

Optimizing Outcomes with Tibial Atherectomy



Main Line Health[®]

Well ahead.[™]

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Below the knee: calcium pathology is differentiated

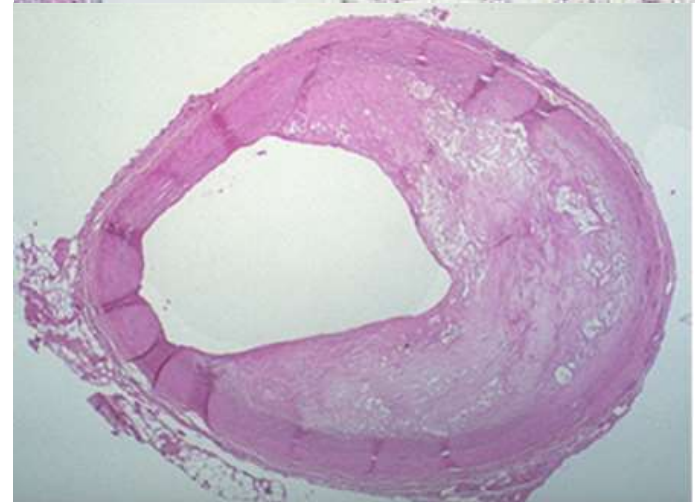
Diabetic Macro Angiopathy:

Symmetric diffuse vessel wall thickening due to connective degeneration and medial (macrophages free) calcification [particularly evident in BTK arteries]



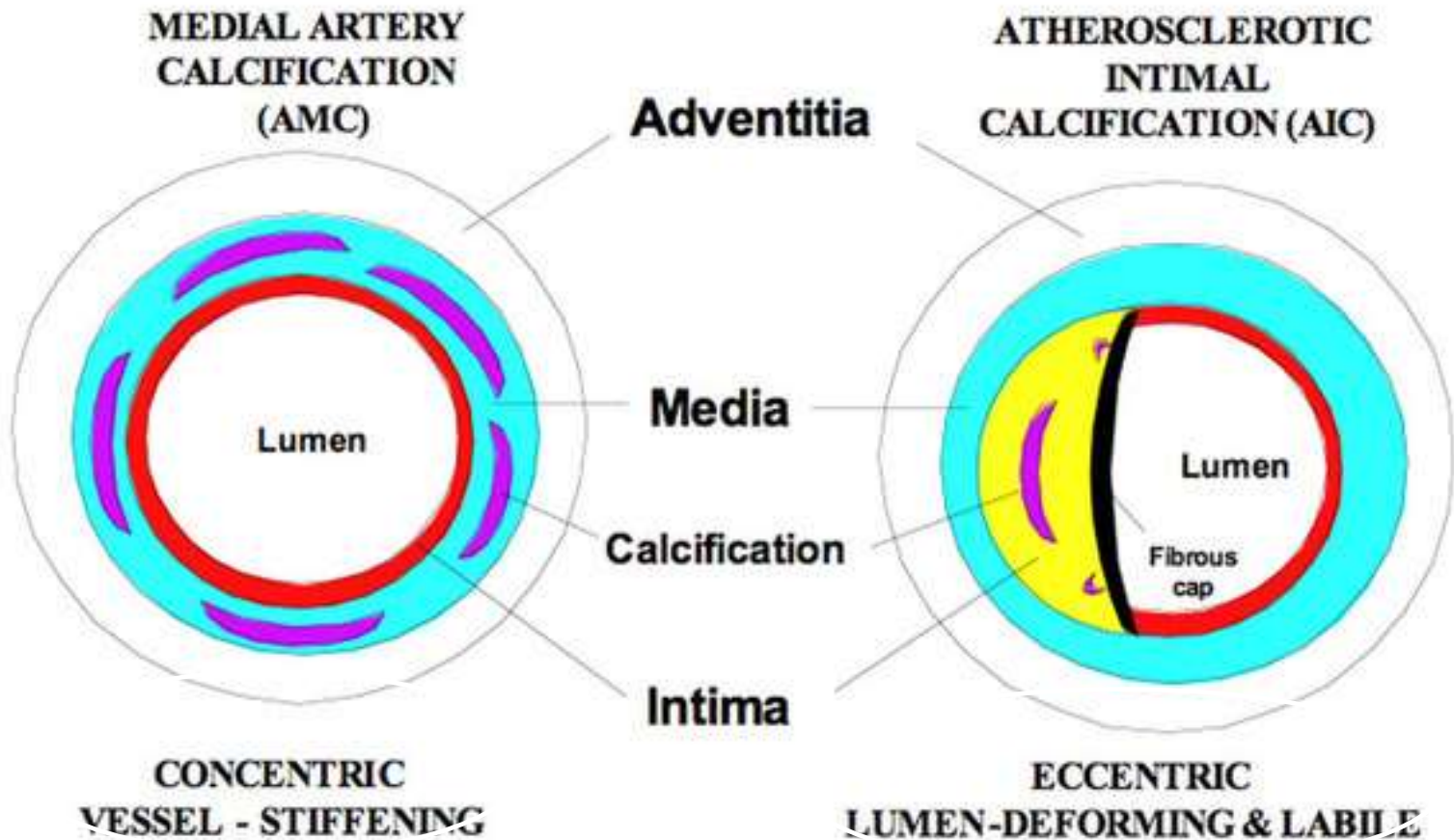
Atherosclerosis:

Asymmetric distribution (plaque) and extension, with focal-eccentric sub-intimal and medial atheroma degeneration (common in Carotid and Iliac arteries; the only one present in the Coronary tree)



