



Making Plaque Lean: Currently Wide Applicable Atherectomy

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“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

**SMOKE KILLS
..... BUT WHEN?**

OUR MEDICAL JOURNALS, CHILDREN'S SCHOOL BOOKS & CARTOONS & OUR NEWS ARE FILLED WITH DRUG INDUSTRY PROPAGANDA, AND ARTICLES THAT ARE BEING GHOST WRITTEN FOR THE DRUG COMPANIES.



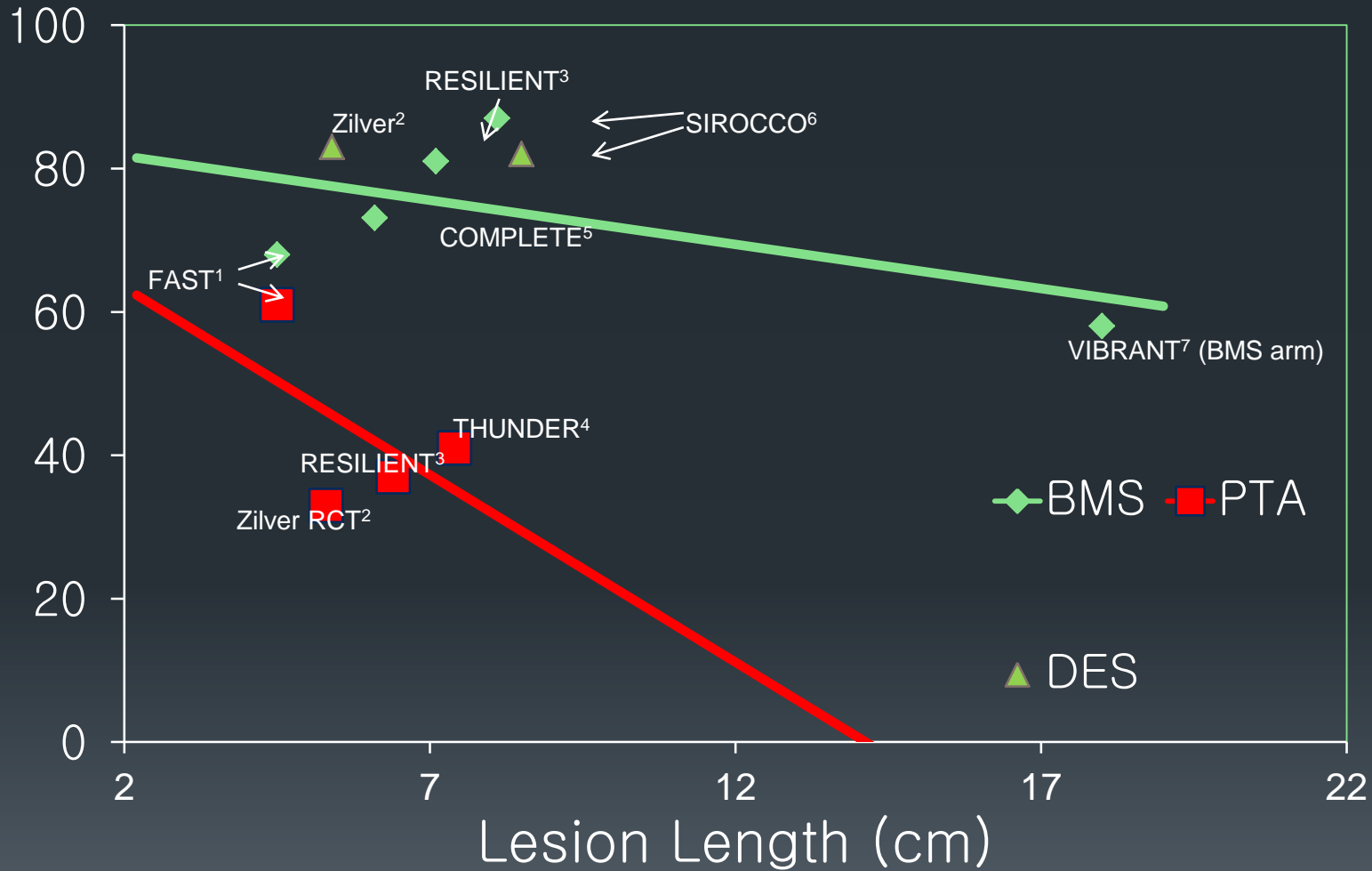
THE PROVEN NUMBER OF PEOPLE EVER 'KILLED' ANYWHERE BY SOMEONE ELSE'S CIGARETTE SMOKE IS ZERO. THE NUMBERS CITED ARE MADE UP. THEY ARE COMPUTER PROJECTIONS BASED ON JUNK 'SCIENCE'.

ROBERT WOOD JOHNSON FOUNDATION (RWJF) OWNS JOHNSON & JOHNSON, & THE PATENT FOR NICODERM. IN 2007 ALONE, THEY DUMPED 90 MILLION DOLLARS INTO THE ANTI-SMOKING MOVEMENT. AT THEIR WEBSITE, YOU WILL FIND THEY ARE ALSO WORKING ON ALCOHOL PROHIBITION, AND THEY ARE ALSO SUPPORTING THE 'WAR ON FAT' (THEY ALSO OWN SPLENDA). TO MY NON-SMOKING FRIENDS, I SAY, 'YOU ARE NEXT'. SEE www.forces.org



SFA 12-MONTH PRIMARY PATENCY

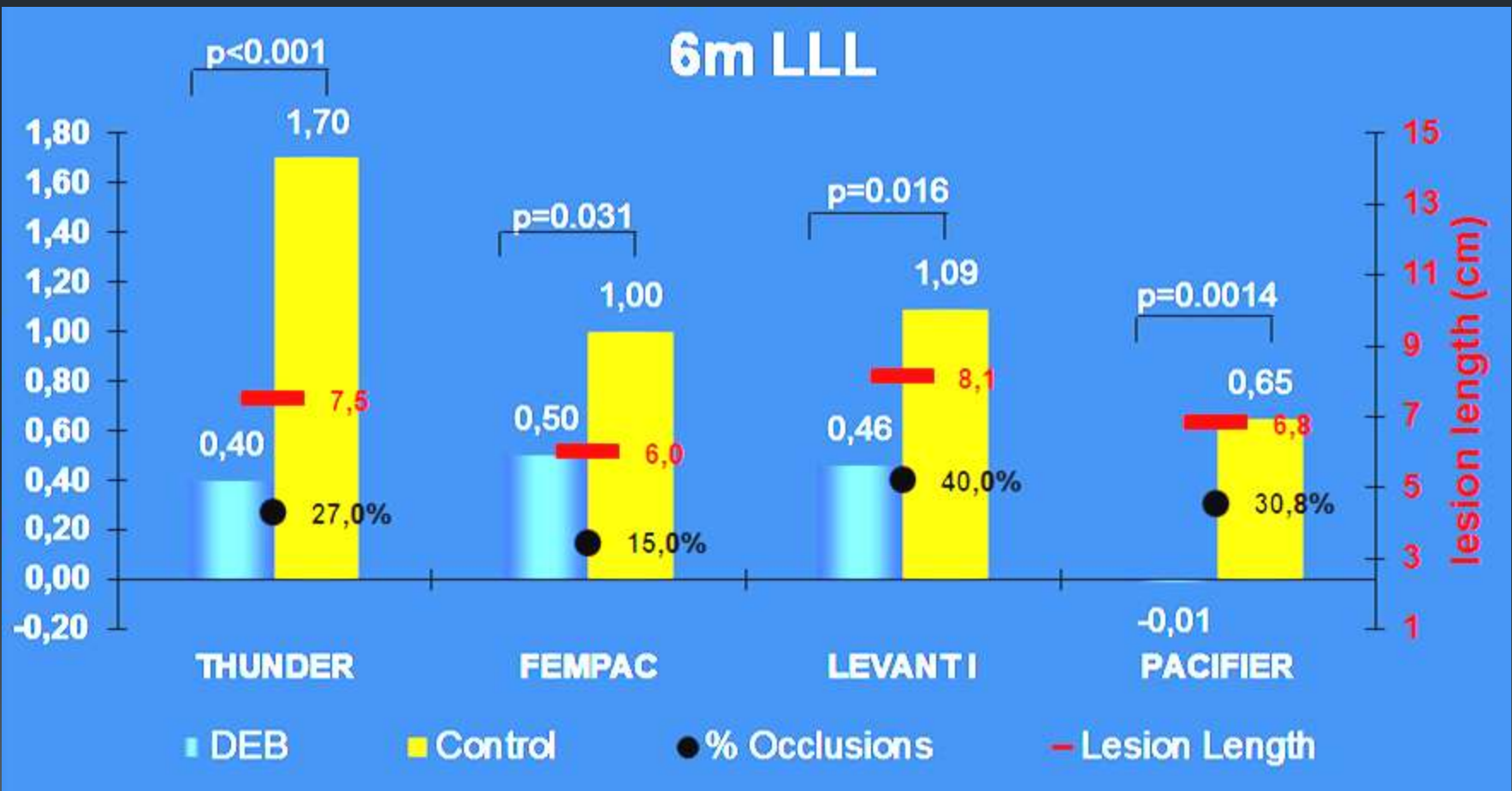
PTA, BMS, DES Sub-Analyses by Lesion Length



1. Krakenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504
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Early DEB Trials



