ATHERECTOMY SHOULD BE PRIMARY THERAPY FOR FEM-POP DISEASE

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Disclosures

Contego Medical: Shareholder

Medtronic: SMAB and speaker

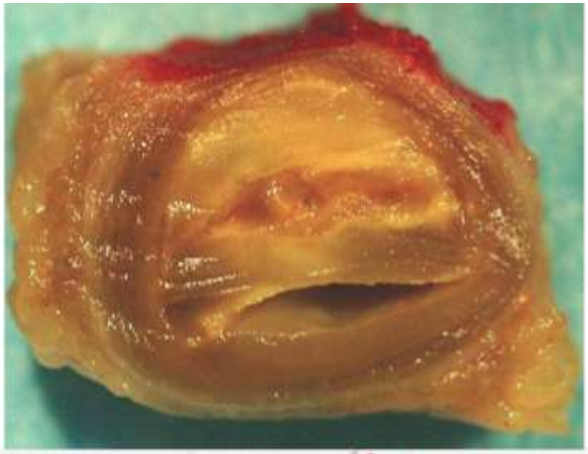
Abbott Vascular: SMAB

Boston Scientific: Consultant

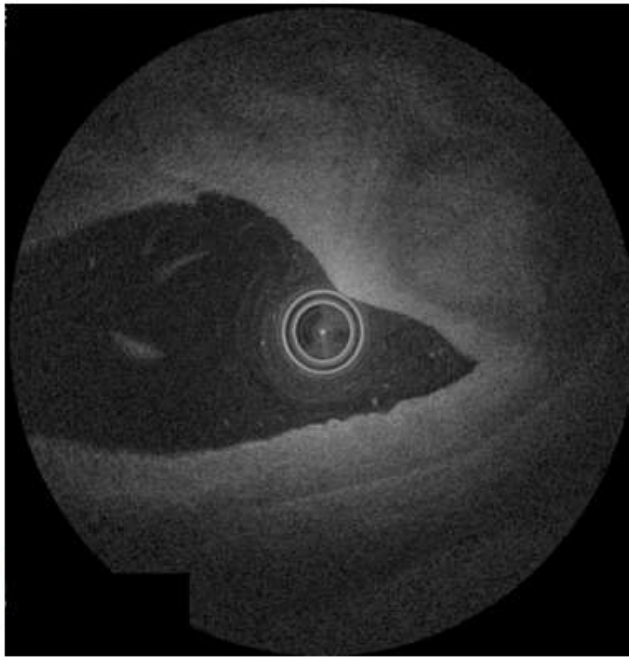
Many Treatment Options for Fem-Pop Disease!

- PTA
- Stent
- Specialty Stent
- Drug Eluting Stent
- Drug Eluting Balloon
- Scoring Balloon
- Atherectomy
- Atherectomy + DEB

PTA - SFA Lesions



SFA



Images courtesy o

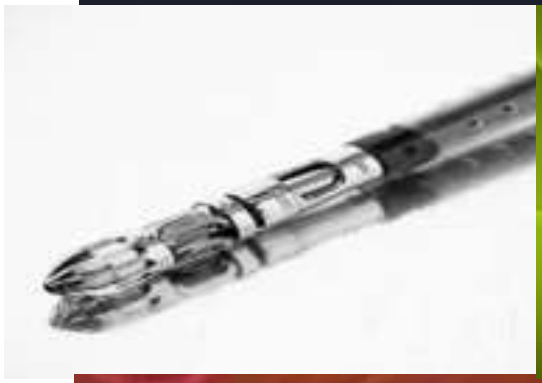
Problems with SFA Stenting….

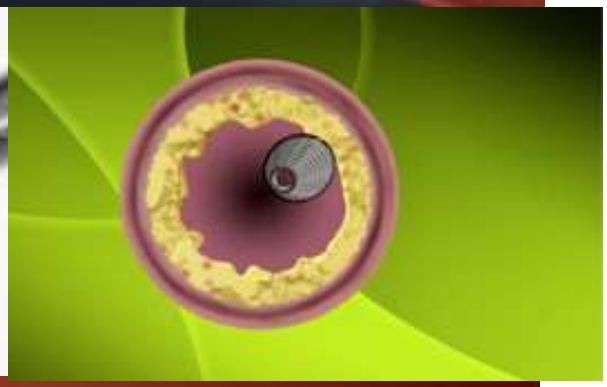
Knee Extension

Knee Flexion

Atherectomy

- **Directional**
- **Rotational**
- **Orbital**
- **Athero-ablative**

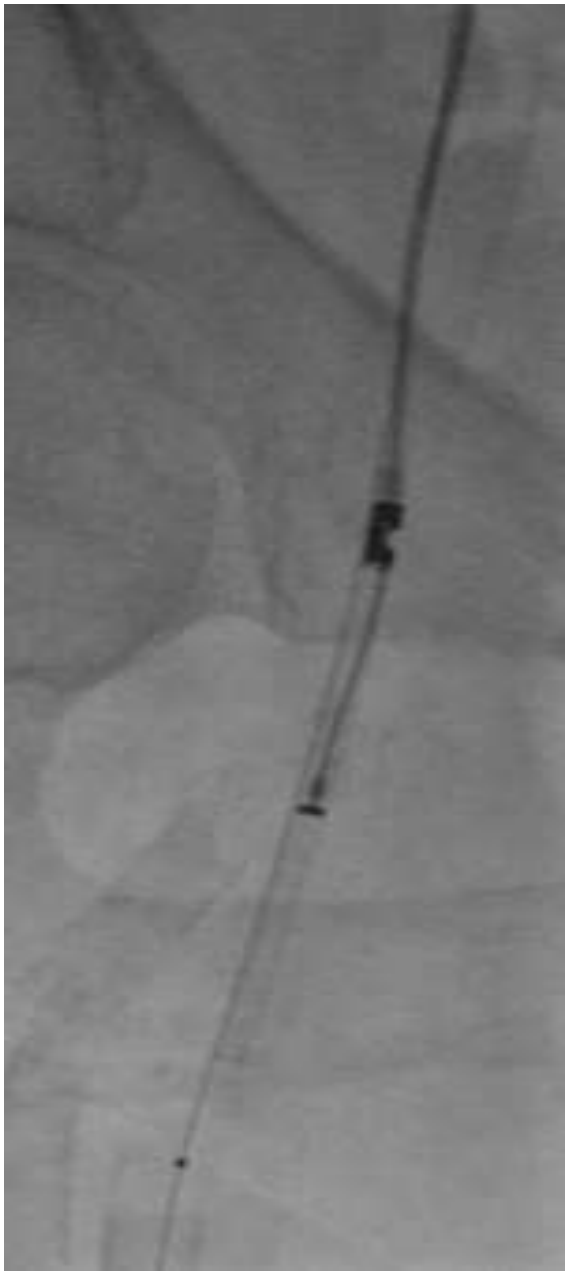




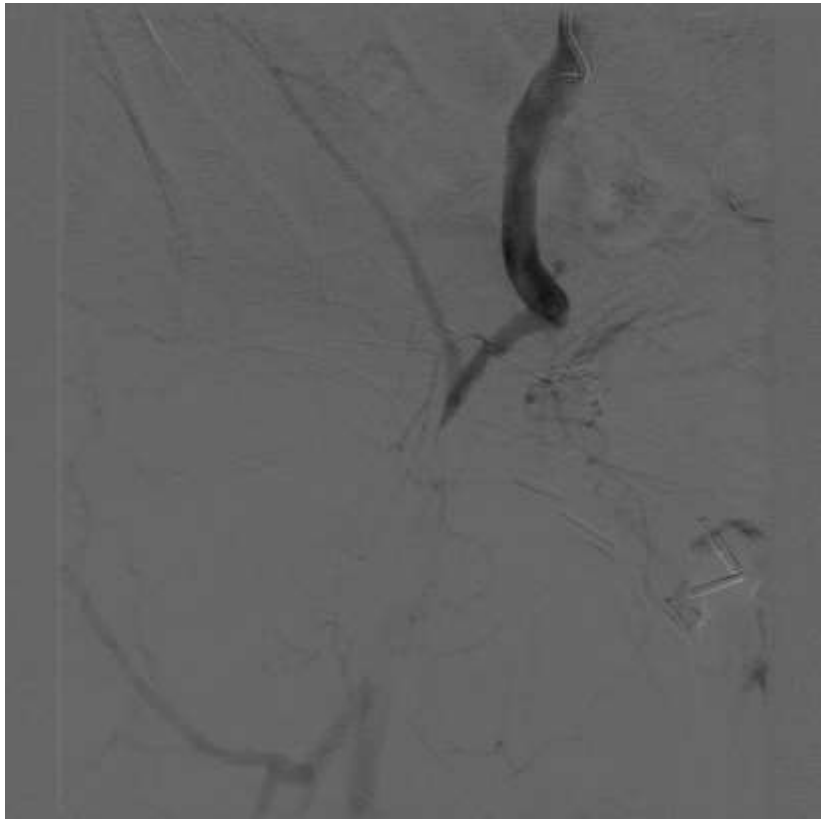
Benefits of Atherectomy

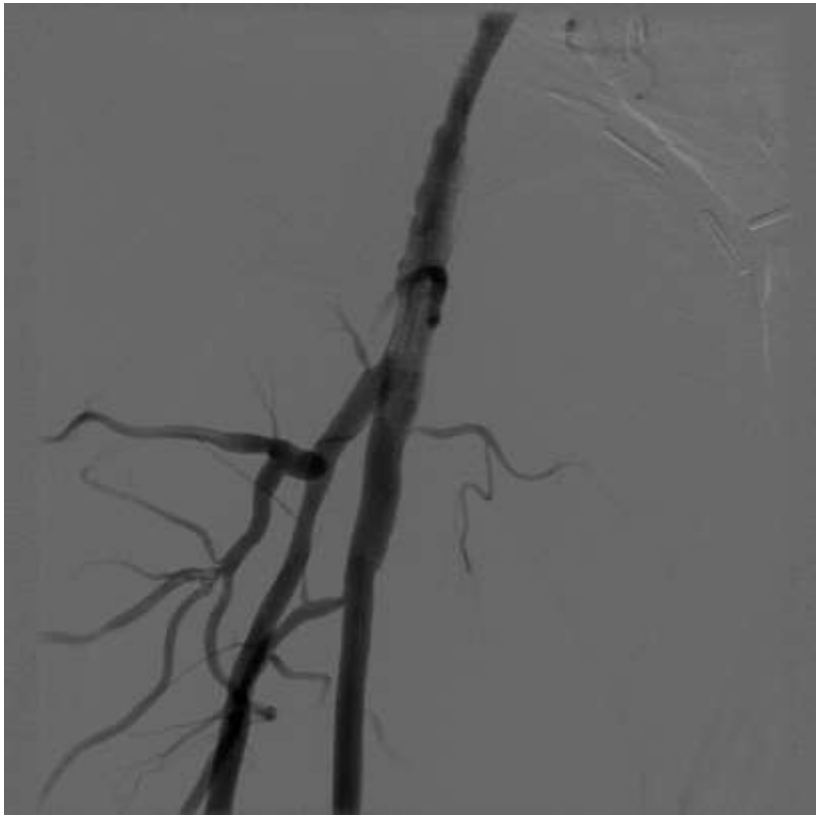
- No-Stent Zones
- Severe Calcification
- Debulking/Vessel Compliance
- In-stent Restenosis
- Preserves Treatment Options