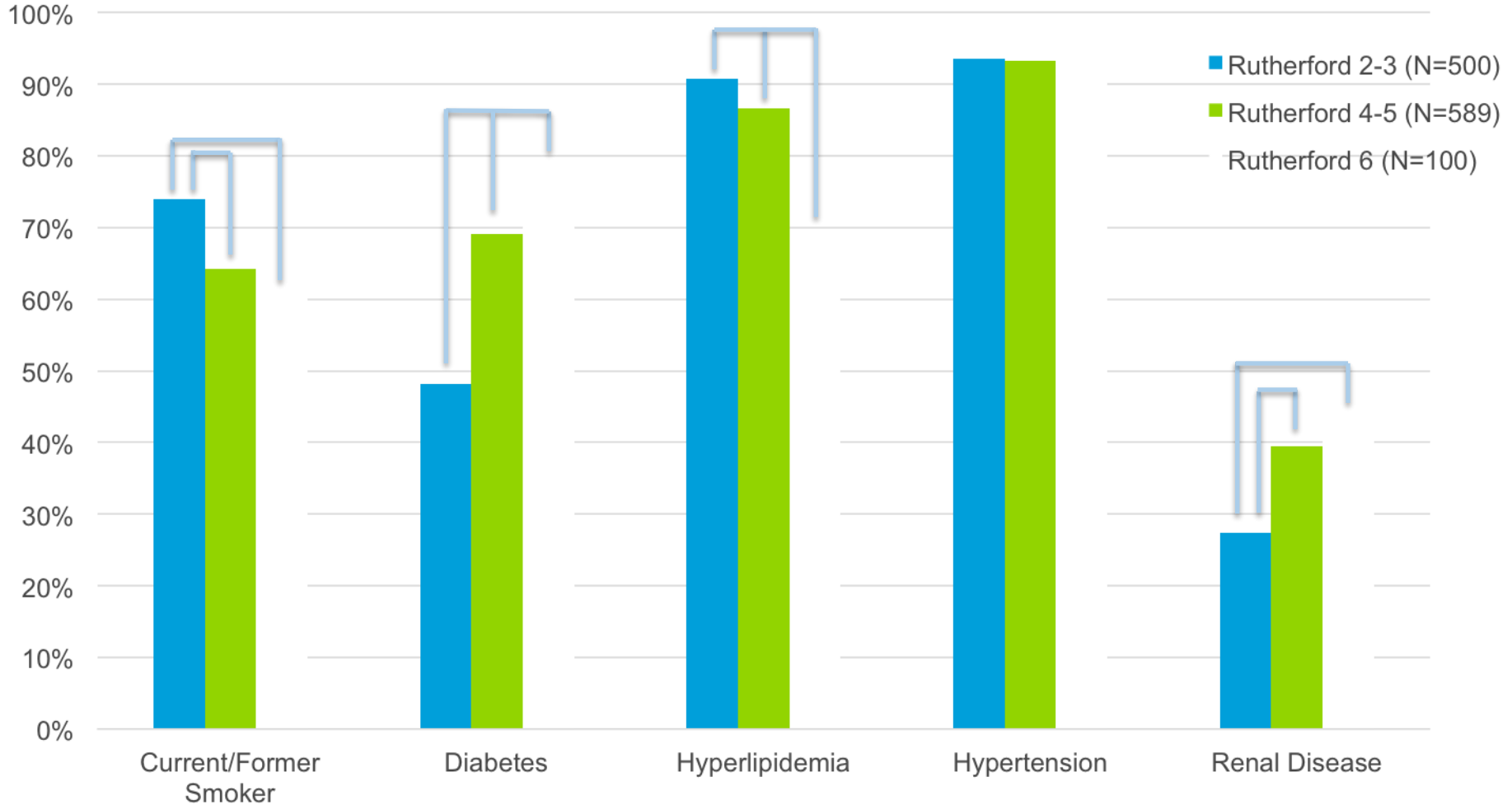
Shanahan, Cary, Salisbury, Proudfoot, Weissberg, Edmonds. Circulation.1999;100:2168-2176

Calcification type as it relates to the lesion



LIBERTY Demographics: Medical History

Comorbidities/Predictors of PAD are prevalent across all Rutherford Classes. Hypertension is a hallmark of PAD.

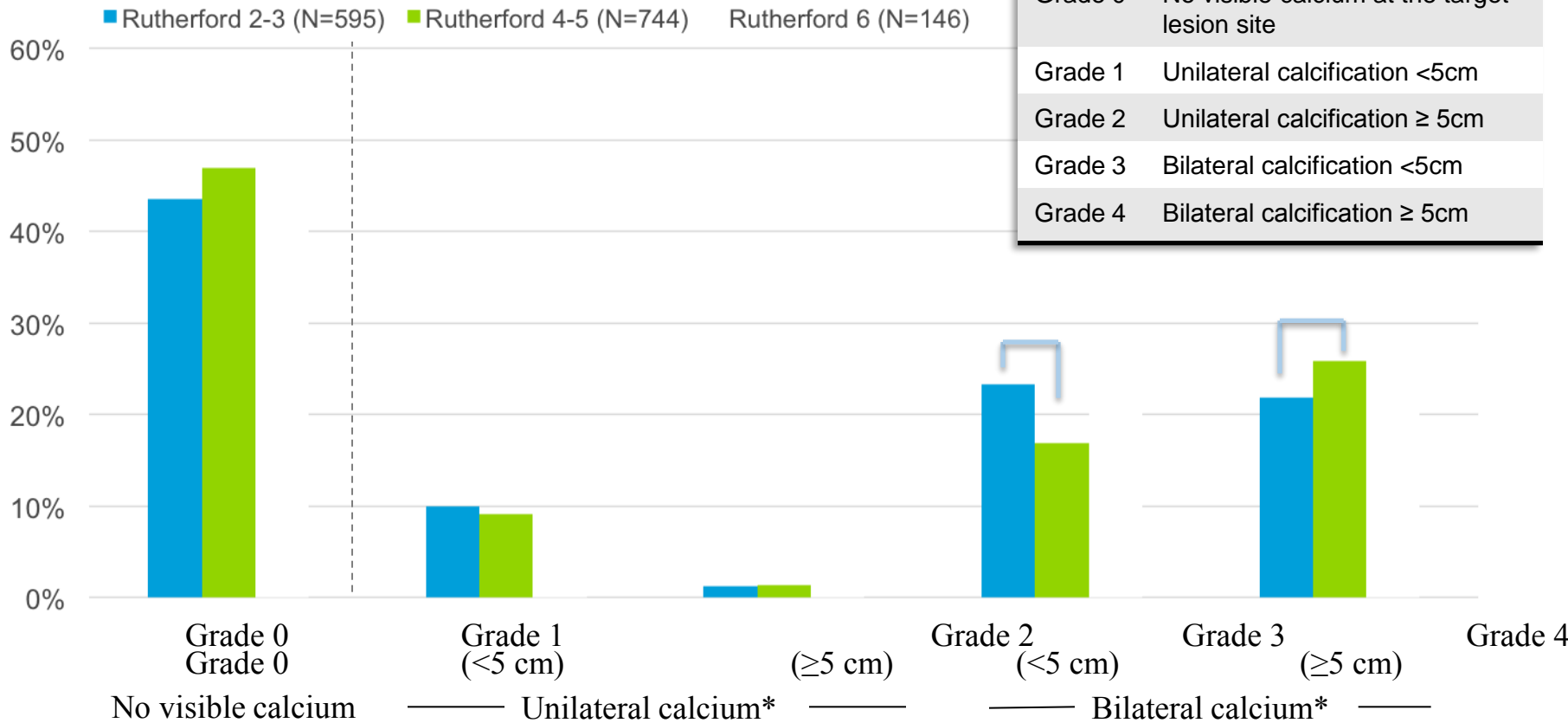


Comparison between Rutherford categories significant ($p < 0.05$)

Patients with reported values may be less than total number of patients enrolled in each arm.

LIBERTY: Target Lesions

High prevalence of calcification regardless of Rutherford Class. Approximately 50% of lesions were calcified (unilateral or bilateral).

