Making Plaque Lean:

Currently Wide Applicable Atherectomy

Ravish Sachar MD, FACC

Interventional Cardiology

North Carolina Heart and Vascular

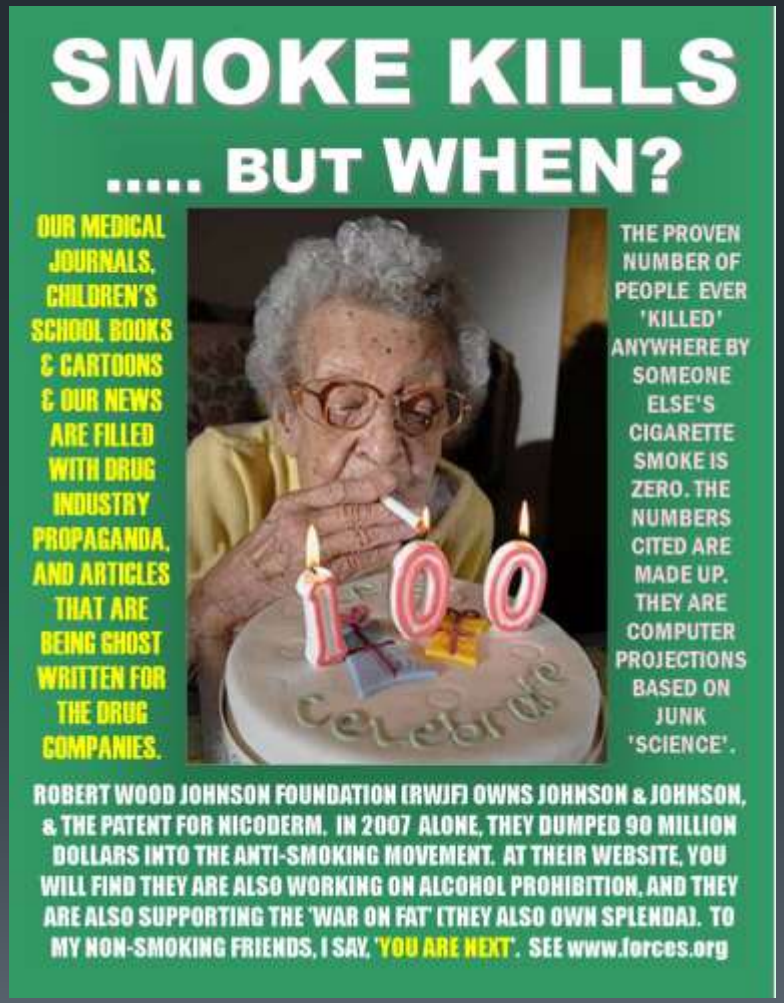
University of North Carolina

Chapel Hill, NC

“Diabetes to Double or Triple in U.S. By 2050, CDC Says”