NO STENT ZONES


CTO Right CFA
Directional Atherectomy





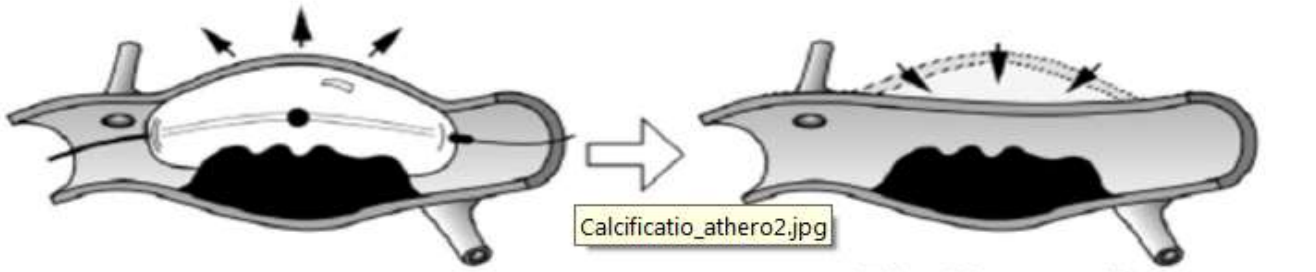
Right Popliteal Stenosis

Directional Atherectomy - Turbohawk LX-M

Severely Calcified Lesions

Calcium Limits Vessel Expansion

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes



Fully inflated balloon

Elastic recoil
Residual, high-grade stenosis

Figure 12.1. Elastic Recoil After PTCA of Calcified Lesions

Rather than cracking the hard, calcified atheroma, PTCA causes stretching of the contralateral plaque-free wall segment and ineffective dilatation.

Freed MS, Safian RD; Manual of Interventional Cardiology, Ch. 12, 245-254

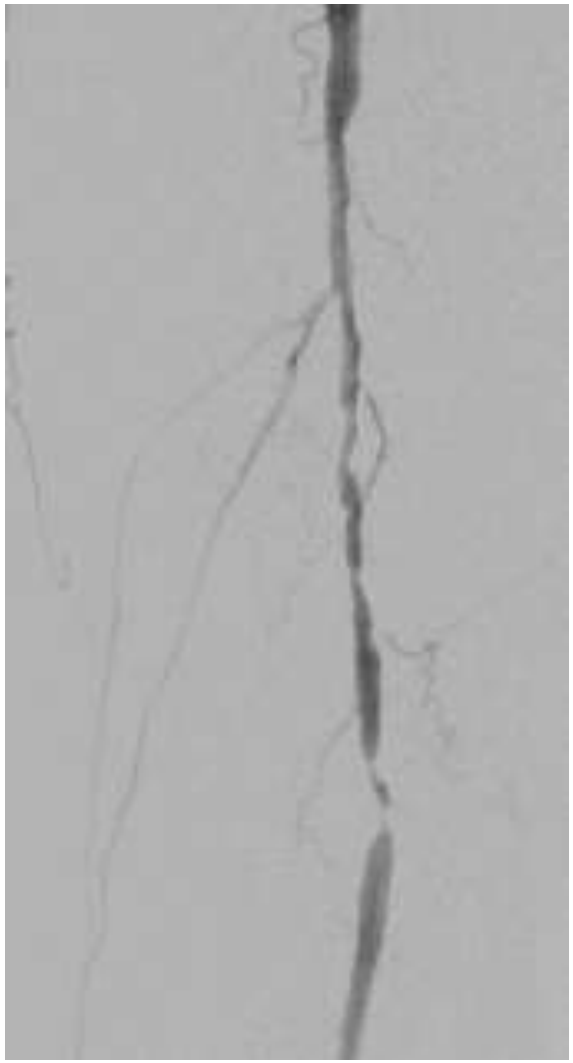
Severely Calcified Disease – Right SFA stenosis

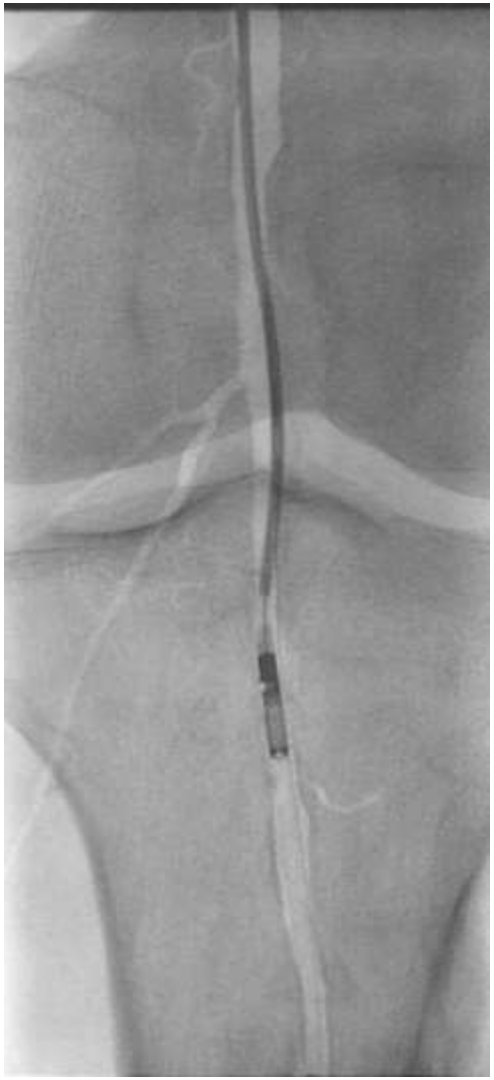
Orbital Atherectomy – 2.0 Solid Crown

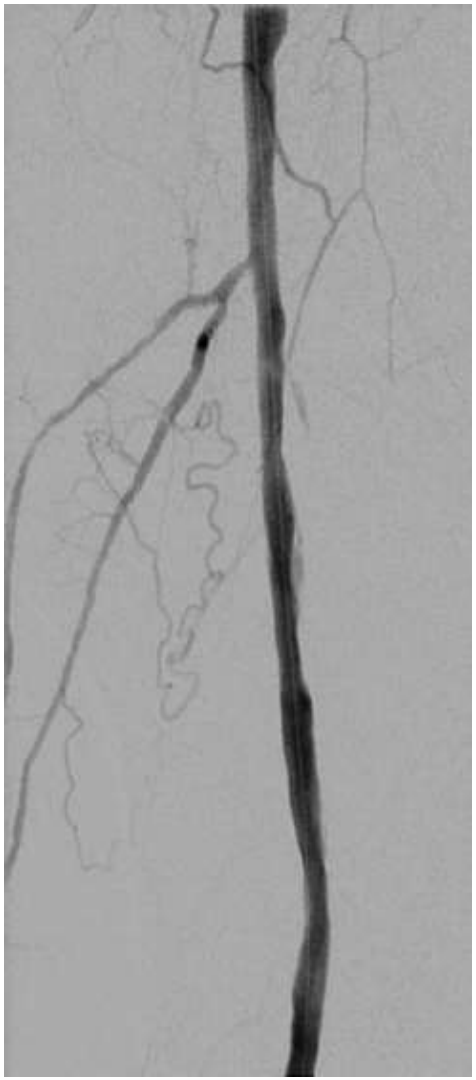
Left CFA Stenosis

Orbital Atherectomy – 2.0 Solid Crown

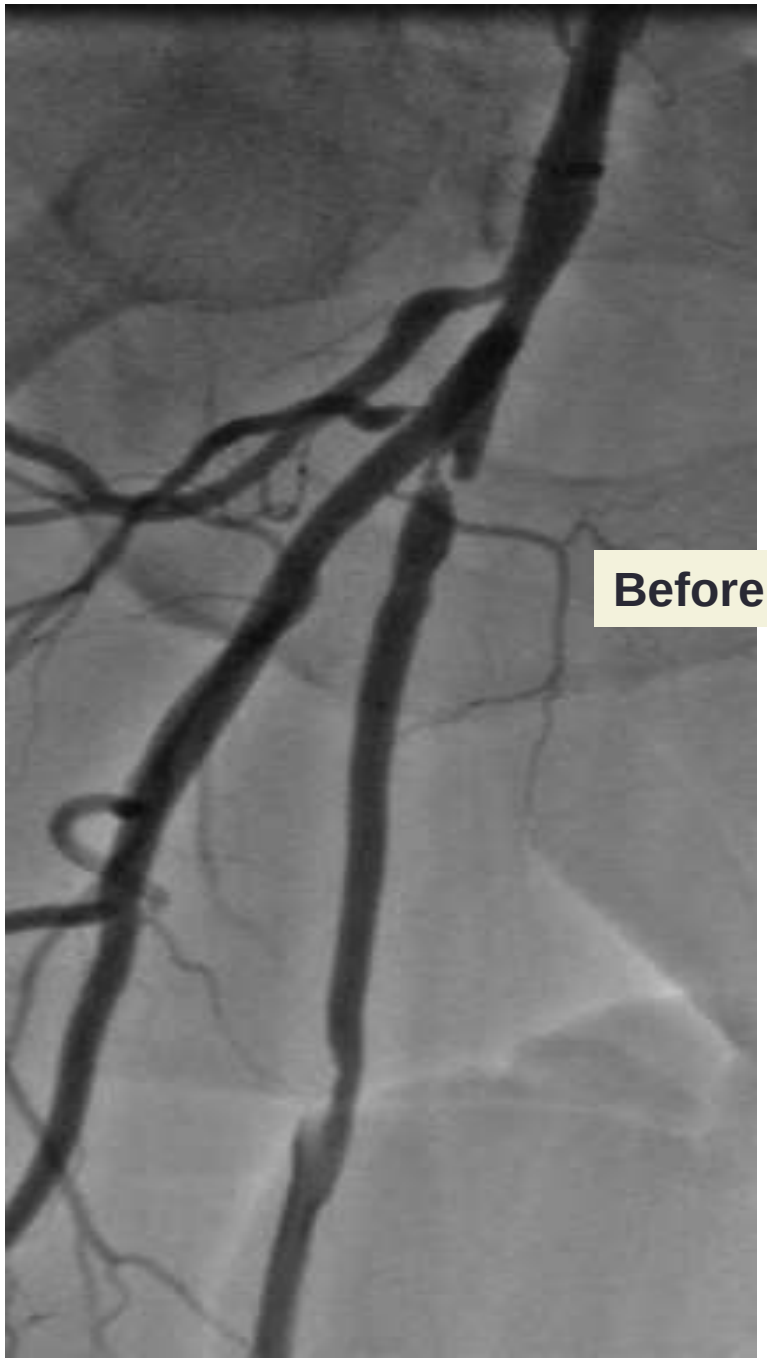
Directional Atherectomy
Severely Calcified Right Popliteal (P1-P2)

