

The logo for LINC (Lipid and Inflammation Network in Coronary) features the letters 'LINC' in white, positioned over a stylized graphic of a heart or flame shape. The graphic is composed of several curved, brushstroke-like elements in shades of blue, red, and yellow.

LINC

TACK ENDOVASCULAR SYSTEM

REAL WORLD TACKING ABOVE AND BELOW THE KNEE

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Conflict of Interest - Disclosure

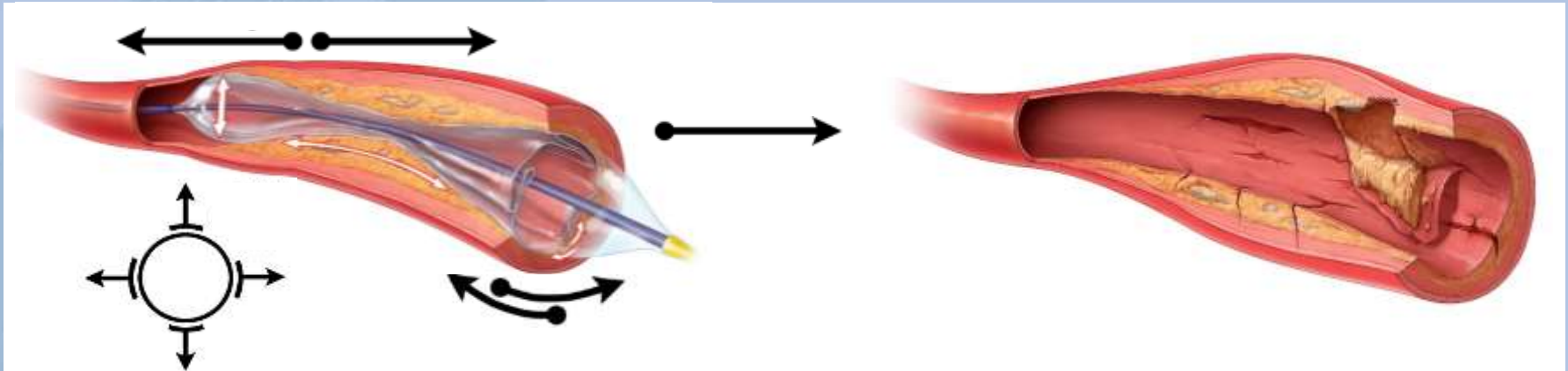
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Company

1. Honoraria for lectures: CR Bard, Boston Scientific AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan, Intact Vascular, Vesper
2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific, Philips, Intact Vascular, Vesper
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, Boston Scientific, LimFlow, Terumo, Philips, Optimed, IPmedical, Intact Vascular, Vesper
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica, Philips, CR Bard, Optimed, Intact Vascular, Vesper

Dissection: Mechanism of Action for Angioplasty



Lesions with dissections have a **TLR rate 3.5 times higher** than lesions without dissection¹

Current tools for dissection repair (stents) have limitations

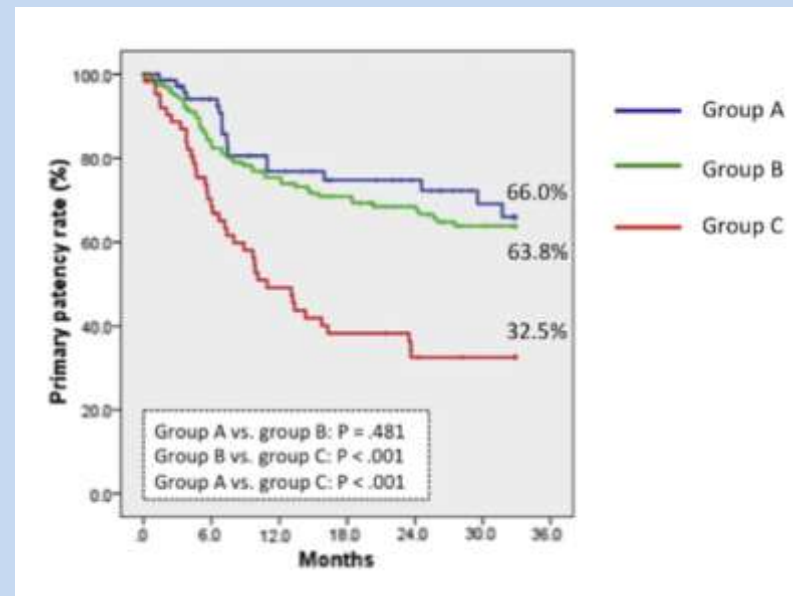
Kobayashi Dissection Grading

Kobayashi N et al. Simple classification and clinical outcomes of angiographic dissection after balloon angioplasty for femoropopliteal disease. *J Vasc Surg.* 2017;67(4):1151–1158.

Category	Width of Dissection
Group A	None
Group B	< 1/3 of lumen
Group C	>1/3 of lumen



Dissections are divided into a three-part grading system analyzing the width of the remaining patent lumen in the dissected arterial segment.