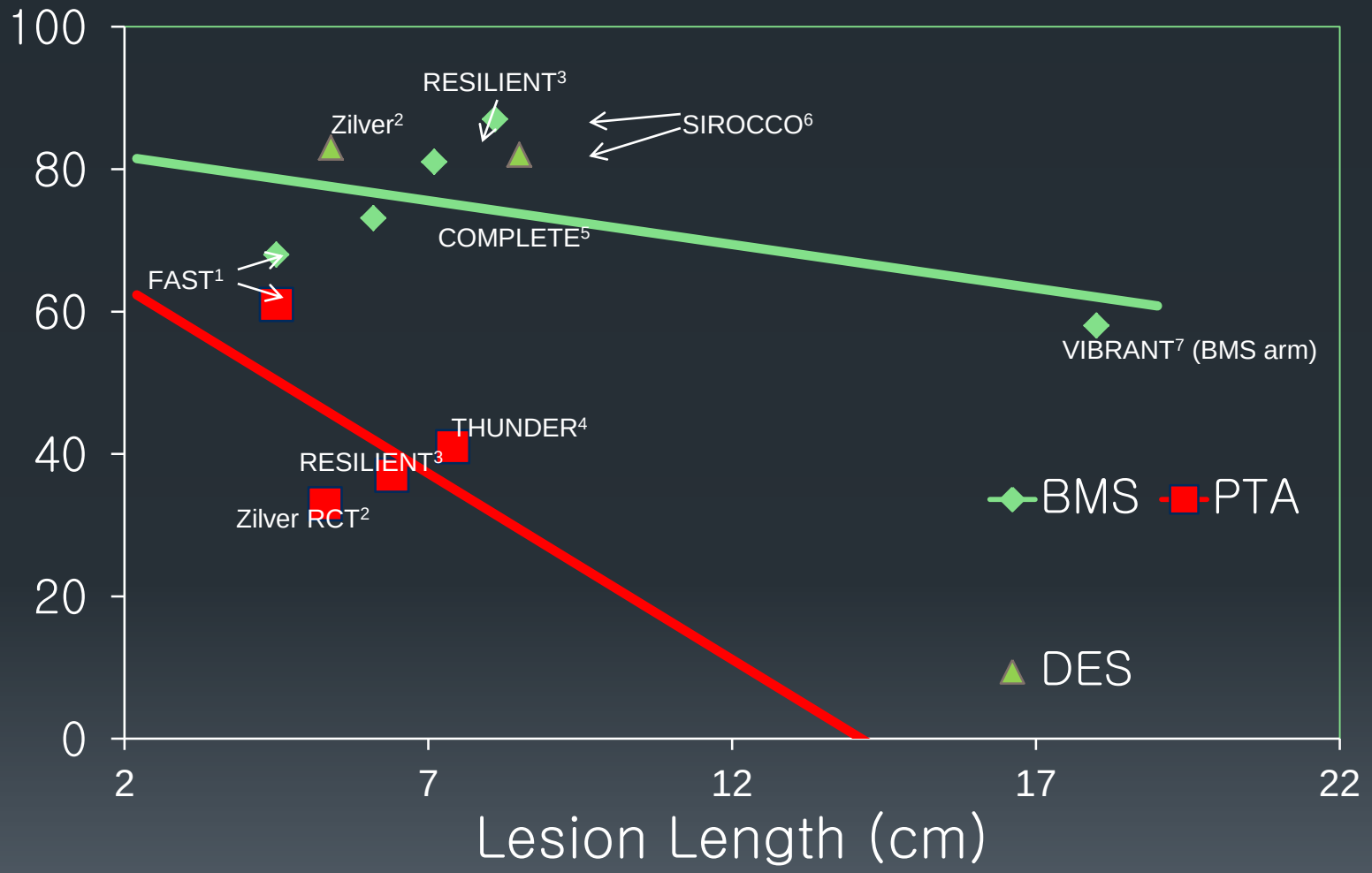
Reuters October 22, 2010

Patients are getting older and continue to have risk factors



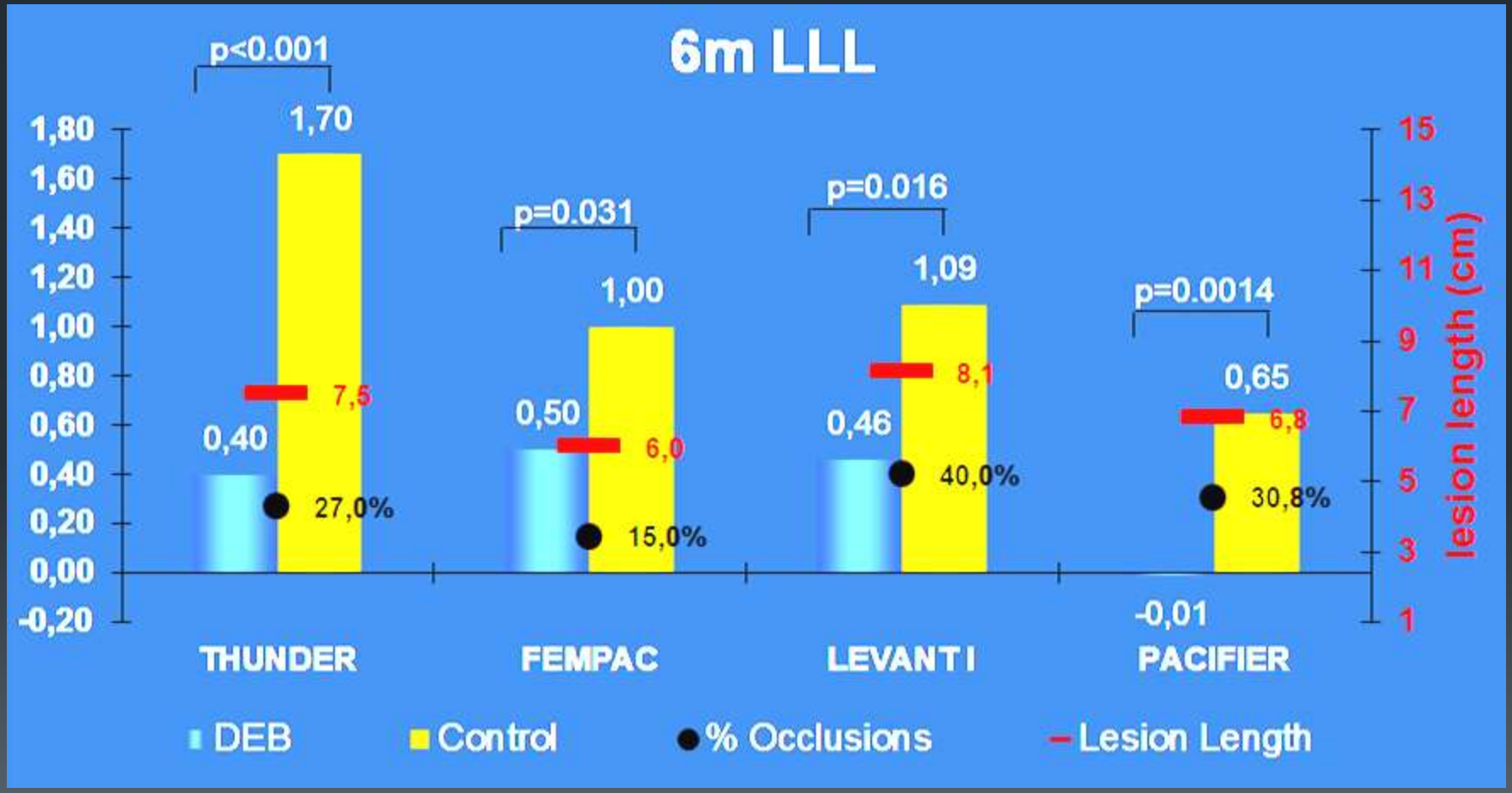
SFA 12-Month Primary Patency

PTA, BMS, DES 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

Early DEB Trials



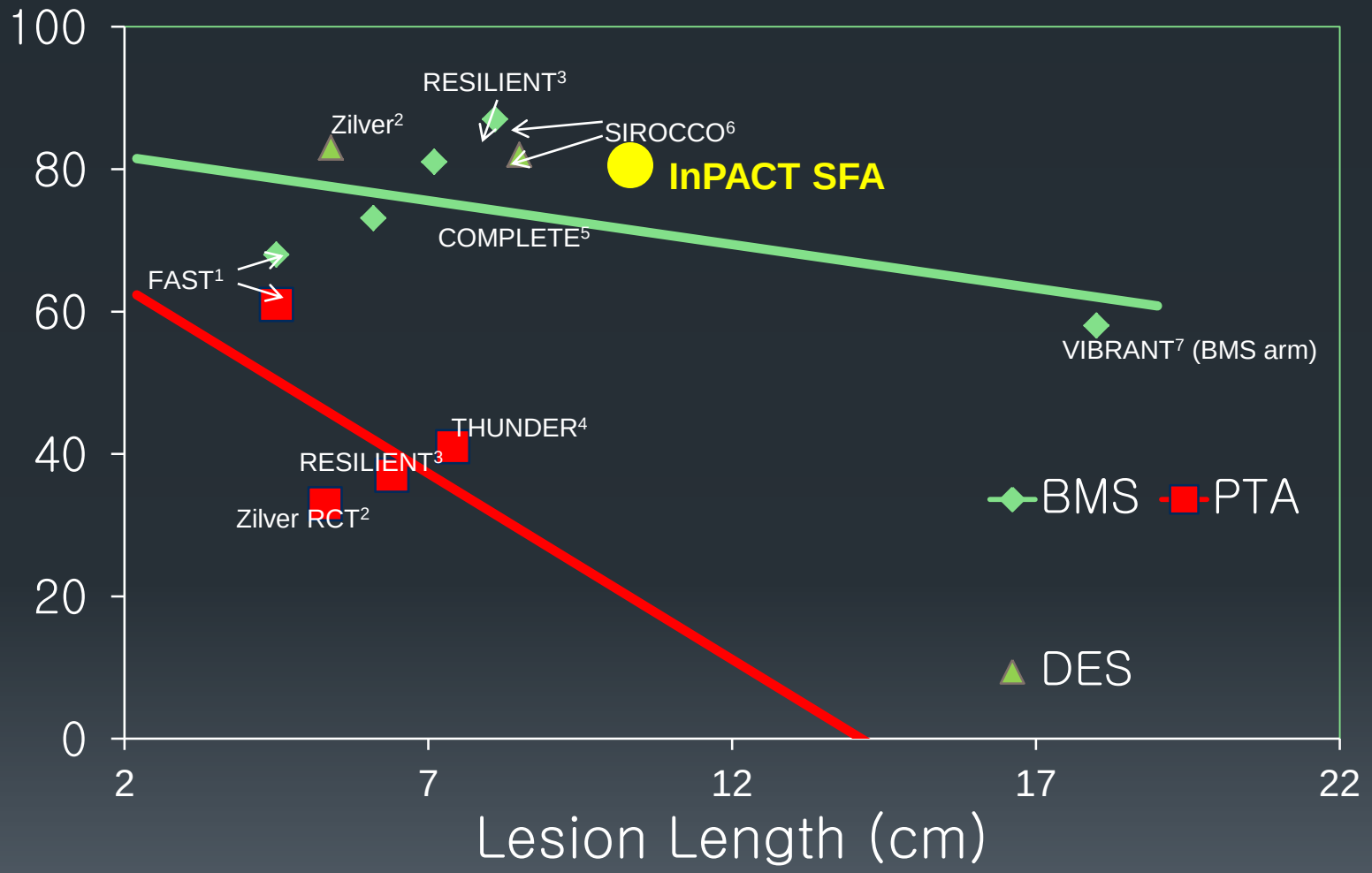
Drug Eluting Ballons
InPACT SFA

One-Year Outcomes: Average 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%

SFA 12-Month Primary Patency

PTA, BMS, DES Sub-Analyses by Lesion Length



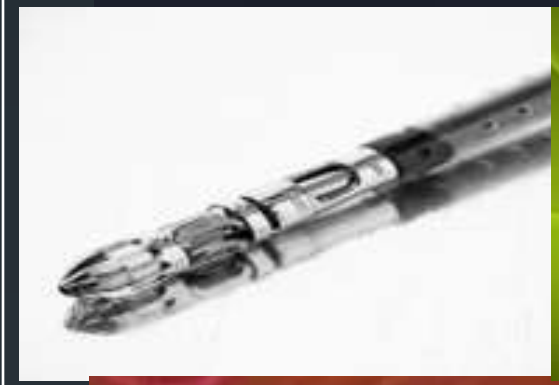
1. Krankenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504)
3. Laird et al. Circ Cardiovasc Interv. 2010; 3: 267-276
4. Tepe et al. NEJM 2008;358:689-99
5. Laird, ISET 2012
6. Duda et al. J Endovasc Ther 2006; 13:701-710
7. Ansel, VIVA 2010