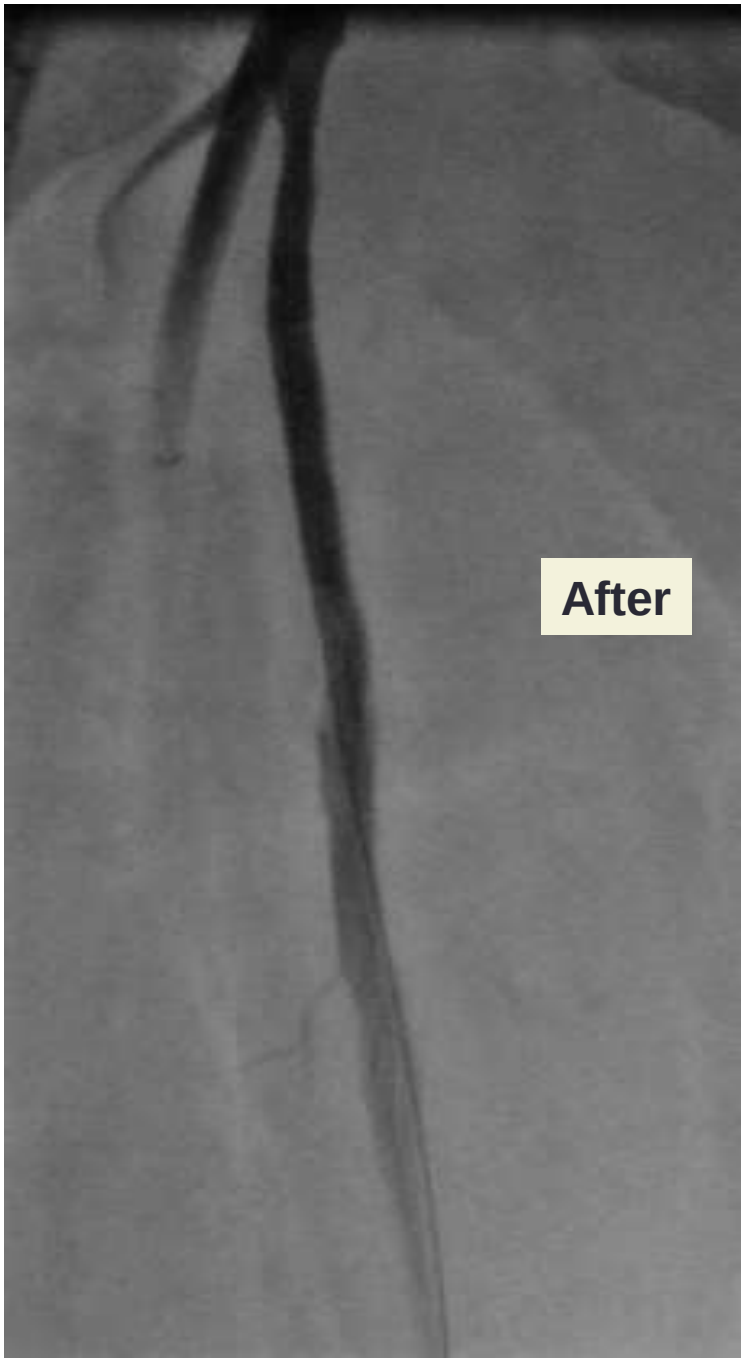






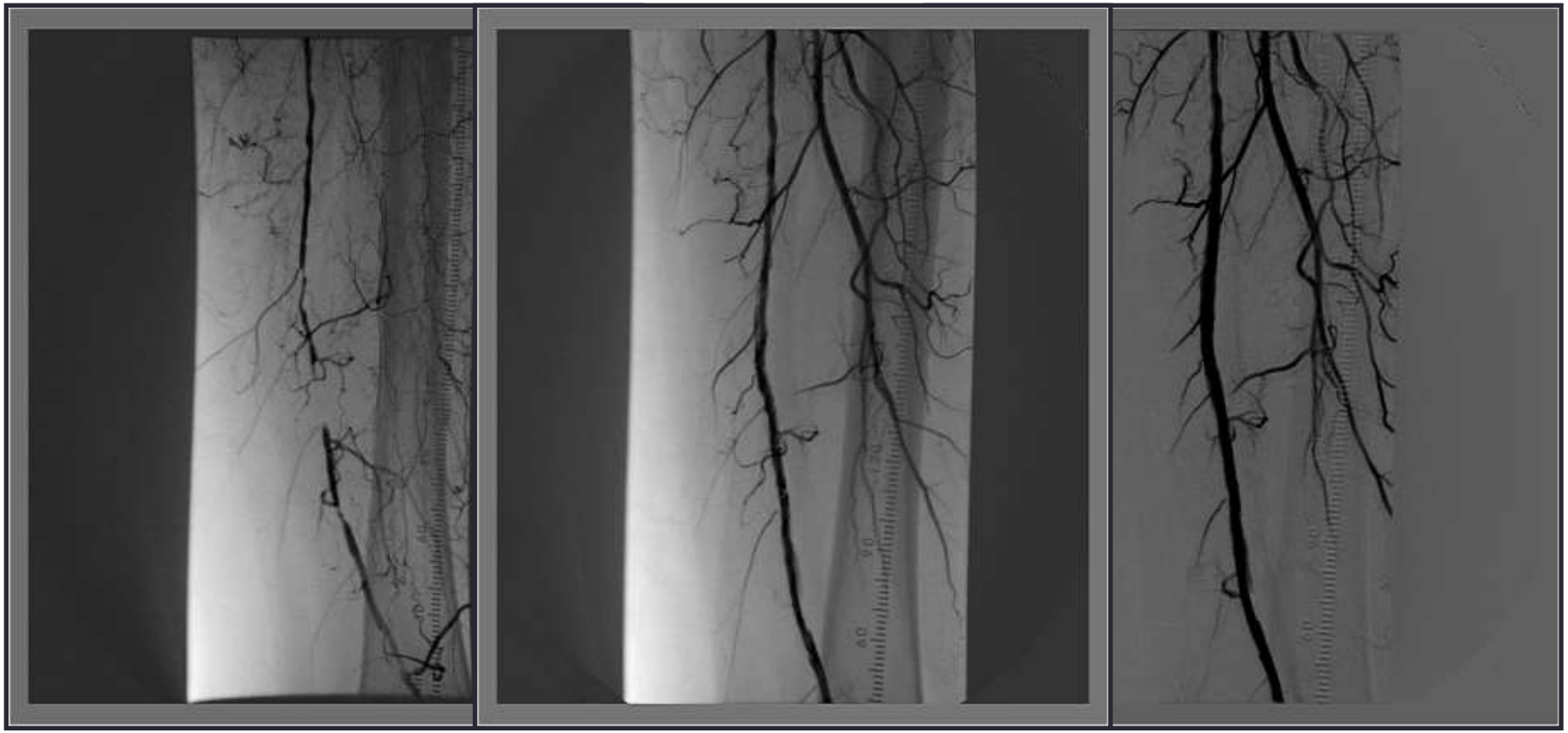
PROXIMAL/MID SFA STENOSIS


Before


After

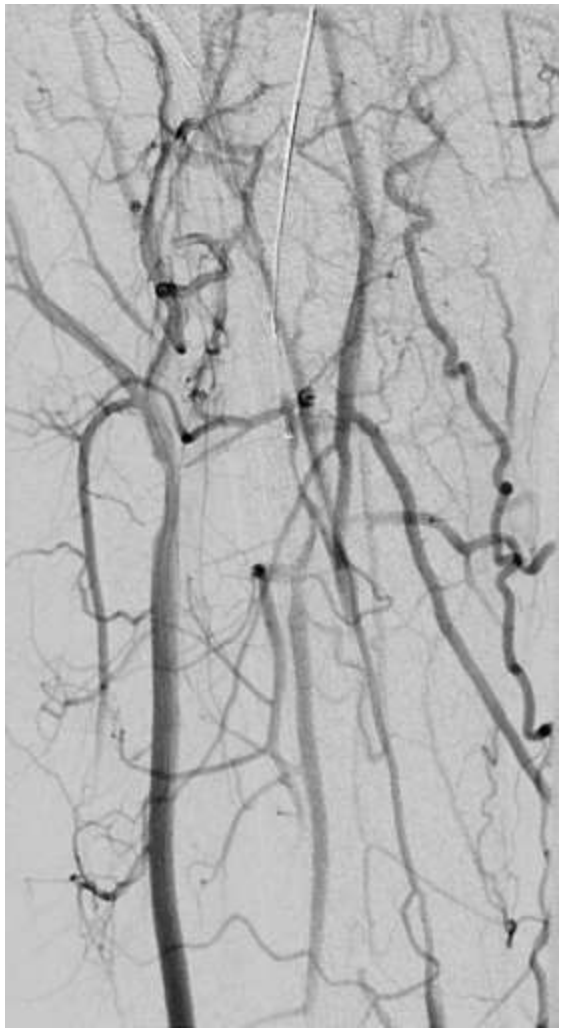
Laser Atherectomy – SFA TURBO-Booster™

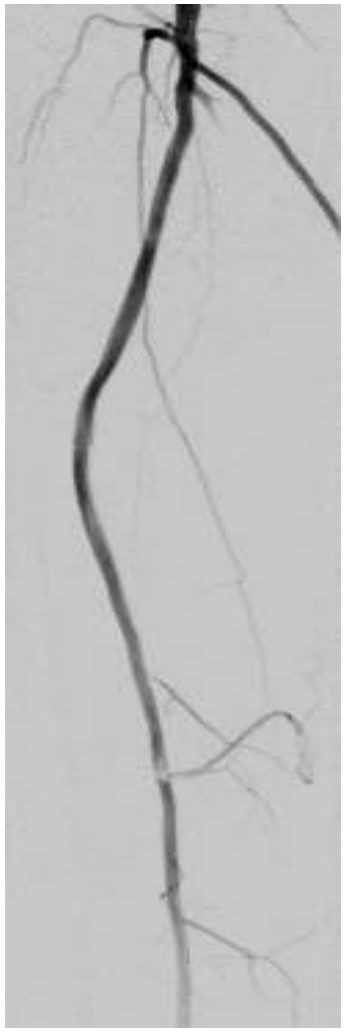
25mm Total Occlusion of the Mid-Left SFA