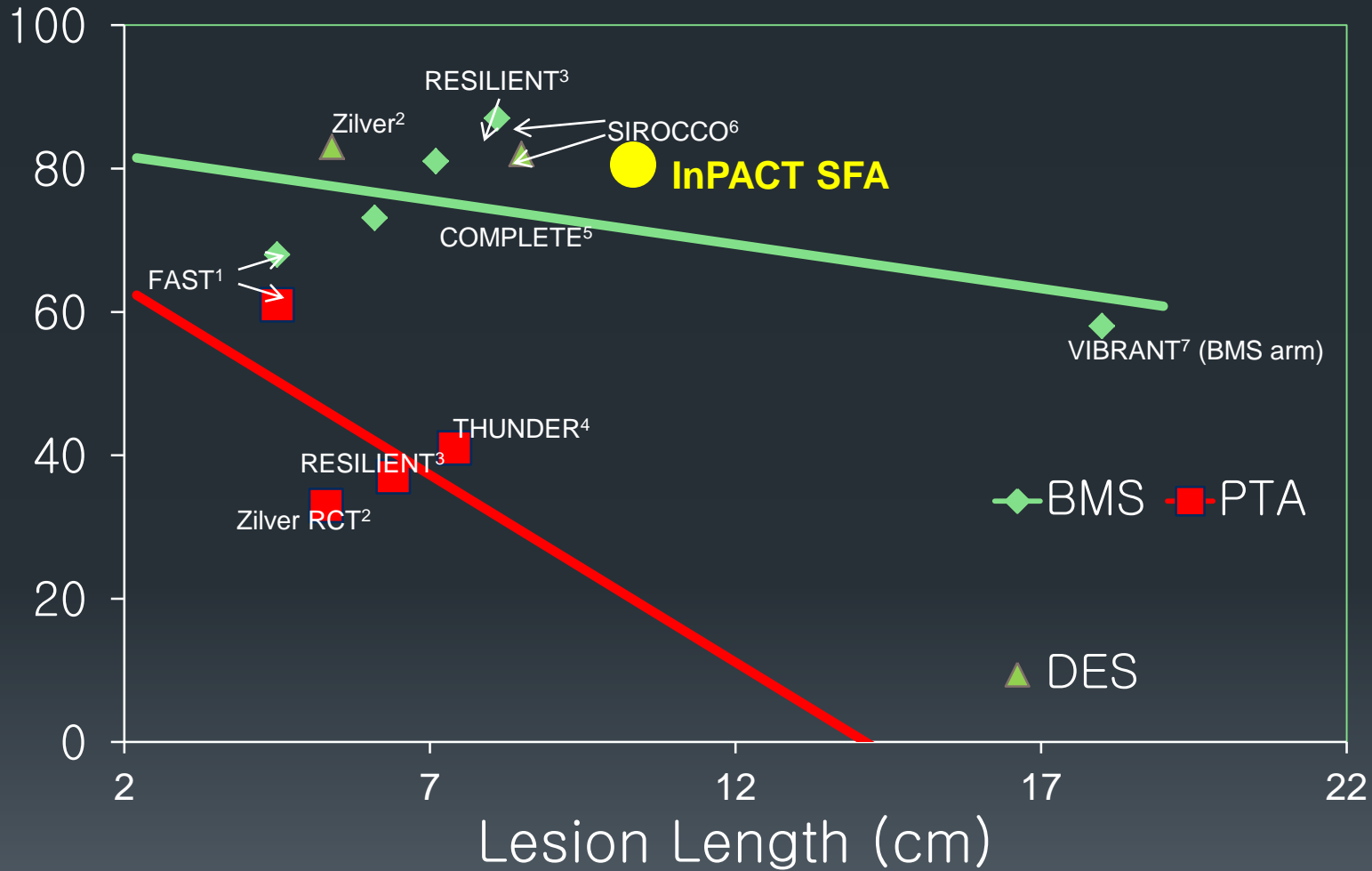
Drug Eluting Ballons InPACT SFA

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%

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WHAT ABOUT LESIONS THAT WERE EXCLUDED FROM TRIALS

No-Stent Zones

Severe Calcification

Not stent candidates

In-stent Restenosis

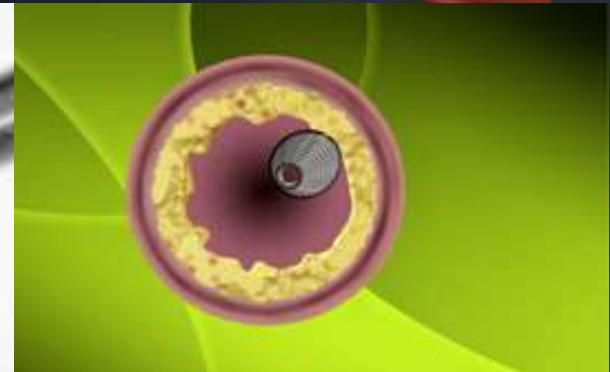


Atherectomy - Advantages

- 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

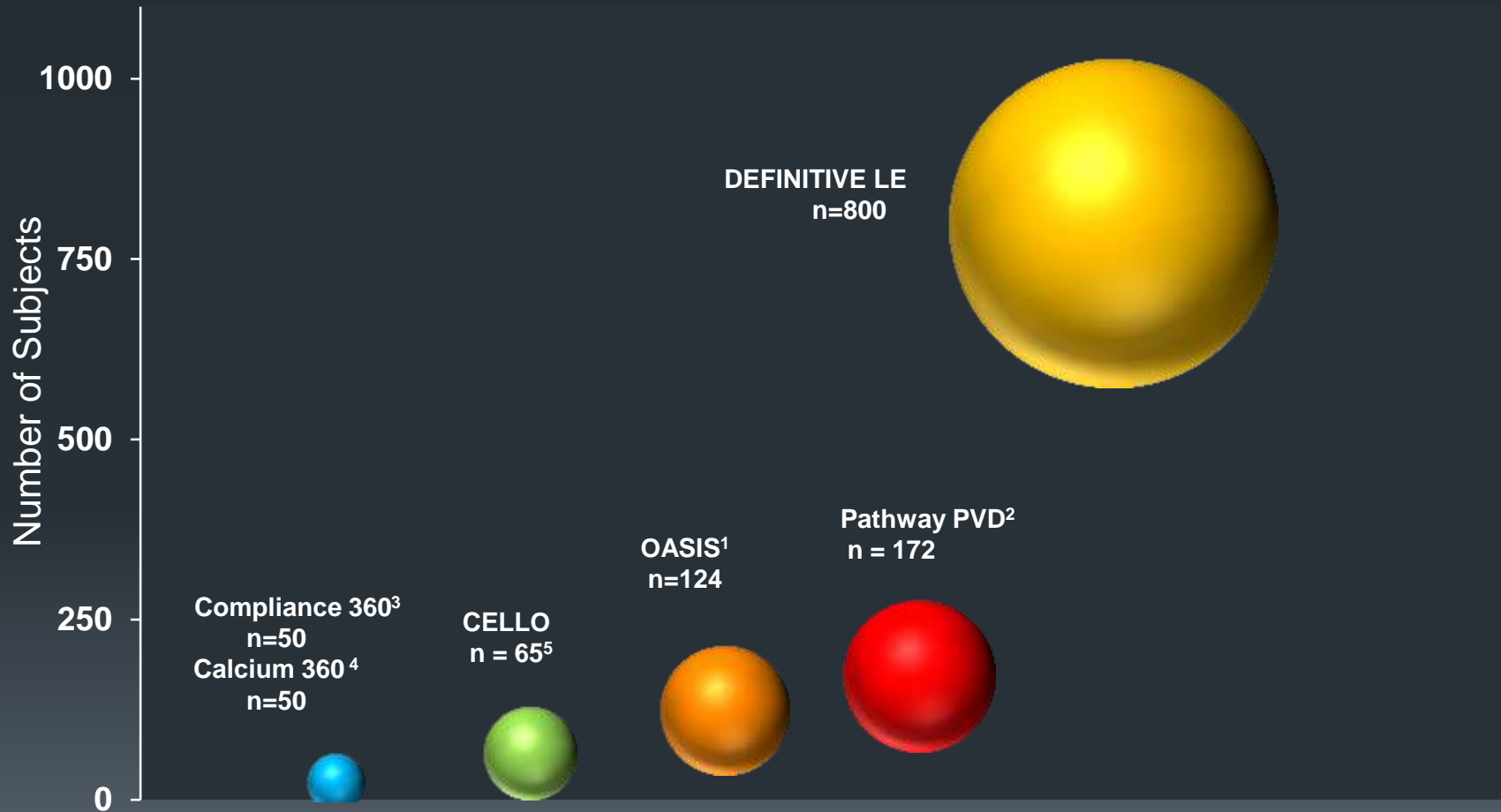
Atherectomy

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



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

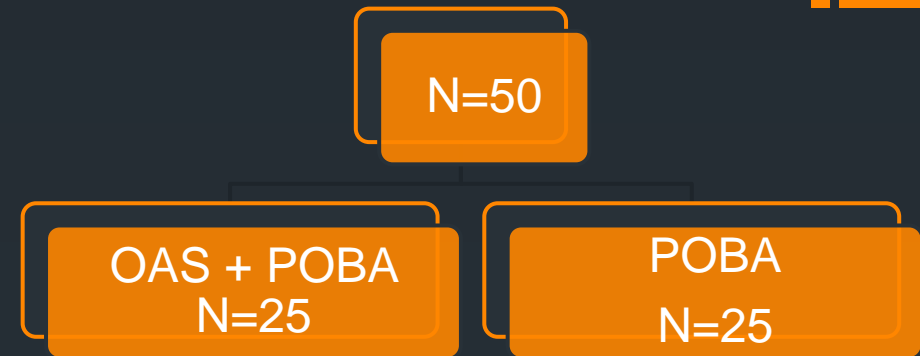


Laser – CELLO Trial: Fem-Pop Disease 12 Month Data