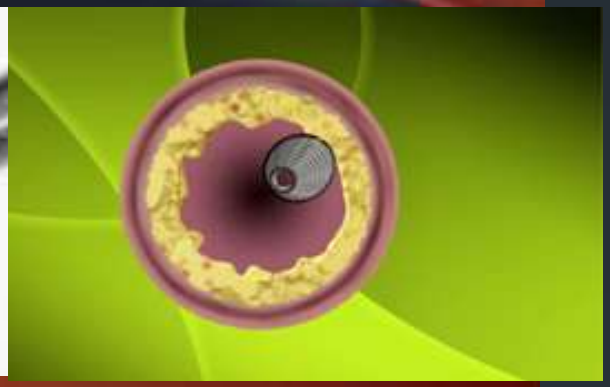
What about lesions that were excluded from trials

- No-Stent Zones
- Severe Calcification
- Not stent candidates
- In-stent Restenosis

Atherectomy

- **Directional**
  - **TurboHawk**
- **Rotational**
  - **Pathway**
- **Orbital**
  - **Diamondback**
- **Athero-ablative**
  - **Laser**

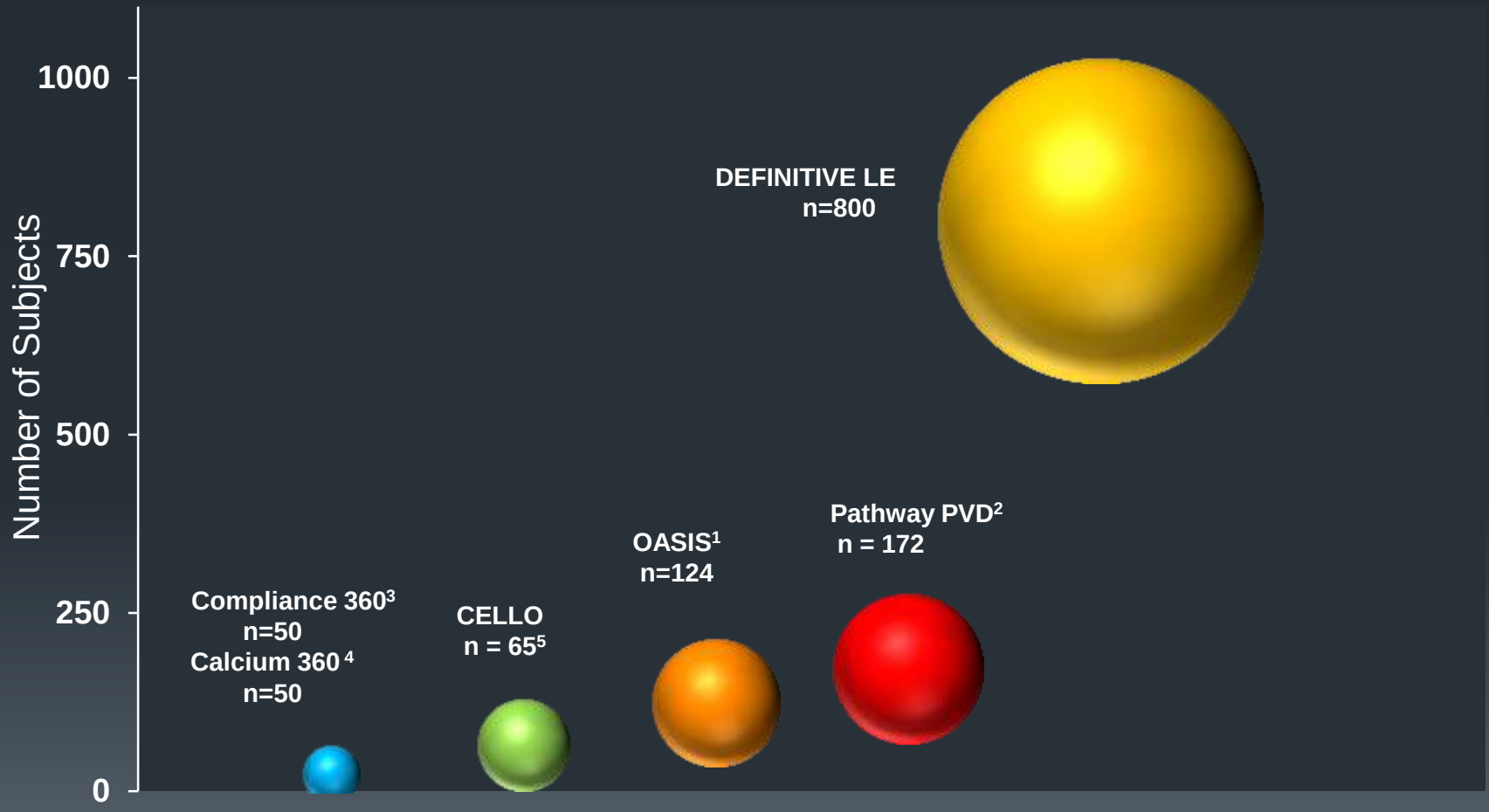




Atherectomy - Advantages

- Treatment of areas where PTA/stents are not ideal – CFA and popliteal
- Allows Debulking and Plaque Modification – improved vessel compliance and reduced risk of dissection with adjunctive PTA
- Treatment of heavily calcific disease
- Preserves treatment options

Atherectomy Trials
Wide variation in sample size



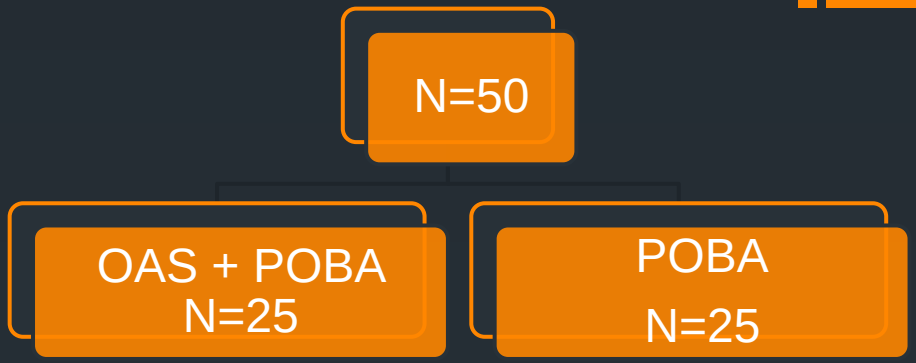
1. Safian et al. Cath & Cardiovasc Interv 73:406:412
2. Zeller et al. J Endovasc Ther 2009;16:653-662
3. Dattilo, TCT 2011
4. Shammas et al. J Endovasc Ther 2012;19:480-488
5. Dave et al. J Endovasc Ther 2009;16:665-675

Laser – CELLO Trial: Fem-Pop Disease 12 Month Data

- 65 Patients, Non-Randomized, Prospective
- High procedural success; 98.5%
- Freedom of TLR of 77% for all patients, and 85% for the stented group
- Patency by duplex ultrasound was 59% and 54% at 6 and 12 months

Orbital - Calcium 360º Study Results

- Prospective, multi-center
- Randomized (1:1)
- Calcified BTK lesions



	OAS + POBA n=29	POBA ARM n=35
Max Avg Balloon Inflation, *$p < 0.001$	5.9 atms*	9.4 atms*
Dissections (≥ Type C)	3.3%	11.4%
Embolization	0	2.8%
Perforation	0	2.8%
Adjunctive Stenting	6.9%	14.3%
12 month TLR	24%	25%
12 months MAE, **$p = 0.006$	6.7%**	42.1%**

MAE (major adverse events: major amputation (above the ankle), all-cause mortality and TLR/TVR).

