Tack Optimized Balloon Angioplasty:

TOBA Trial

12 months Results

New Paradigm for Managing Post PTA Dissections

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Disclosure

Speaker name:

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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

Challenges with Angioplasty & Stents

Balloons=

Too much acute injury

- Acute injury results in dissections
- Risk of occlusion and thrombus
- Drug coated balloons also cause dissection

Location	Study	Dissection Rates
SFA	PACIFIER	47.4% PTA 73.5% DCB
SFA-pop	THUNDER	56%
SFA	LEVANT 2	72.3% PTA 63.7% DCB

Stents=

Too much chronic injury

- In-stent restenosis from chronic inflammation
- Stent fractures due to motion and external forces

Stent (study)	Re-stenosis	Stent Fracture
Scheinert (JACC 2005)	34.4% re-occlusion	37.2% @ 10.7 mos
Zilver Zilver PTX	16% @ 1yr 10% @ 1yr	0.9% RCT 1.5% SAT
Supera (SUPERB)	13% @ 1yr	0.0% @ 1yr
SMART (SIROCCO)	18% @ 6mos	18.2% @ 6mos
EverFlex (Durability)	28% @ 1yr	0.4%
LifeStent (Resilient)	19% @ 1yr	3.1% @ 1yr
Dynalink-E (STRIDES)	32% @ 1yr	2% @ 1 yr

What Does The Literature Tell Us?

- Dissection is mechanism of action for balloon angioplasty.
- But, do Grades A and B matter?
- YES!!!

Comparison of 6 month THUNDER Study Angiographic Data				
	PTA w/o Dissections	**Dissection Grade A/B**	**Dissection Grade C/D/E**	**All Dissection**
Binary restenosis	43%	50%	62%	55%
Patency (extrapolated from restenosis data)	**71%-91%**	**50%**	**38%**	45%
Target Lesion Revascularization	**10.5%**	**33%**	**44%**	37%

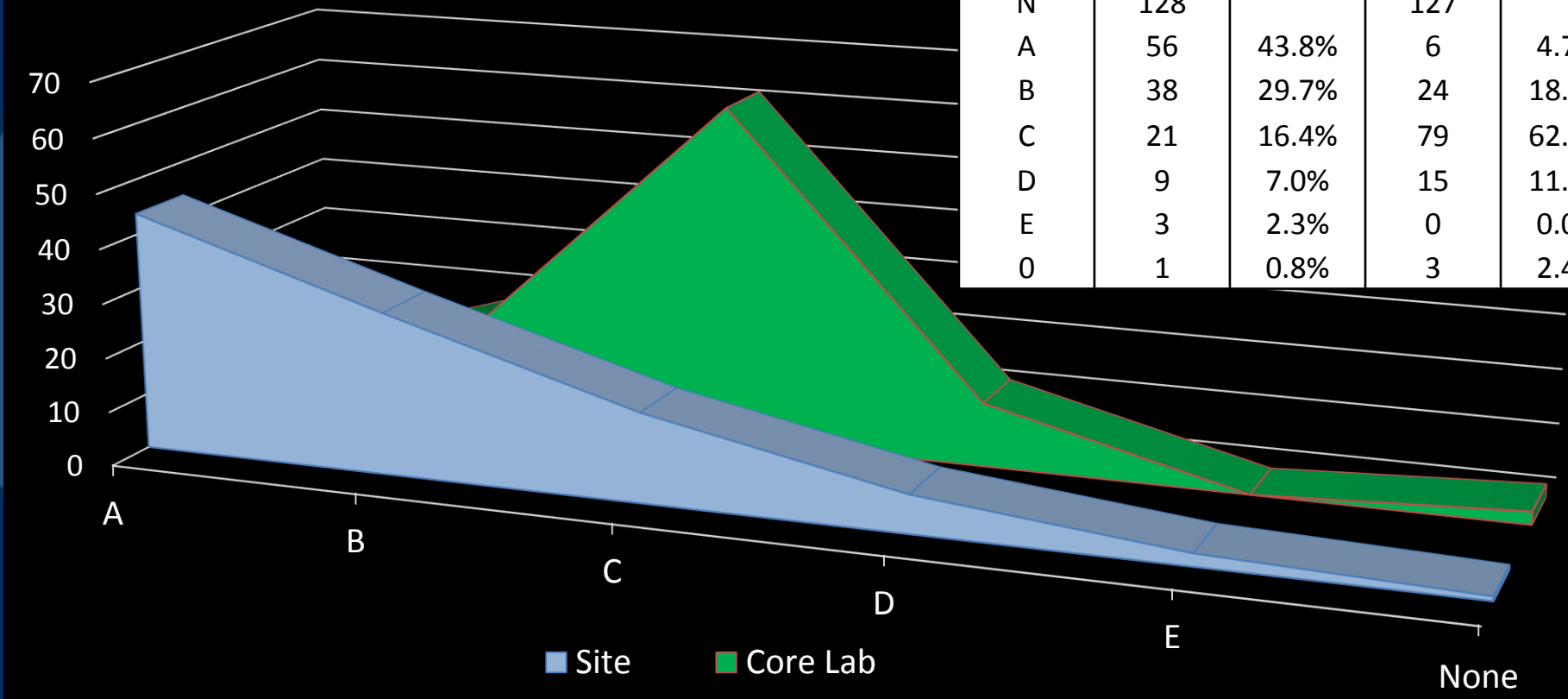
24 Month Clinical Results of THUNDER Study			
	Dissection Grade A/B	**Dissection Grade C/D/E**	**All Dissection**
Target Lesion Revascularization	**43%**	**78%**	56%