Tack Endovascular System[®]

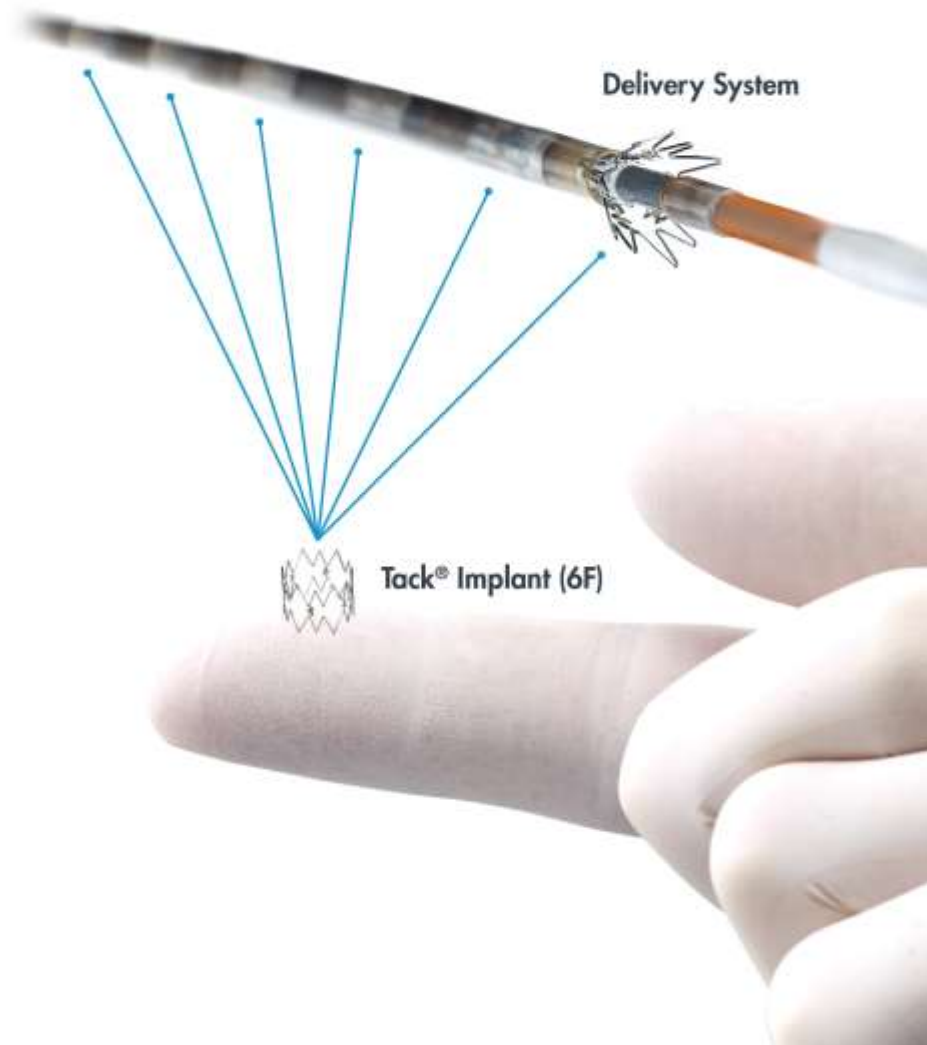
PURPOSE-BUILT. PRECISION REPAIR. PRESERVES OPTIONS.

Tack[®] Implants



- Multiple pre-loaded implants on a single catheter
- **Adaptive Sizing[™]** self-sizes to tapering ATK anatomy (3.5 – 6.0mm)
- Nitinol with gold radiopaque markers
- 6mm deployed length

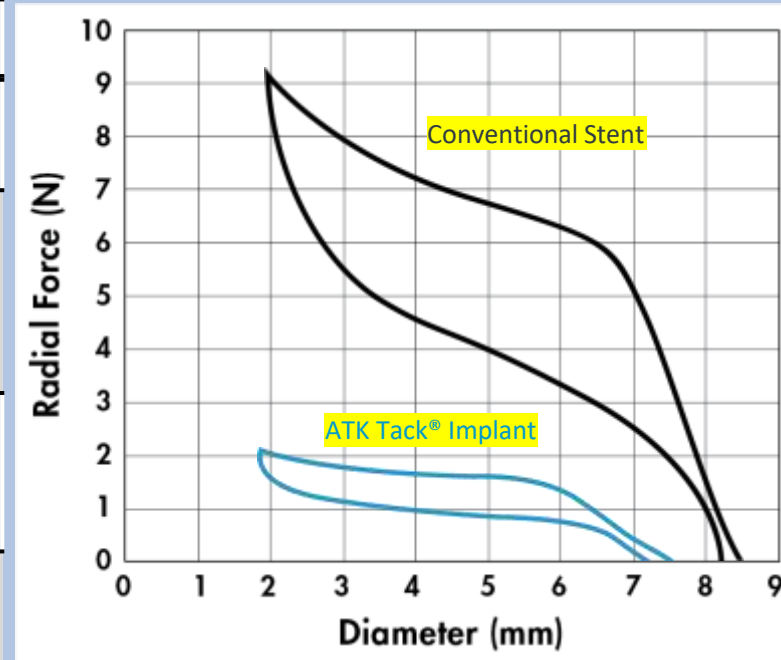
Delivery System

- 6F / .035" – 6 implants pre-loaded on an OTW delivery system
- Accurate (≤ 1 mm) deployment



Tack[®] Implants and Conventional Stents

	Tack [®]	Stent
Radial force	Low	High
Inflammation	Minimal	Chronic hyperplastic changes
Pre-clinical study histology images¹		
Metal burden	6mm length, open cell design	>70% more metal to treat the same length dissection ²
Sizing	Self-sizes from 3.5 – 6.0 mm; 1 SKU for ATK	Requires more precise sizing; multiple SKU



¹Schneider, *JACC: Cardiovasc Interv* 2015

²Bosiers, *J Vasc Surg* 2016

TOBA Dissection Repair Trials (N=820)

ATK	TOBA (N=138)	Prospective, single arm 13 European sites	<i>Journal of Vascular Surgery</i> ¹ <ul style="list-style-type: none"> • 89.5% K-M freedom from CD-TLR • 76.4% K-M patency rate • 98.5% technical success rate
	TOBA II (N=213) Pivotal IDE	Prospective, single arm 33 US/European sites POBA or Lutonix® DCB	12-month pivotal trial data ² <ul style="list-style-type: none"> • 86.5% 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	12-M data complete IN.PACT® Admiral® DCB
BTK	TOBA BTK (N=35)	Prospective, single arm 6 Europe/New Zealand sites	<i>Catheterization and Cardiovascular Intervention</i> ³ <ul style="list-style-type: none"> • 93.5% K-M freedom from CD- TLR • 84.5% amputation-free survival • 78.4% K-M patency rate
	TOBA II BTK (N=233) Pivotal IDE	Prospective, single arm 41 US and international sites	Enrollment complete 6-month primary endpoint



All studies utilized angiographic and DUS core labs, CEC, and DSMB

Lutonix® is a registered trademark of BD Interventional
IN.PACT® and Admiral® are registered trademarks of Medtronic, Inc.