Rotational - Pathway PV™ Atherectomy System

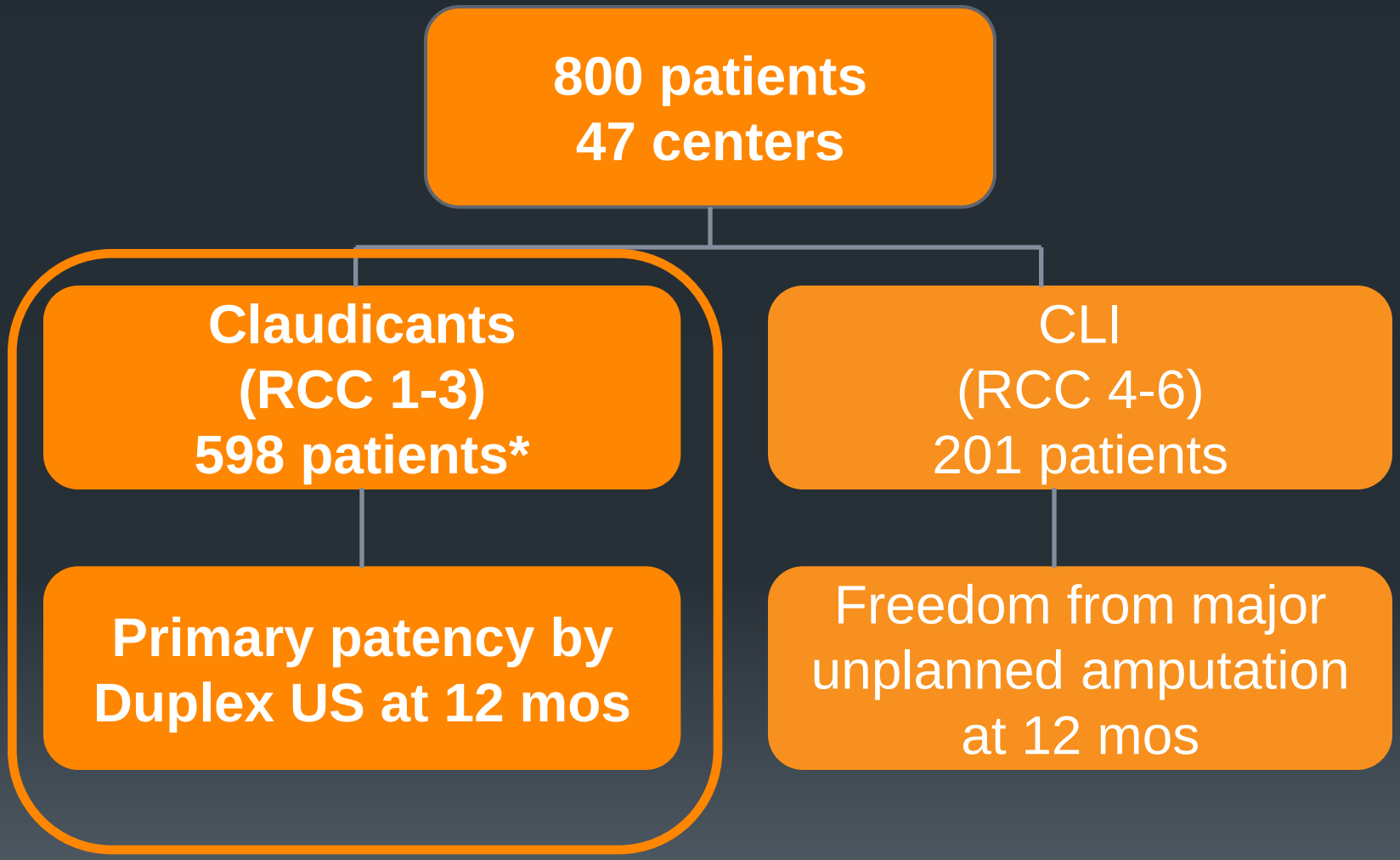
- 172 patients/210 lesions
- 47% Diabetic
- Average length 4.1cm
- Moderate to high Ca 52%