Sources: Literature review, and THUNDER study publications

Operators Routinely Underestimate Dissection Severity…

TOBA: Baseline Dissection Grade

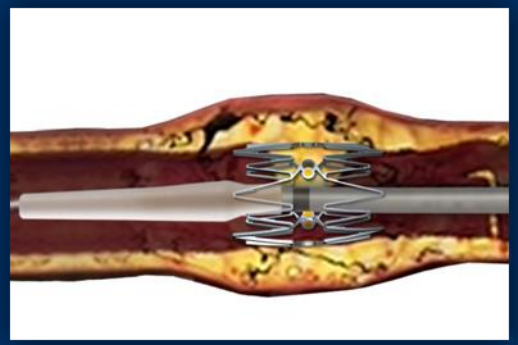
Grade	Site	%	Core Lab	%
N	128		127	
A	56	43.8%	6	4.7%
B	38	29.7%	24	18.9%
C	21	16.4%	79	62.2%
D	9	7.0%	15	11.8%
E	3	2.3%	0	0.0%
0	1	0.8%	3	2.4%

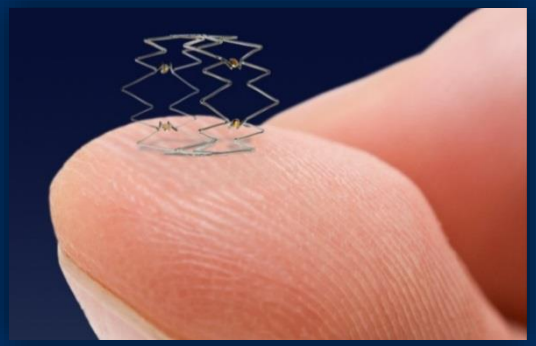


Major disparity between site reported and core lab reported

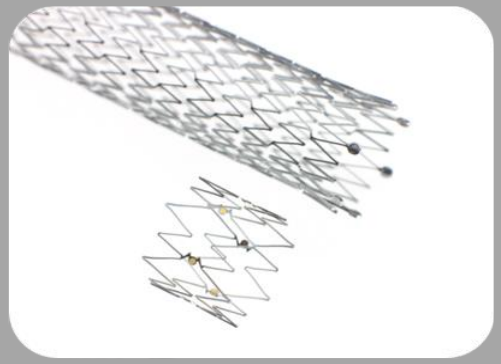
Tack Endovascular System™

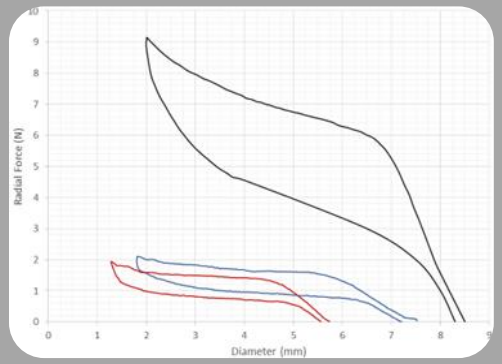
Key Components	6F System
Delivery System: - # Tacks - Working length - Guidewire	 4 Tacks 112cm 0.035" Guidewire
Tack: - Length - Radiopaque markers - Fixation elements	 6.0mm 6 6
Treats Vessel Diameters:	2.5mm – 6.0mm

