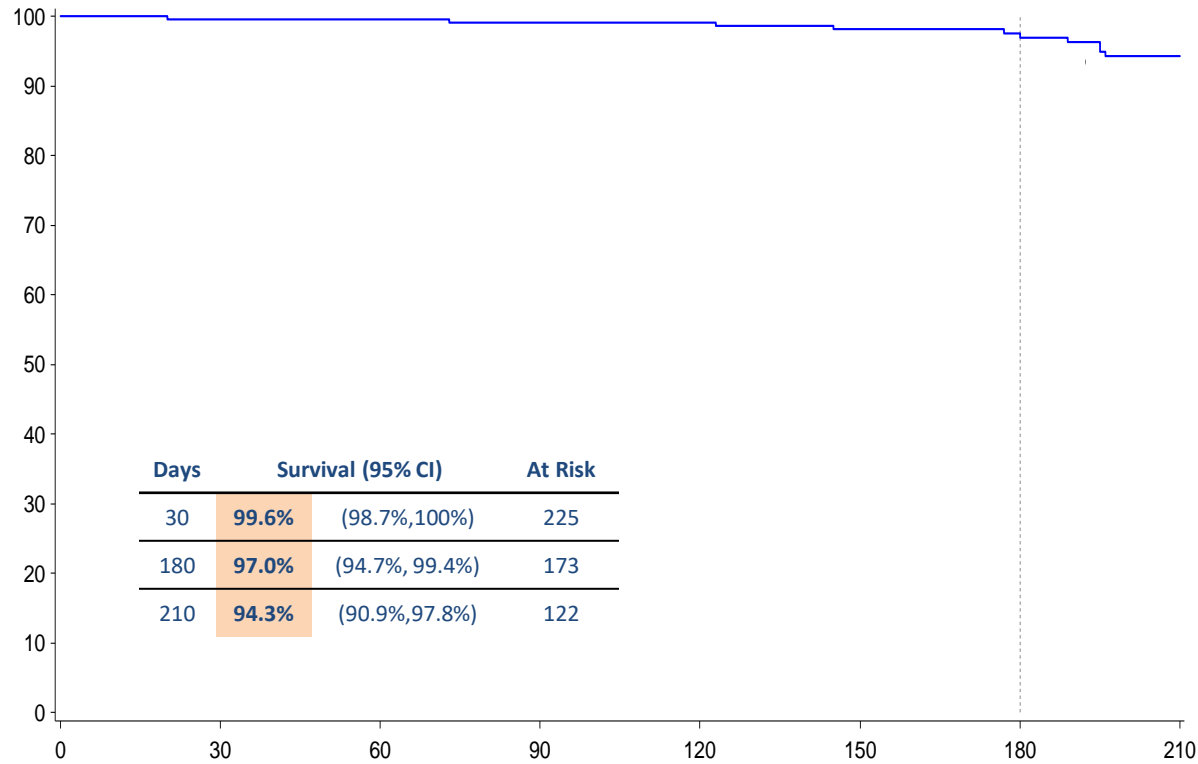


6m K-M Freedom from CD-TLR: **92.0%**

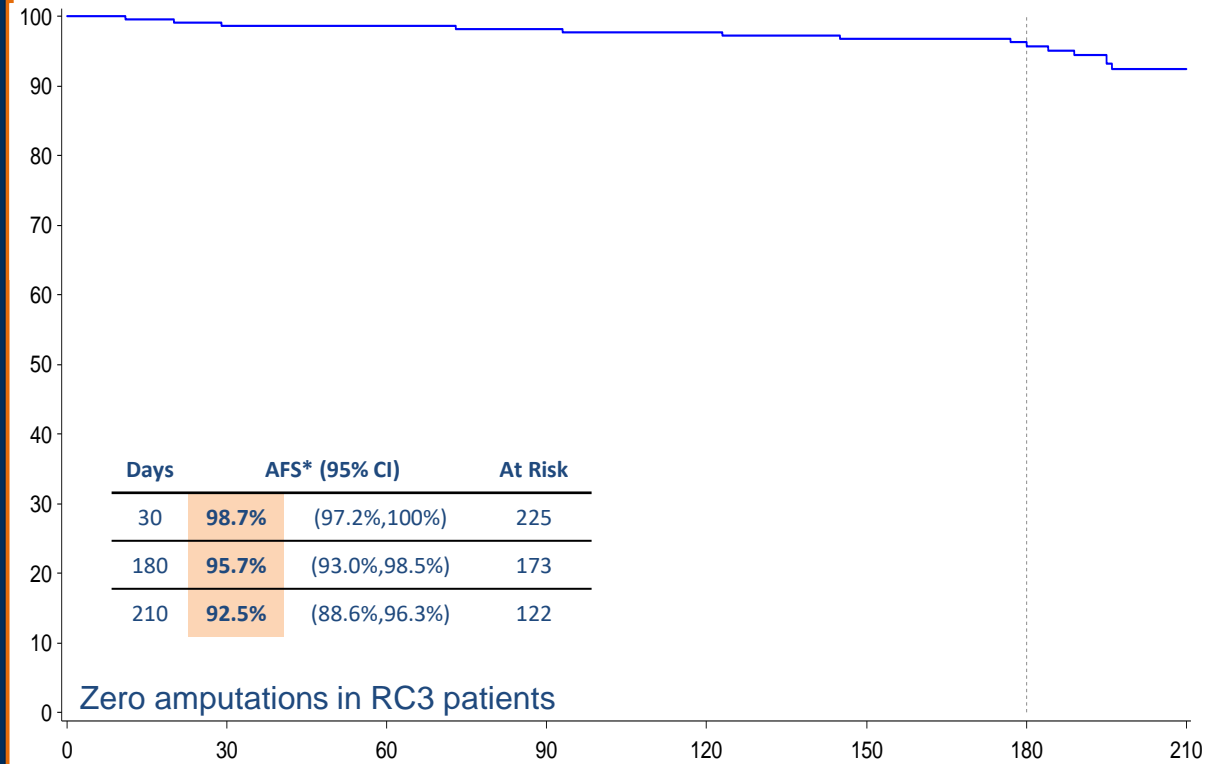


All-Cause Mortality, Amputation-Free Survival (ITT population)