Pretreatment | **Post TURBO-Booster** | **Post PTA**

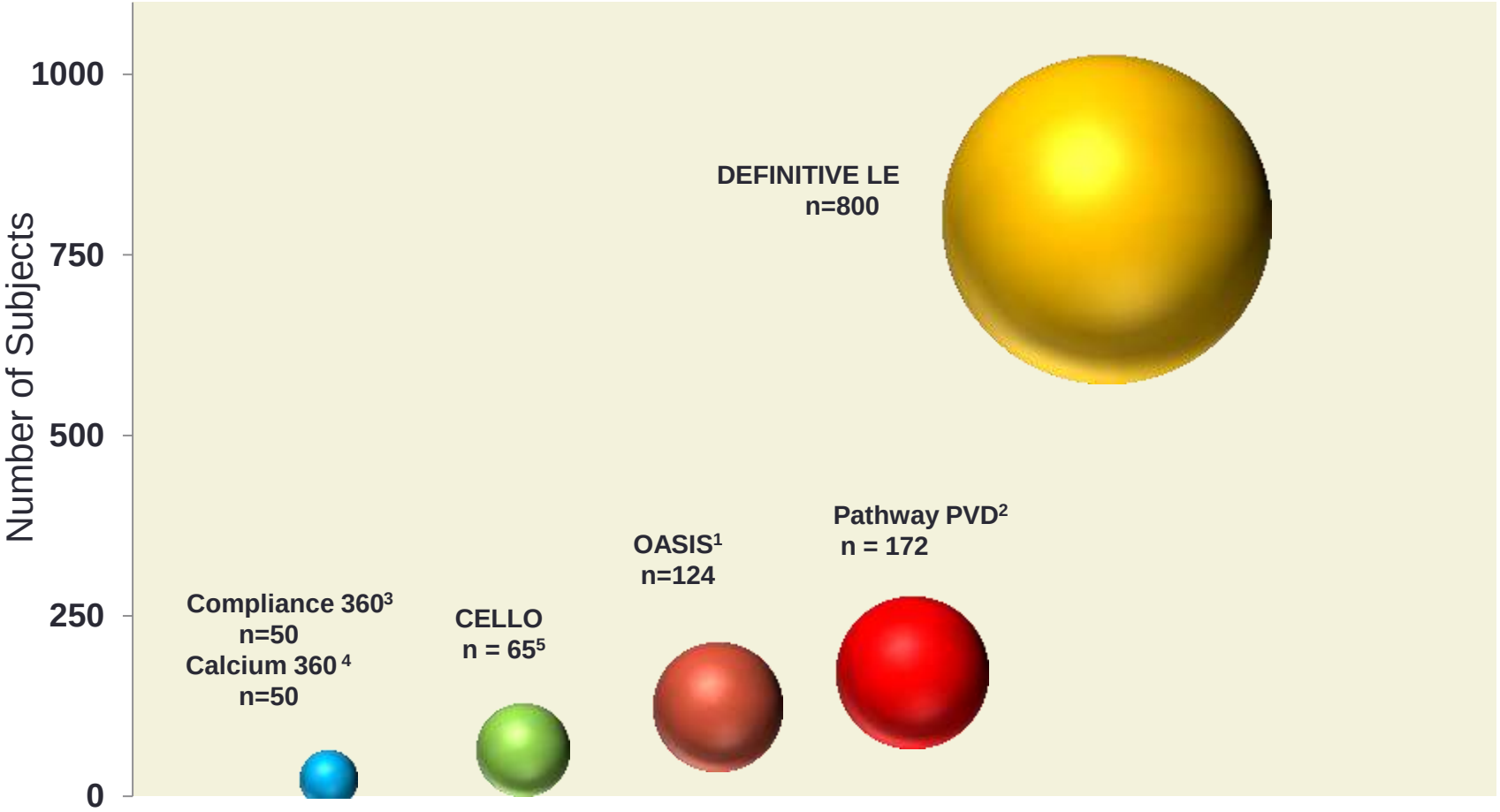
Subintimal Dissection and Atherectomy Through Occluded Popliteal





DATA?

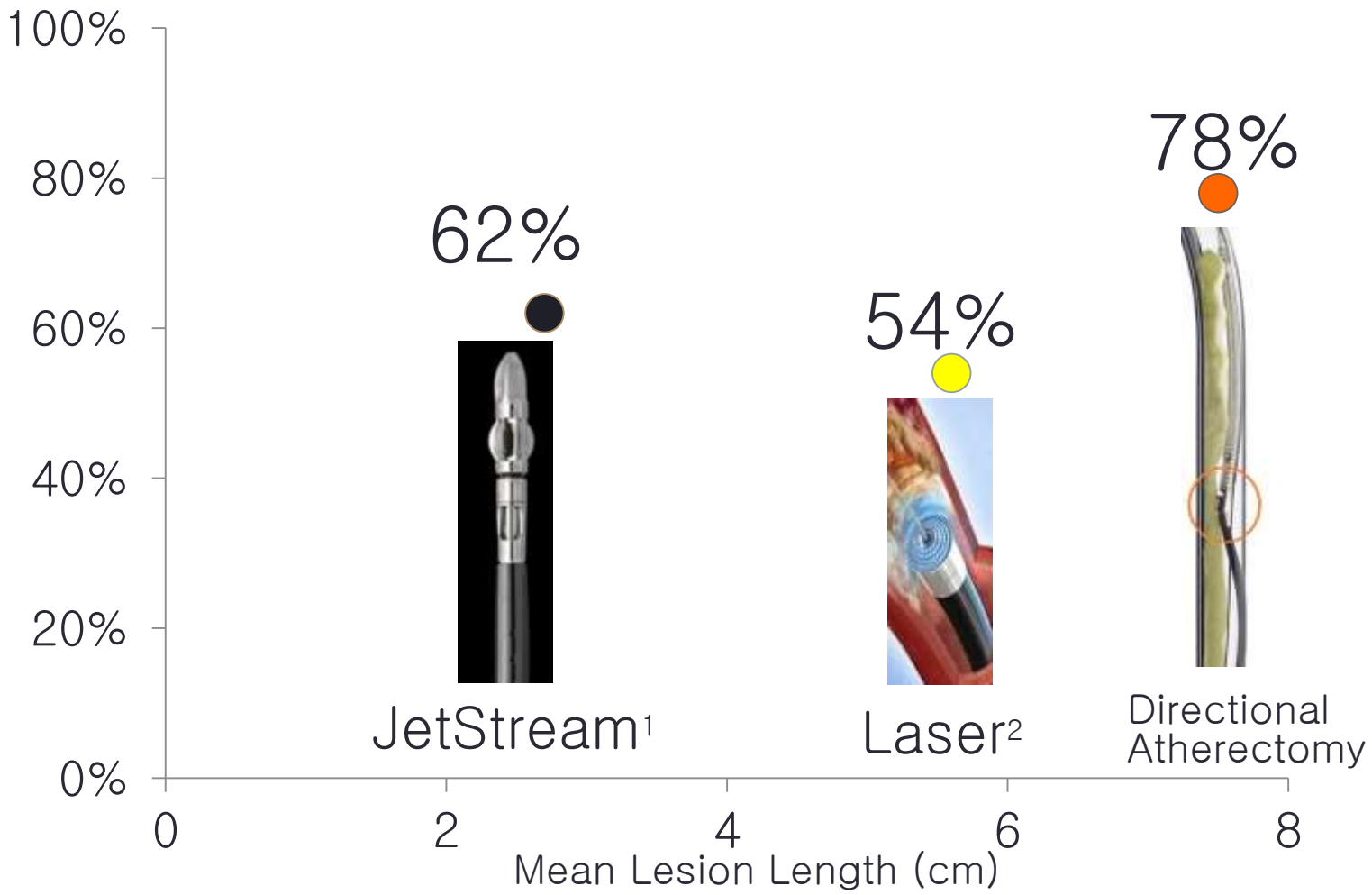
Atherectomy Trials
Fem – Pop Disease



1. Safian et al. Cath & Cardiovasc Interv 73:406:412
2. Zeller et al. J Endovasc Ther 2009;16:653-662
3. Dattilo, TCT 2011
4. Shammas et al. J Endovasc Ther 2012;19:480-488
5. Dave et al. J Endovasc Ther 2009;16:665-675