- 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 360° Study Results

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



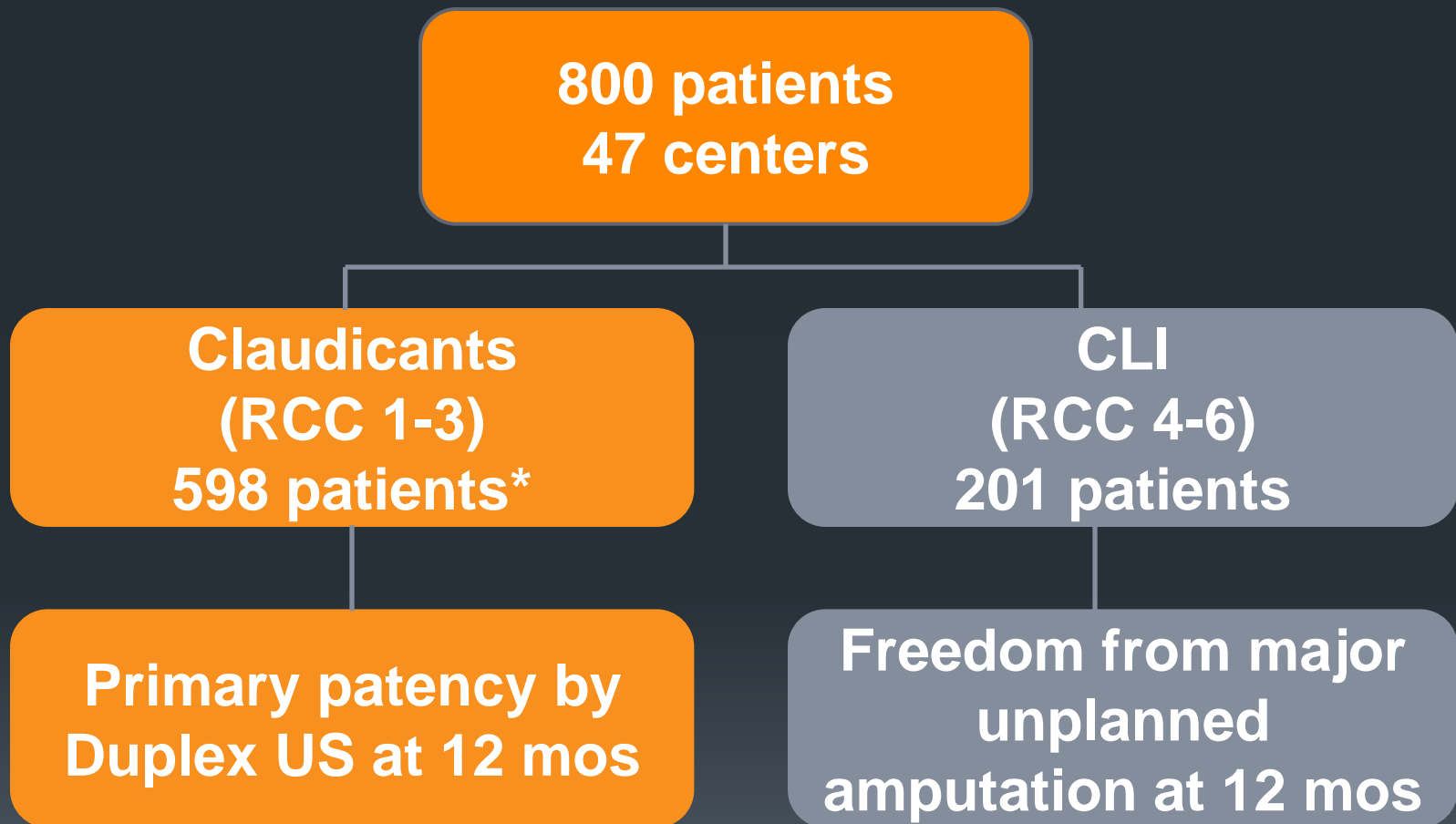
	OAS + POBA n=29	POBA ARM n=35
Max Avg Balloon Inflation, * $p < 0.001$	5.9 atms*	9.4 atms*
Dissections (\geq Type C)	3.3%	11.4%
Embolization	0	2.8%
Perforation	0	2.8%
Adjunctive Stenting	6.9%	14.3%
12 month TLR	24%	25%
12 months MAE, ** $p = 0.006$	6.7%**	42.1%**

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%

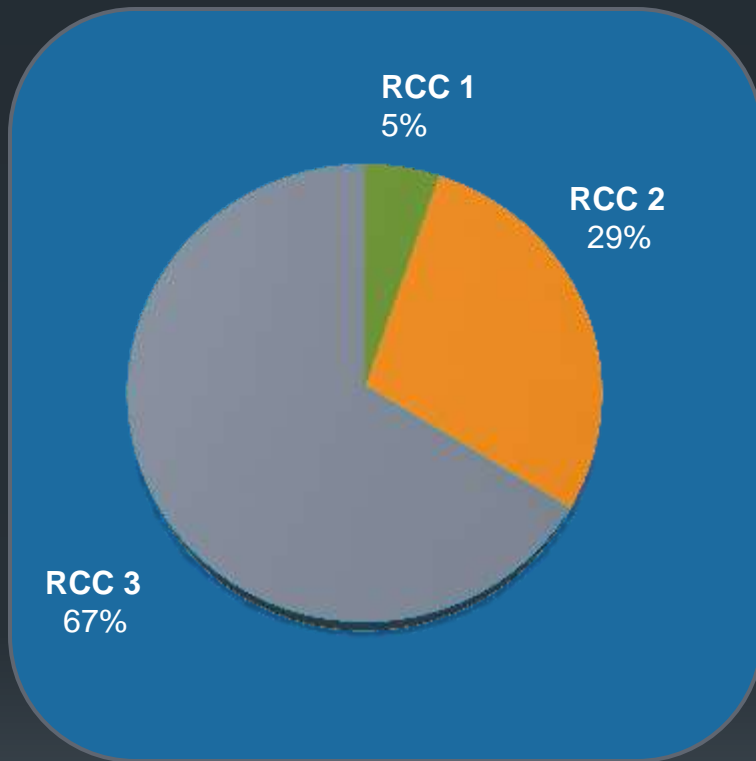
Definitive LE



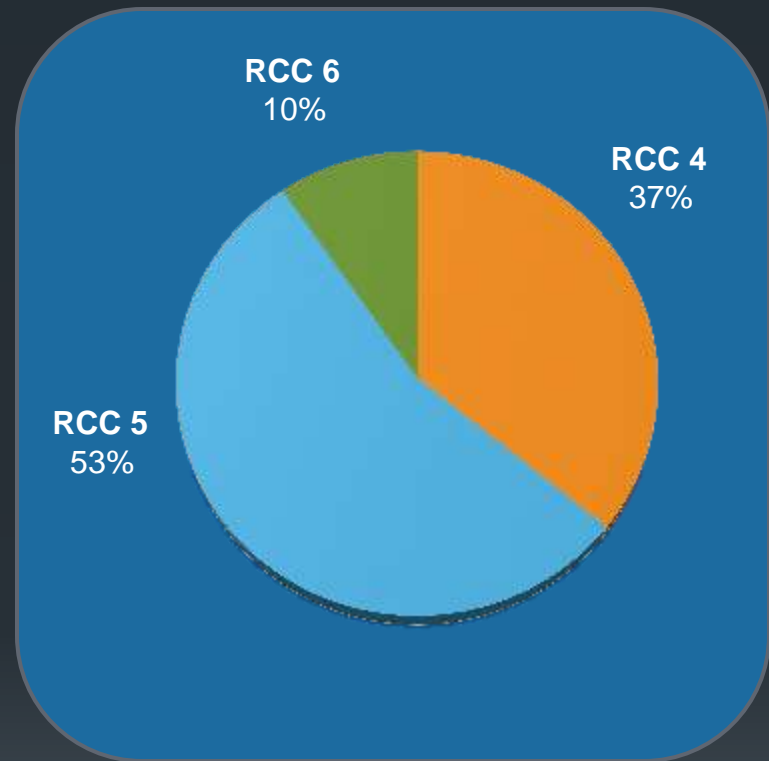
*1 censored due to informed consent violation

Baseline Rutherford Clinical Category

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Claudicants
(n=598)



CLI
(n=201)