- Lesion Location
  - SFA 64%
  - Popliteal 28%
  - Tibial/ Peroneal 9%

- Procedural Success 99%
- MAE 2.9%

- 12 month patency: 61.8%
- 12 month clinically driven TLR: 26%

Directional Atherectomy - Definitive LE



*1 censored due to informed consent violation

Stent-like Primary Patency

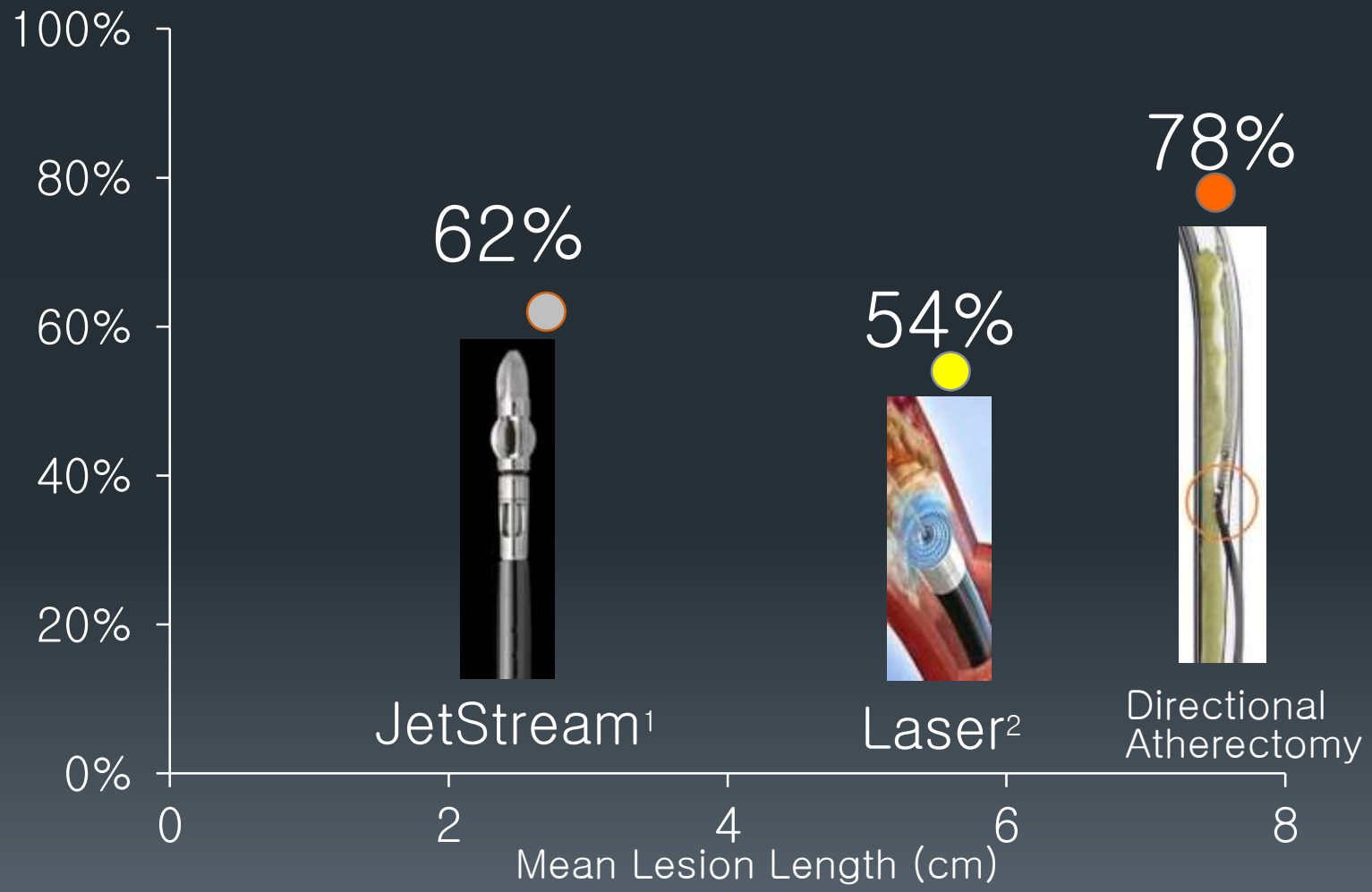
Claudicant Cohort

743	Lesions
7.5 cm	Mean lesion length
72.7%	Mean baseline stenosis

PSVR ≤ 3.5	82%
PSVR ≤ 2.4	78%

Atherectomy Trials

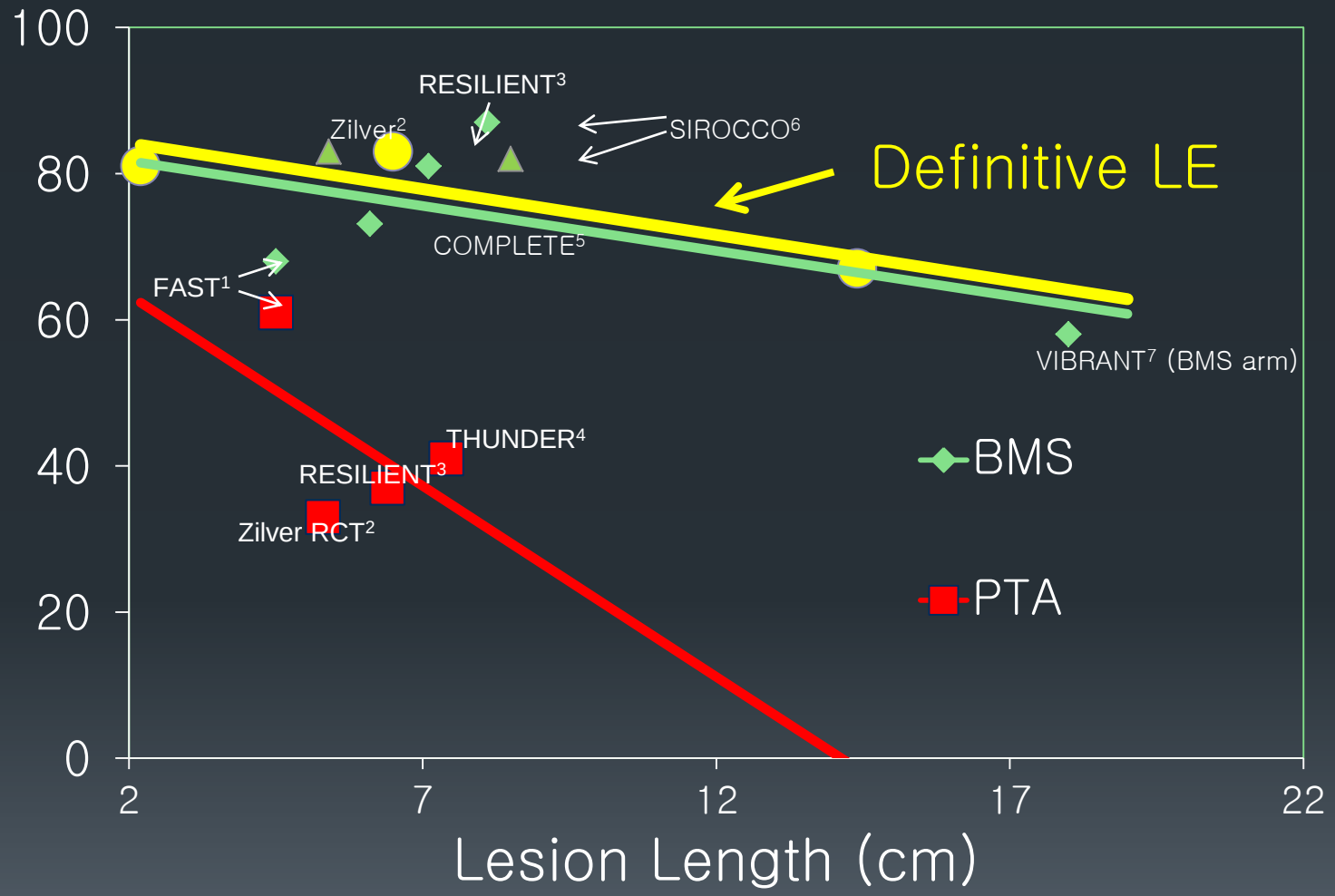
Core-Lab Adjudicated 12-mo. Patency



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

SFA 12-Month Primary Patency

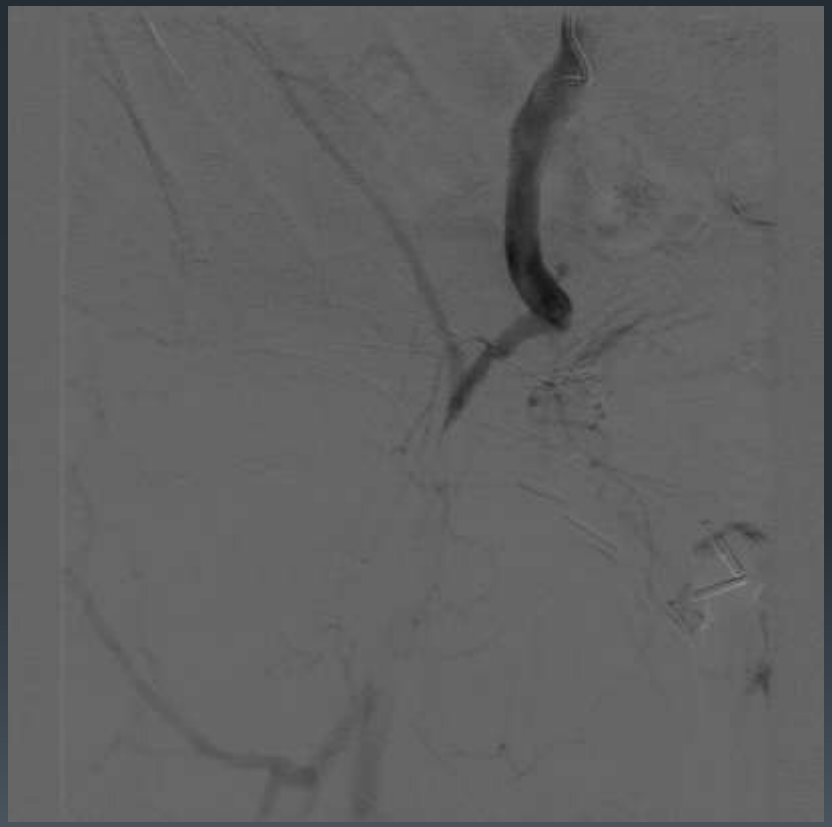
PTA, BMS, DES and DEF LE Sub-Analyses by Lesion Length