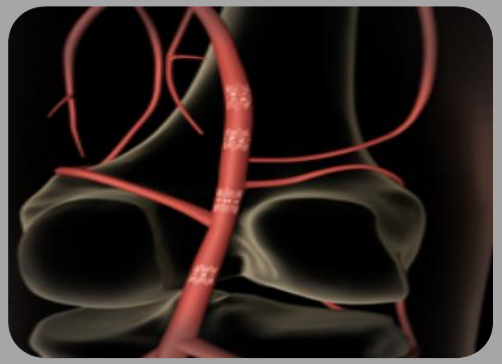




The Tack Endovascular System™ is Designed to Provide Better Healing of Dissections







Minimal Metal

Short open cell design

Low Radial Force

Flat force curve

Focal Treatment

Treat only where needed

Gives Physicians More Control Over Where They Treat

Maintains Normal Vessel Biomechanics

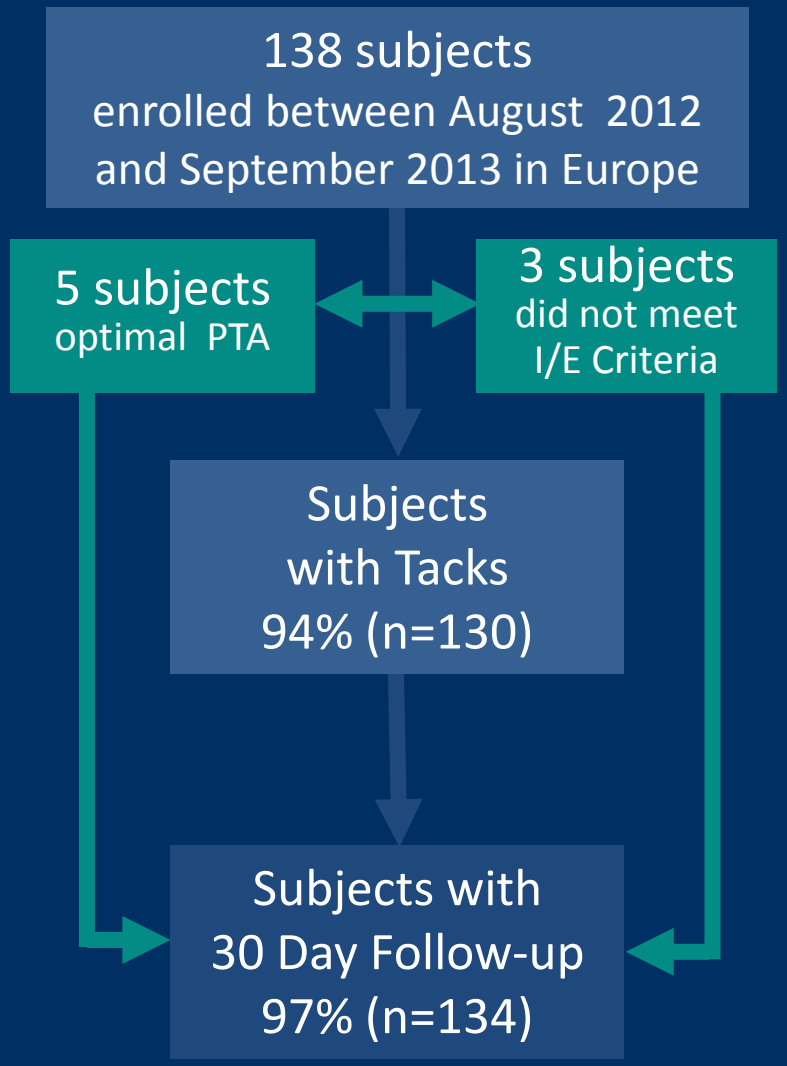
Preserves Future Treatment Options

Tack Endovascular System™ Clinical History

- **First in Man:** Demonstrated feasibility from SFA to Ankle
- **TOBA**: Prospective, Multicenter Tack Optimized Balloon Angioplasty Study for Femoropopliteal Arteries
  - 30 Day Data presented at LINC 2014
- **TOBA BTK**: Prospective, Multicenter, Tack Optimized Balloon Angioplasty Study for Below the Knee
  - Enrollment Completed November 2014
- **Additional studies** planned for DCB and U.S. approval

TOBA Study

- **Design**: Prospective, single-arm, multi-center confirmatory trial for optimization of SFA and popliteal artery balloon angioplasty.
- **Objective**: To collect confirmatory data in support of the safety and performance of the Intact Vascular Tack Endovascular System™.
- **Intended Use**: The Tack Endovascular System™ is indicated for tissue apposition to optimize balloon angioplasty. Dissection or tissue flaps after angioplasty may be indicated for Tack placement