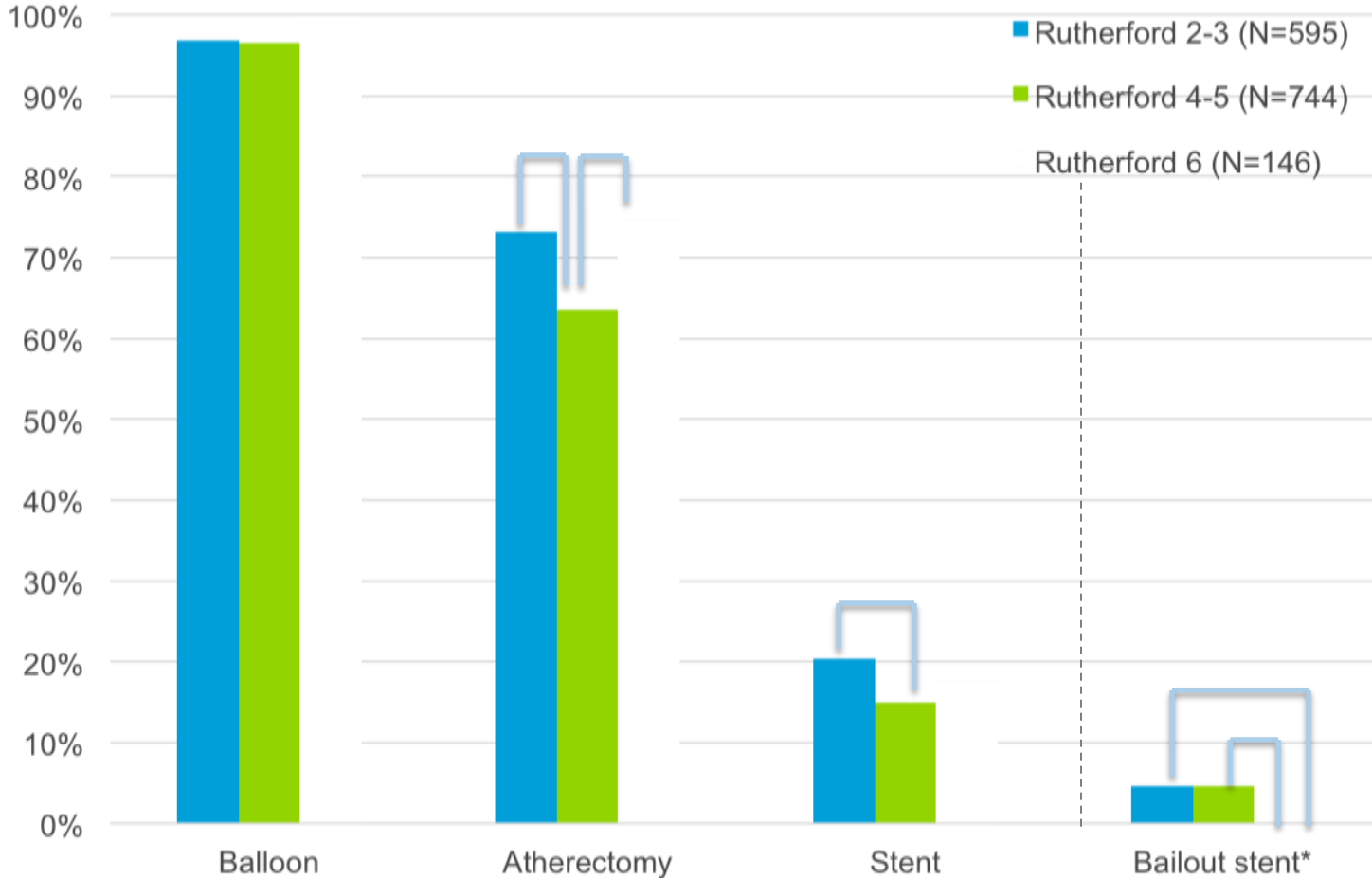


Peripheral Arterial Calcification Scoring System (PACSS)¹

*Calcium on one (unilateral) or both sides (bilateral) of the target artery/lesion

LIBERTY Device Usage by Lesion

Balloon and/or atherectomy were preferred devices



Comparison between Rutherford categories significant ($p < 0.05$)

LIBERTY Physician Reported Outcome

The LIBERTY 360 physicians selected devices they thought appropriate for each lesion being treated. Approximately 95% of those that responded, indicated that the lesion outcome was desirable.

Case Report Form Question: “In investigator’s opinion, was desired outcome achieved?”

Rutherford 2-3
(N=373)



■ Yes

Rutherford 4-5
(N=552)



■ Yes

Rutherford 6
(N=74)



Yes

Site reported lesions.

Question was asked at time of lesion treatment, not all physicians responded for all lesions treated.

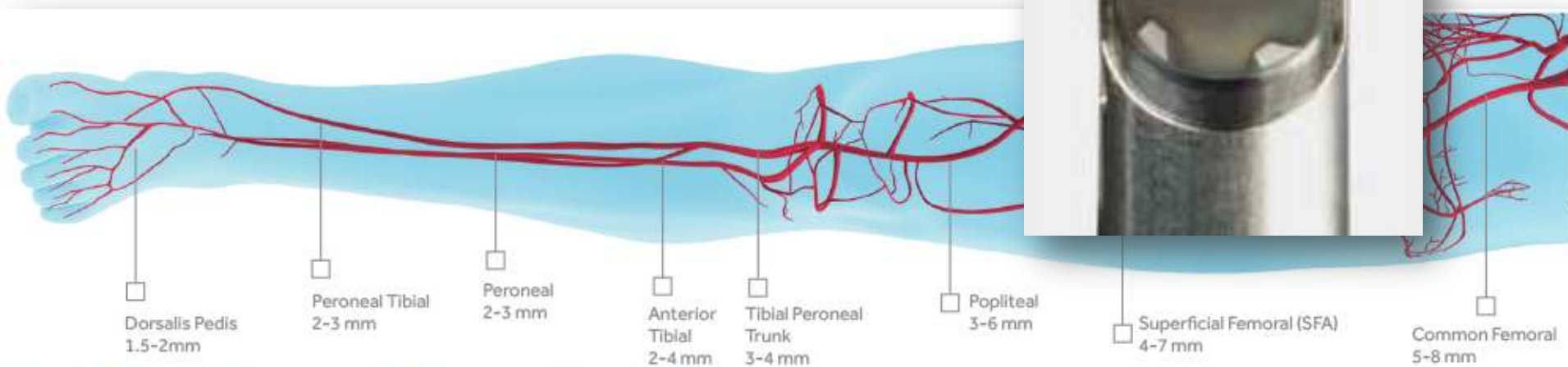
When to debulk?

- Resistant lesions
- Obvious long segments of exophytic calcium
- When you think about debulking...