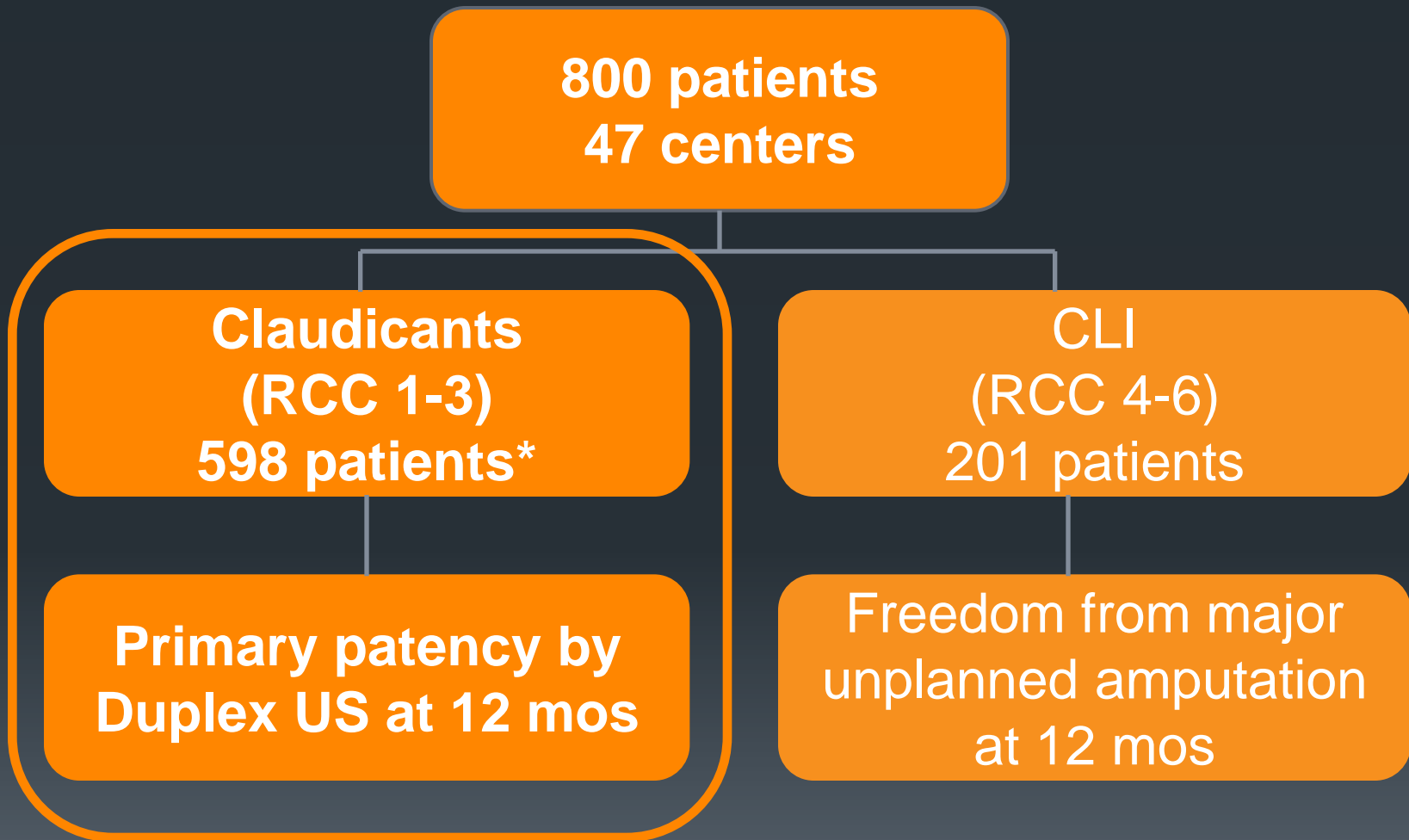
Procedural Success

Outcome	Claudication (RCC 1-3)	CLI (RCC 4-6)	All Subjects (RCC 1-6)
Device Success ($\leq 30\%$ stenosis after directional atherectomy)			
Investigator-Reported	87%	87%	87%
Core Lab	76%	72%	75%
Procedure Success ($\leq 30\%$ stenosis at end of procedure)			
Investigator-Reported	99%	98%	99%
Core Lab	91%	83%	89%

Periprocedural Complications (All Subjects)

Outcome	Incidence (n)
Distal Embolization	3.8% (30)
No Intervention	2.1% (17)
Surgical Intervention	0.1% (1)
Endovascular Intervention	1.5% (12)
Dissection (flow-limiting)	2.3% (18)
No Intervention	0.8% (6)
Surgical Intervention	0.0% (0)
Endovascular Intervention	1.5% (12)
Perforation	5.3% (42)
No Intervention	1.1% (9)
Surgical Intervention	0.1% (1)
Endovascular Intervention	4.0% (32)
OVERALL intervention rate	7.6% (61)