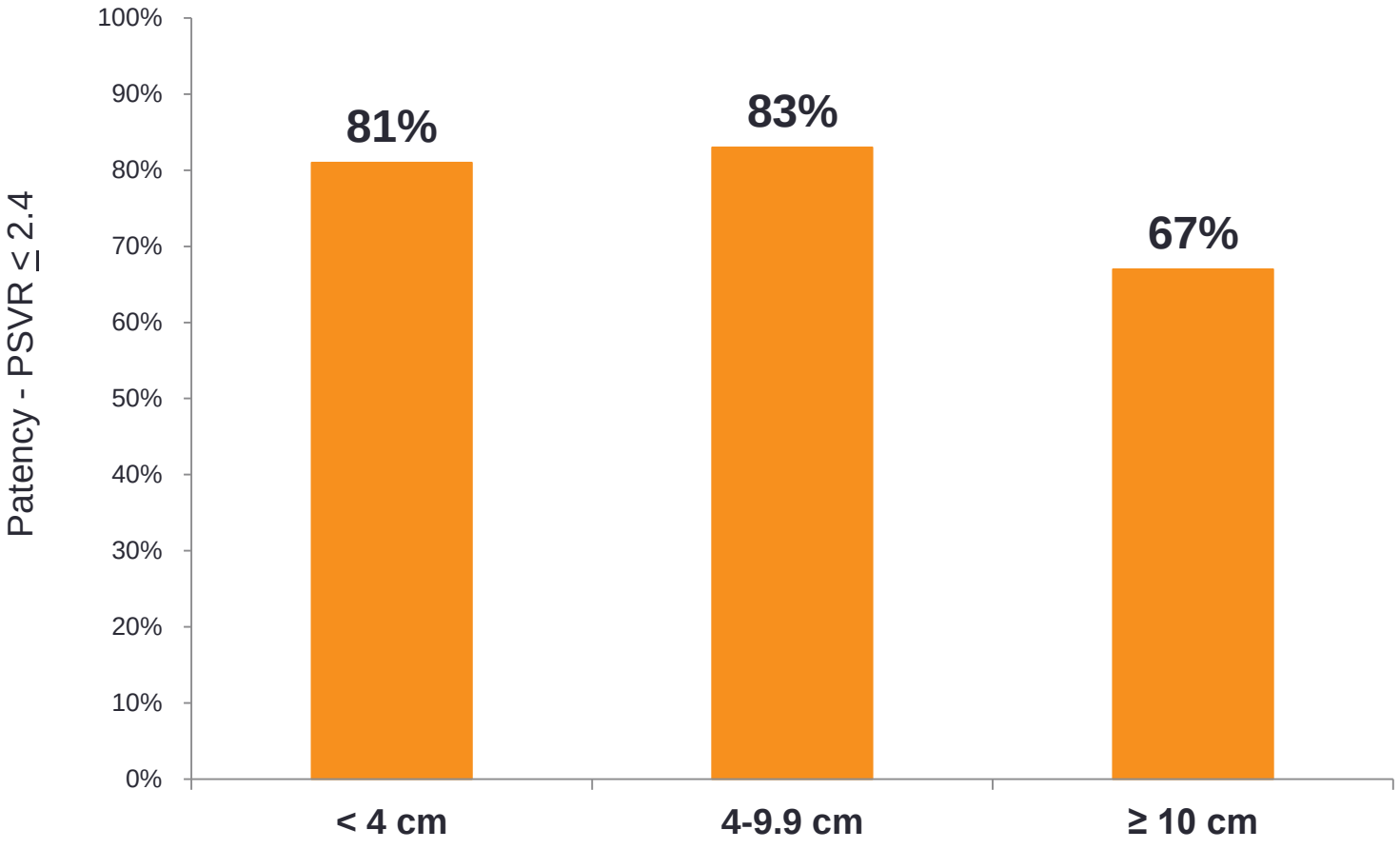
Atherectomy Trials

Core-Lab Adjudicated 12-mo. Patency



1. Dave J. Endovasc. Ther. 2009;13:665-675
2. Zeller et al. J Endovasc. Ther. 2009;16:653-662

Primary Patency by Lesion Length

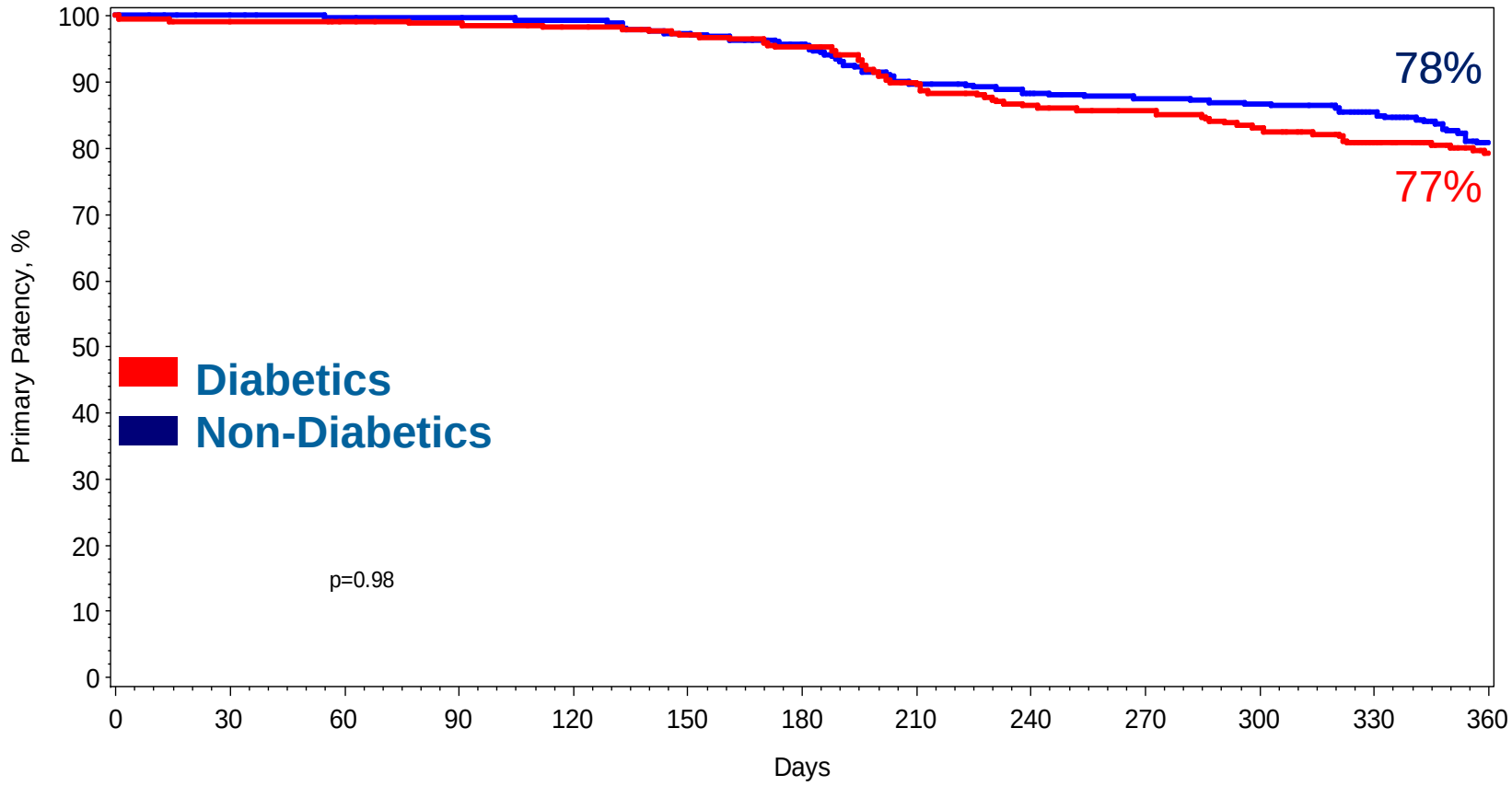


Mean length :	**2.2 cm**	**6.5 cm**	**14.4 cm**
Number of lesions:	**220**	**307**	**214**

Primary Patency by TASC Classification
Claudicant Cohort (PSVR ≤ 2.4)

	Patency (PSVR ≤ 2.4)	Lesion Length (cm)
All (n=743)	**78%**	**7.5**
TASC Classification		
TASC A (n=440)	81%	4.6
TASC B (n=212)	71%	9.9
TASC C (n=85)	72%	16.5

Primary Patency Rates are Equivalent Between Diabetic and Non-Diabetic Claudicants



*PSVR ≤ 2.4

Nitinol Stents

Durability II:
Freedom from Loss of Primary Patency (PSVR < 2.0) at 2 Years

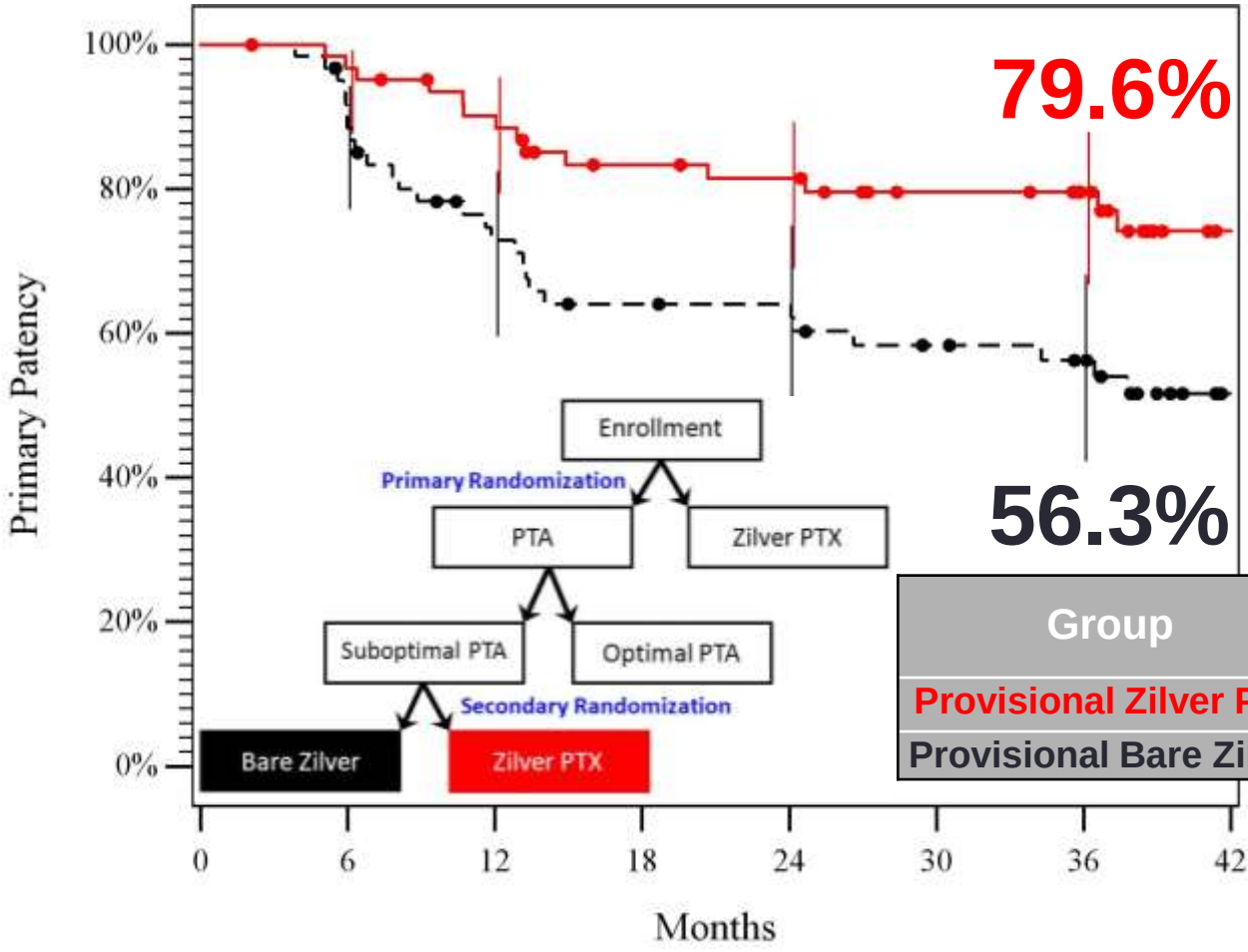
Freedom from TLR	1-Year (N= 287)	2-Year (N= 287)	3-Year (N=287)
All Subjects	77.9%	65.9%	60%
≤ 80 mm (n=133)	87.5%	80.8%	71%
> 80 mm (n=154)	69.6%	53.1%	50.5%

CTO: 48.1%
Mean Lesion Length: 8.9 cm
Severely Calcified: 43.2%

Zilver PTX vs. BMS: 3-Year Data

Patency (PSVR < 2.0)