TOBA Enrolling Sites

Principal Investigator	Clinical Site
Marc Bosiers	A.Z. St. Blasius Hospital, Belgium
Marianne Brodmann	Medical University Hospital, Austria
Jean-Paul DeVries	St. Antonius Hospital, The Netherlands
Hans Martin Gissler	Hochrhein-Eggberg Clinic, Germany
Jeroen Hendriks	Antwerp Untiversity Hospital, Belgium
Hans Krankenberg	Center for Cardiology & Vascular Intervention Andreas-Gruntzig-Haus, Germany
Lieven Maene	Onze-Lieve-Vrouwziekenhus Moorselbaan 164, Belgium
Patrick Peeters	Imeldaziekenhuis Imeldalaan 9, Belgium
Jens Ricke	Universitatsklinikum Magdeburg, Germany
Dierk Scheinert	Park-Krankenhaus, Germany
Robert Staffa	St. Anne's Faculty Hospital, Česká Republika
Christian Wissgott	Westküstenklinikum Heide, Germany
Thomas Zeller	Herz-Zentrum, Germany

Baseline Clinical Characteristics

Major Inclusion Criteria

- Rutherford 2 – 4
- ABI ≤ 0.90
- RVD 2.5 - 5.5 mm
- Target lesion is ≤ 10 cm
- Target lesion ≤ 30% RS post PTA

Major Exclusion Criteria

- Previously implanted stent
- Severe calcium
- Stenosis or occlusion of inflow tract not treated prior to index procedure

Subjects (n)	130
Age (Y)	68.1 ± 9.68
Male Gender	66.9%
Diabetes	28.5%
Hypertension	77.7%
Hyperlipidemia	66.9%
Current Smoker	43.0%
Smoking History	72.3%

Baseline Lesion Characteristics

Lesion Location	ITT Population
Ostial SFA	0.8%
Proximal SFA	14.6%
Mid-SFA	44.6%
Distal SFA	31.5%
Proximal Popliteal	7.7%
Mid-Popliteal	0.8%

Calcification	Core Lab
None/Mild	34.1%
Moderate	60.5%
Severe	5.4%

Characteristic	Core Lab
Lesion Length (mm)	52.72 ± 30.48
Treated Length (mm)	82.08 ± 39.63
Proximal RVD (mm)	5.48 ± 0.65
Distal RVD (mm)	5.51 ± 0.68
% Diameter Stenosis Pre-PTA	81.8 ± 15.62
% Diameter Stenosis Post-PTA	20.9 ± 7.55
Total Occlusion	34.40%
Dissection Grade C and greater	74.0%

Exceptional Safety Profile and Technical Success Rates

	Cumulative to 30 days (N=126)
Major Adverse Events	0
Tack Embolization	0
Emergent Revascularization	0
TLR	0
Major Amputation	0

