

Leave Nothing Behind: Algorithm in Treatment of Peripheral Artery Disease

Junmin Bao, MD

Changhai Hospital, Shanghai

Disclaimers

This program is provided for general educational purposes only and should not be considered the exclusive source for this type of information. This training does not replace or supersede approved labeling. The content will be shared with healthcare professionals who seek a deeper understanding of the operation and use of Medtronic products and therapies with the intent of enhancing their knowledge of features and operations described in the clinician manuals. The patient data represented has been changed or removed to protect the privacy of the patient and is designed for educational purposes. At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation. Changes in a patient's disease and/or medications may alter the efficacy of a device or related features and results may vary.

COMPENSATION

This faculty is being paid as a consultant for the services being provided and will be reported in accordance with the Sunshine Act.

Off-Label:

This program, sponsored by Medtronic, is intended to educate and train customers on the approved therapies and FDA indicated uses of Medtronic products.

Medtronic product Instructions for Use can be found at <http://manuals.medtronic.com/>

For questions related to an unapproved use of a Medtronic product, please contact Medtronic's Peripheral Office of Medical Affairs. Email: rs.oma@medtronic.com

Disclaimer cont'd

CAUTION STATEMENT

The content, case study, images, logos, charts, information, and opinions are those of the physician faculty presenting the material and do not necessarily reflect the opinions or position of Medtronic. The materials presented here are provided by and used with permission from the physician faculty. This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

If you are located in the United States, please refer to the brief statement(s) at the end of this presentation to review applicable indications, safety and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1.763.514.4000 and/or consult the Medtronic website at www.medtronic.com.

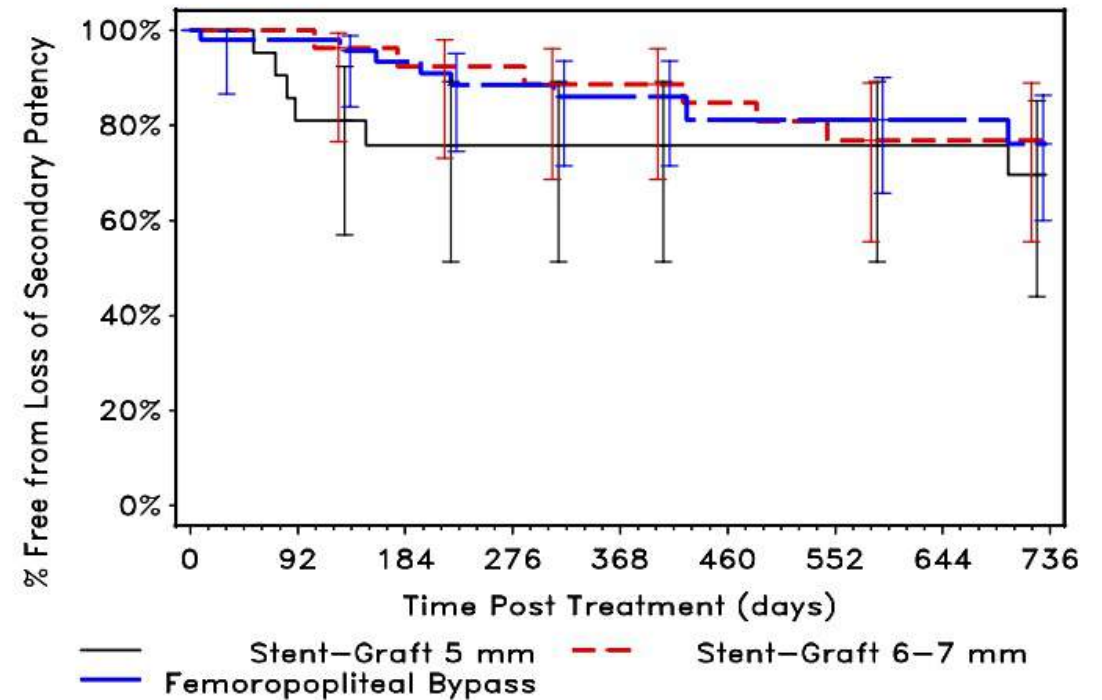
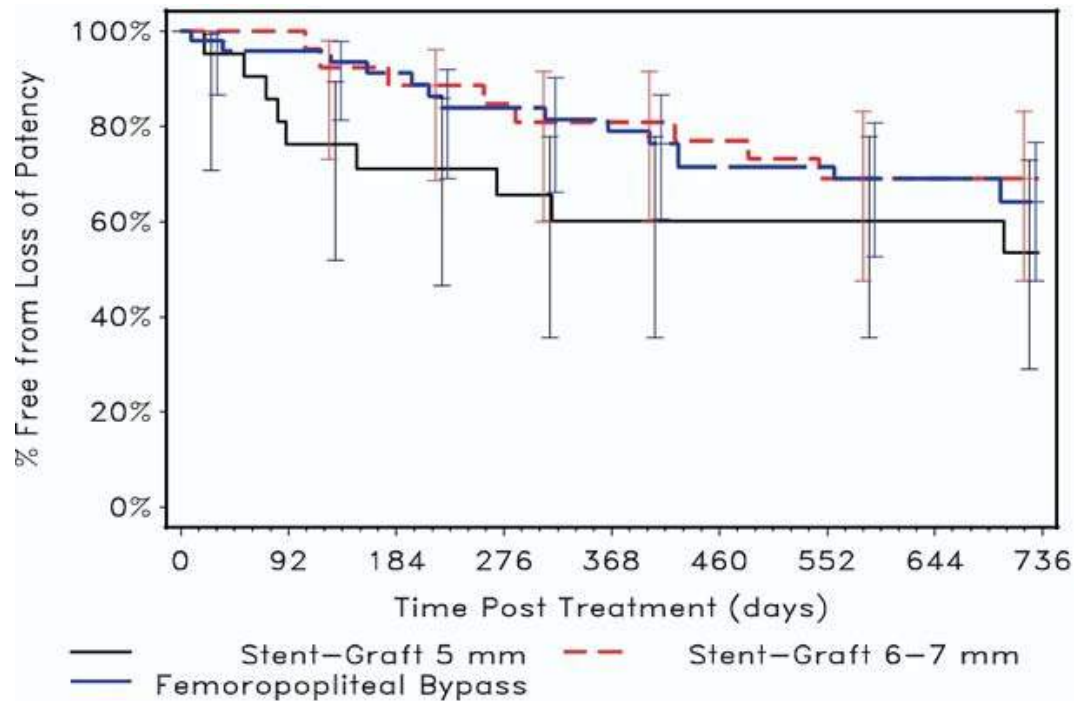
If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