Mean Lesion Length 5.5 cm



Provisional Zilver PTX 44 lesions

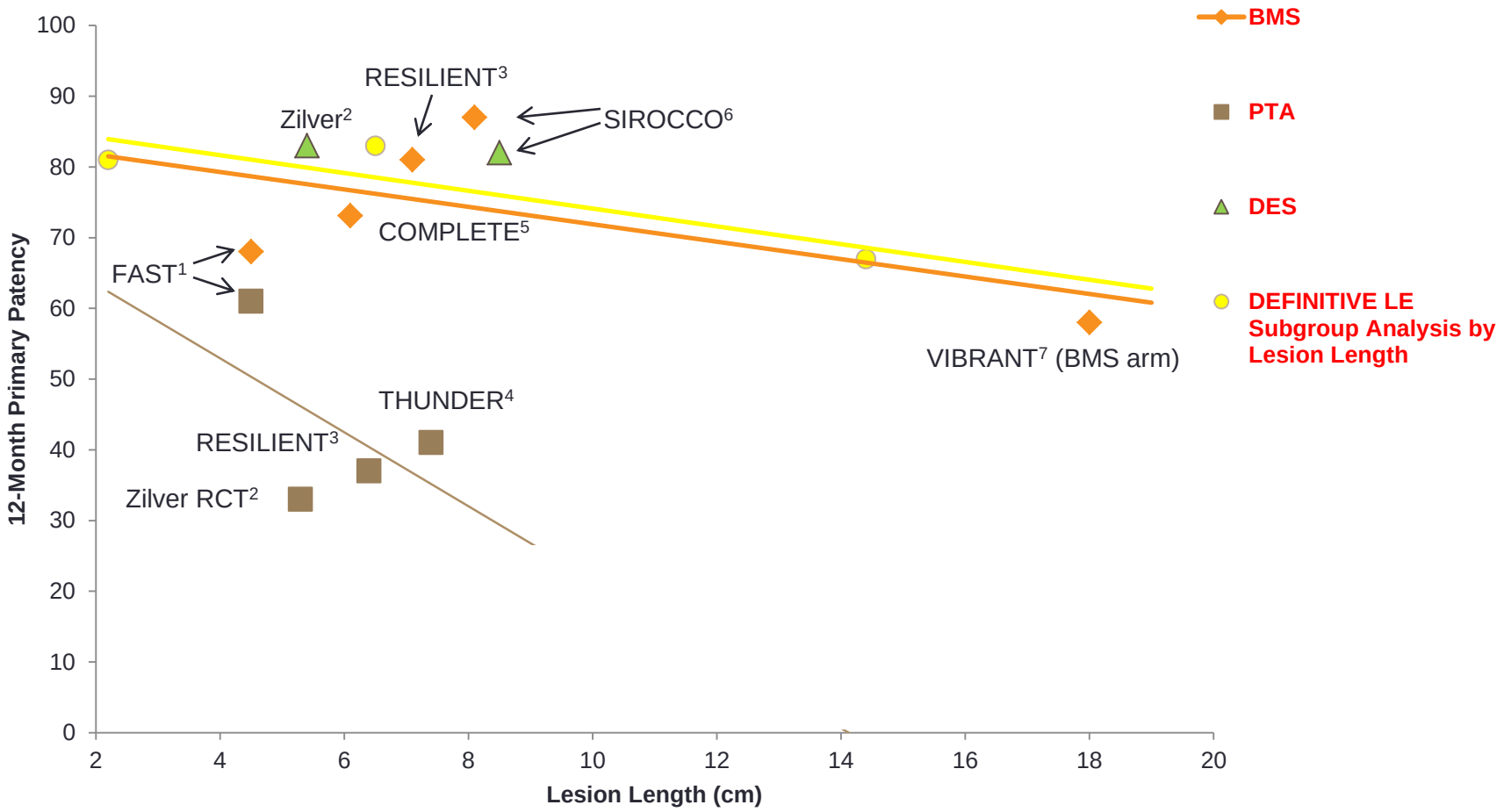
Provisional Bare Zilver 51 lesions

$p = 0.02$ log-rank

Group	3-year Restenosis	
	Rate	Reduction
Provisional Zilver PTX	20.4%	53%
Provisional Bare Zilver	43.7%	

SFA 12-Month Primary Patency

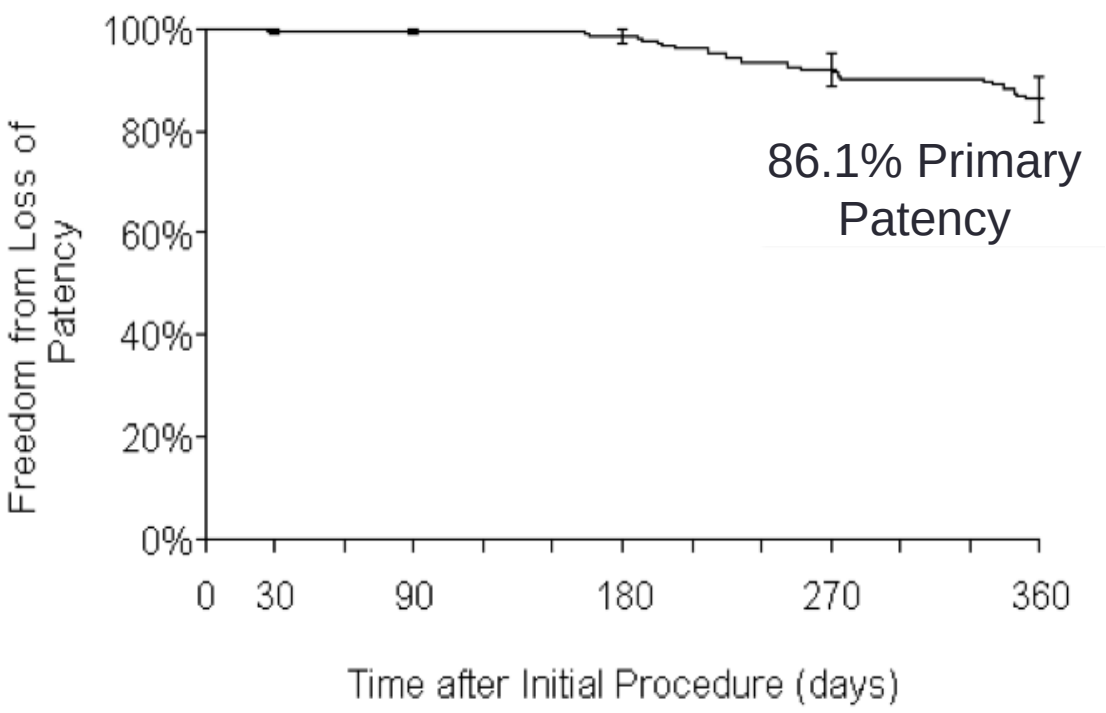
PTA, BMS, DES and DEF LE Sub-analyses by Lesion Length



1. Krankenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504)
3. Laird et al. Circ Cardiovasc Interv. 2010; 3: 267-276
4. Tepe et al. NEJM 2008;358:689-99
5. Laird, ISET 2012
6. Duda et al. J Endovasc Ther 2006; 13:701-710
7. Ansel, VIVA 2010

Abbott Supera

Freedom from Loss of Primary Patency at 1 Year (PSVR < 2.0)



- Superb Study: Primary Patency at 1 yr - 86%
- Mean Lesion Length 7.7 cm
- Supera 500 Registry Primary Patency at 2 years 73%
- Mean Stent Length 12.2 cm
- **Difficult to deploy in severe Ca++**

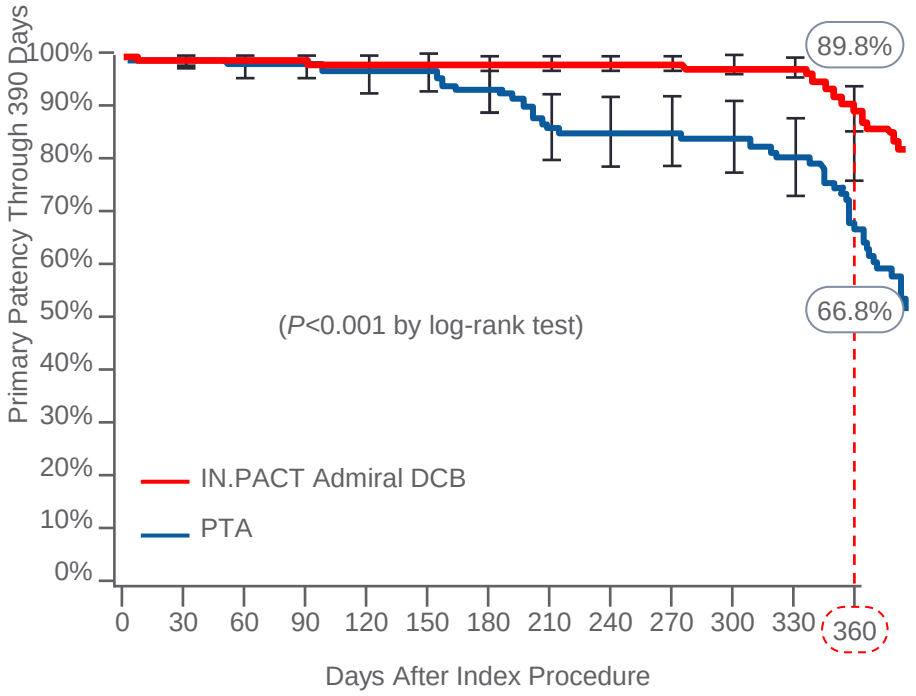
Medtronic InPACT: One Year Outcomes

Mean lesion length 8.9 cm

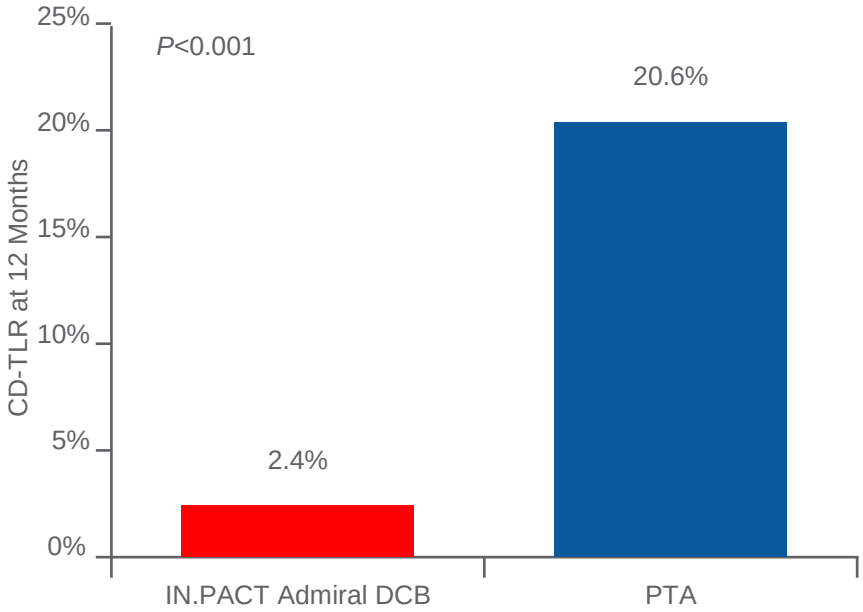
	DEB (n = 220)	**Angioplasty** (n = 111)
Primary Patency	82.2%	52.4%
Clinically Driven TLR	2.4%	20.6%
Primary Sustained Clinical Improvement	85.2%	68.9%
Primary Safety Endpoint	95.7%	76.6%
MACE	6.3%	24.3%

IN.PACT SFA 12-Month Efficacy Outcomes

Primary Patency Kaplan Meier (All ITT)[1]



Clinically-Driven Target Lesion Revascularization (CD-TLR)[2]