0.0% MAEs

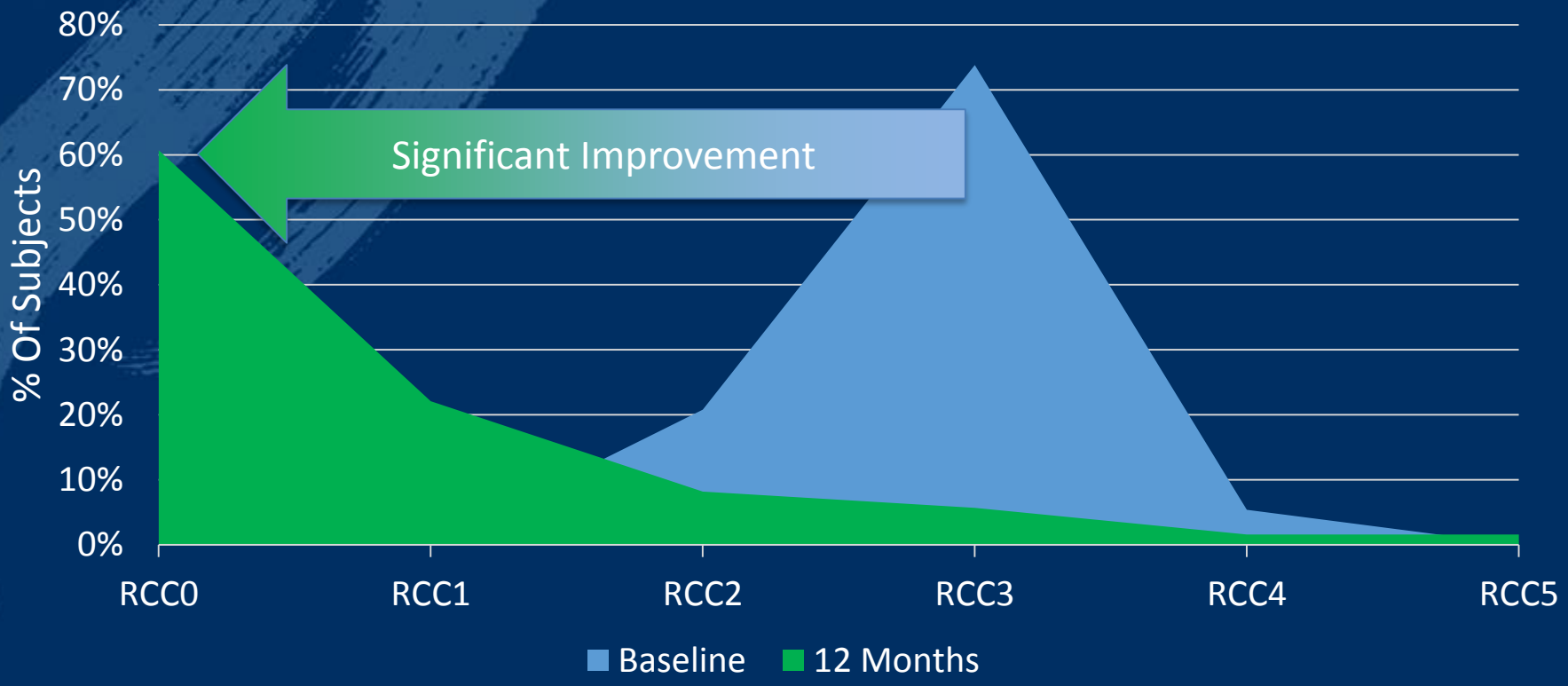
98.5% Technical Success Rate

(only 2 out of 130 received bailout stents)

No Tack migrations through 1 year

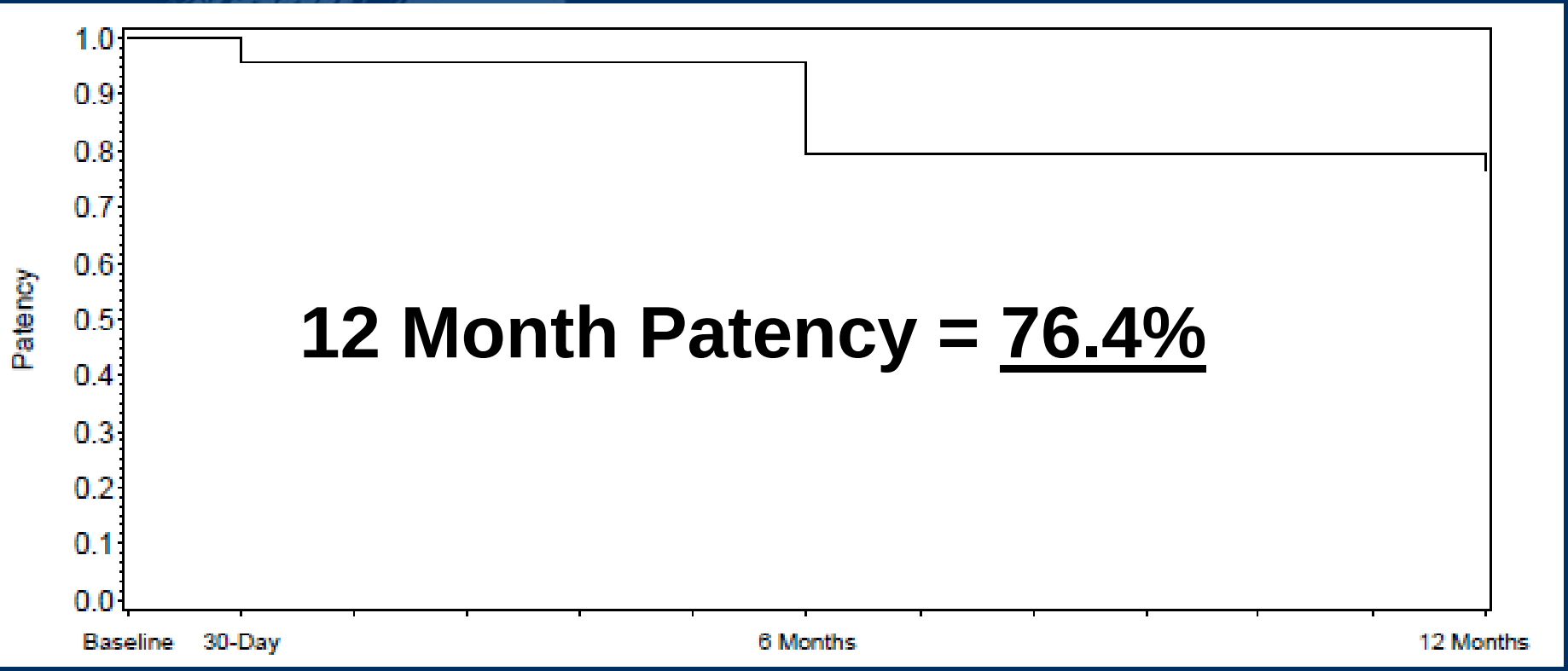
Change in Rutherford Clinical Category and ABI