PAD Treatment: Endovascular vs Open

Meta analysis:

In SFA occlusive lesions, no significant difference between primary patency of endovascular treatment and open surgery at 24mo.



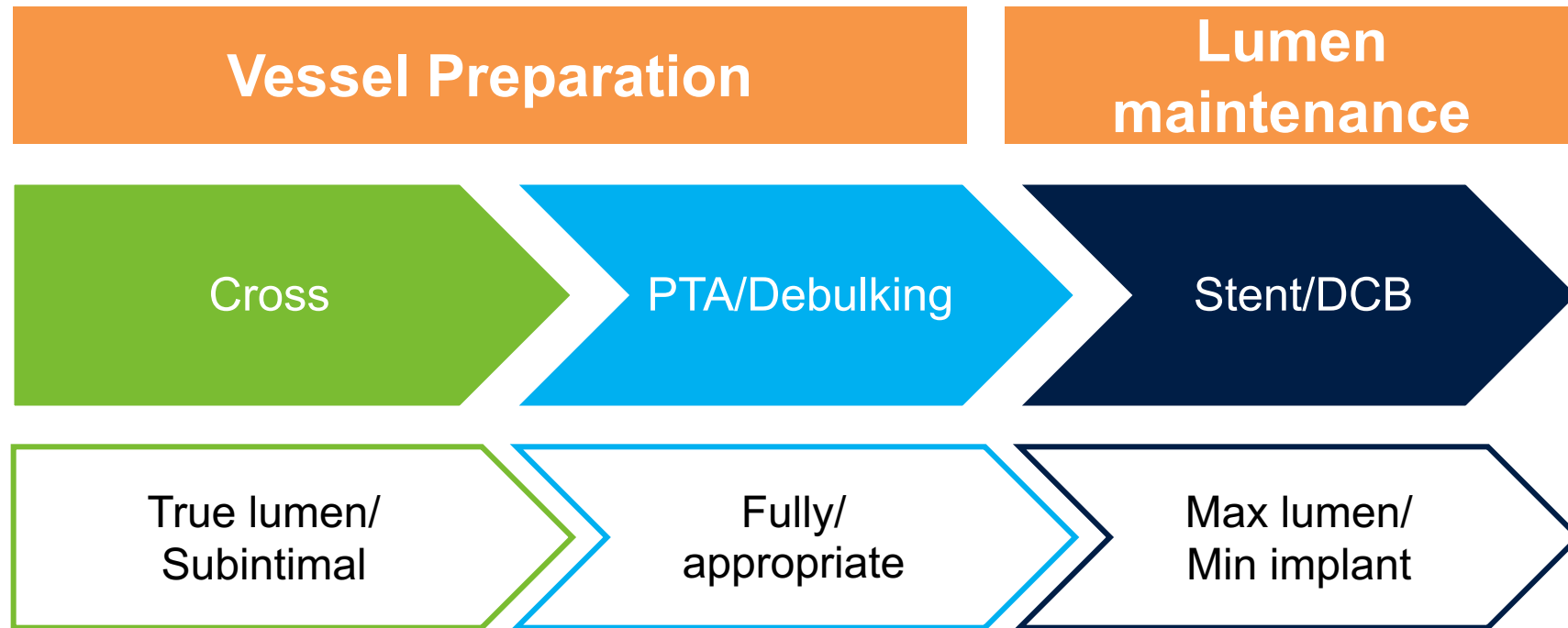
1. McQuade K, Gable D, Hohman S, et al. J Vasc Surg. 2009;49(1):109-15, 116.e1-9; discussion 116.

Leave nothing behind
Leave something behind
Leave the right thing behind

- **Lesion characteristics** : stenotic/CTO, Length
thrombosis/calcification
- **Individual factors** : age, gender, smoking, DM/HP...
- **Technical factors**: TX method, device selection...