Definitive LE – Claudicant Arm

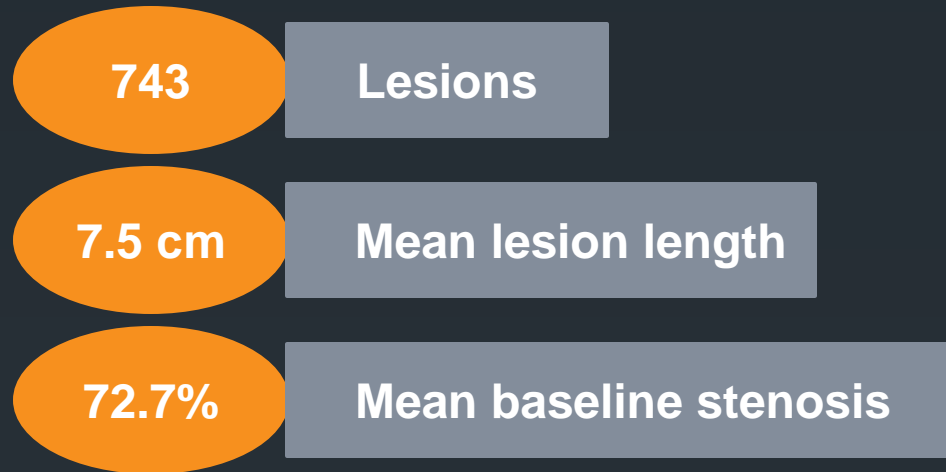


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Primary Patency

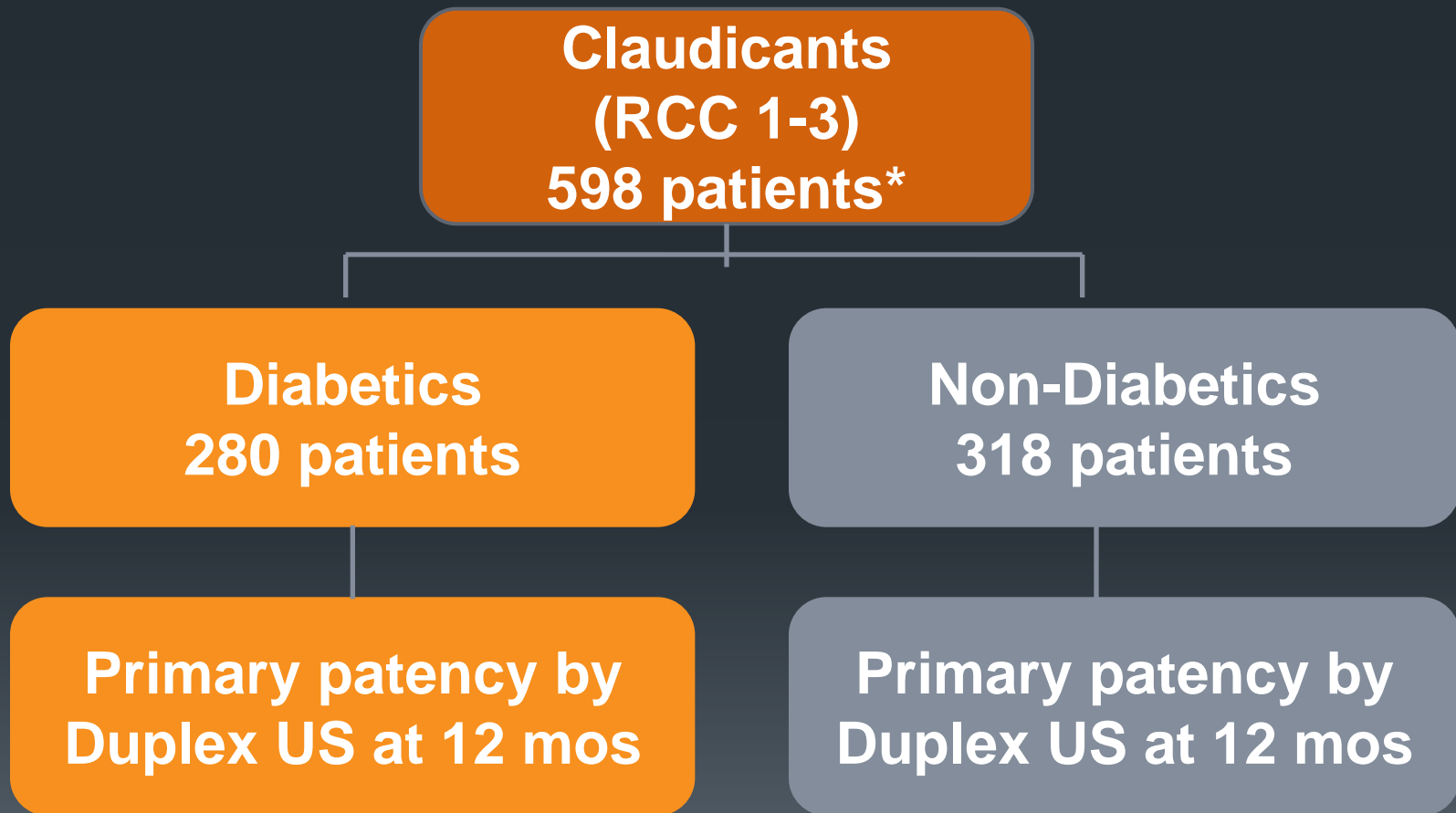
Claudicant Cohort

21 |



Pre-Specified, Non-Inferiority Analysis

Diabetic vs. Non-Diabetic Claudicants



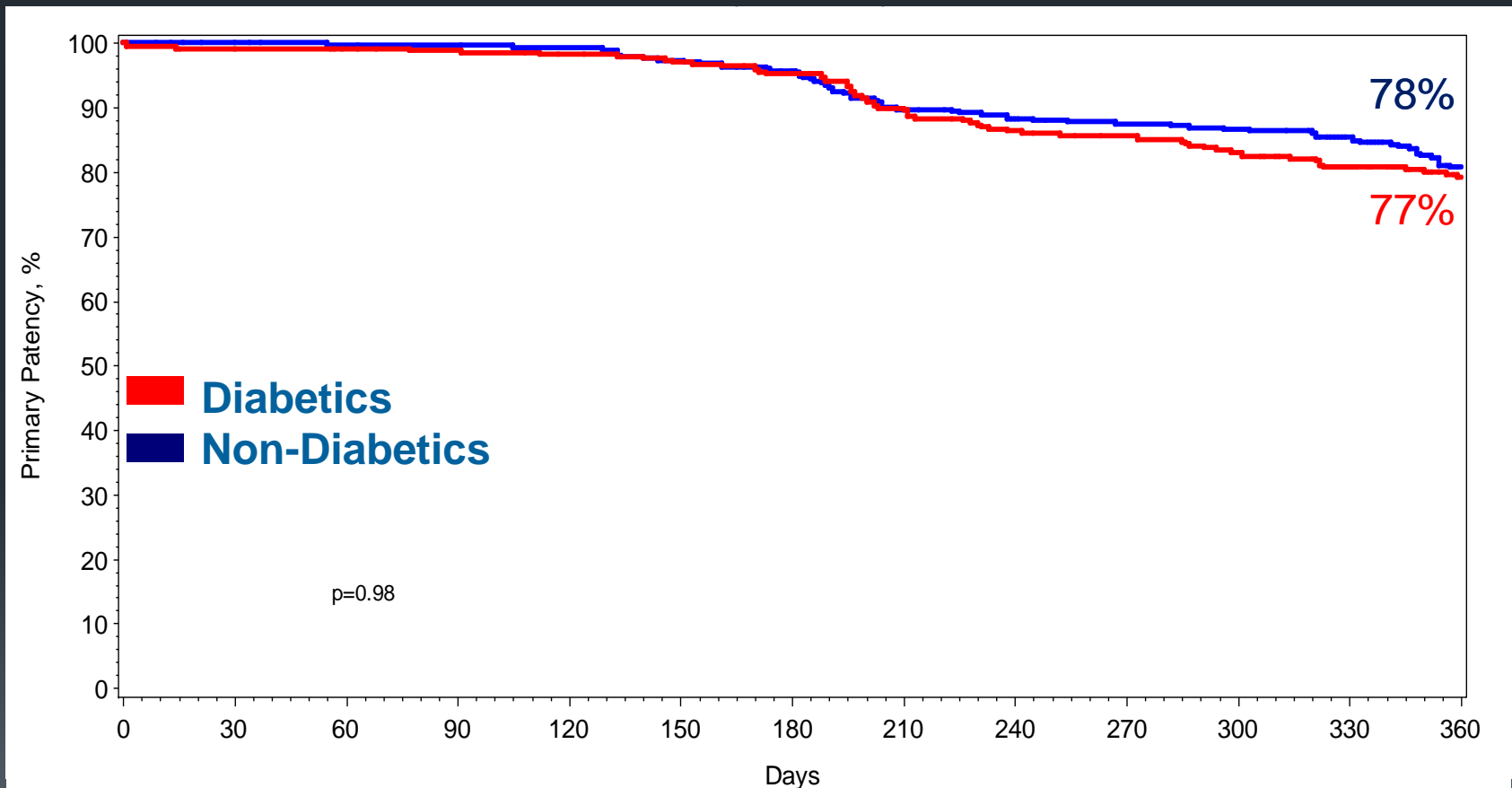
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Primary Patency Rates are Equivalent Between Diabetic and Non-Diabetic Claudicants

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Subgroup (lesions analyzed)	Mean Lesion Length (cm)	Mean Baseline Stenosis (%)	365-Day Patency (PSVR \leq 2.4)
All claudicants (743)	7.5	72.7	78%
Diabetic (n= 345)	7.6	72.0	77%
Non-diabetic (n = 398)	7.4	73.3	78%

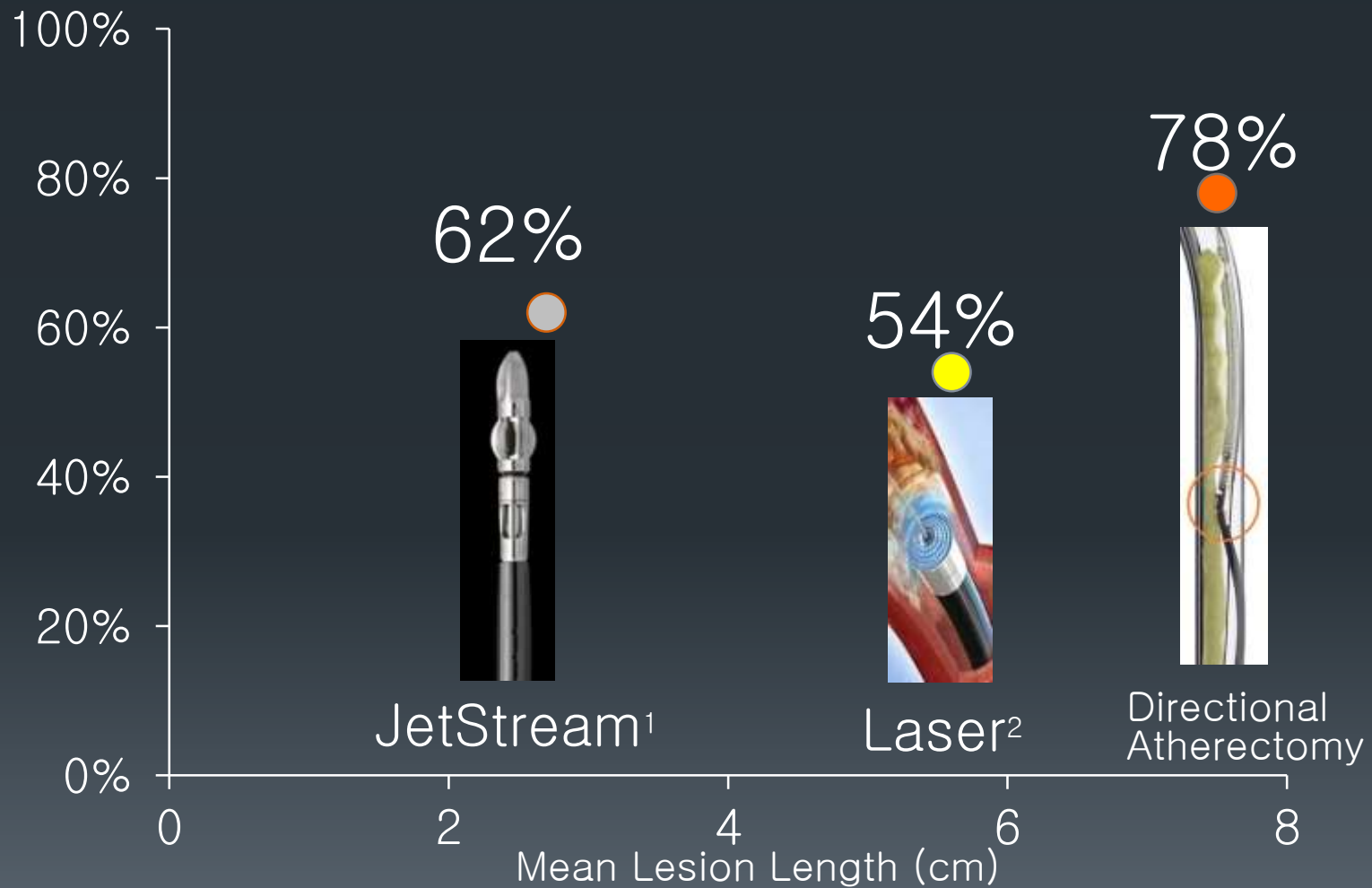
Primary Patency Rates are Equivalent Between Diabetic and Non-Diabetic Claudicants