(ITT population)



ABI	Baseline	12 Month	Change from Baseline	P-Value
N	123	116	110	
Mean (SD)	0.68 (0.179)	0.94 (0.153)	0.27 (0.209)	<.0001
% Change in ABI			38%	

Tack Optimized Balloon Angioplasty
12 Month Patency



12 Month Freedom from TLR = 89.5%

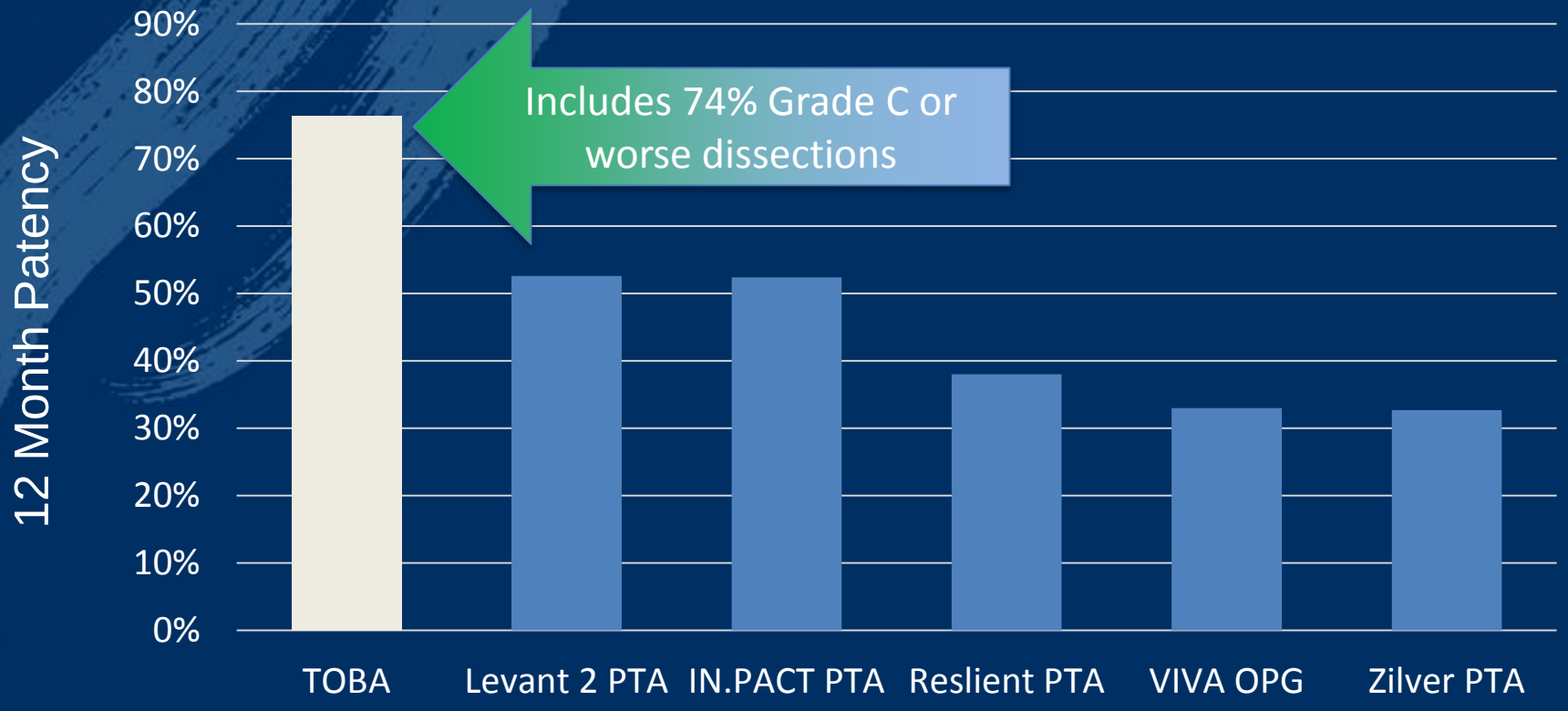
What Have We Learned About Tack Placement?