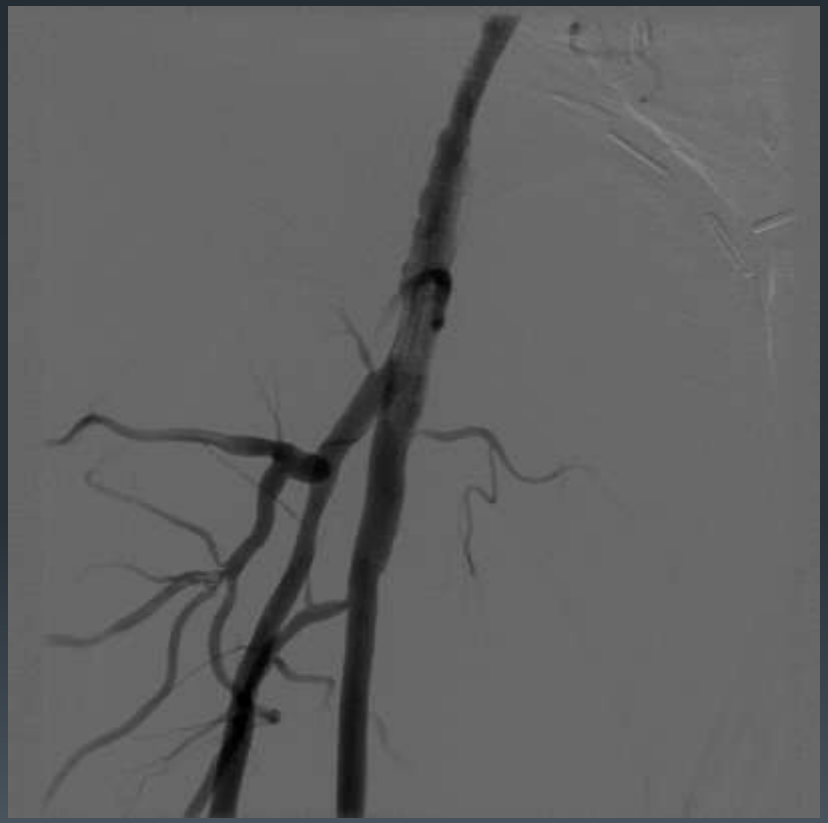


1. Krankenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504)
3. Laird et al. Circ Cardiovasc Interv. 2010; 3: 267-276
4. Tepe et al. NEJM 2008;358:689-99
5. Laird, ISET 2012
6. Duda et al. J Endovasc Ther 2006; 13:701-710
7. Ansel, VIVA 2010