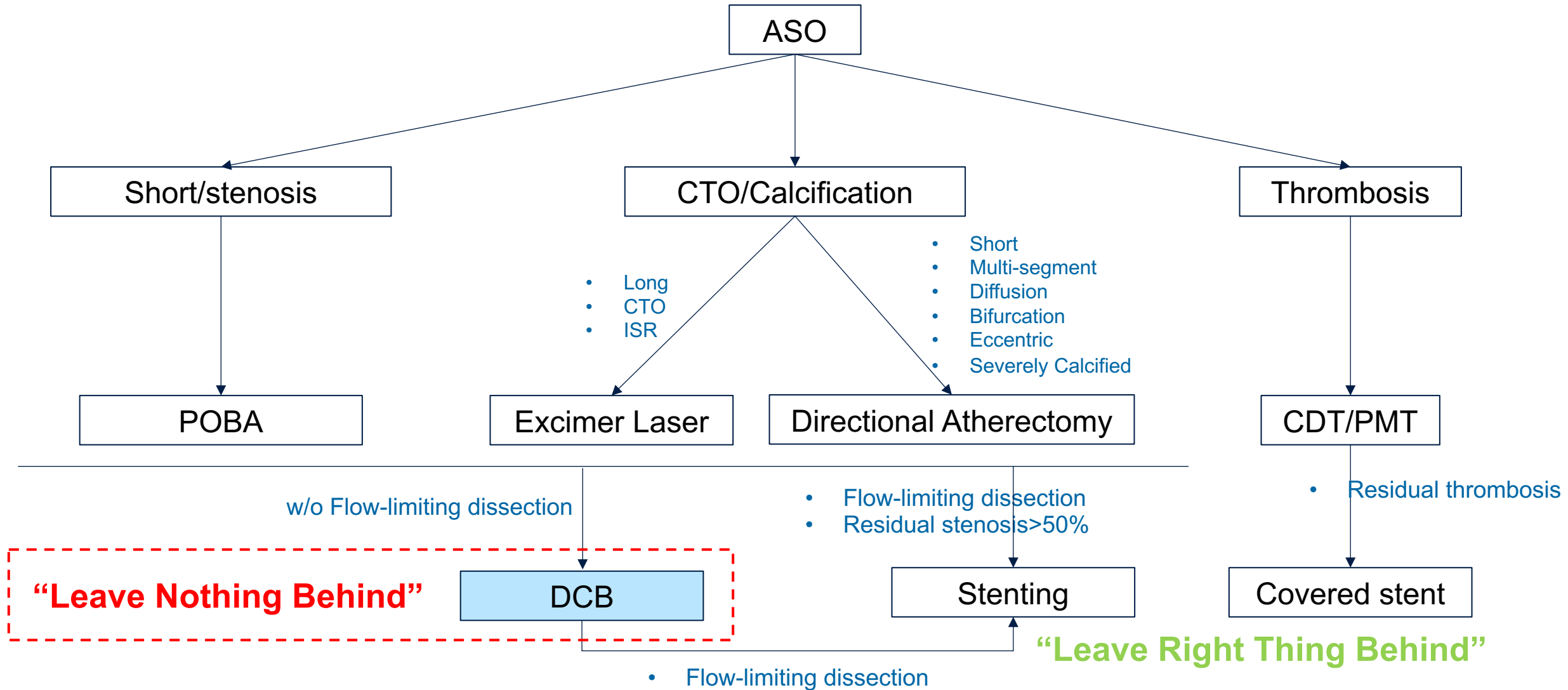
PAD: Treatment Algorithm

PAD Treatment Algorithm



**Optimization of PAD treatment algorithm is key to improve efficacy
Lesion characteristics is criteria of treatment option.**

“Leave Nothing Behind” Algorithm in Treatment of PAD



Vessel Preparation

For better Drug uptake or stenting:

- POBA, Debulking- remove or modify plaque to gain lumen

Criteria of Vessel Preparation:

- maximize lumen gain;
- minimize recoil,
- minimize residual stenosis (<30%)
- minimize flow-limiting dissections (NHLBI classification, pressure gradient, IVUS)

POBA

Mechanism of PTA

Adventitial stretching,
medial necrosis,
dissection or plaque fracture



Acute lumen gain



Blood flow restoration

- **Vessel properties**
 - muscular vs elastic properties
- **Lesion characteristics**
 - Location
 - extent of vessel wall calcification

Optimal PTA outcome:

- <30% residual stenosis
- Without flow-limiting dissection



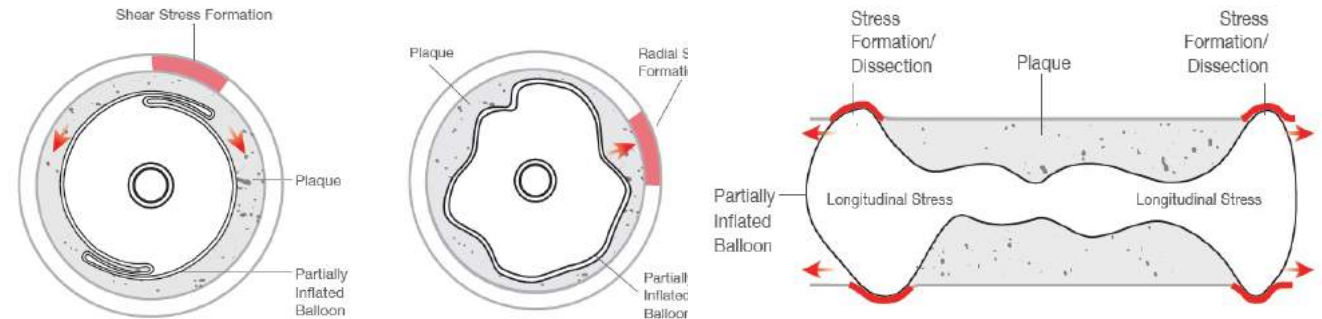
**Dissection
Recoil
Early restenosis**

(the diffuse nature of infrapopliteal disease and plaque complexity)