6m K-M Survival: **97.0%**



6m K-M Amputation-Free Survival: **95.7%**



Improvement in Wound Status

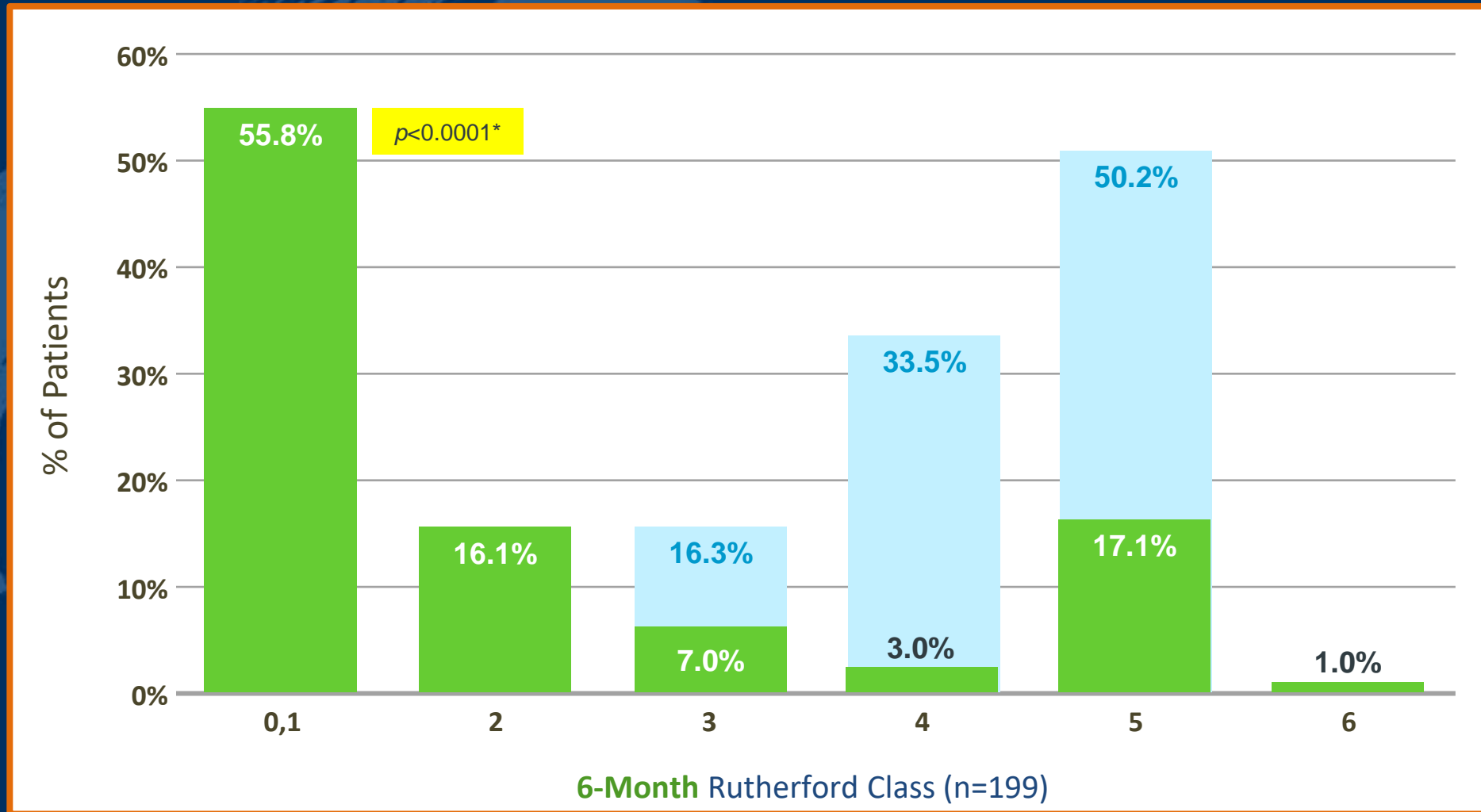
(Site reported; ITT population)