¹Bosiers, *J Vasc Surg* 2016

²Manuscript pending, *JACC: Cardiovasc Interv* 2019

³Brodmann, *Cathet Cardiovasc Interv* 2018

TOBA III Study Design

Tack **O**ptimized **B**alloon **A**ngioplasty Study for Post-PTA Dissection Repair of the Superficial Femoral and Proximal Popliteal Arteries (TOBA III)

Prospective, multi-center, single-arm, non-blinded study in 14 European sites

201 patients, all with post-PTA dissection following IN.PACT® Admiral® angioplasty:

169 patients with lesions $\leq 150\text{mm}$ and **32** patients with lesions $>150\text{mm} - \leq 250\text{mm}$

Primary Safety Endpoint

Freedom from the occurrence of any new-onset MAE(s) at 30 days

- Index limb amputation (above the ankle)
- CEC adjudicated CD-TLR
- All-cause death at 30 days

Primary Efficacy Endpoint

Primary patency at 12 months

- Freedom from CEC adjudicated CD-TLR *and*
- Freedom from core lab adjudicated DUS-derived binary restenosis (PSVR ≥ 2.5)

Key Observational Endpoints

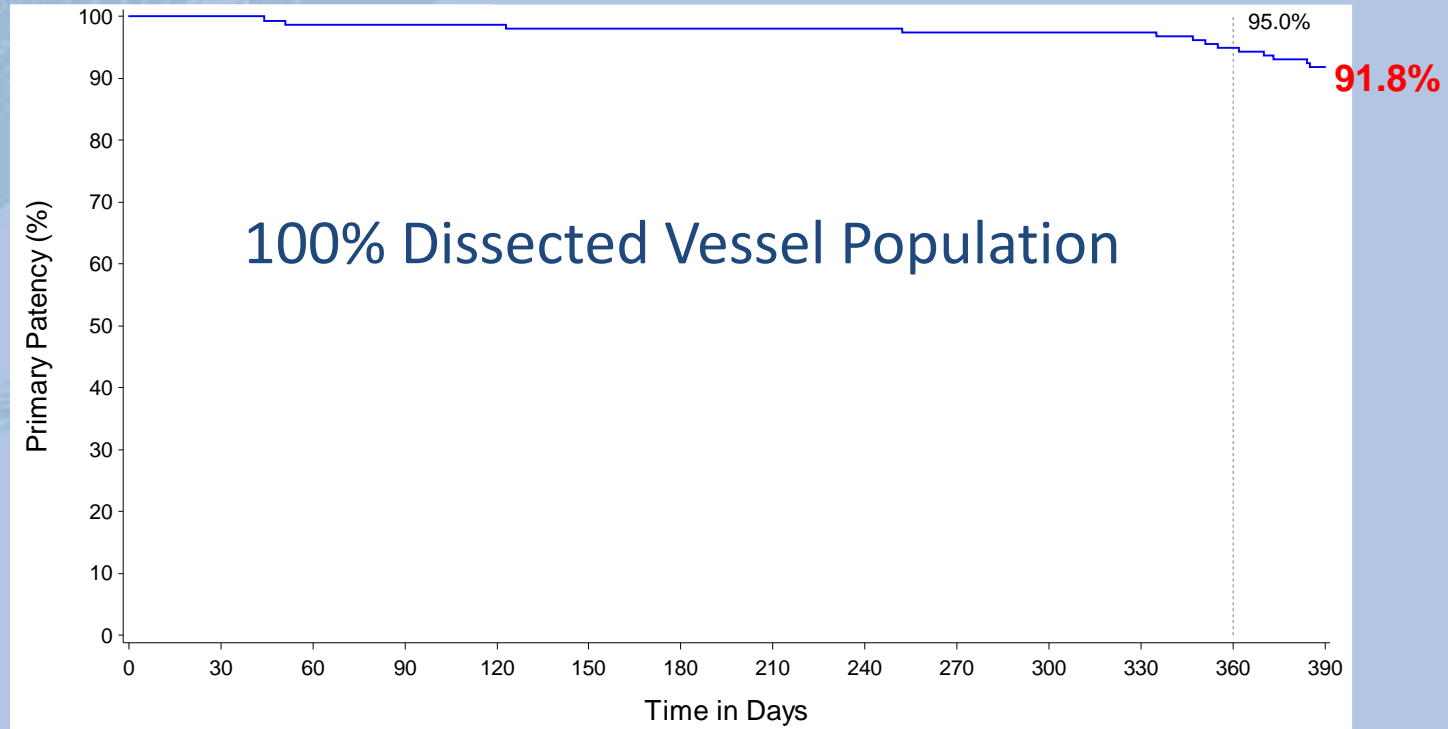
- Freedom from CEC adjudicated CD-TLR
- Dissection Resolution
- Changes in Rutherford, ABI and Quality of Life measures

IN.PACT® and Admiral® are registered trademarks of Medtronic, Inc.