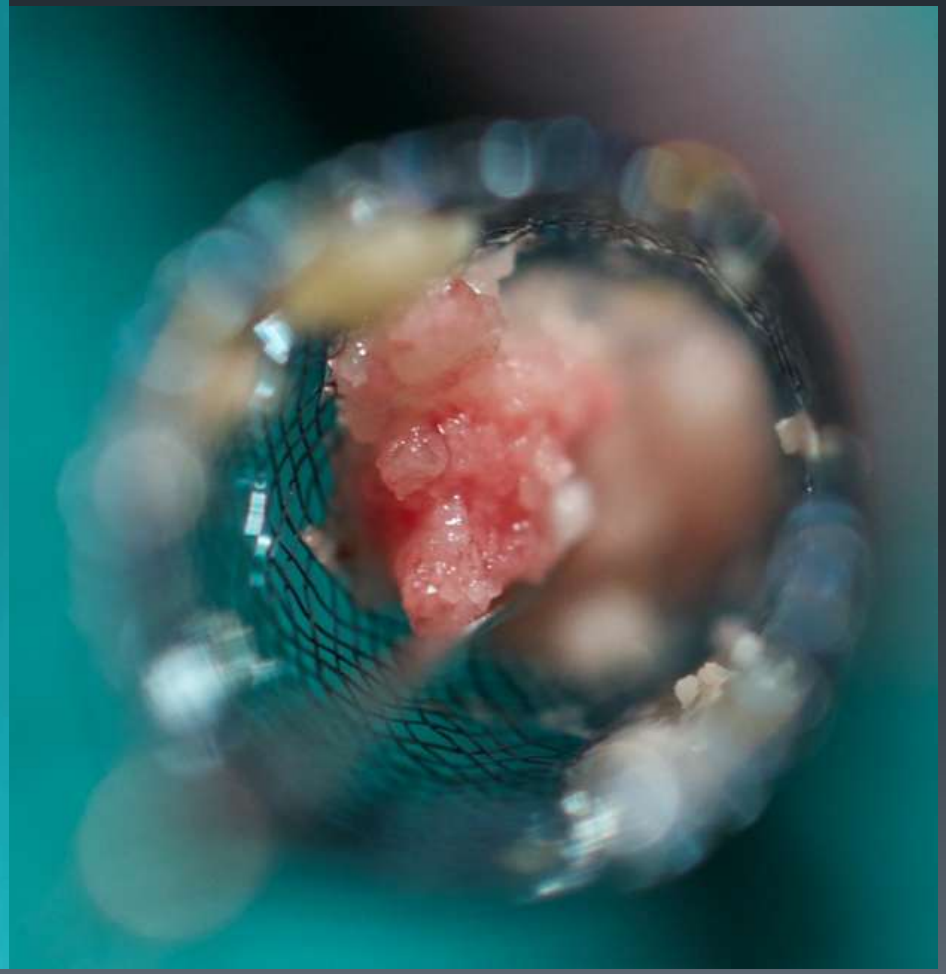
Right SFA stenosis
Orbital Atherectomy

Right CFA CTO
Directional Atherectomy

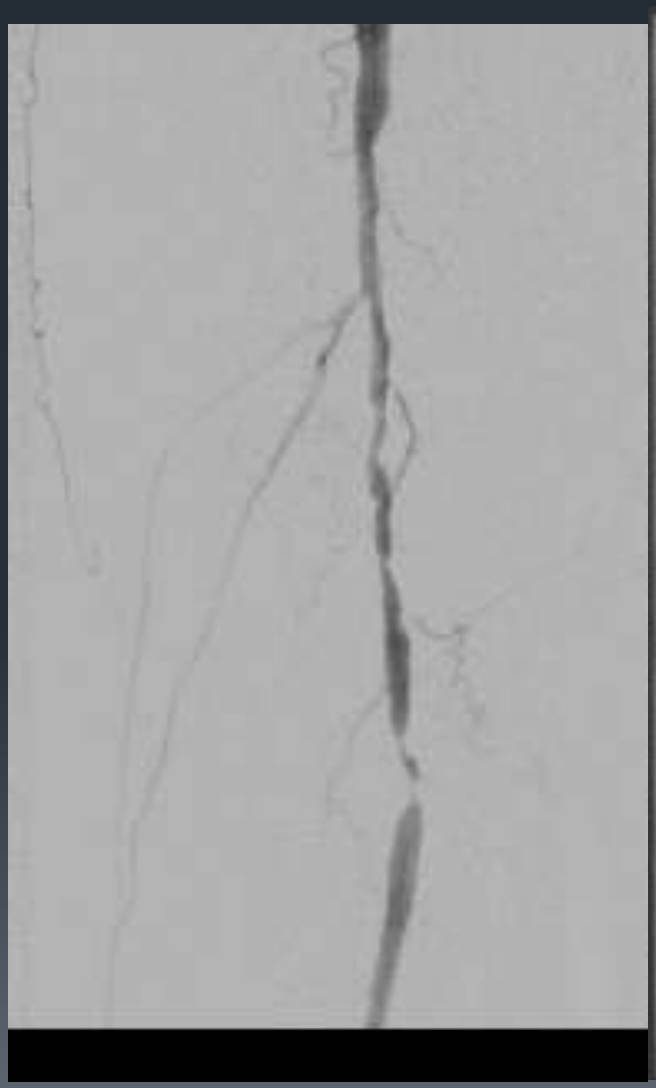


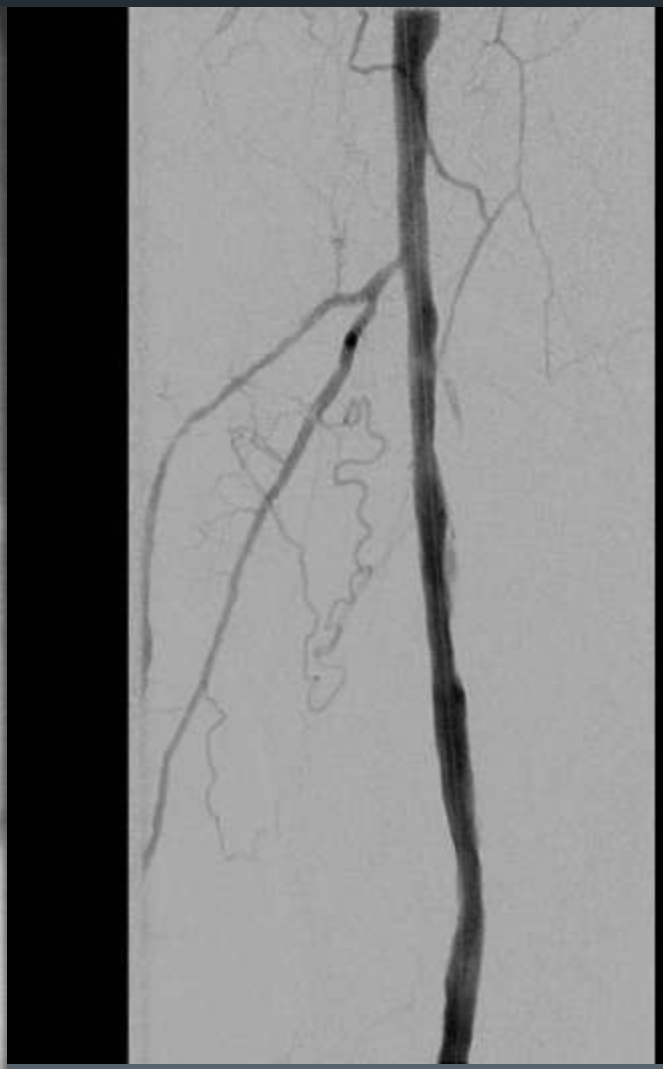


Embolic Protection

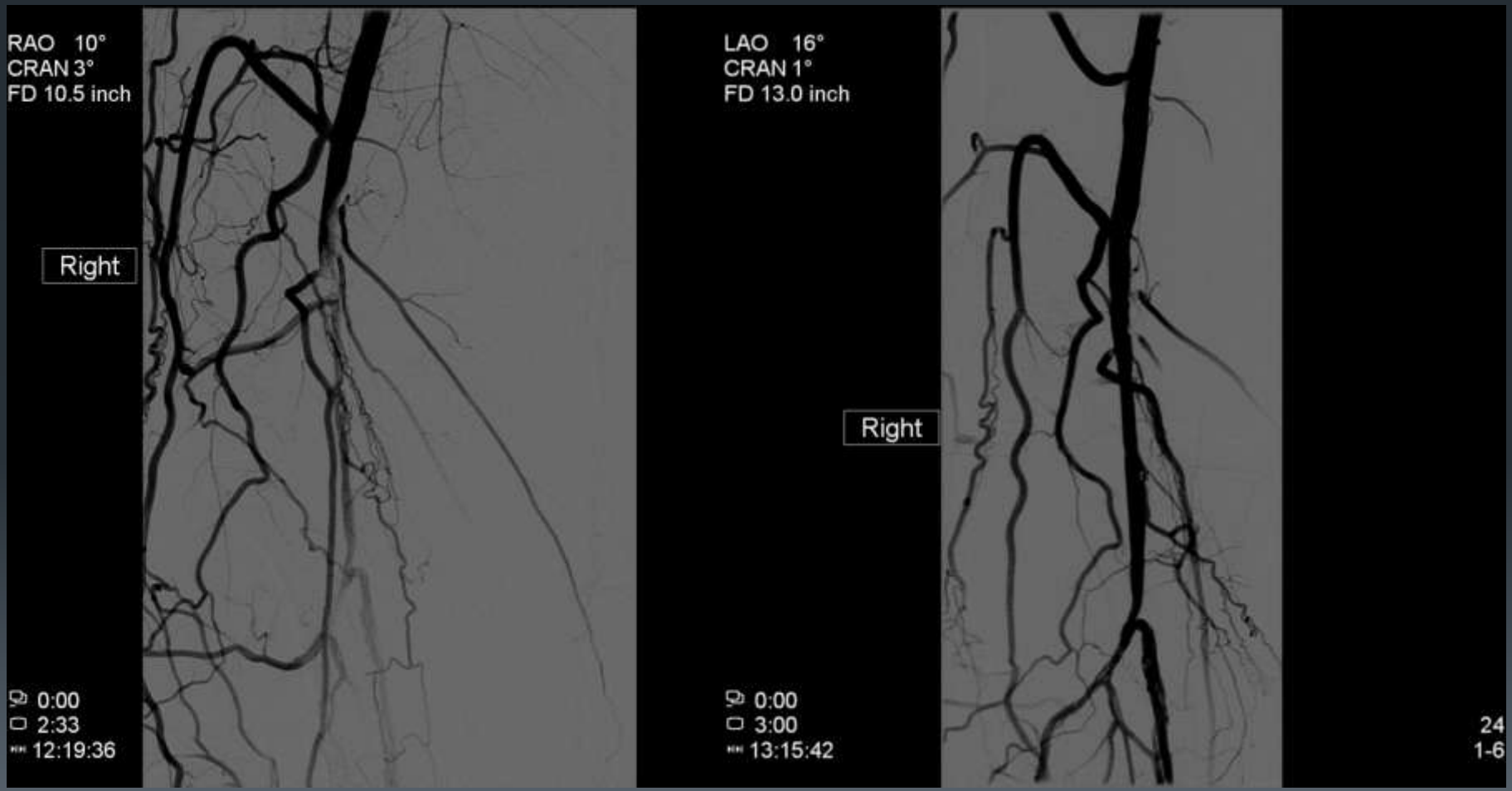


Heavily Calcified
Right Popliteal Stenosis

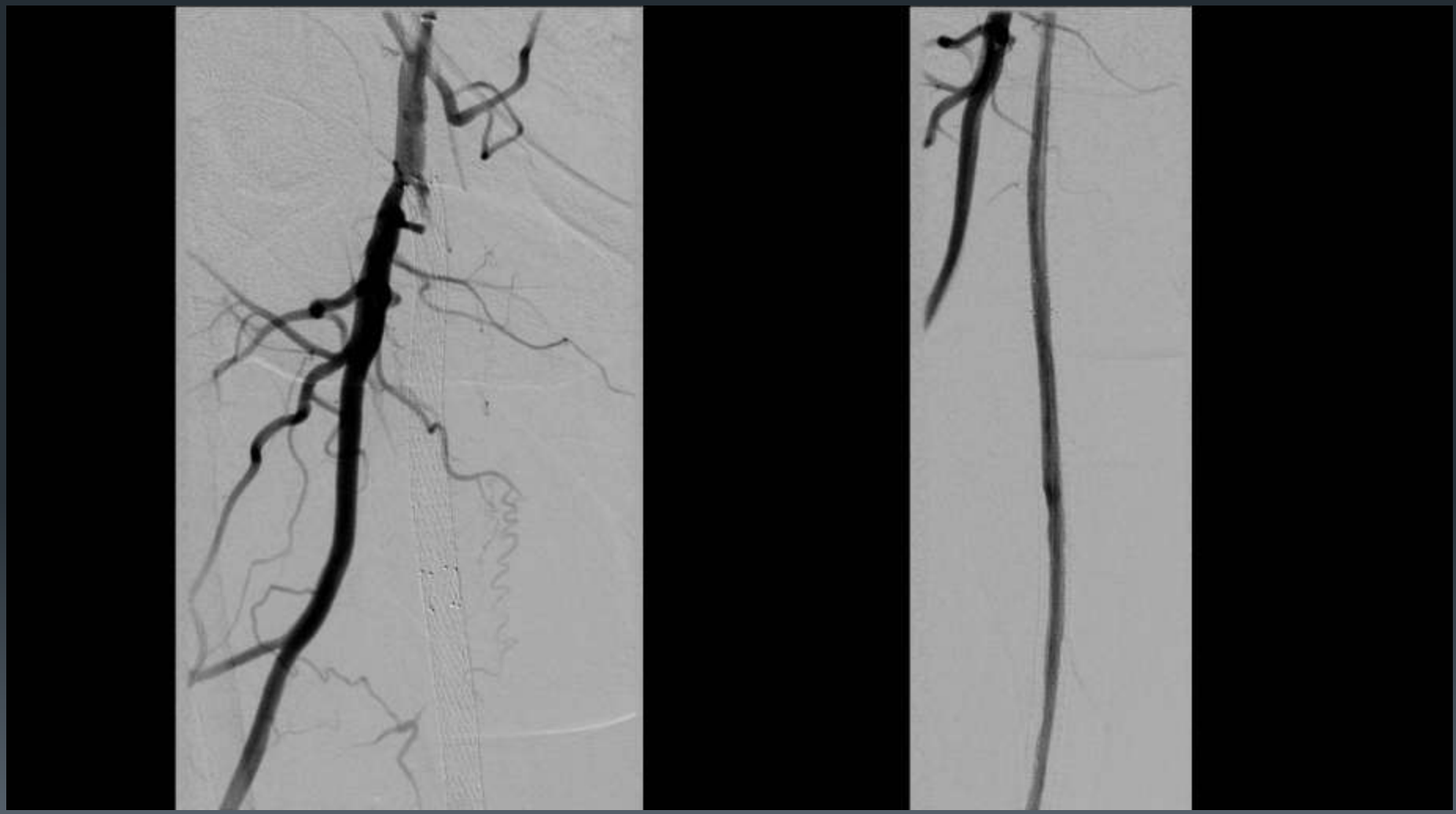




Heavily Calcified Right Popliteal Stenosis



100% Right SFA ISR
Laser Atherectomy



How to treat?

- Bare Metal Stent
- Drug Eluting Stent
- Atherectomy
- Drug Eluting Balloon
- Atherectomy + DEB

Atherectomy + DEB: Higher Acute Technical Success

Defined as ≤ 30% residual stenosis following the protocol-defined treatment at the target lesion as determined by the Angiographic Core Laboratory.

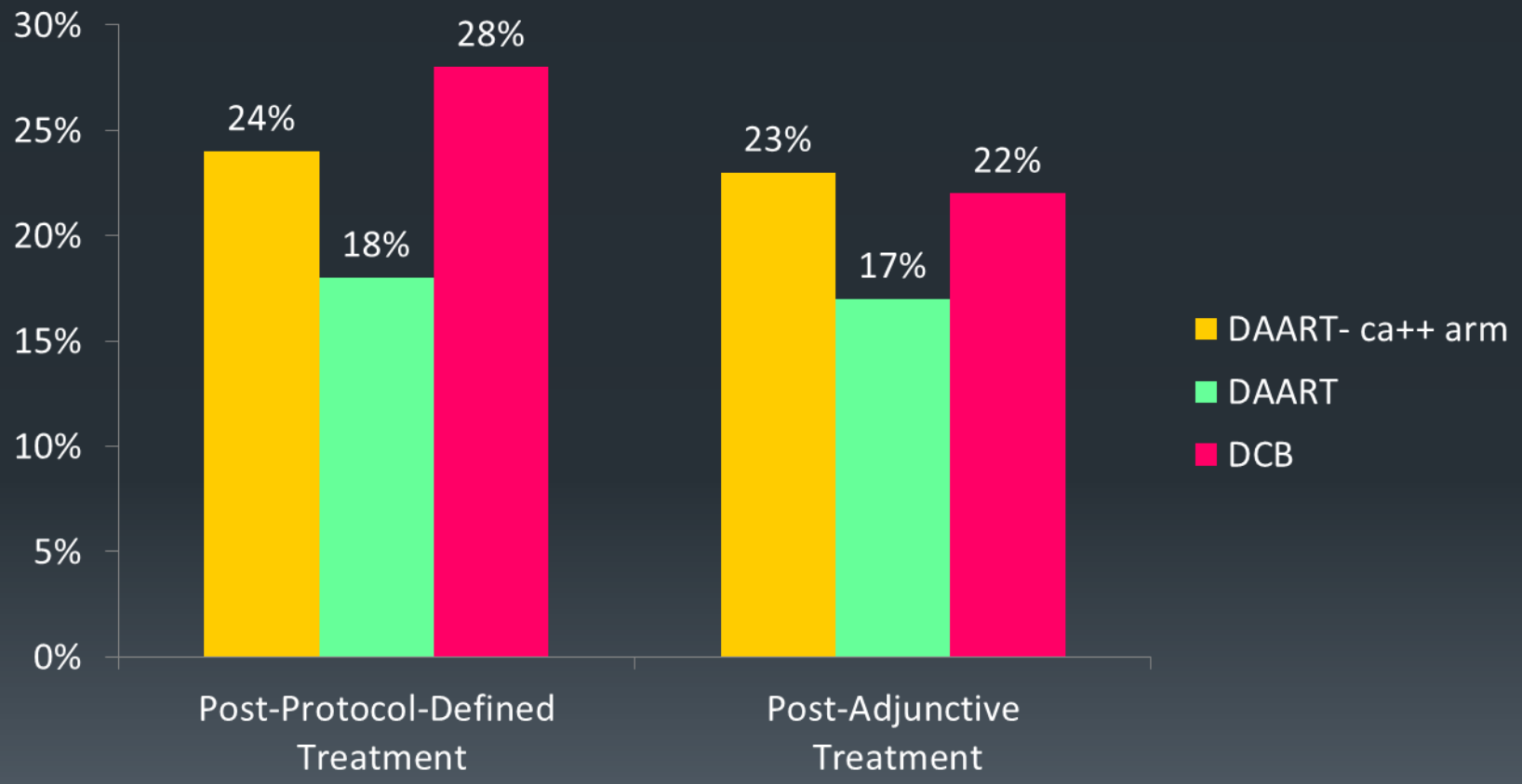
	DAART Severe Ca^{++}	DAART	DCB	P Value (DAART vs. DCB)
Technical Success	84.2%	89.6%	64.2%	0.004

Atherectomy + DEB: Lower need for post PTA and Bail Out Stenting

	DAART Severe Ca^{++}	DAART	DCB	P Value (DAART vs. DCB)
Adjunctive Therapy				
PTA (post-dil)	0	6.3% (3/48)	33.3% (18/54)	0.0011
Bail-out Stent	5.3% (1/19)	0	3.7% (2/54)	0.4968

Residual Stenosis was significantly lower in the DAART arms

Per Core Lab assessment



What do we know

- We have good data for what to do with SFA disease which is about 8 cm in length – Can expect about an 80% patency at 1 yr

- In certain subsets of patients atherectomy is really the only good option

What don’t we know

- What happens at 2, 3, 4 yrs and beyond - Which option will give the most durable results
- How should we treat longer lesions - 15-30 cm?
- What is the best treatment for heavily calcified lesions?
- How should we approach ISR?

Thank You!