POBA Dissection Rate

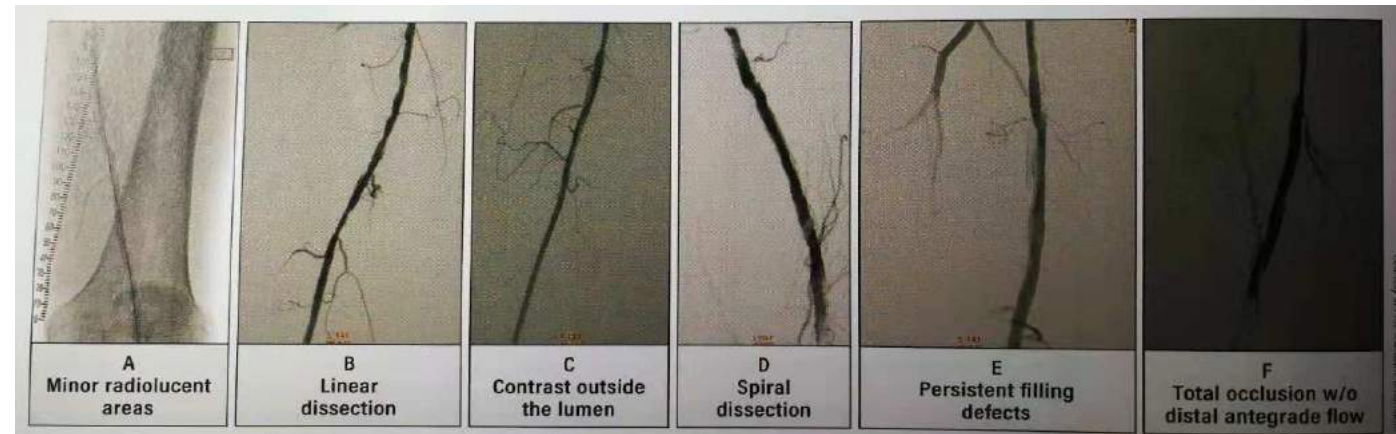
■ SFA

- All types: 42%~88%
- Severe, flow-limiting (C-F): >42%



■ Infrapopliteal

- Limited data source, even higher

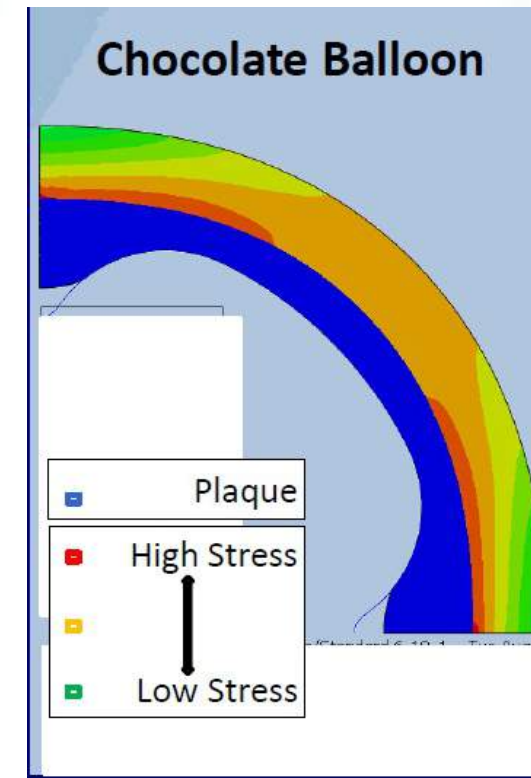
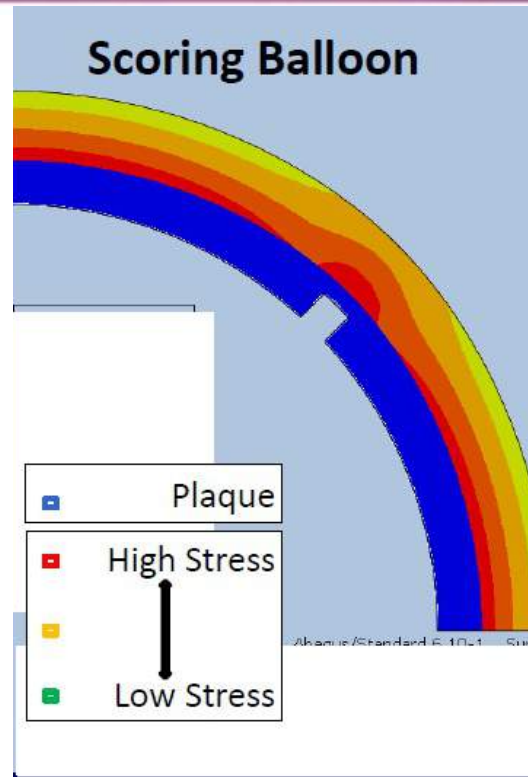
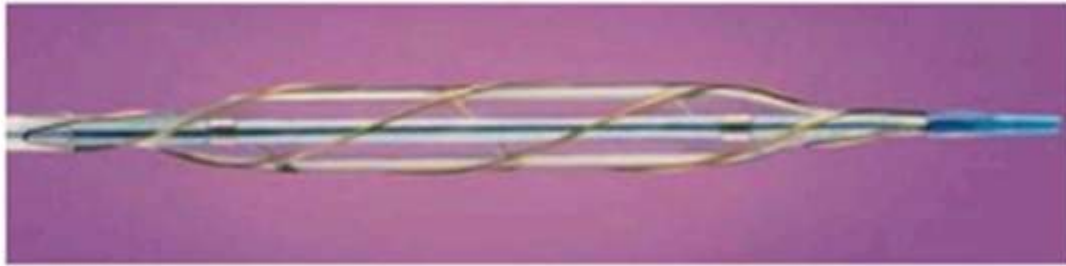