	Overlapping *Tacks*	No Overlapping *Tacks*	Fisher's Exact Test P-value
Major Adverse Events (MAE)	**6/27 (22.2%)**	**8/101 (7.9%)**	**0.0745**
MAE Components:			
***Tack* Embolization**	**0**	**0**	**NA**
Emergent Revascularization	**1 (3.7%)**	**0**	**0.2109**
Target Lesion Revascularization	**5 (18.5%)**	**8 (7.9%)**	**0.1459**
Major Amputation	**0**	**0**	**NA**
Patency Rate	**65.2%**	**77.8%**	
Freedom from TLR	**81.5%**	**92.1%**	

Performance improved when Tacks did not overlap: Decrease in TLR and increase in patency at 12 months

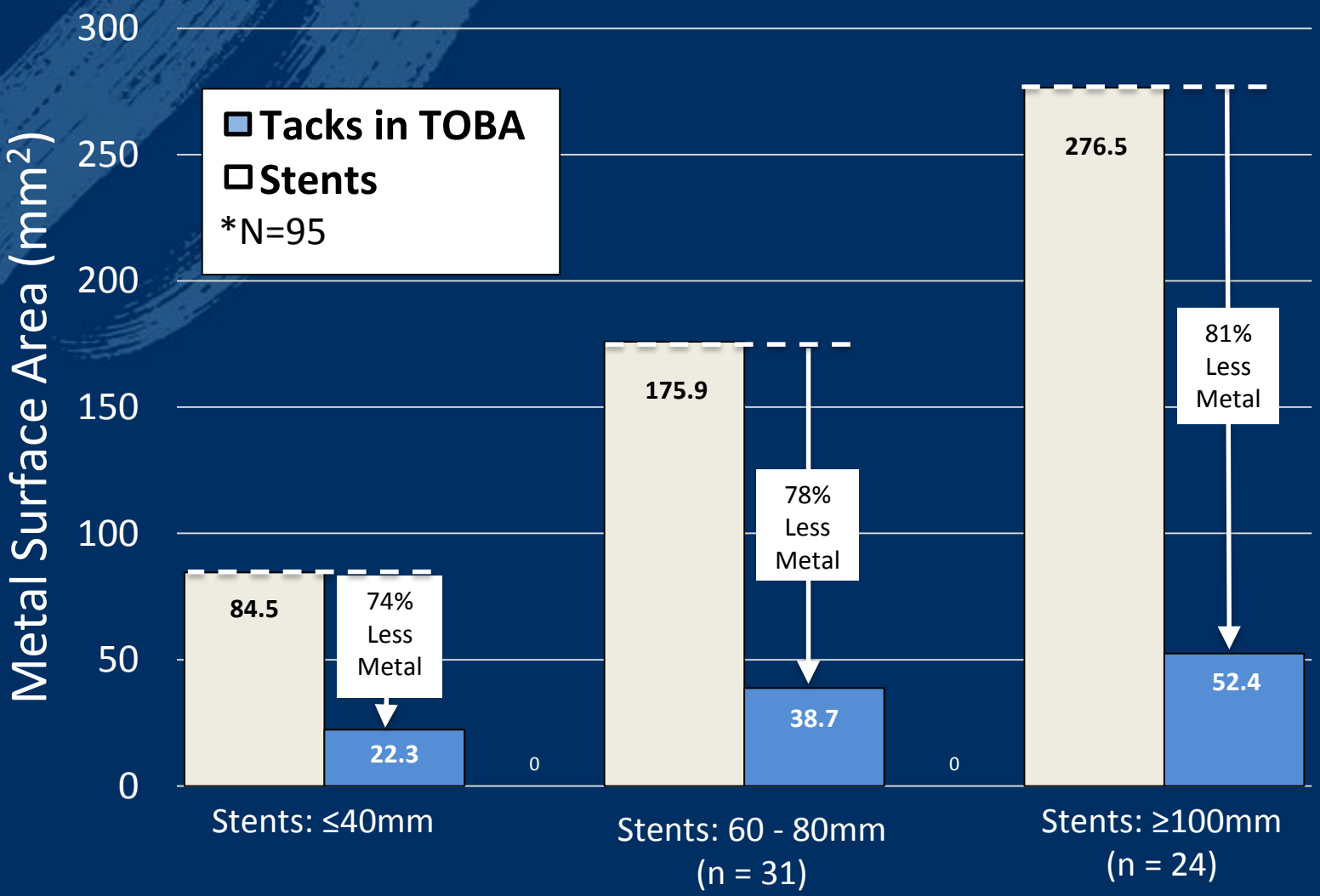
12 Month POBA Put in Perspective…

Tacks improved the results of angioplasty

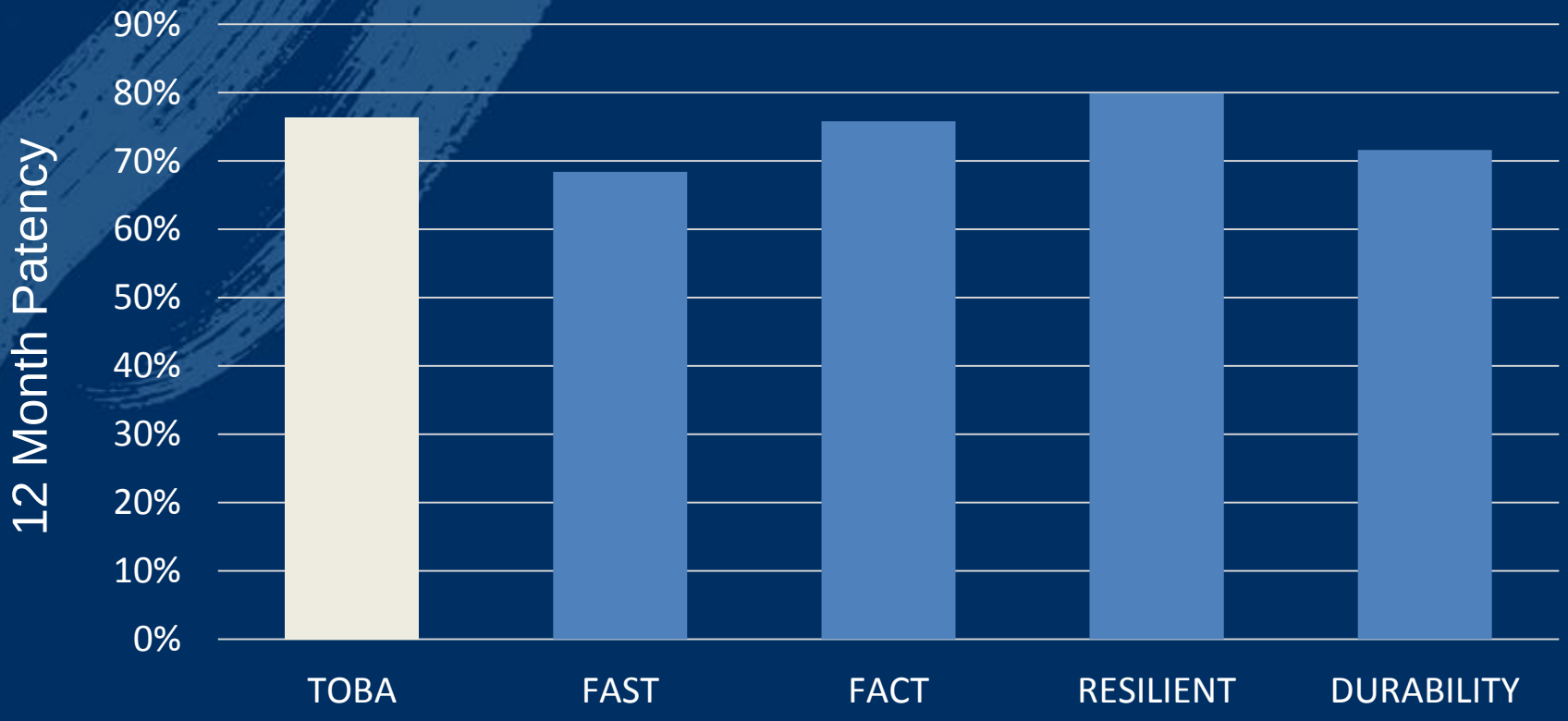


What will the Tack add to DCB patency?

Tacks=Decreased Metal Burden

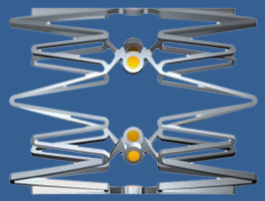


Comparable to Stenting Without Limiting Future Treatment Options



Minimal metal preserves treatment options for any future intervention.

Conclusions



The Tack Endovascular System™ substantially improved 12 month patency in patients with dissections following balloon angioplasty

- ✓ Severity of dissections is frequently underestimated
- ✓ Tack demonstrated positive clinical outcomes and benefits for dissections without the drawbacks of stents
- ✓ New paradigm – manage dissections with minimal metal, minimal outward force, minimal injury to vessel
- ✓ Holds similar promise for DCBs