*PSVR \leq 2.4

ATHERECTOMY TRIALS

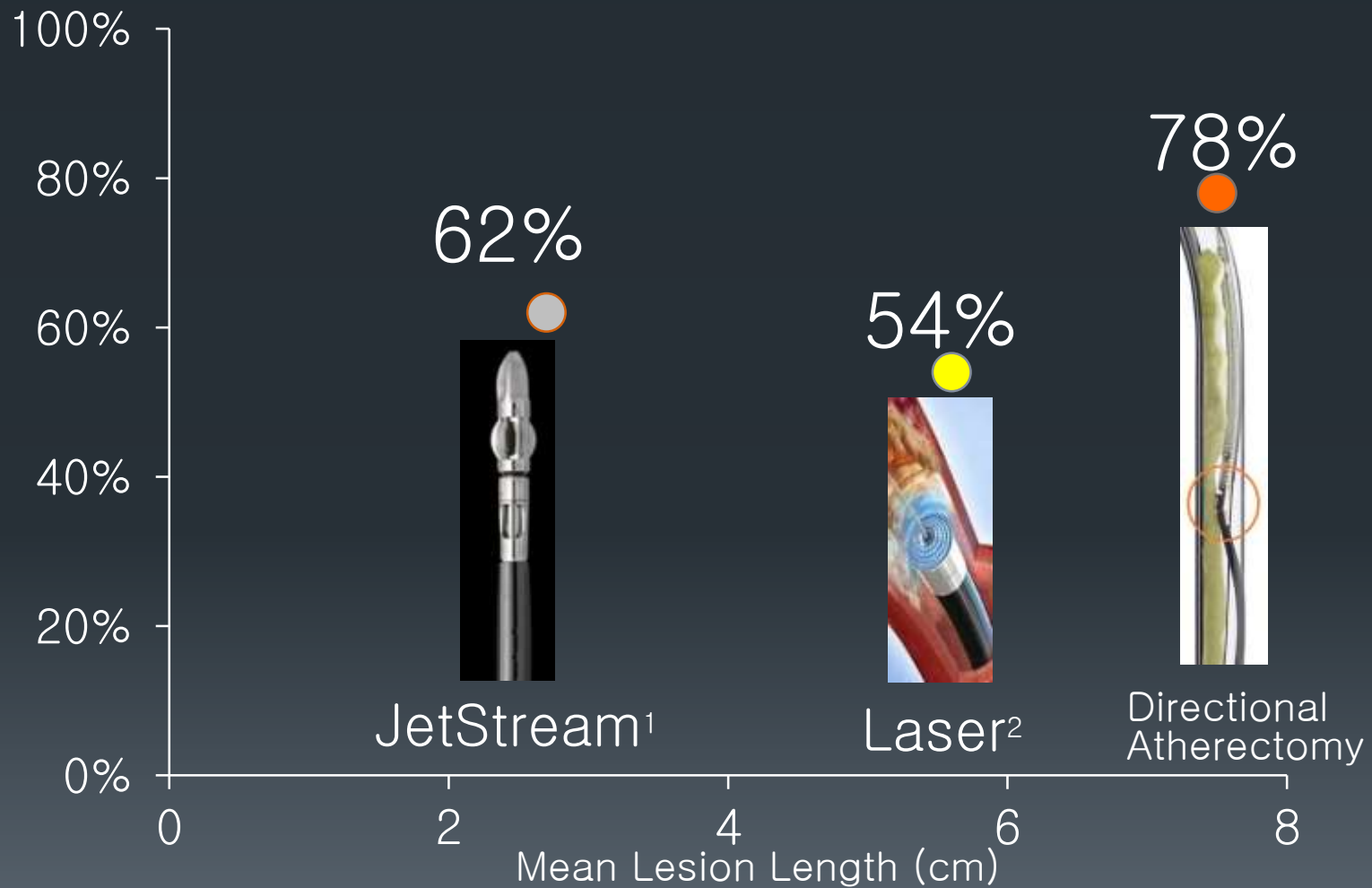
CORE-LAB ADJUDICATED 12-MO. PATENCY



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ATHERECTOMY TRIALS

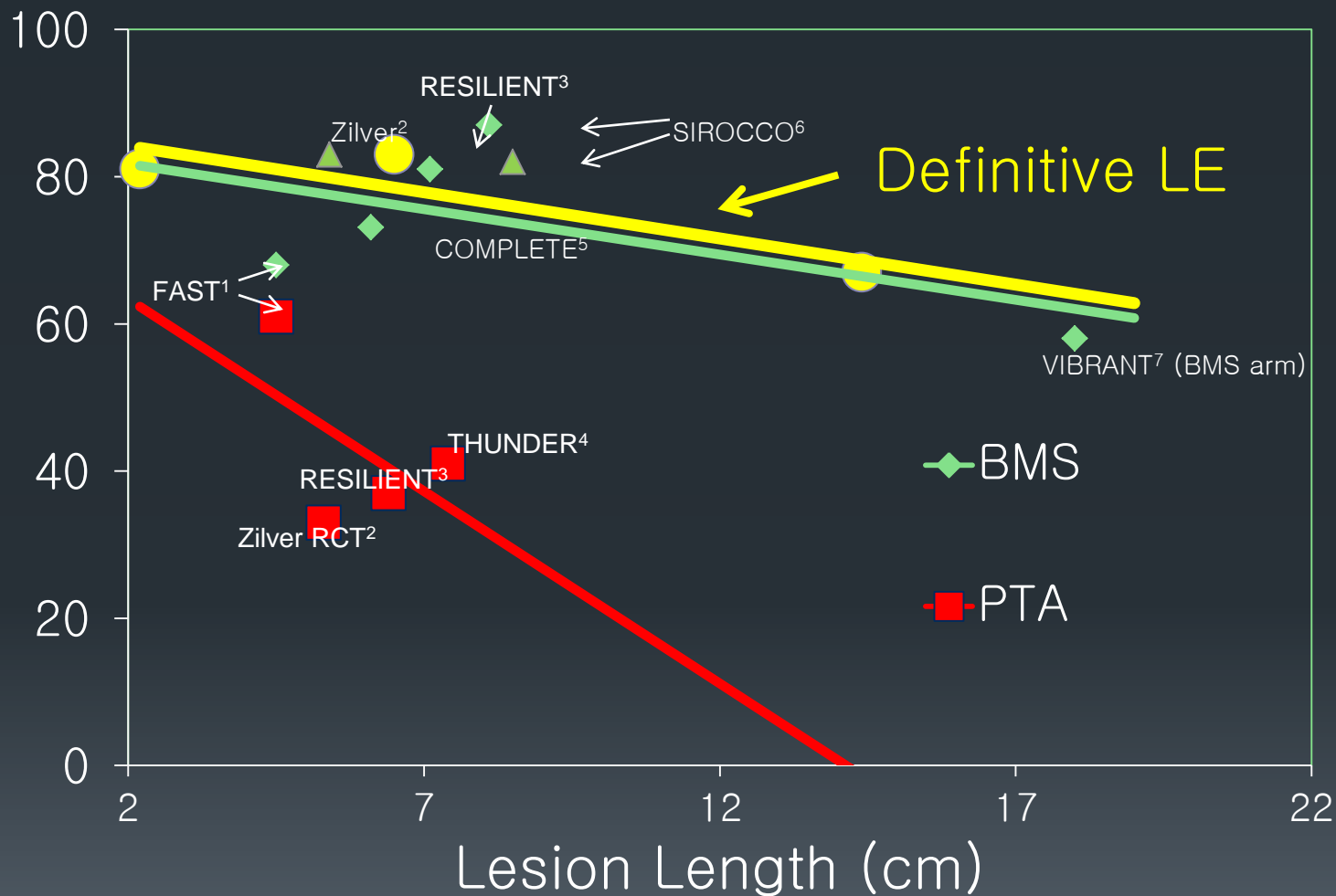
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Right SFA stenosis

Atherectomy - LXC



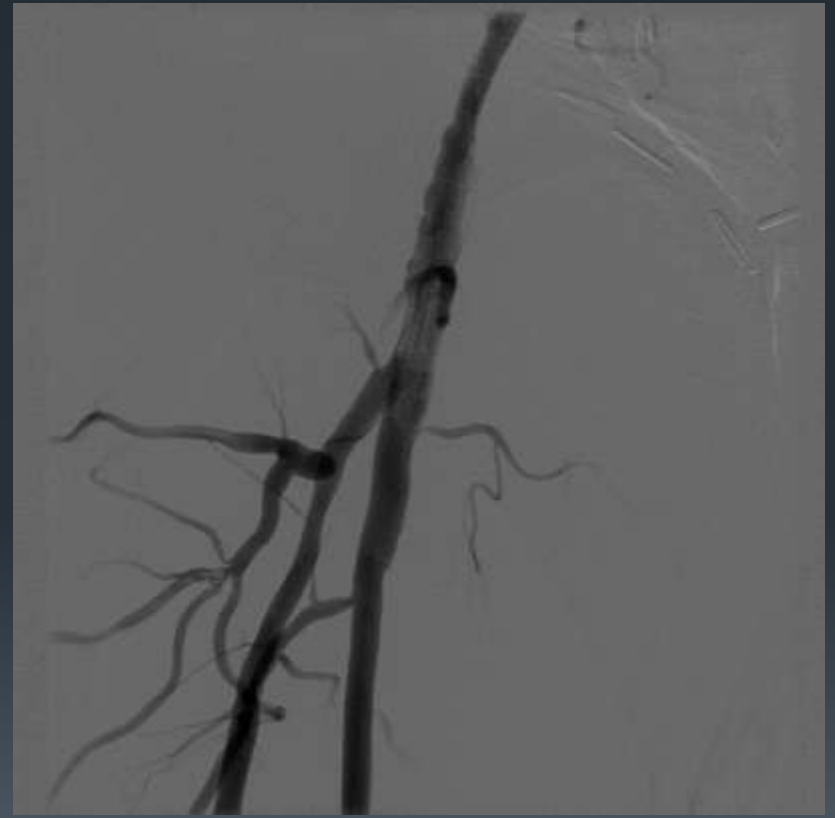
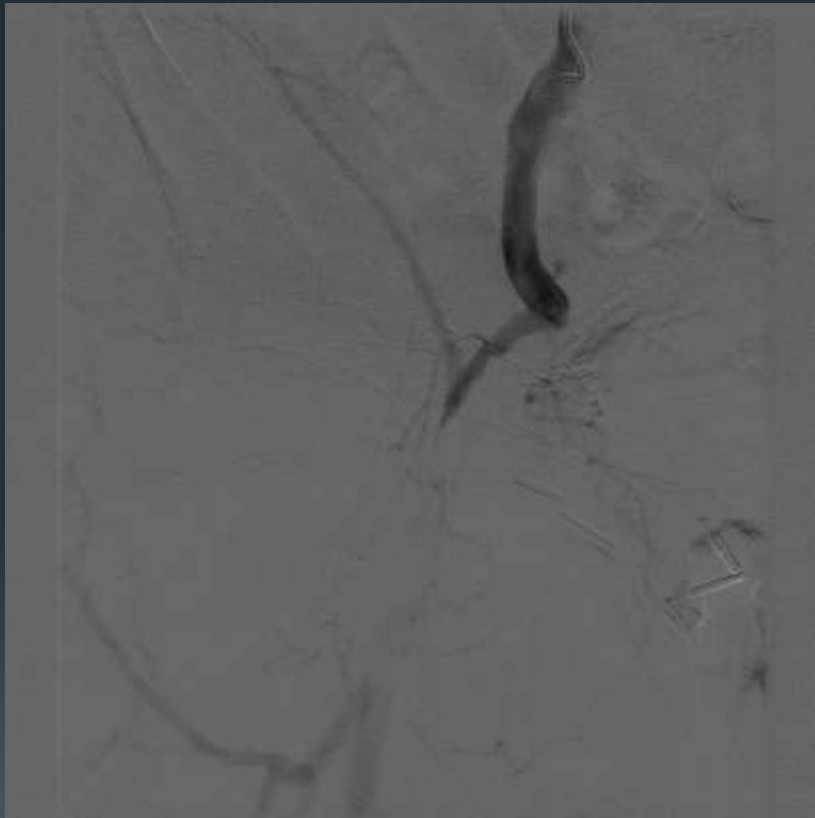
Left Popliteal Stenosis