S. SPILIOPOULOS ET AL. EXPERT REVIEW OF MEDICAL DEVICES 2019, VOL. 16, NO. 7, 581–588

Optimized POBA Dilatation

- Slower dilatation with longer balloon, lower pressure
- Sequential dilatation
- Non-compliant balloon
- Lower and focal pressure dilatation (scoring), constraining (Chocolate balloon)

Specialty Balloon

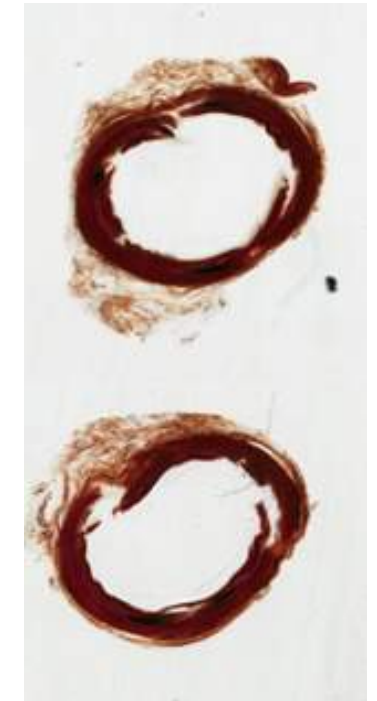
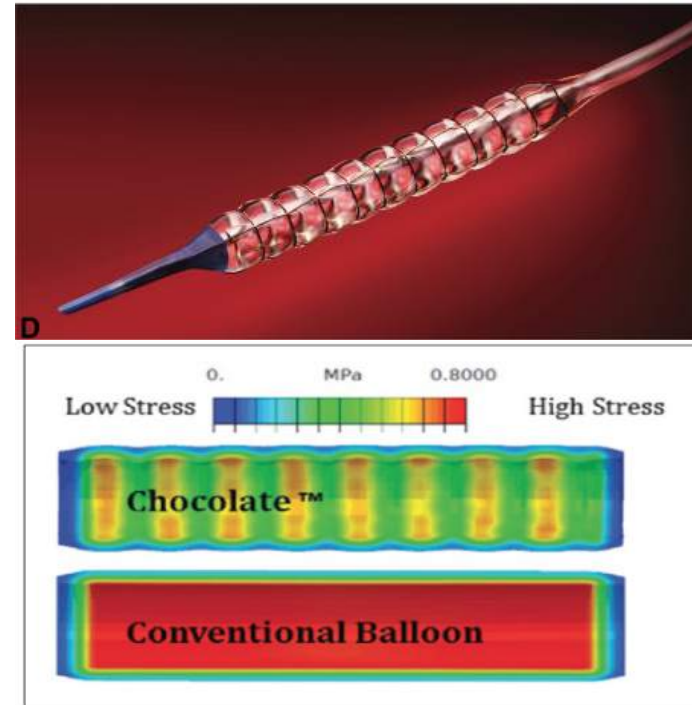


Chocolate Balloon Design

- Shield the vessel wall from torsional stress. Creates “pillows” and “grooves” that relief plaque pressure, limit dissection and increase the contact surface area to **120%**
- Grooves prevent dissection to expand



**Limited provisional stenting;
Minimize neointimal proliferation caused by
barotrauma and inflammatory reaction.**



Chocolate oversize 1.3:1
2 mm apart

Debulking

Atherectomy:

- Directional atherectomy (TurboHawk™ plaque excision system): short, multi-segment, eccentric, severely calcified and popliteal lesions
- Excimer laser atherectomy (Turbo Elite): thrombosis, calcification, CTO, ISR

Thrombectomy:

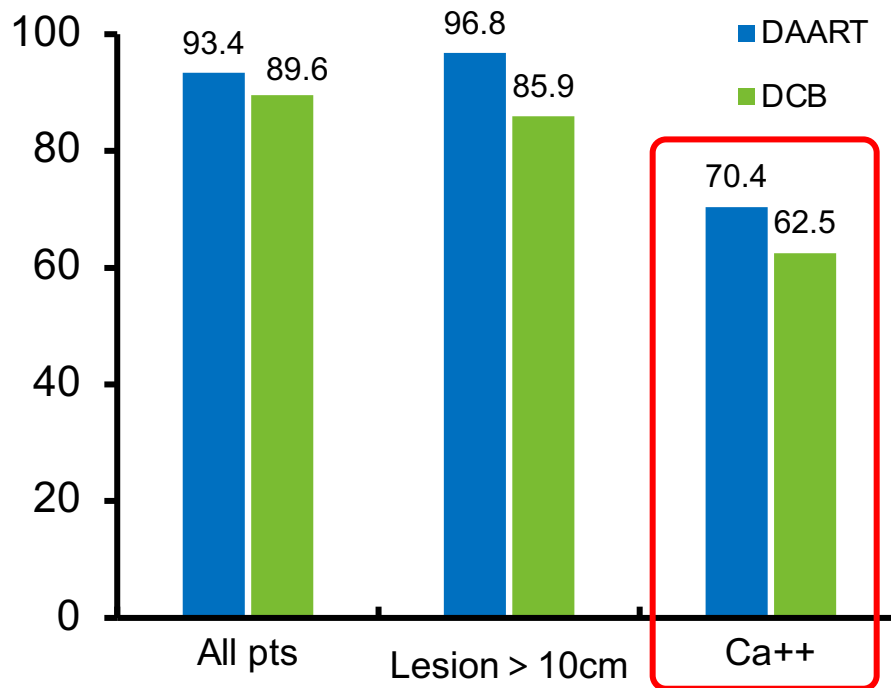
- Rotarex™*: acute and subacute thrombosis
- Anjojet™*: acute thrombosis

Indication of Different Debulking Devices

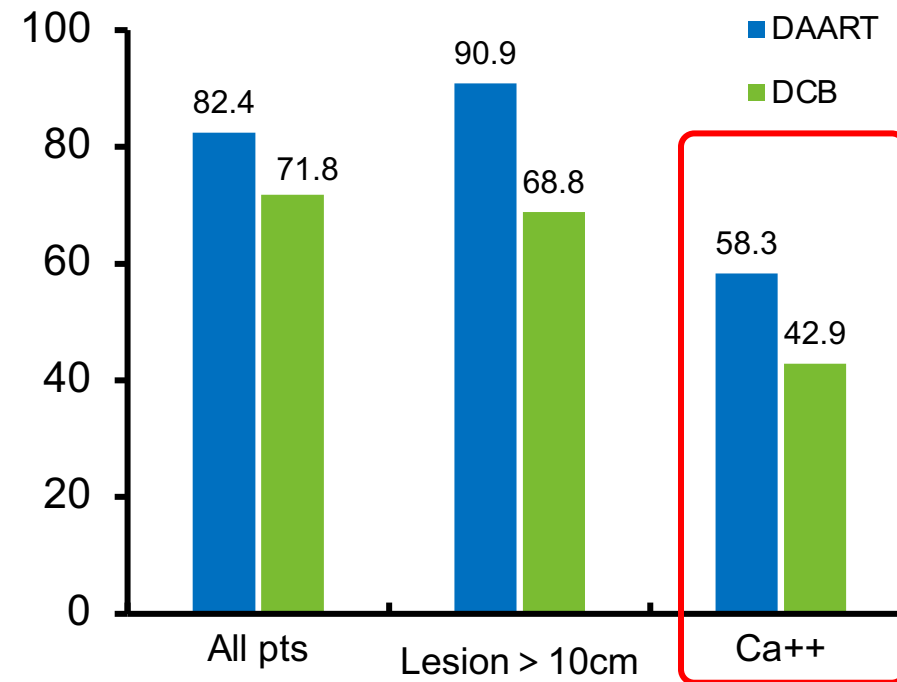
	Directional	Rotational	Laser	Orbital
	TurboHawk system	Jetstream™* XC	Excimer Laser	Diamondback™* 360
Short, eccentric	√√	√	√	√
Thrombosis	—	√√	√	—
BTK	√	√	√	√
Calcified	√√	√	√	√
ISR	—	—	√√	—
CTO	√√	√√	√√	√