Debulking Devices

- HawkOne (Medtronic)
- JetStream (BSC)
- DiamondBack 360 (CSI)
- Turbo Elite excimer laser (Spectranetics)
- Phoenix (Volcano)

Medtronic HawkOne



HawkOne™ Directional Atherectomy System

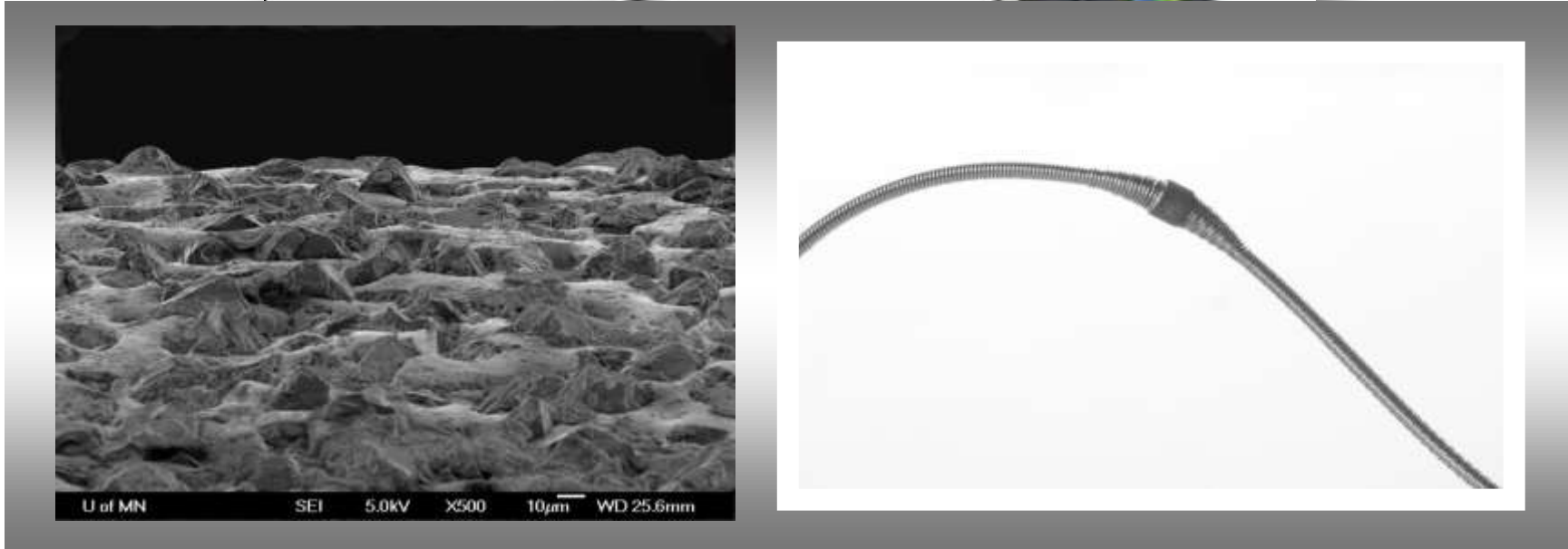
	Model name	Catalog number	Vessel diameter (mm)	Sheath compatibility (F)	Maximum guidewire (in)	Crossing profile (mm)	Working length ¹ (cm)	Effective length ² (cm)	Tip length (cm)	Maximum cut length (mm)	Packing device
7F	HawkOne LS Standard Tip	H1-LS	3.5 - 7.0	7.0	0.014	2.6	114	107	6.6	50	■
	HawkOne LX Extended Tip	H1-LX	3.5 - 7.0	7.0	0.014	2.6	114	104	9.6	75	■

¹Working Length - Distal end of pre-loaded flush tool, in the proximal position, to the distal end of tip.
²Effective Length - Distal end of pre-loaded flush tool, in the proximal position, to the proximal end of cutter window

BSC Jetstream



CSI OAS



CSI: Calcium 360 randomized trial

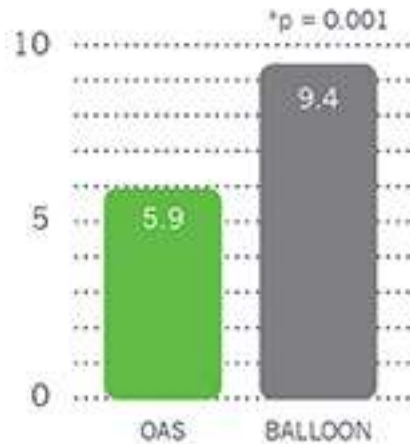
Calcium 360 Study Design

- **Prospective, multi-center**
- **Randomized 1:1: Diamondback 360 vs POBA**
- **Inclusion Criteria**
 - **Clinical evidence of PAD in in the popliteal, peroneal and/or tibial vessels**
 - **Rutherford Classification 4-6**
 - **Symptoms of rest limb pain, ulcerations or severe claudication**
 - **Lesion must be classified as at least mildly calcified, defined as fluoroscopically visible calcium \geq 25% of the treated segment**
- **50 patients enrolled at 8 sites in US**
 - **29 lesions in OAS arm**
 - **35 lesions in POBA arm**