Angiographic Core Laboratory/Clinical Events Committee: Yale Cardiovascular Research Group

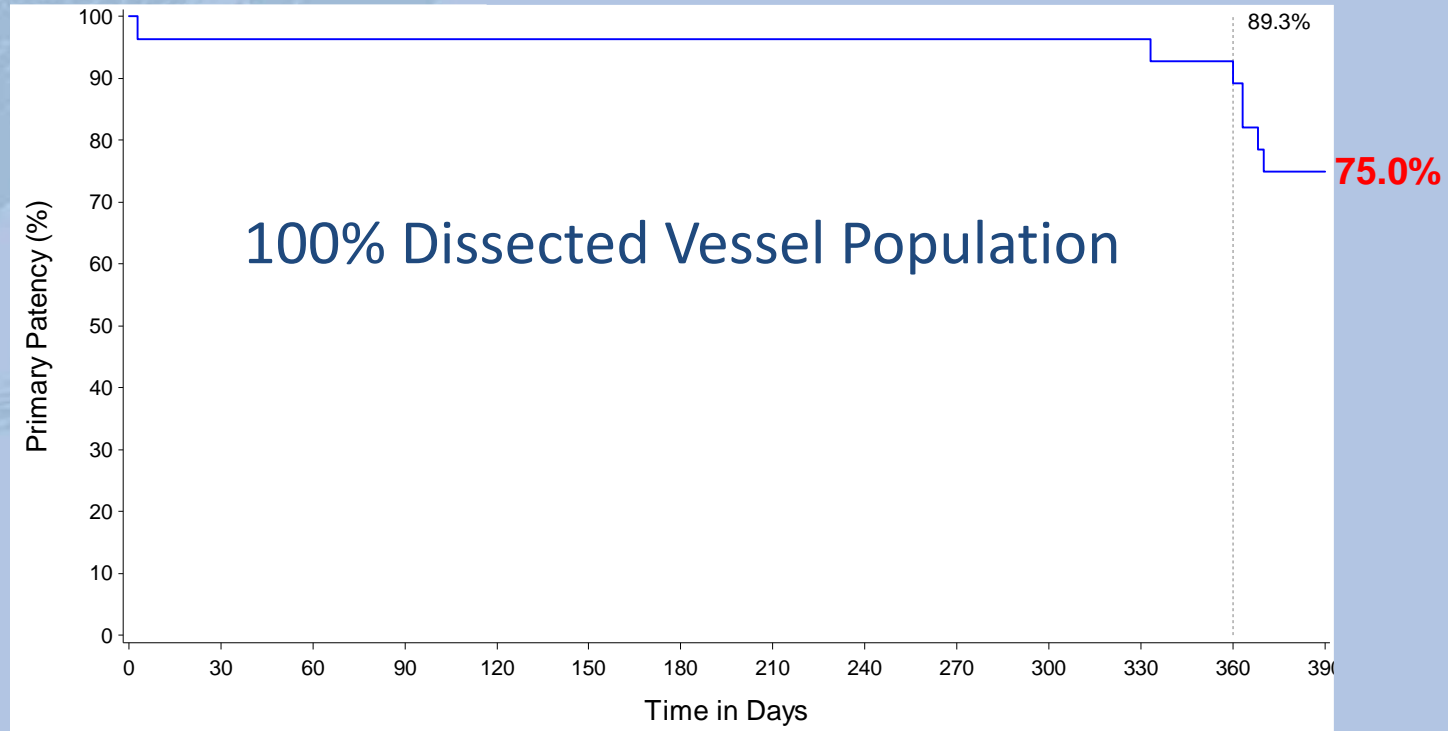
Vascular Ultrasound Core Laboratory: VasCore

12-Month KM Primary Patency (ITT Population: Standard Lesion)



Primary Patency: freedom from CEC-adjudicated CD-TLR and freedom from core lab-adjudicated DUS-derived binary restenosis (PSVR \geq 2.5)

12-Month KM Primary Patency (ITT Population: Long Lesion > 150 mm)



Primary Patency: freedom from CEC-adjudicated CD-TLR and freedom from core lab-adjudicated DUS-derived binary restenosis (PSVR ≥ 2.5)

Practical Applications of Tack Implants for Infrainguinal Dissection Repair – a Single Center Experience

J Endovasc Ther. 2019 Oct 22

- This study aimed to assess the practical application and acute outcomes of the Tack Endovascular System for infrainguinal dissection repair in a real-world setting.
- Consecutive patients who underwent endovascular revascularization for symptomatic peripheral artery disease and experienced dissections requiring treatment, were included in the prospective, single-center, single-arm study.
- A total of 51 patients with 51 lesions and 63 dissections were treated between January and June 2019

NHLBI Scale for Coronary Dissections

0

No dissection

A

Minor linear radiolucency with dye injection with rapid clearance

B

Appearance of a “double-lumen” lucency which rapidly clears

C

Contrast extravasation outside the lumen which persists after dye clears from the lumen

D

A spiral dissection with persistence staining after contrast clears from the vessel

E

A persistent filling defect within the lumen

F

A dissection leading to complete occlusion of the distal vessel

Treatment within the registry



Patient and Lesion Characteristics at Baseline

	Total cohort n = 51	ATK lesions ^b n = 25	BTK lesions ^c n = 26	P-value
Rutherford category				p = 0.017
3	21 (41.2)	15 (60.0)	6 (23.1)	
4	10 (19.6)	4 (16.0)	6 (23.1)	
5	17 (33.3)	4 (16.0)	13 (50.0)	
6	3 (5.9)	2 (8)	1 (3.8)	
Lesion length ≥ 10 cm	39 (76.5)	23 (92.0)	16 (61.5)	p = 0.019
Mean lesion length (cm)	13.2	12.8	18.3	
RVD, mm	4.3 ± 1.5	5.6 ± 0.6	3.1 ± 1.0	p < 0.0001
Diameter stenosis				p = 0.565
70 – 99%	18 (35.3)	10 (40.0)	8 (30.8)	
Total occlusion	33 (64.7)	15 (60.0)	18 (69.2)	
Calcification				p = 0.002
None/mild	18 (35.3)	9 (36.0)	4 (15.4)	
Moderate	20 (39.2)	13 (58.0)	7 (26.9)	
Severe	13 (25.5)	3 (12.0)	15 (57.7)	