DAART

PP@12mo - DUS



PP@12mo - Angiography



In treating heavily calcified lesions, DAART may be superior to DCB alone

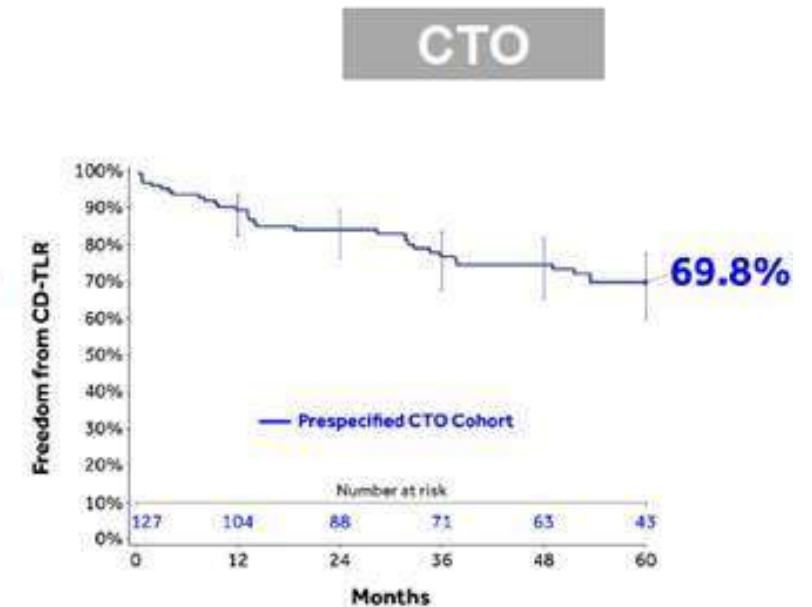
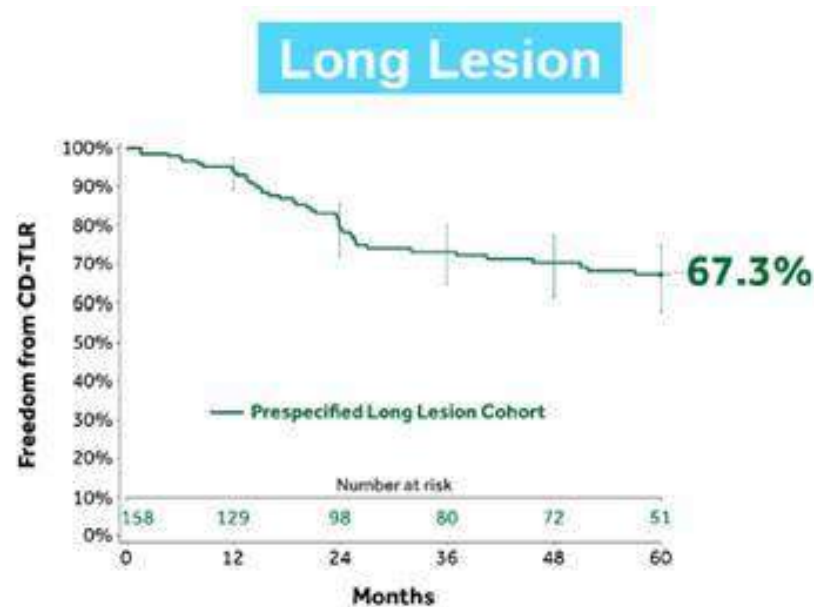
DCB

Pre-DCB, It's important to evaluate-

- Lesion length and calcification
- True lumen or subintimal
- Optimized vessel preparation

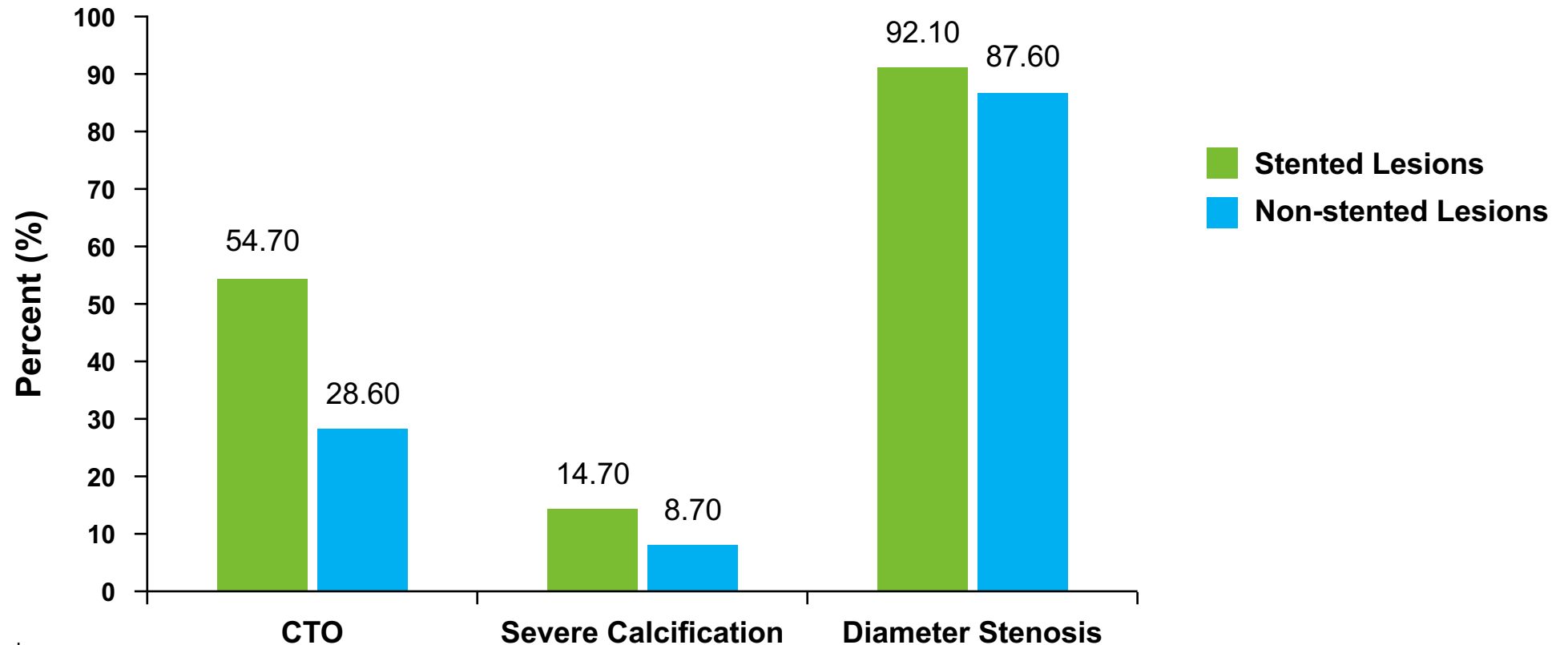
Updated DCB Efficacy Results in Complex Lesions