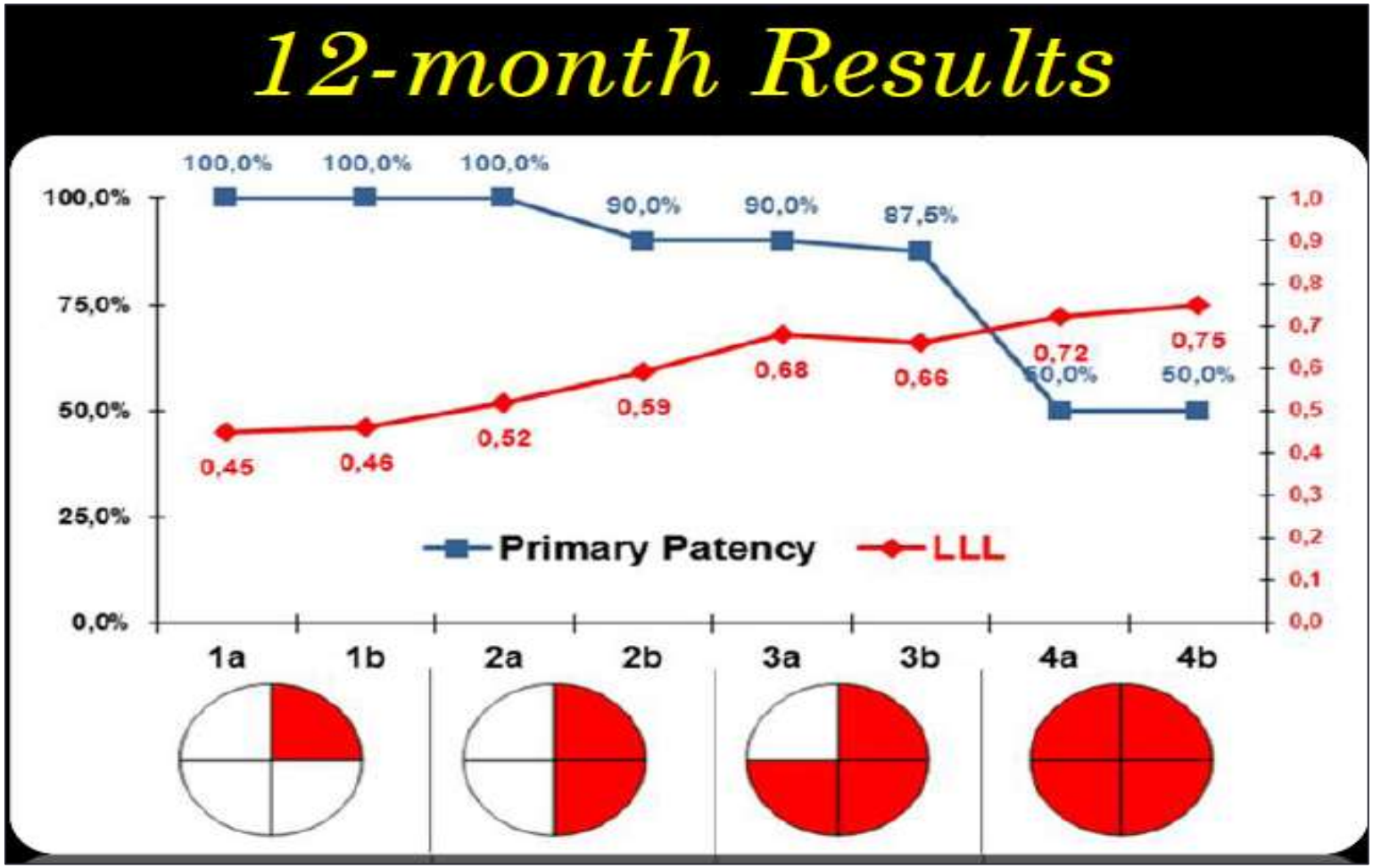


1. Primary patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by DUS PSVR ≤2.4
2. Clinically-driven TLR defined as any re-intervention due to symptoms or drop of ABI/TBI of >20% or >0.15 compared to post-procedure ABI/TBI

Limitations of DEB Trials

- Residual stenosis > 70% after PTA – NOT INCLUDED
- Residual dissection after PTA – NOT INCLUDED
- CTO > 10 cm – NOT INCLUDED
- Severe Calcification – NOT INCLUDED
- Lesions > 18 cm – NOT INCLUDED

Calcium May Limit Drug Effect[2]

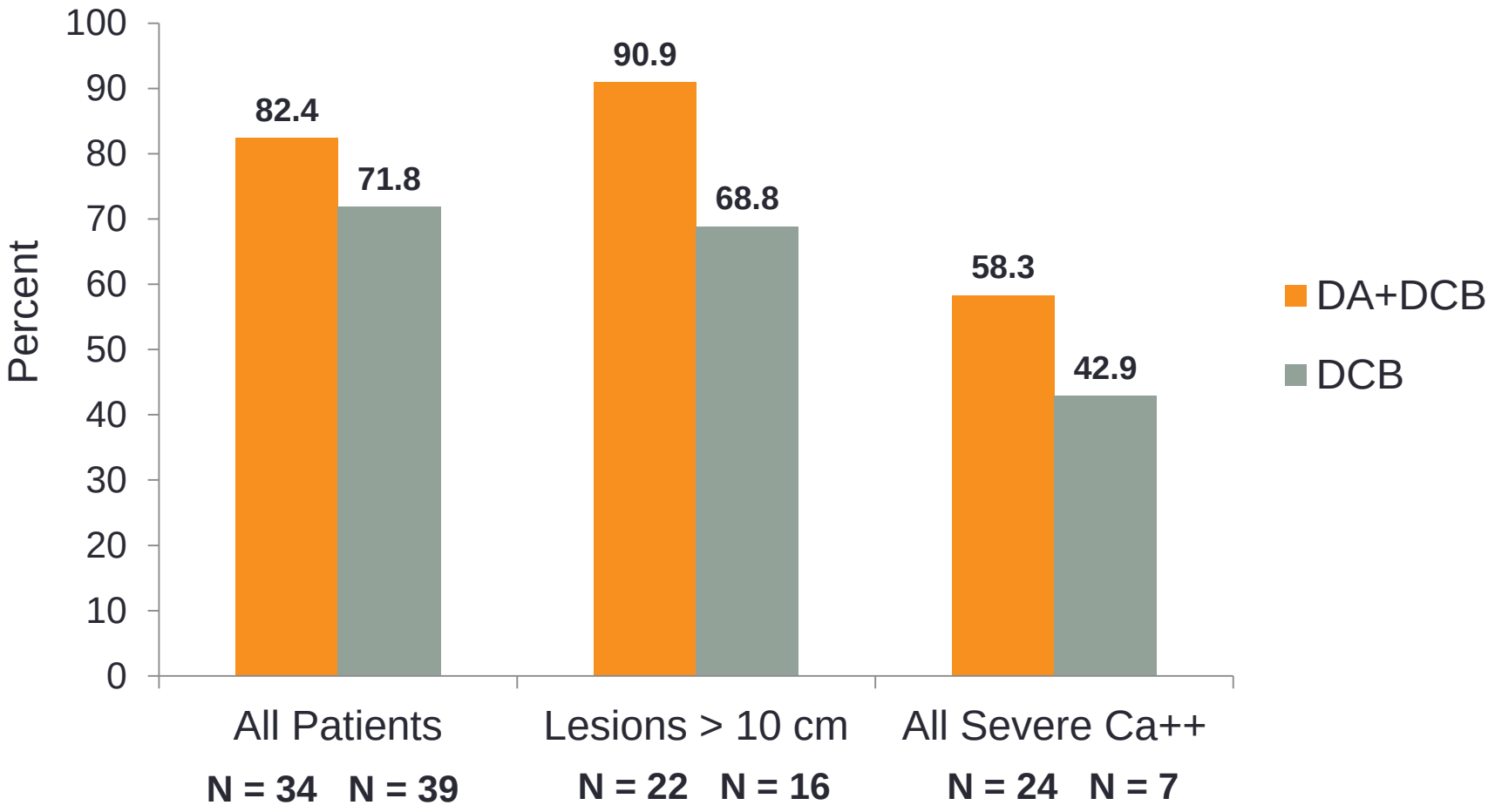


DEFINITIVE AR

- Prospective, multi-center, randomized (DA+DCB vs DCB alone); plus non-randomized DA+DCB registry arm for severely calcified lesions
- **121** subjects enrolled at **10** investigational sites
- Primary Outcome
- Target Lesion Percent Stenosis at 1 Year: Defined as the narrowest point of the target lesion divided by the estimated native vessel diameter at that location as determined by the Angiographic Core Laboratory.
- Clinical follow-up at pre-discharge, 30 days, 6 months and 1 year post-procedure
- Independent CEC, Angiographic and DUS Core laboratory analyses

Definitive AR

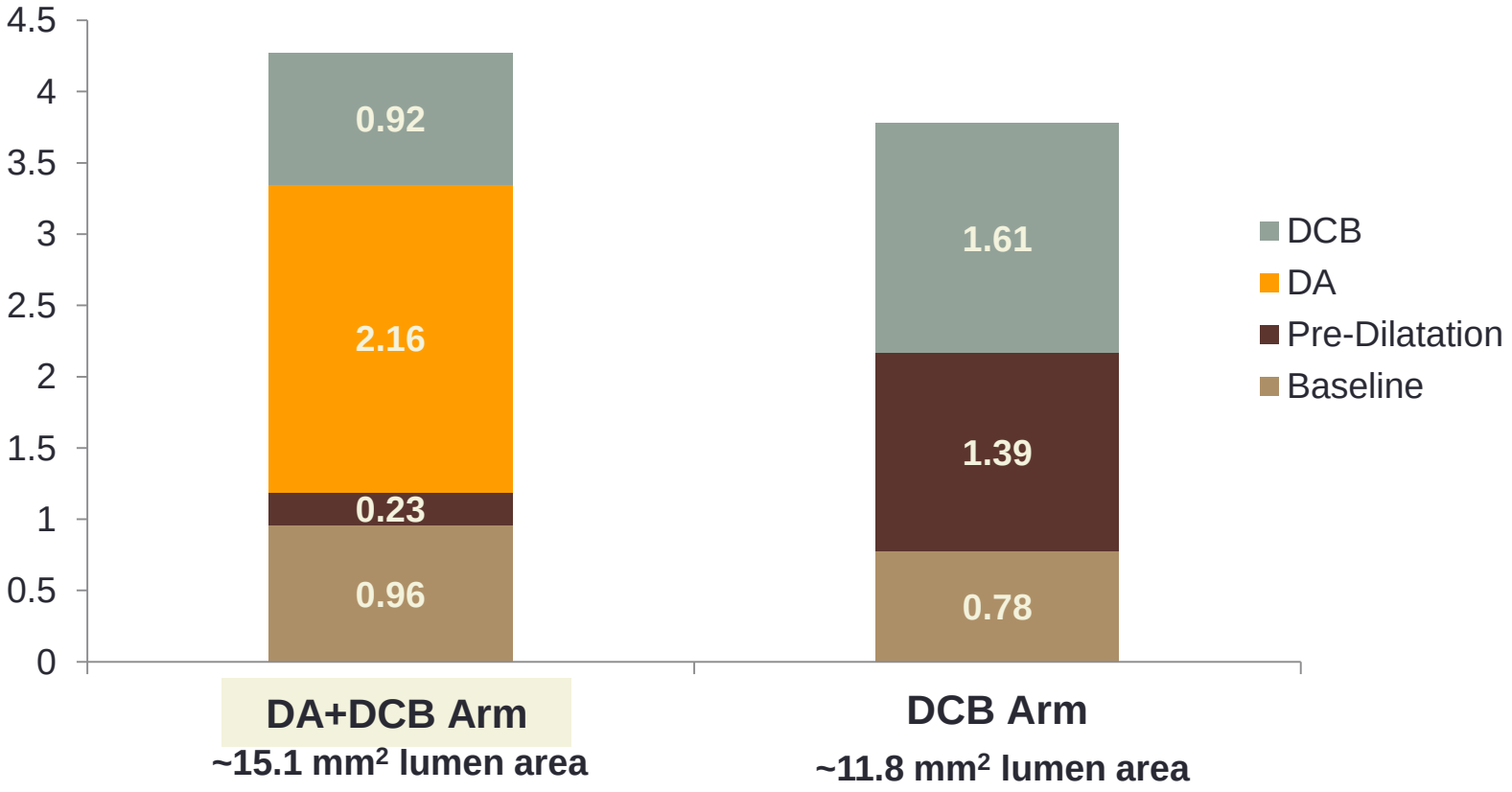
Angiographic Patency (<50% Stenosis) at 12 Months



What is the Impact of Lumen Gain with DA+DCB?