Procedural details at baseline

	Total cohort n = 51	ATK lesions ^b n = 25	BTK lesions ^c n = 26	P-value
Contralateral access	20 (40.0)	13 (54.2)	7 (26.9)	p = 0.082
Sheath size				< 0.0001
4	1 (2.0)	1 (4.2)	4 (15.4)	
5	1 (2.0)	0	12 (46.2)	
6	24 (48.0)	12 (48.0)	10 (38.5)	
7	6 (12.0)	0	0	
8	3 (12.0)	3 (12.5)	0	
Treatment				
Approaches/lesion	2.3 ± 0.8	2.7 ± 0.5	1.9 ± 0.8	p = 0.001
POBA only	12 (23.5)	0	12 (46.2)	p < 0.0001
DCB	35 (68.6)	22 (88.0)	13 (50.0)	p = 0.006
Atherectomy	13 (25.5)	11 (44.0)	2 (7.7)	p = 0.004
Lithotripsy	4 (7.8)	3 (12.0)	1 (3.8)	p = 0.350
Stent	2 (3.9)	2 (8.0)	0	p = 0.235

Only 2 ATK lesion with Stent implantation

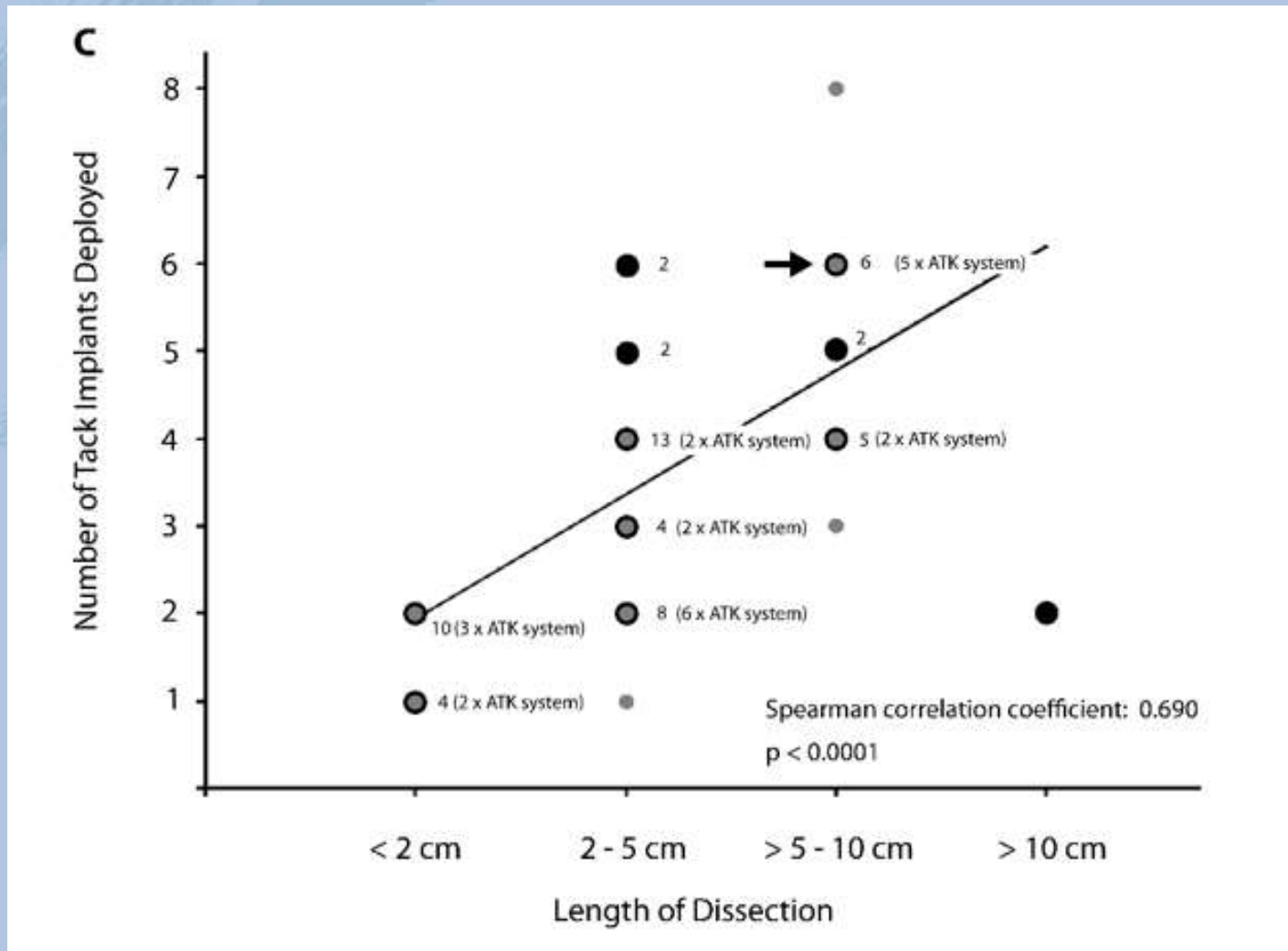
Characteristics of Dissections

	Total cohort n = 63	ATK lesions ^b n = 31	BTK lesions ^c n = 32	P-value
Dissections/Lesion	1.2	1.2	1.2	
NHLBI Grade				p = 0.424
B	7 (11.1)	3 (9.7%)	4 (12.5)	
C contrast outside the lumen	44 (69.8)	22 (71.0)	22 (68.8)	
D	10 (15.9)	5 (16.1)	5 (15.6)	
E	2 (3.2)	2 (6.5)	0	
Dissection length				p = 0.062
<2 cm	14 (22.2)	5 (16.1)	9 (28.1)	
2 – 5 cm	31 (49.2)	15 (48.4)	16 (50.0)	
>5 – 10 cm	16 (25.4)	10 (32.3)	6 (18.8)	
> 10 cm	2 (3.2)	2 (6.5)	0	
Popliteal artery	19 (30.2)	10 (32.3)	9 (28.1)	p = 0.788
P1	4 (6.3)	2 (6.5)	2 (6.3)	
P2	10 (15.9)	6 (19.4)	4 (12.5)	
P3	5 (7.9)	2 (6.5)	3 (9.4)	