5-Year Outcomes From the IN.PACT Global Study Prespecified Cohorts: CTO, Long Lesions, and ISR| Prof. Gunnar Tepe



Stenting: IN.PACT Global Study

Complexity at Baseline Baseline Lesion Characteristics

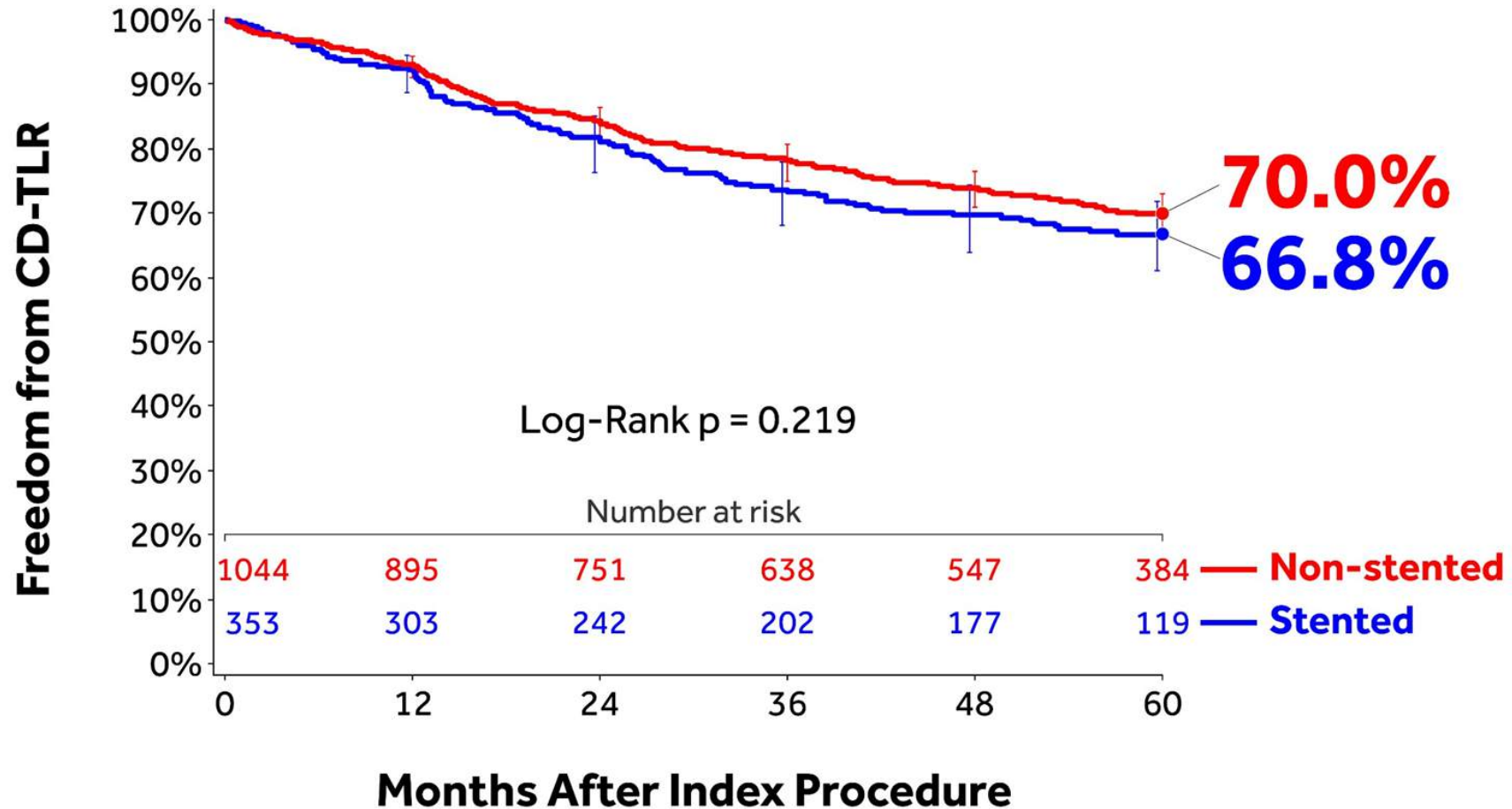


- *Data is site reported per lesion.

¹Severe calcium definition used by study sites and core laboratory is bilateral calcium at the same location (also measured in sections), \geq half of the total lesion length, $\geq 180^\circ$ (both sides of the vessel at the same location). Dattilo R, et al. *J Invasive Cardiol.* 2014;26(8):355-360.

Stenting: IN.PACT Global Study

Freedom from CD-TLR Through 5 Years



Conclusion

- Endovascular treatment has become preferred option in PAD treatment (De novo and restenosis);
- In vessels without indication of stenting, especially the popliteal artery, optimized vessel preparation with appropriate devices plus drug-coated balloon could be a rationalized algorithm of “Leave Nothing Behind” at current stage; Provisional stenting can be back up when necessary;
- Thorough evaluation of lesion characteristics and capable of different methods or tools is crucial to the success of PAD treatment.