Wound Status	6 Month (n=122)
Wound has healed	57.4%
Wound is improving	16.4%
Wound is unchanged	4.9%
Wound is worsening	2.5%
Unable to assess	18.9%

73.8% of wounds were
healed or improving
at 6 months



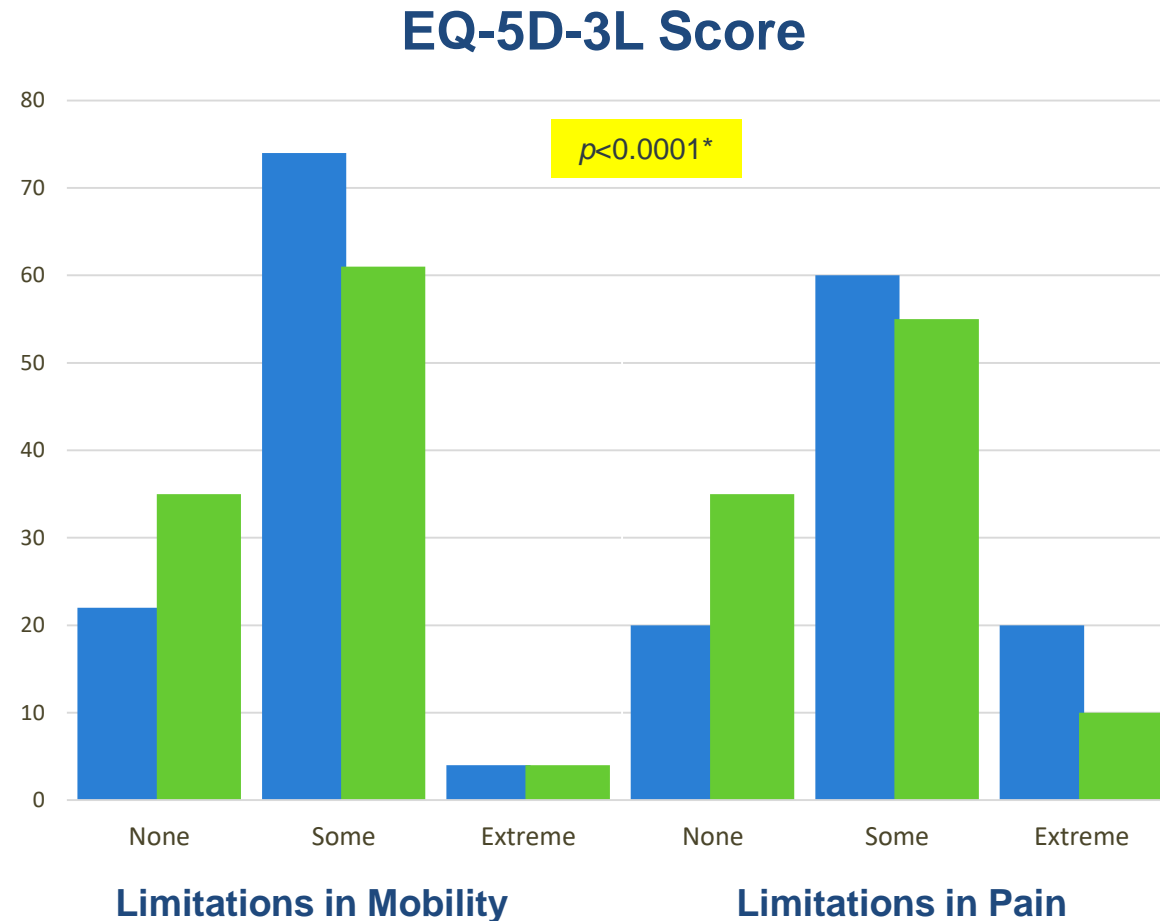
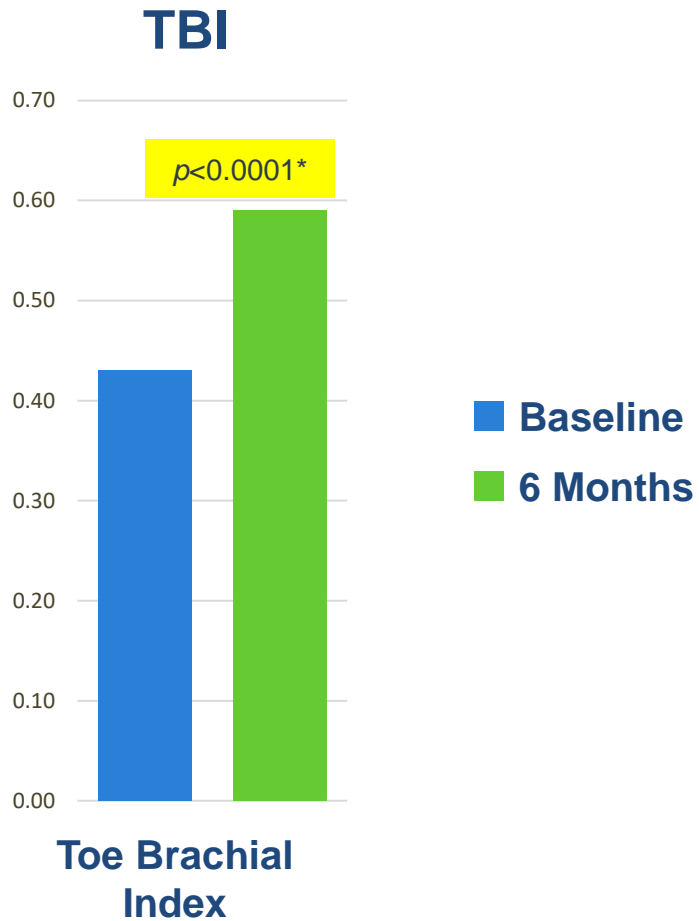
Significant Improvement in Rutherford Class (ITT population)



74.0% of CLI patients improved to RC ≤ 3

45.3% of all patients improved ≥ 3 classes

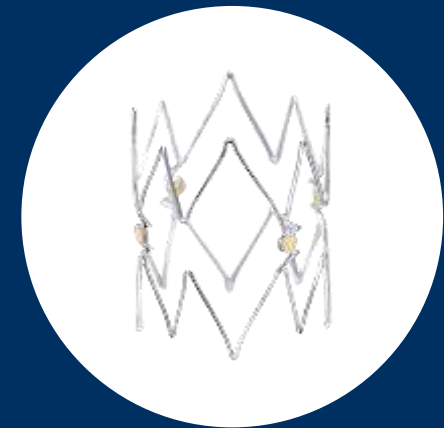
Hemodynamic and QoL Improvement (ITT population)



*Wilcoxon Signed Rank test.

Tack: A New Therapy for BTK Dissection Repair

- Unique trial: first BTK IDE to enroll **100%** dissected vessels
- Successfully met all primary and secondary endpoints
- Demonstrated that the Tack implant repaired **100%** of BTK dissections:
 - **87.3%** 6m K-M target lesion patency
 - **92.0%** 6m K-M freedom from CD-TLR
 - **73.8%** of wounds healed or improved at 6 months
 - **74.0%** of CLI patients decreased to RC ≤ 3 at 6 months
 - **95.7%** 6m K-M amputation-free survival
- Preserves future treatment options



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