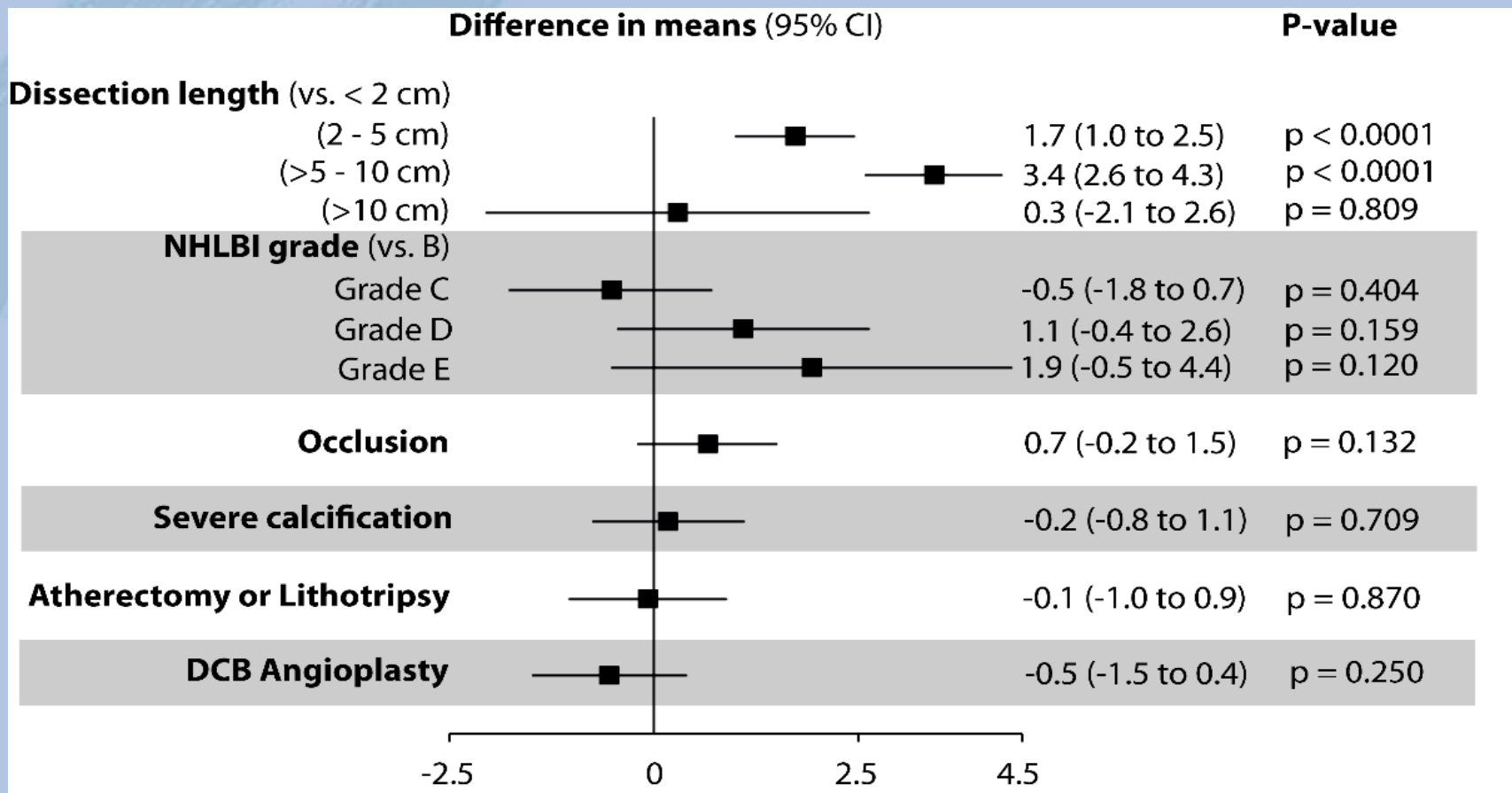
Treatment of Dissections and Outcome

	Total cohort n = 63	ATK lesions ^b n = 31	BTK lesions ^c n = 32	P-value
Tack implanted	60 (95.2)	28 (90.3)	32 (100)	p = 0.226
Type of tack implant				p < 0.0001
6F.035" system	30 (50.0)	26 (86.7)	4 (13.3)	
4F.014" system	30 (50.0)	2 (6.7)	28 (93.3)	
2 tack systems used	3 (4.8)	1 (3.2)	2 (6.3)	p = 0.978
Implants/Dissection	3.4 ± 1.6	3.8 ± 1.7	3.1 ± 1.5	p = 0.181
Post-dilation ^d	61/63 (96.8)	29/31 (93.5)	32 (100)	p = 0.458
Implant resolved dissection	59 (98.3)	27/28 (96.4)	32 (100)	p = 0.946