CSI: Calcium 360 study

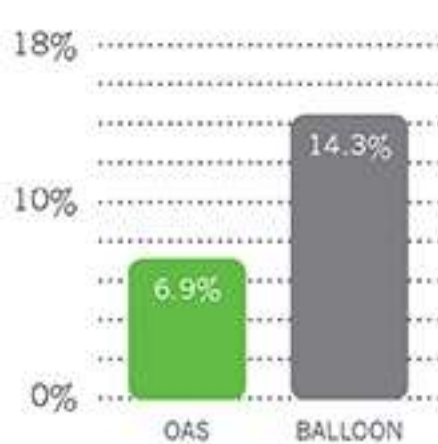
Max Balloon Pressure

Average Max Balloon Pressure (atm)*

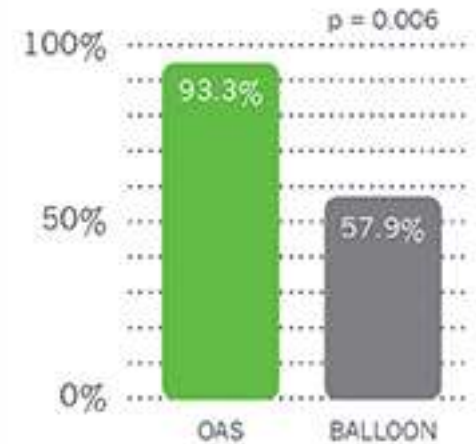


Bail-Out Stenting

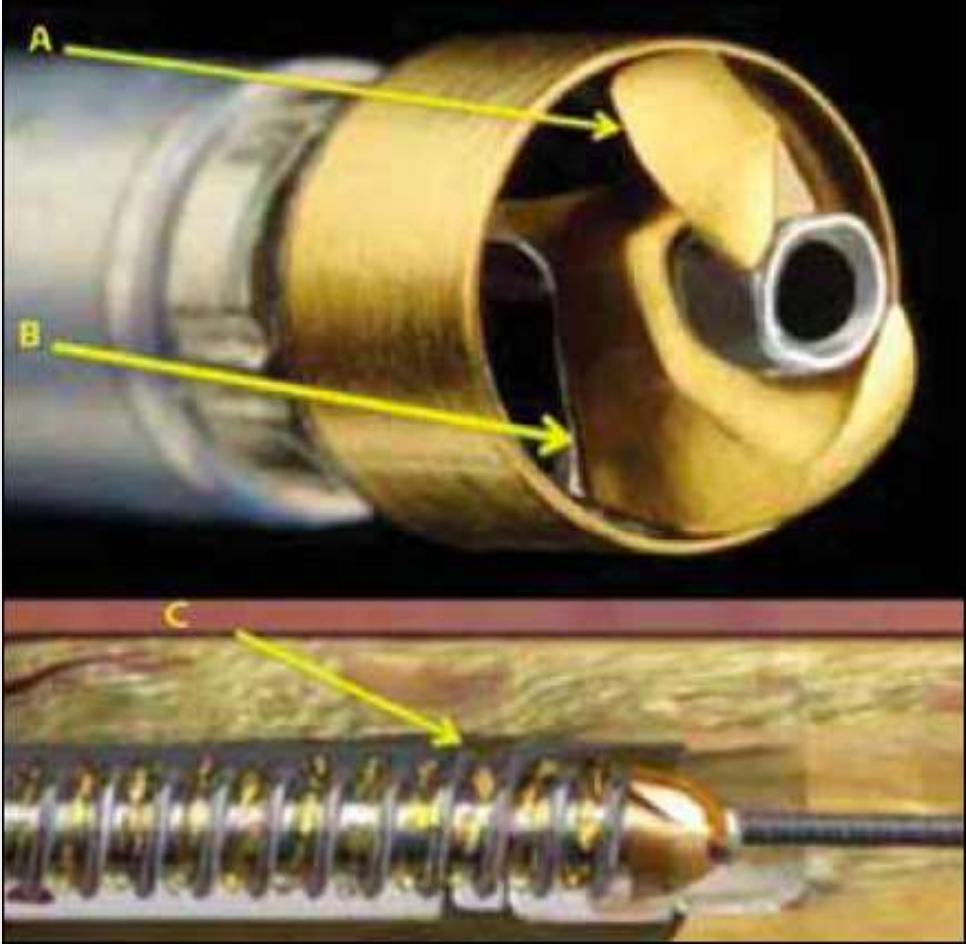
% Patients Requiring Bail-out Stents



Freedom from Major Adverse Events (MAE)*

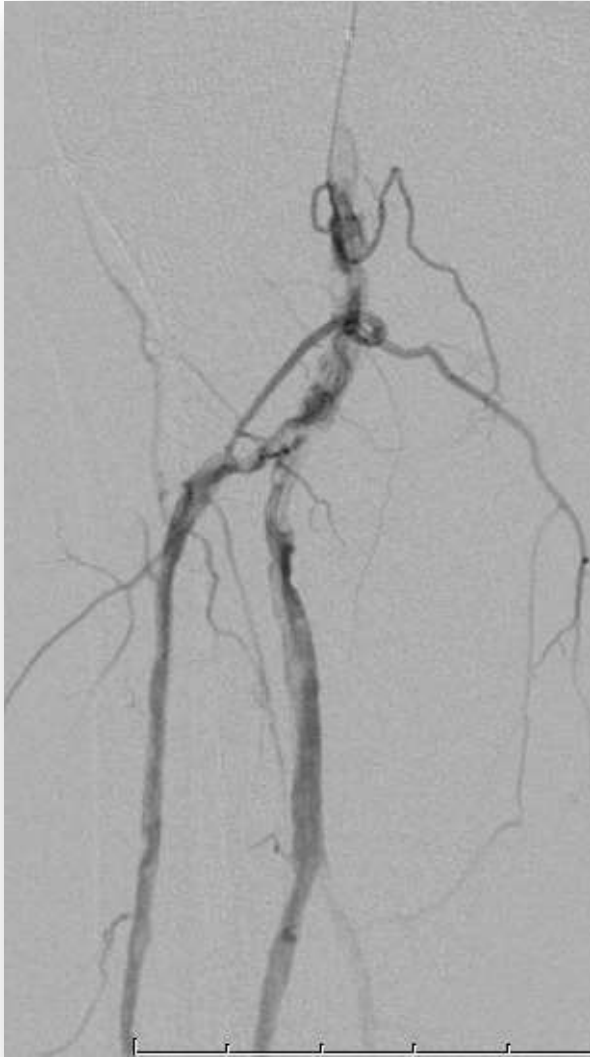


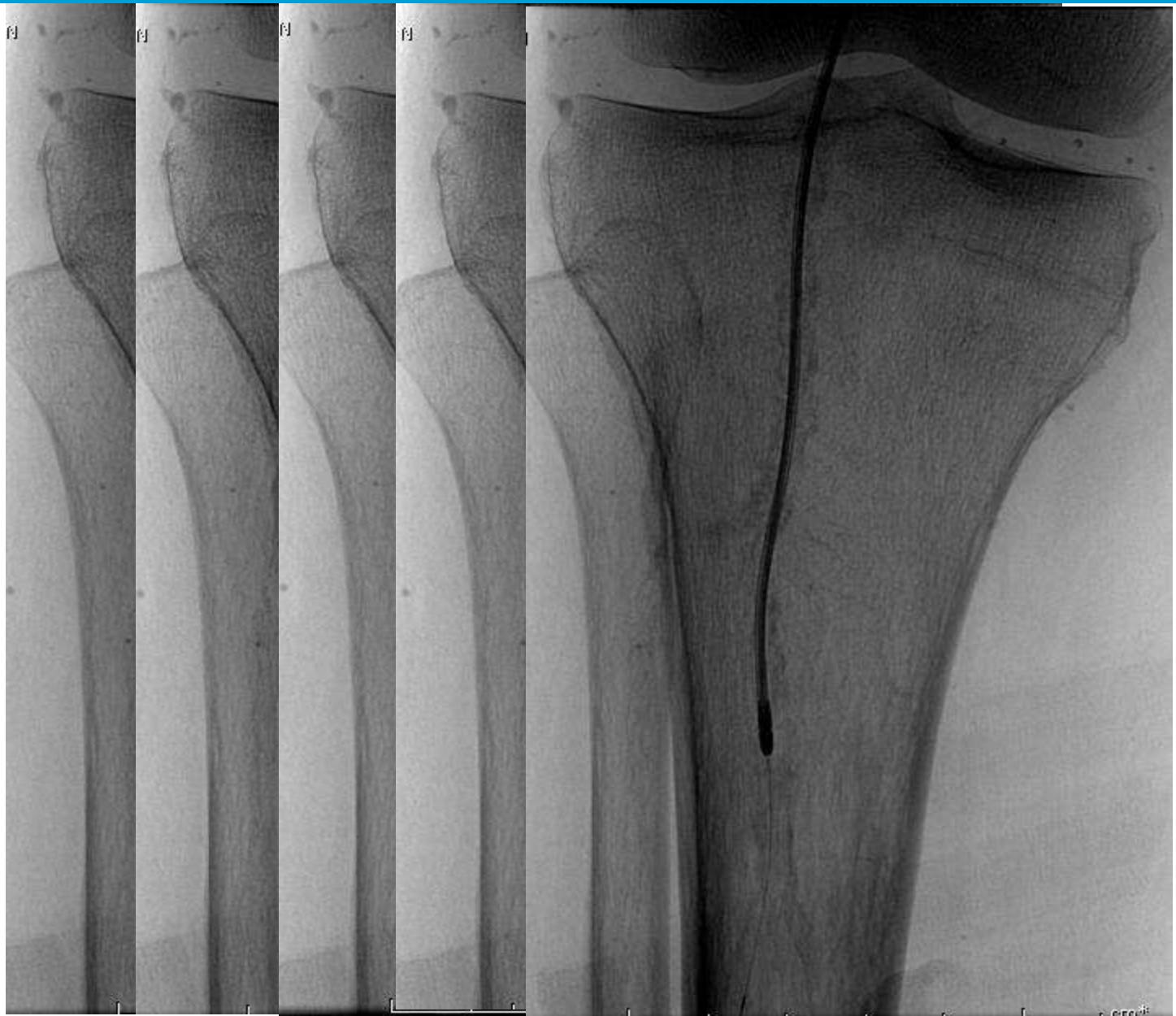
Volcano Phoenix

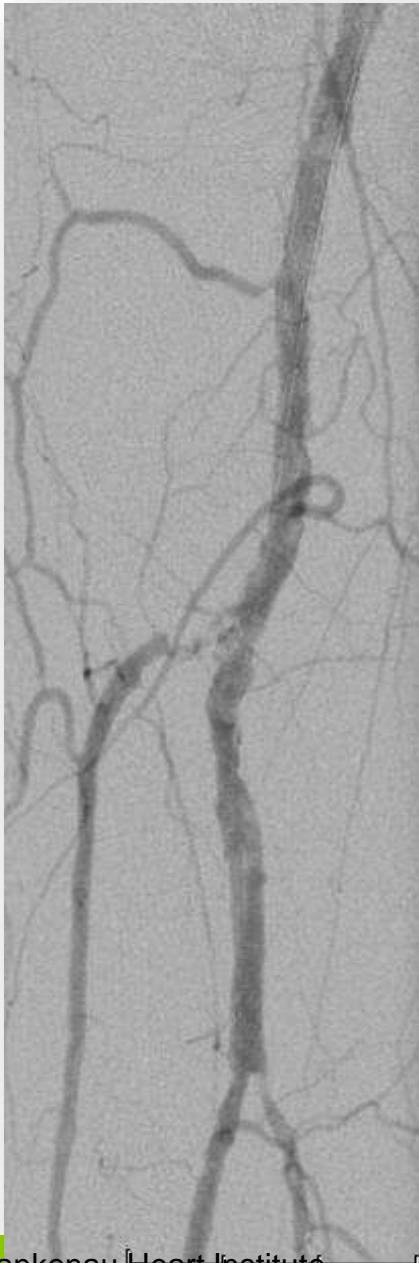


Case examples

BSC Jetstream



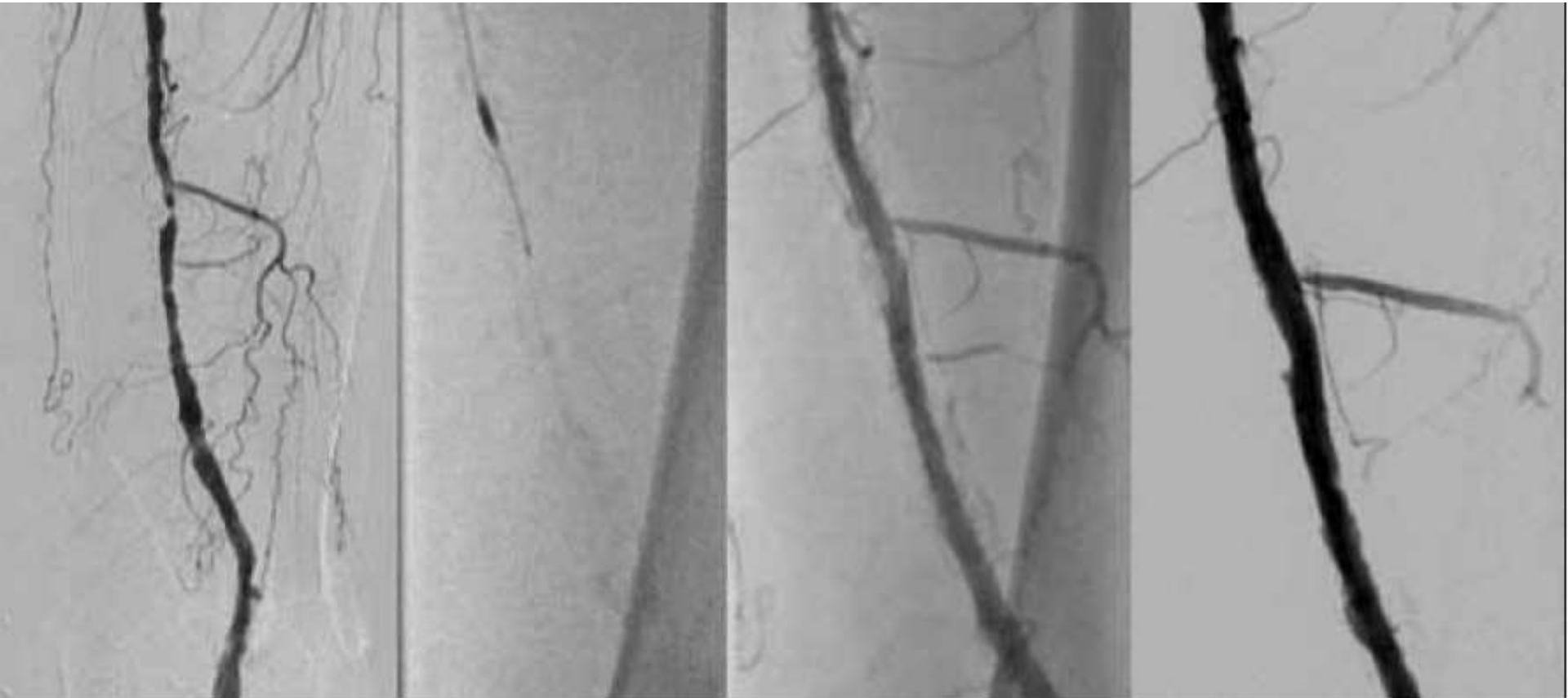


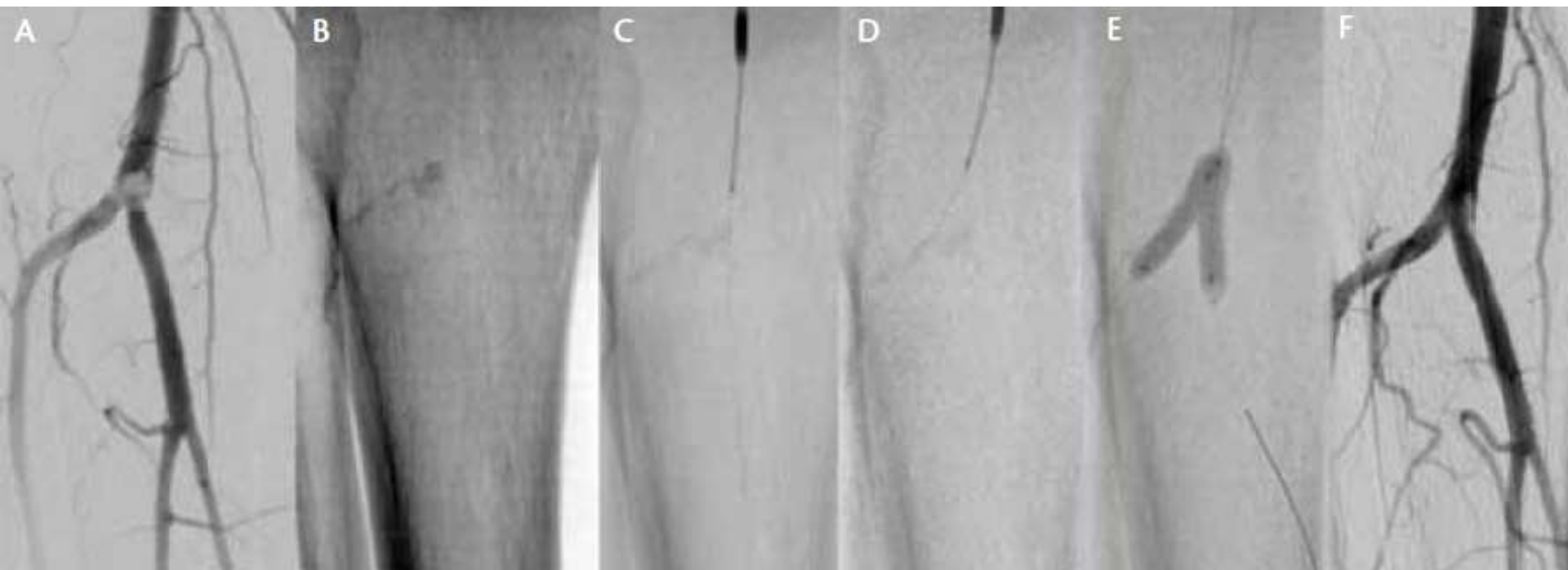


3 mm Xience V