Atherectomy - LXC

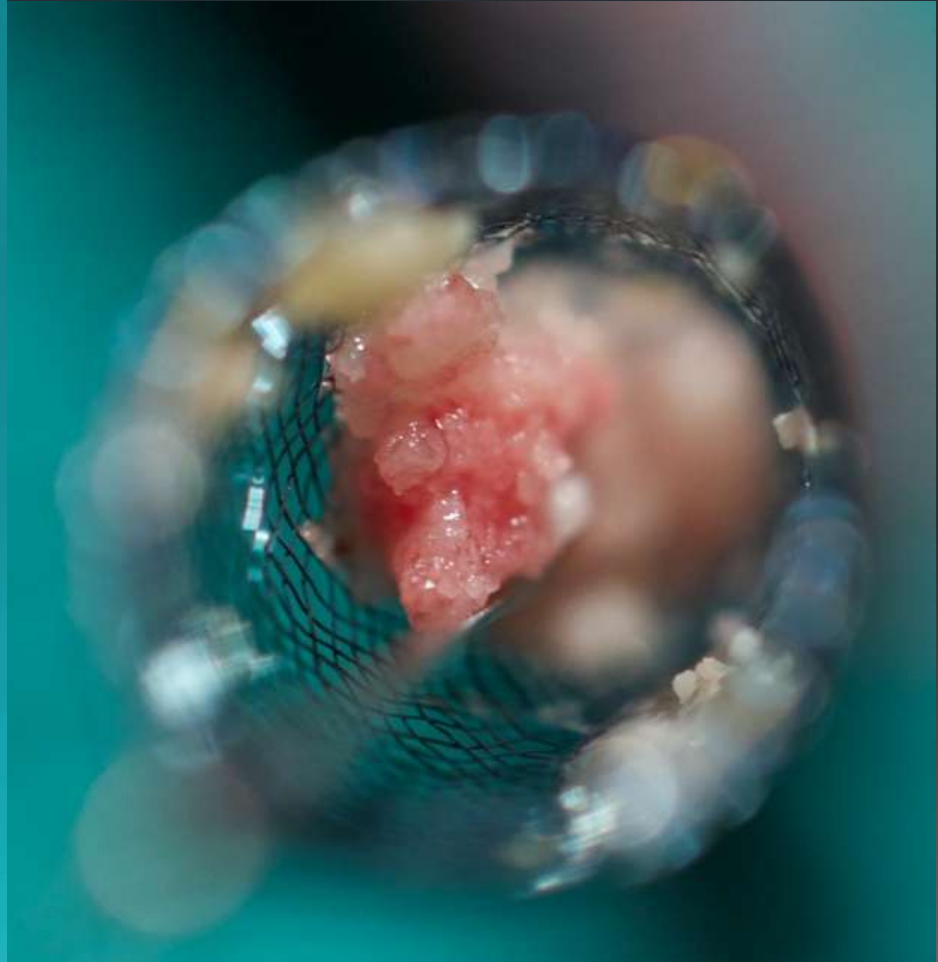


Right CFA CTO

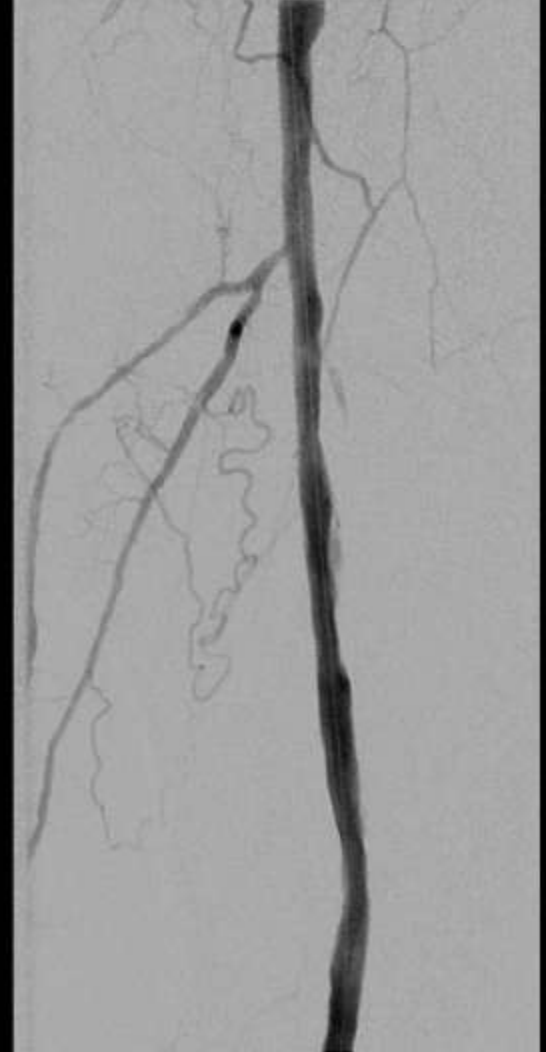
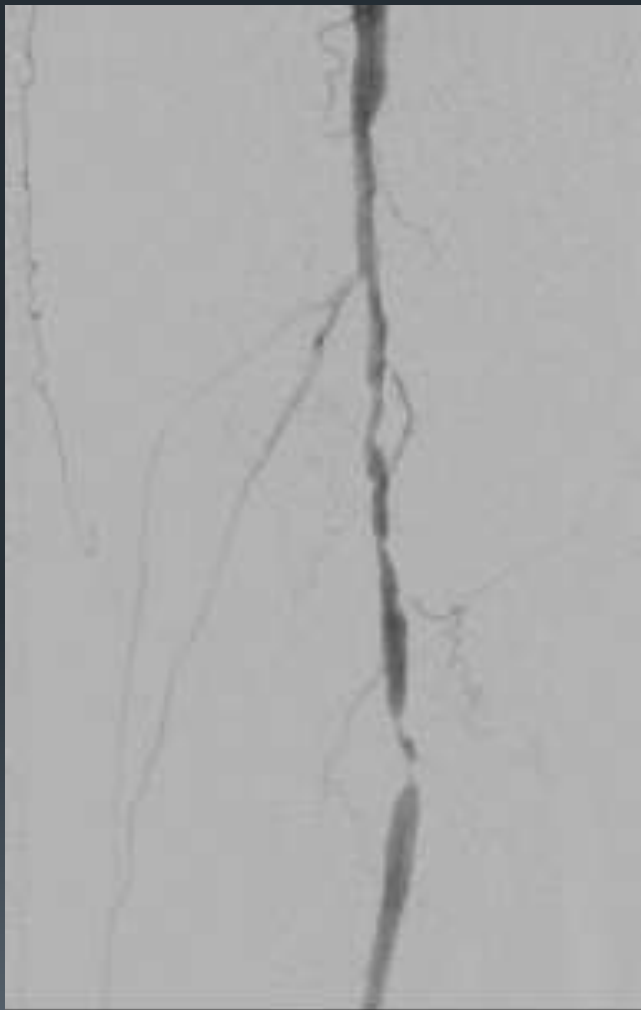
Directional Atherectomy – LXC