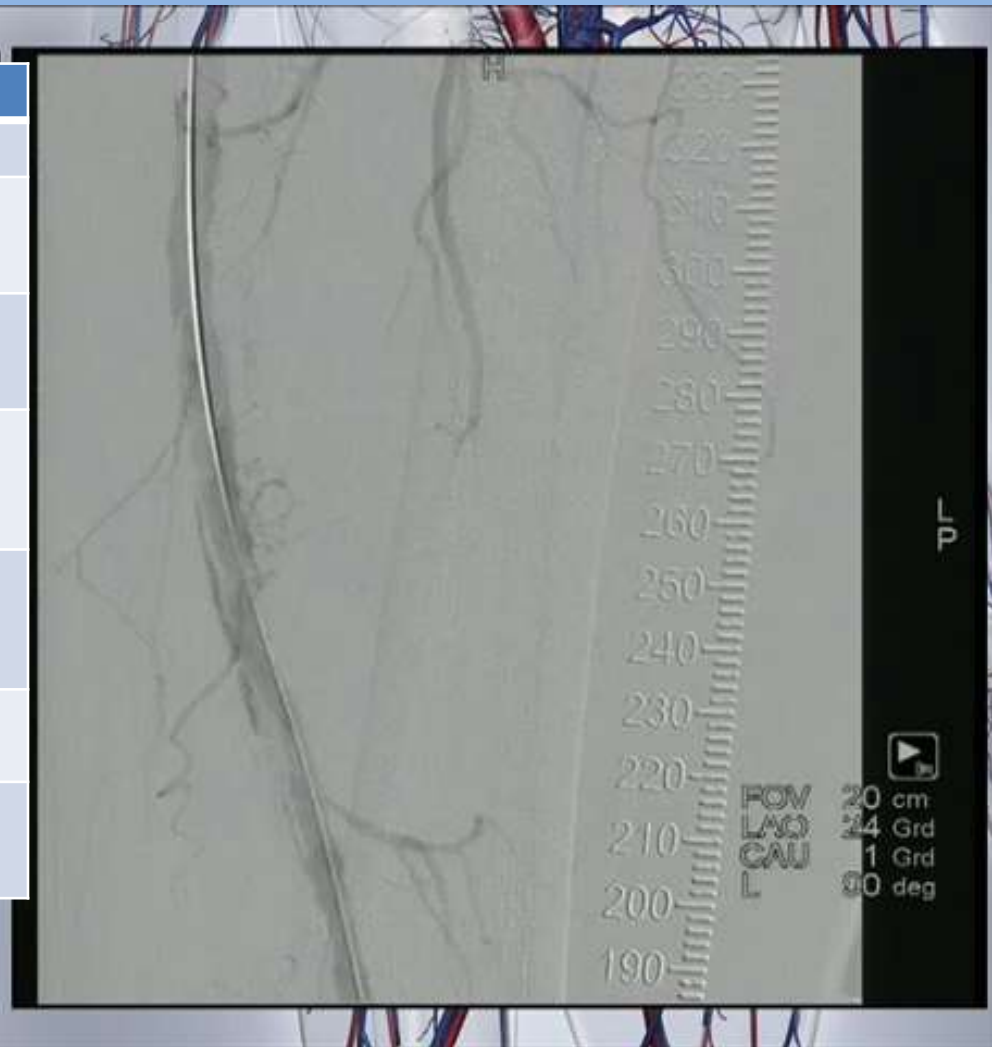
Correlation between length of dissection and number of tack implants of the ATK and BTK system