CSI OAS

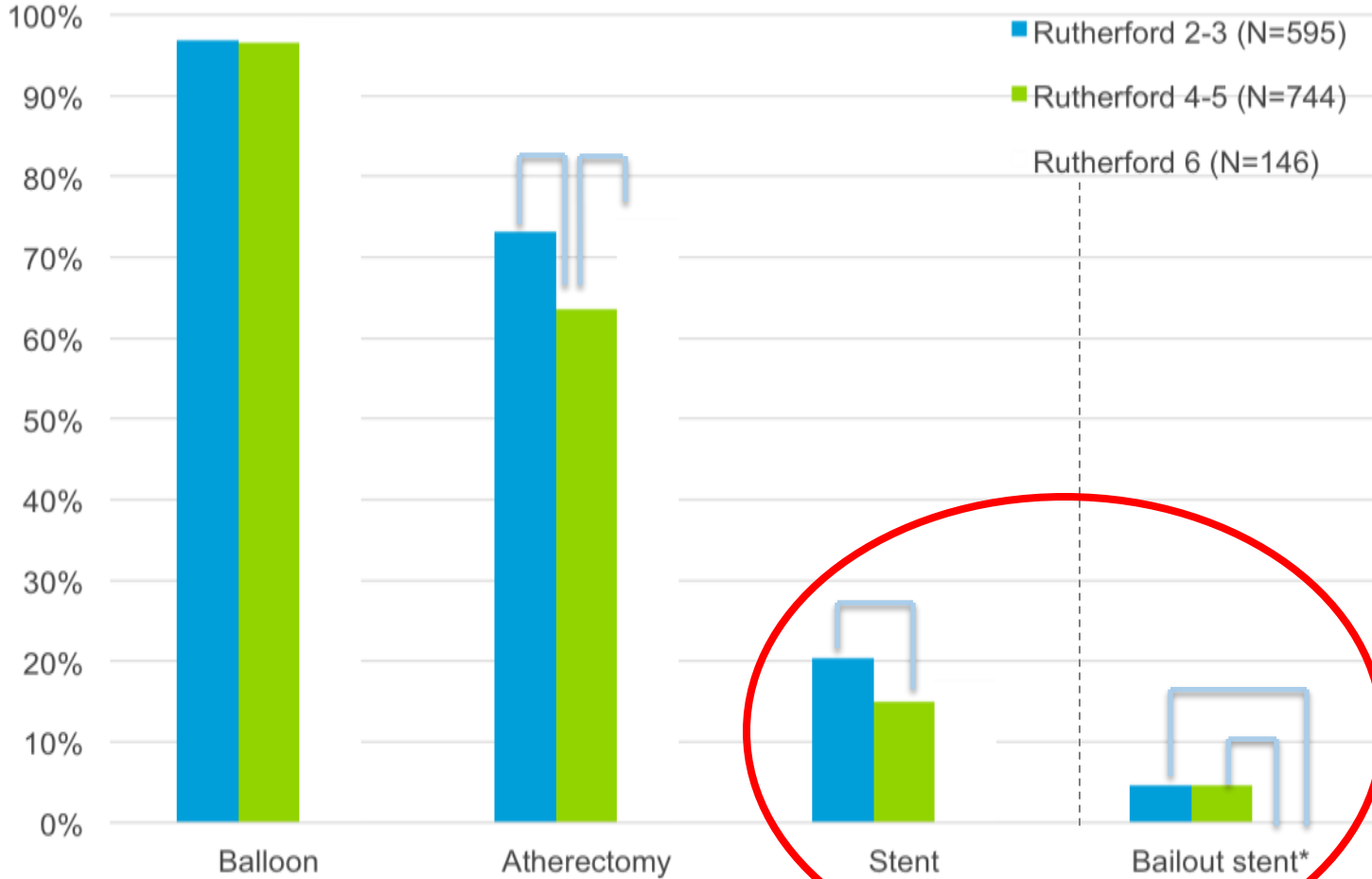




What about after debulking?

LIBERTY Device Usage by Lesion

Balloon and/or atherectomy were preferred devices



Comparison between Rutherford categories significant ($p < 0.05$)

Other reasons to debulk?

DCB-BTK Evidence: IN.PACT DEEP

Failure to meet Primary Efficacy Endpoint

Primary IN.PACT DEEP Outcomes

Primary Efficacy	DEB	PTA	<i>p</i>
12-month LLL (mm) ^[1]	0.61 ± 0.78	0.62 ± 0.78	<i>0.950</i>
12-month CD-TLR ^[2]	9.2% (18/196)	13.1% (14/107)	<i>0.291</i>

Primary Safety	DEB	PTA	<i>p</i>
6-month Death, Major Amputation or CD TLR	17.7% (41/232)	15.8% (18/114)	<i>0.021 (non-inferiority)</i> <i>0.662 (superiority)</i>

1. Angio Cohort, Corelab adjudicated. Angiographic Imaging 12-month FU compliance = 70.9% (DEB) vs. 71.4% (PTA)

2. Clinically driven TLR of the target lesion in the (major) amputation free surviving subjects at 12 months. "Clinically driven TLR" defined as any TLR of the target lesion associated with: a) deterioration of RC and / or b) Increase in size of pre-existing wounds and / or c) occurrence of a new wound(s), with b) and c) adjudicated by the Wound Healing Core lab