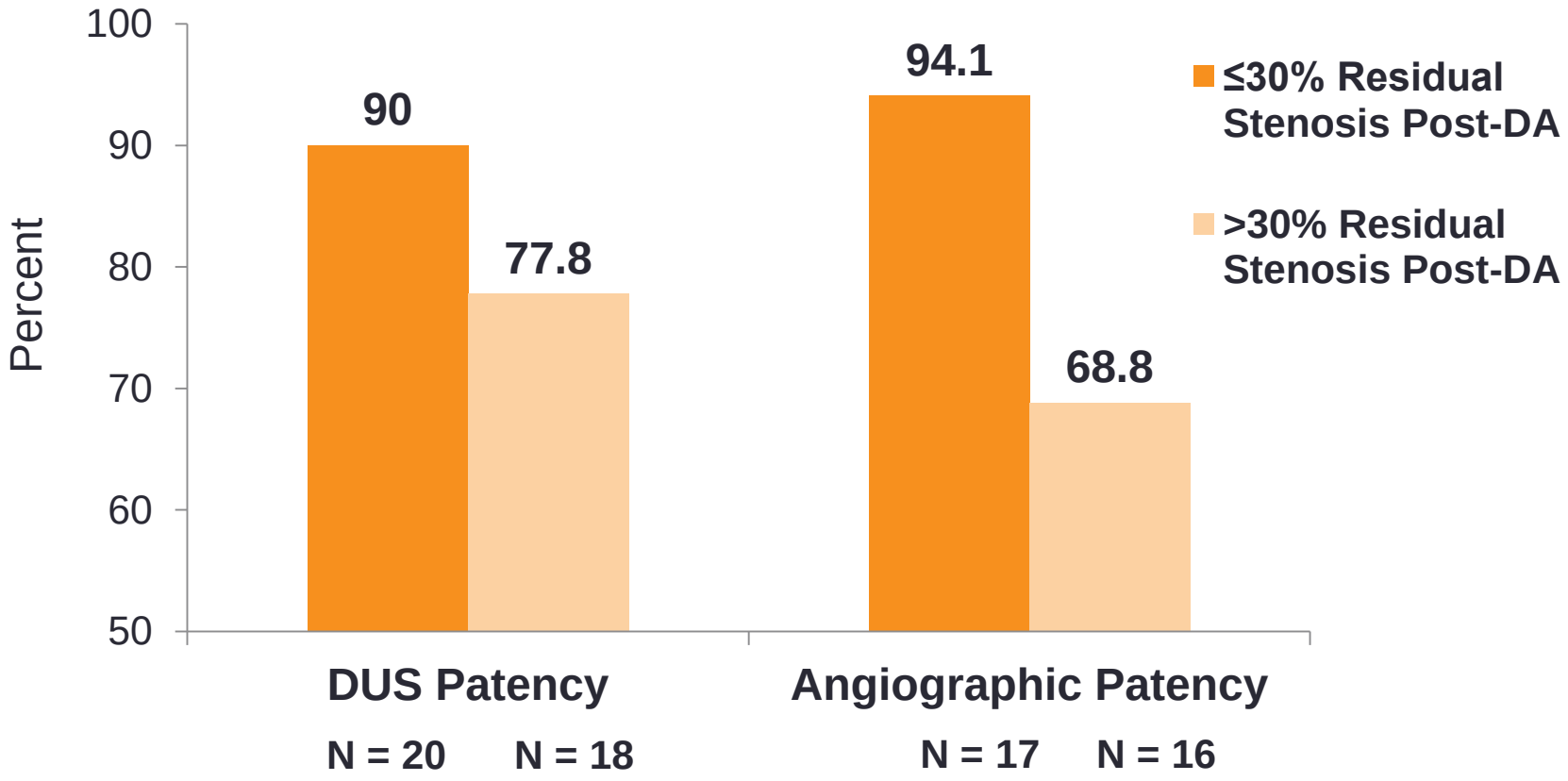
Post Procedure MLD (DA+DCB vs DCB alone)

DA+DCB resulted in a significantly larger minimum lumen diameter (MLD) following the protocol-defined treatment in DEFINITIVE AR



12-Month Patency: DA+DCB RCT Patients

Increased lumen gain with DA before DCB may result in improved 12-month patency

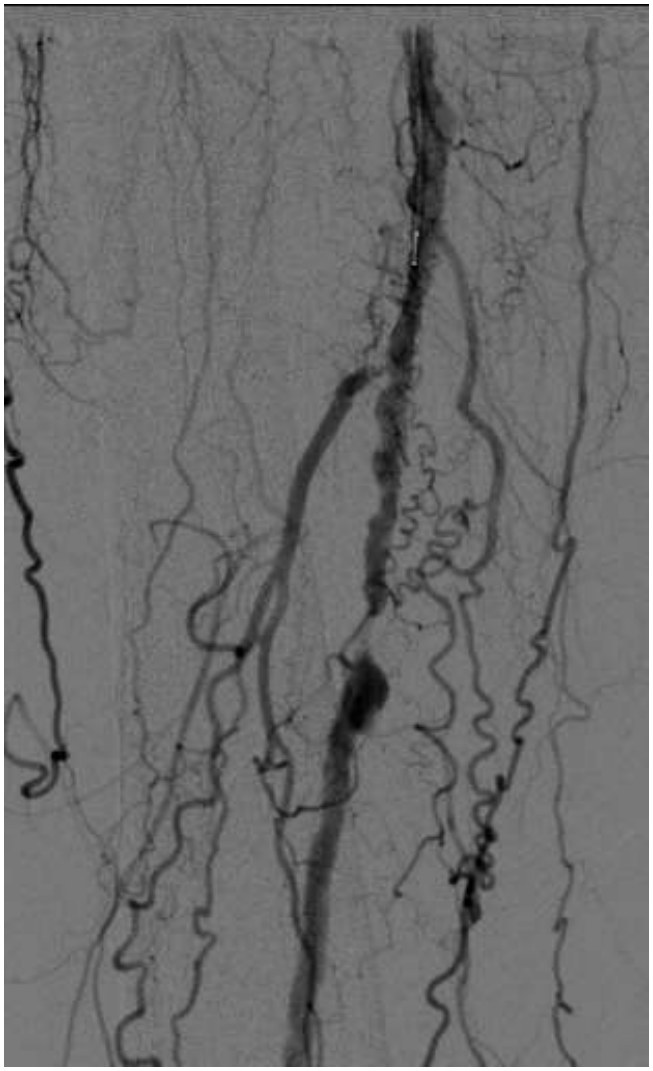


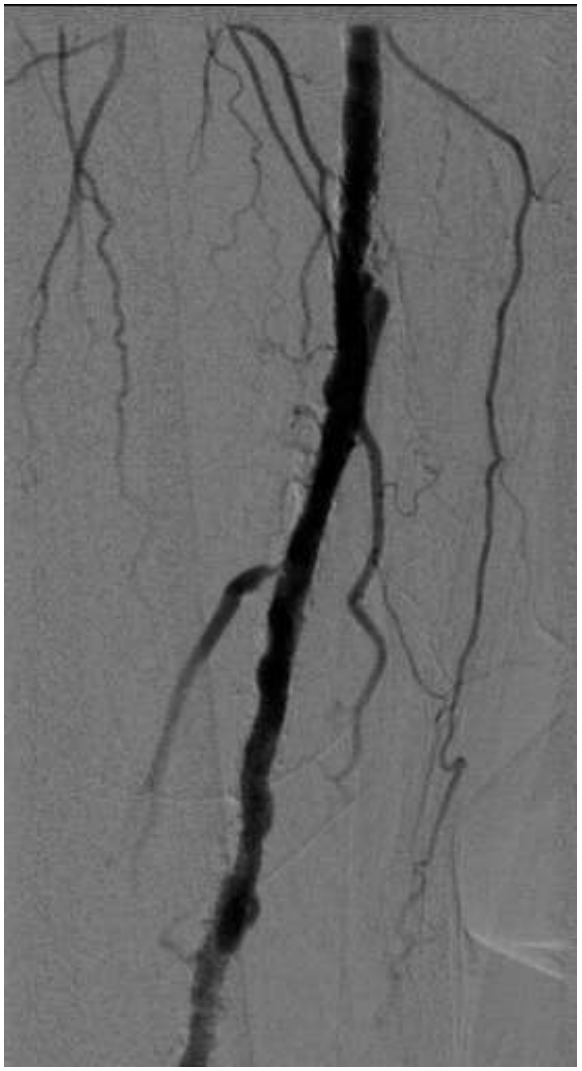
Directional Atherectomy with Admiral DEB

7 mm Spider

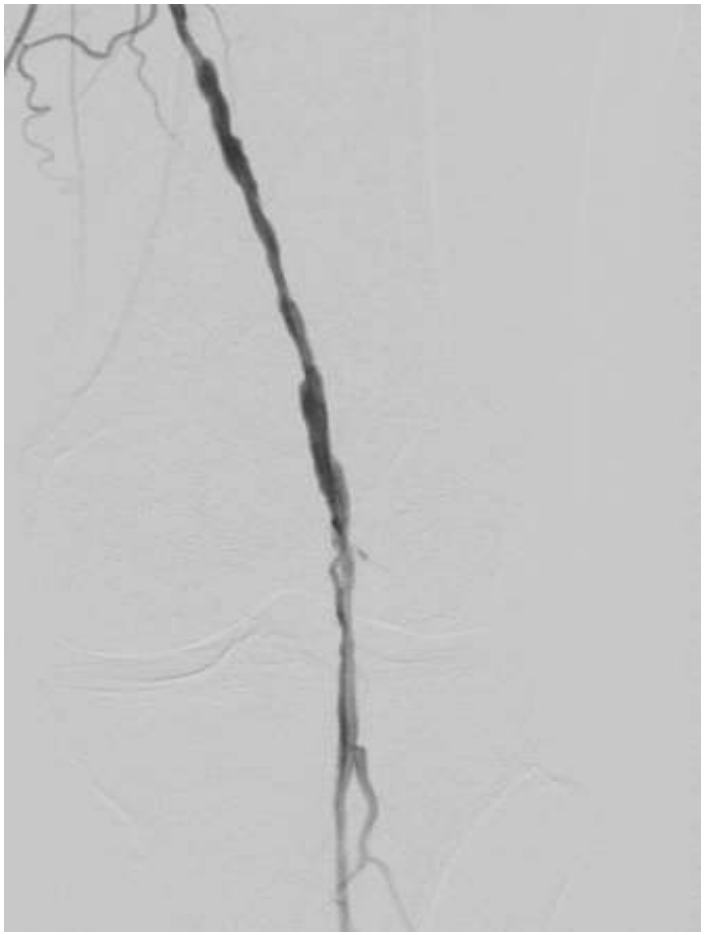
Plaque Removed from Device

Directional Atherectomy with Admiral DEB





So how should we treat this left popliteal lesion?



Directional Atherectomy with DEB?

Conclusions

- Short lesions (< 4 cm) – Most options work well in short and long term
- Real World:
  - CFA and Popliteal Disease
  - Severely Calcified Lesions
  - Long Lesions/CTO's
- Atherectomy (Directional) – Good one year data
- Early Data for Directional Atherectomy followed by DEB are encouraging
- Preserves treatment options
- May be the best option for complex disease (TASC C/D)
- Larger and Longer trials needed