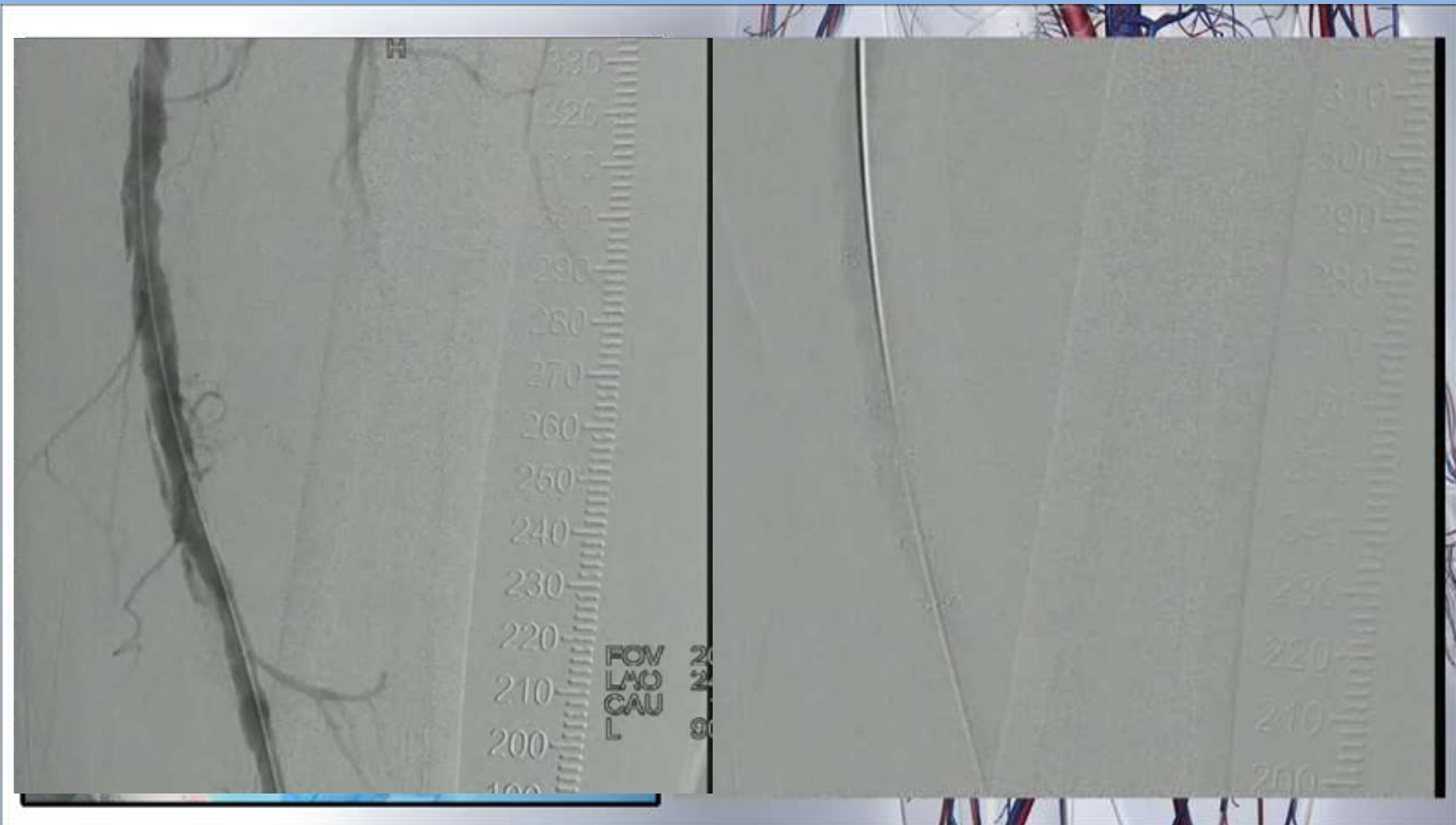


Difference in means of the number of tack implants per dissection depending on selected lesion, procedure, and dissection characteristics.



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0	No dissection
A	Minor linear radiolucency with dye injection with rapid clearance
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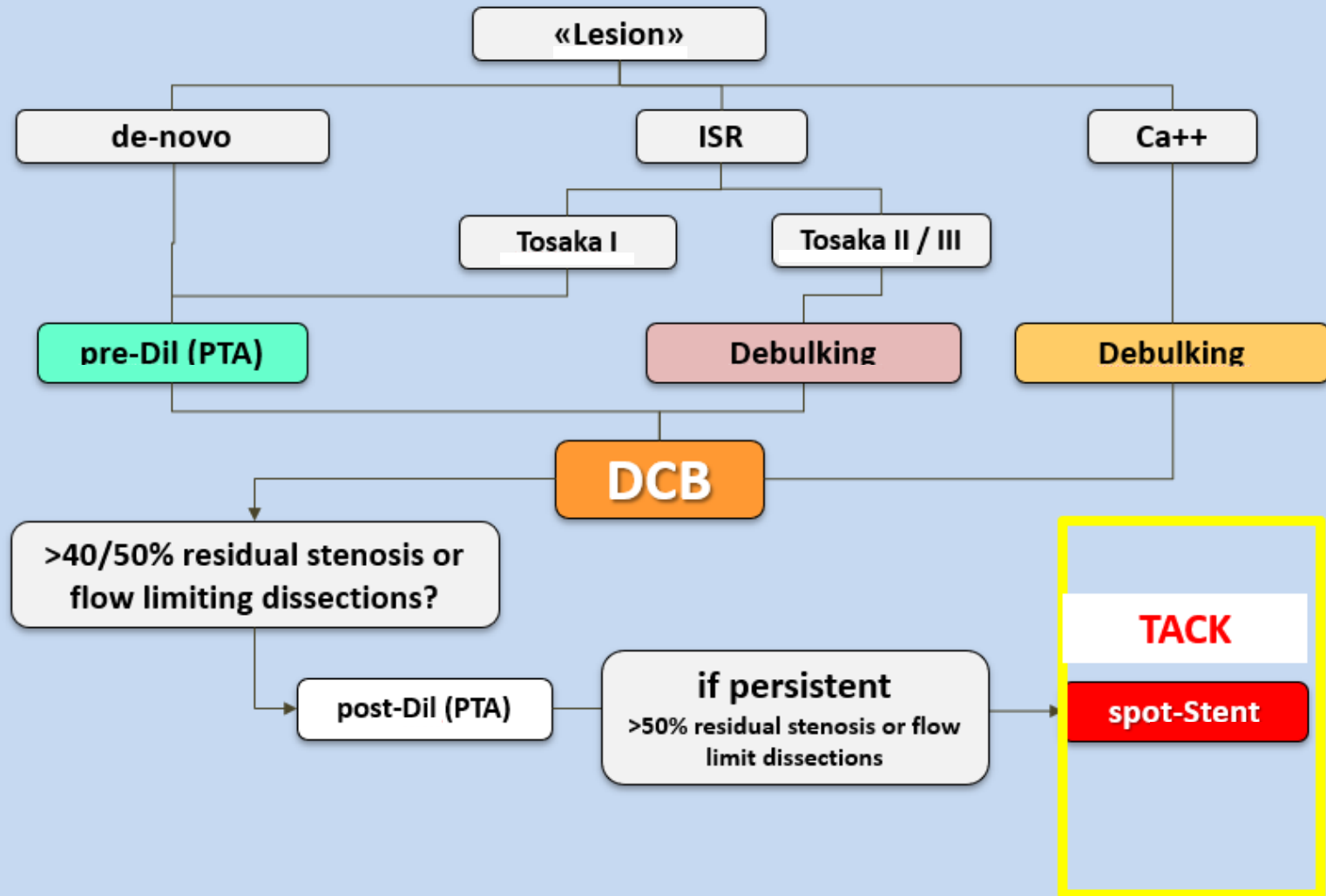




Conclusions

- Treatment with Tack implants resolved 59 of 60 dissections successfully (technical success: 98.3%)
- A lesion preparation therapy (atherectomy, lithoplasty) improved technical outcome
- No periprocedural major adverse event or device related complication occurred (patient related procedural success: 98.0%)
- Only two standard nitinol stents were implanted

CONCEPT OF HOT SPOT STENTING



The LINC logo features the letters 'LINC' in a white, sans-serif font, positioned over a stylized graphic of three curved, overlapping brushstrokes in dark blue, red, and yellow.

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REAL WORLD TACKING ABOVE AND BELOW THE KNEE

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