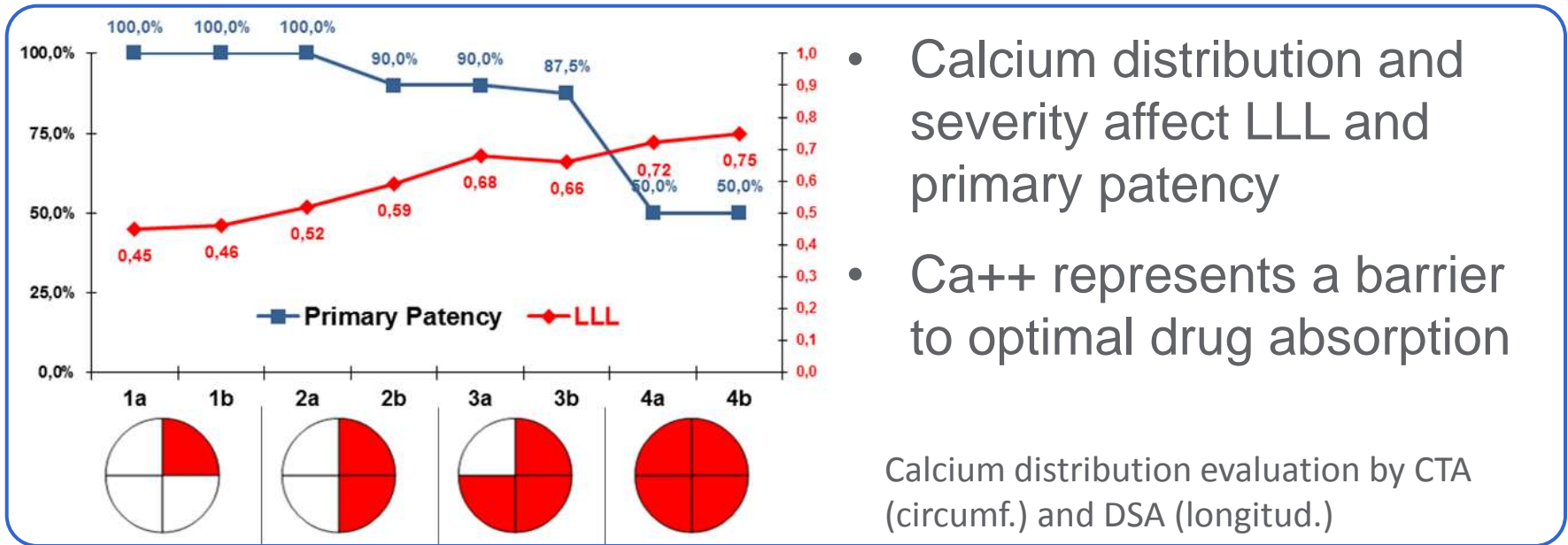
- 13 -

Thomas Zeller, MD LINC 2014

DCB and Calcium

GROUP	DIAMETER	LENGTH
1 a	0 – 90 °	< 3 cm
1 b		> 3 cm
2 a	90 – 180 °	< 3 cm
2 b		> 3 cm
3 a	180 – 270 °	< 3 cm
3 b		> 3 cm
4 a	270 – 360 °	< 3 cm
4 b		> 3 cm

- 60-patient registry
- SFA de-novo (~ 6 cm)
- CTO: 31.7%
- IN.PACT DEB with PTA pre-dil

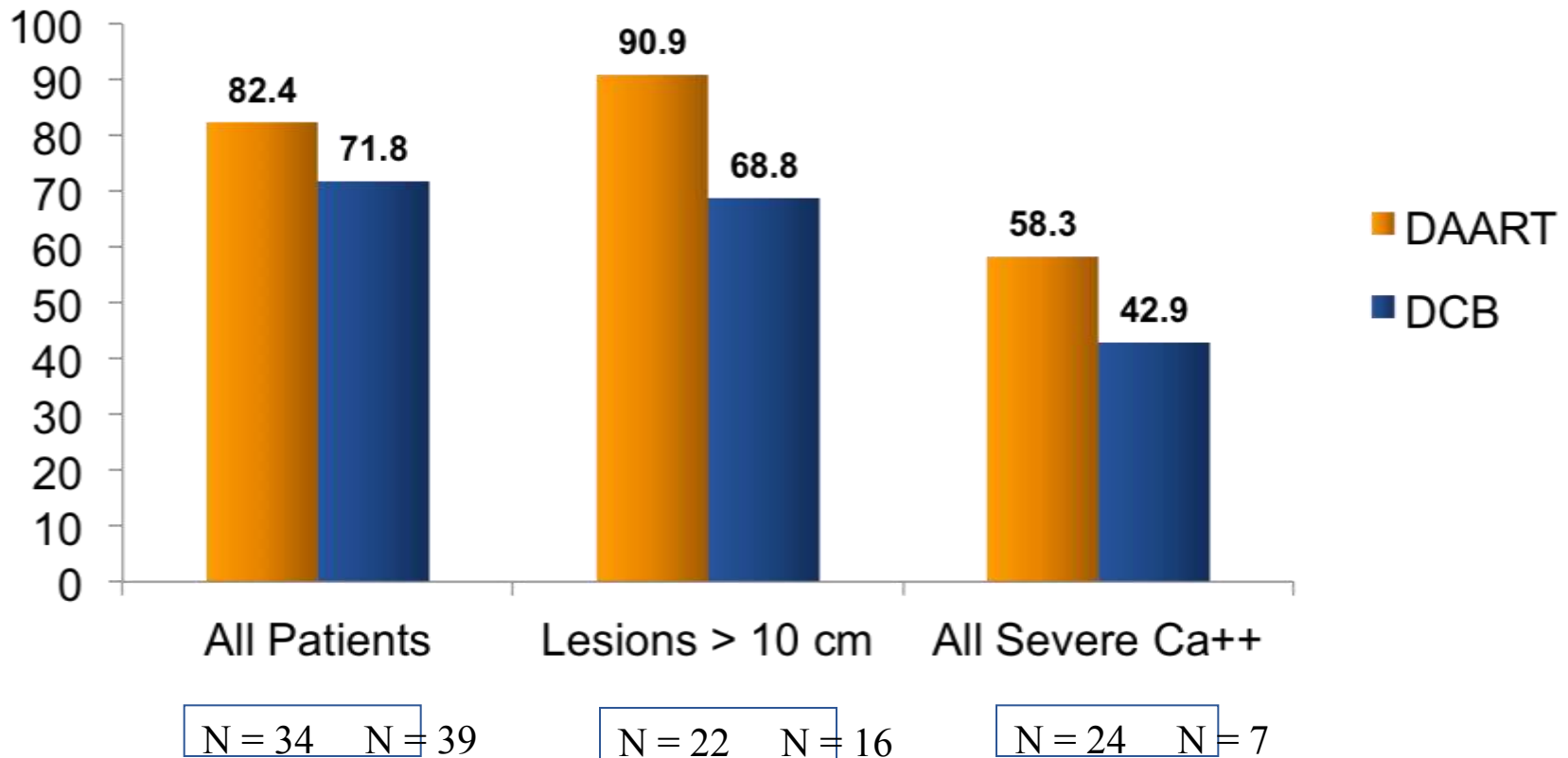


- Calcium distribution and severity affect LLL and primary patency
- Ca++ represents a barrier to optimal drug absorption

Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.)

(F.Fanelli LINC 2013)

DEFINITIVE AR: 12 Month outcomes



Results for all patients who returned for angiographic follow-up

Summary

- Calcium in infra-popliteal disease is extremely common
 - Types of calcification can be distinguished by background clinical factors
- Debulking calcium:
 - May lead to fewer stents, improved stent expansion and/or DCB performance
 - Procedures currently considered “successful” angiographically, may yet be determined (by flow metrics) to be suboptimal, therefore increasing the role of debulking calcium