EMBOLIC PROTECTION



Heavily Calcified - Right Popliteal Stenosis TurboHawk LXC



Heavily Calcified Right Popliteal CTO TurboHawk LXC



100% Right SFA ISR Atherectomy with LXM



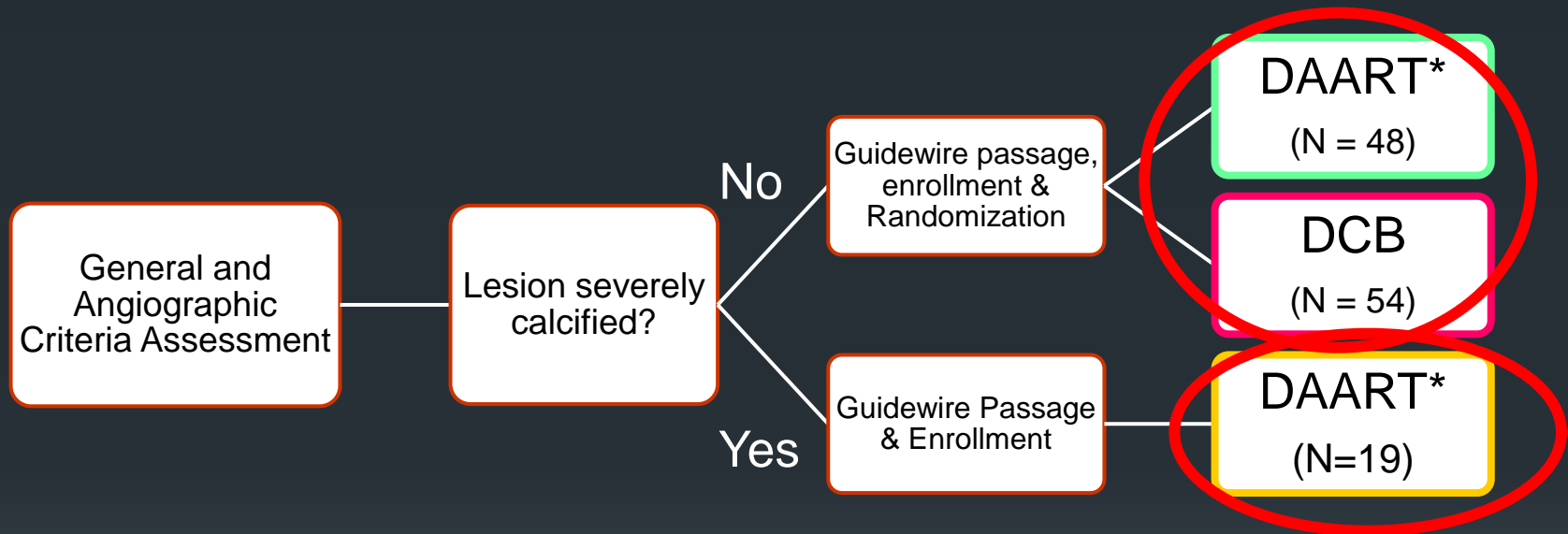
Left LE Claudication – How should this lesion be treated?

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



Definitive AR

Purpose: Pilot study designed to assess and estimate the effect of treating a vessel with directional atherectomy + DCB (DAART) compared to treatment with DCB alone



Severe Calcification: Dense circumferential calcification and calcification extending more than five (5) continuous centimeters of length prior to contrast injection or digital subtraction angiography

Registry arm for severely calcified lesions created to limit bail-out stenting (and therefore variables) in randomized arm.

* Directional Atherectomy + Anti-Restenotic Therapy

Devices



**Covidien's
SilverHawk™ & TurboHawk™
peripheral plaque excision
systems**



**Bayer HealthCare's
Peripheral
Paclitaxel-coated
angioplasty catheter with
Paccocath® Technology**

Baseline Lesion Characteristics

Per Core Lab Assessment

	DAART Severe Ca++ Arm (N=19)	DAART (N= 48)	DCB (N = 54)
Lesion Length (cm)	11.9	10.6	9.7
Diameter Stenosis	88%	82%	85%
Reference vessel diameter (mm)	5.1	4.9	4.9
Minimum lumen diameter (mm)	0.7	1.0	0.8

Atherectomy + DEB: Higher Acute Technical Success

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

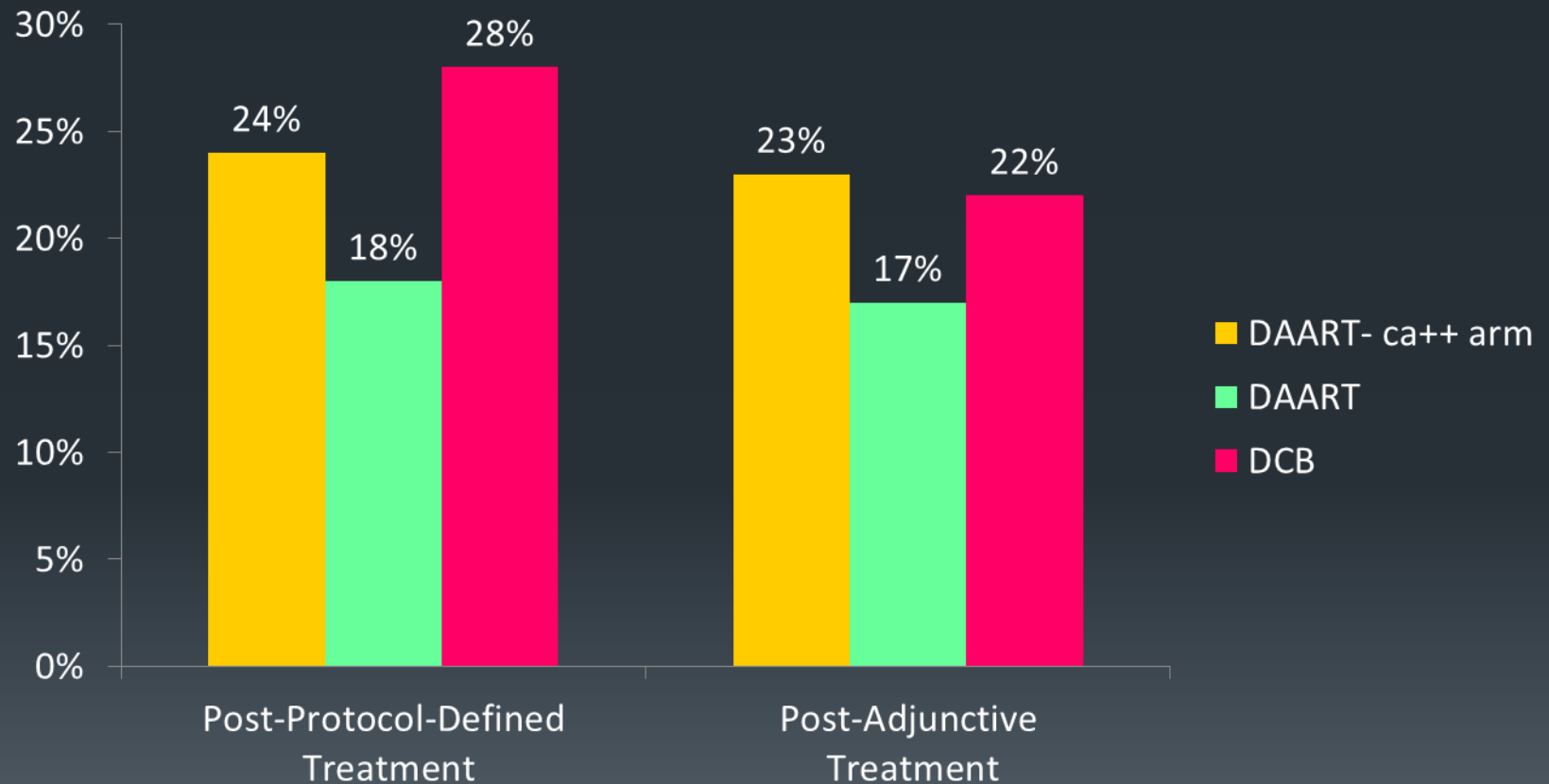
	DAART Severe Ca⁺⁺	DAART	DCB	P Value (DAART vs. DCB)
Technical Success	84.2%	89.6%	64.2%	0.004

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

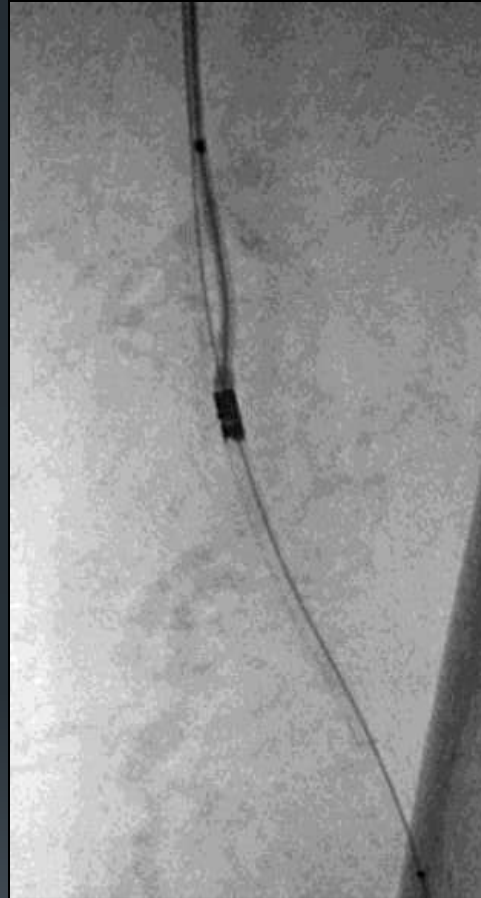
	DAART Severe Ca ⁺⁺	DAART	DCB	P Value (DAART vs. DCB)
Adjunctive Therapy				
PTA (post-dil)	0	6.3% (3/48)	33.3% (18/54)	0.0011
Bail-out Stent	5.3% (1/19)	0	3.7% (2/54)	0.4968

Residual Stenosis was significantly lower in the DAART arms

Per Core Lab assessment



So how should we treat this lesion?



Is Atherectomy + DEB the answer?

Summary

- Directional Atherectomy is safe and we can expect about 78% patency for 7.5 cm lesions at 1 yr
- Directional Atherectomy appears to have better results for treatment of Fem-Pop disease as compared to other atherectomy devices.
- In some patients, atherectomy is really the only good treatment option
- Atherectomy + DEB appears to have good acute results.



Thank You!