

# Heavy Calcific Femoral-Popliteal Lesions: Atherectomy and DCB is Standard

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# Disclosure

*Ravish Sachar, MD*

I have the following potential conflicts of interest to report:

- Consulting – Medtronic, Boston Scientific
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

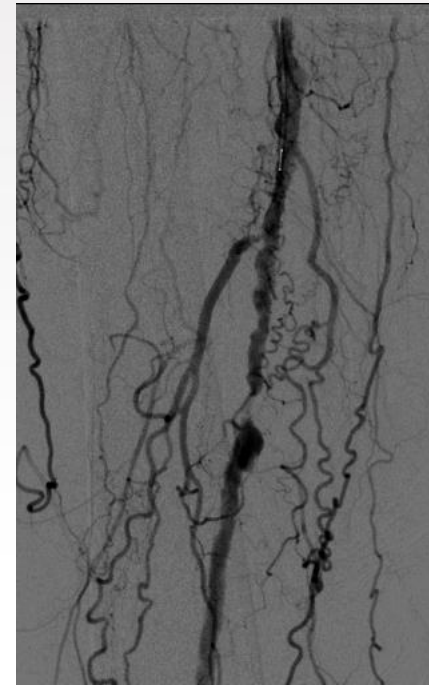
# Heavily Calcific Femoral-Popliteal Disease



Diffuse



Focal

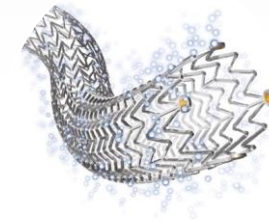
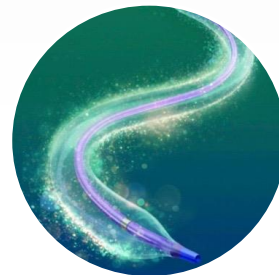
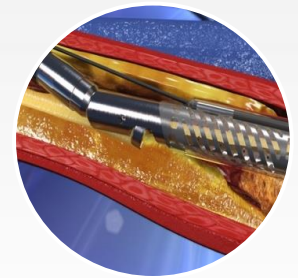
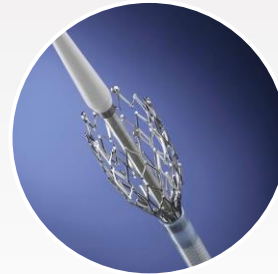


Eccentric

**Achilles Heal of EV Intervention  
Or is it?**

# Treatment Options For Fem-Pop Disease :

- PTA
- Stent
- Specialty Stents
- Drug Eluting Stents
- Drug Coated Balloons
- Scoring Balloons
- Lithoplasty
- Atherectomy
- Atherectomy + DCB

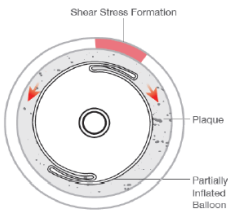


# What Are The Goals of EVT?

- Acute Outcomes
  - Maximal Luminal Diameter
  - No dissection
  - Minimal Recoil
  - Minimize the use of stents - Leave Nothing Behind
- Long term
  - Patency and freedom for TLR for Claudicants
  - Wound Healing for Patients with CLI
  - Maintain Treatment Options

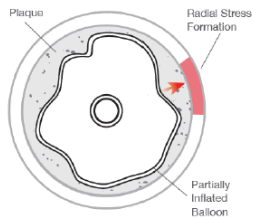
# Limitation of POBA

## 1. Torsional (Twisting)



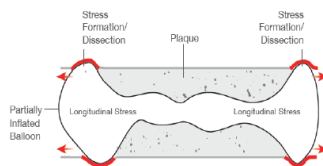
**Unfolding**  
-> Torsional (shear) stress

## 2. Radial (Expanding)



**Expansion**  
-> Radial stress

## 3. Longitudinal (Elongating)

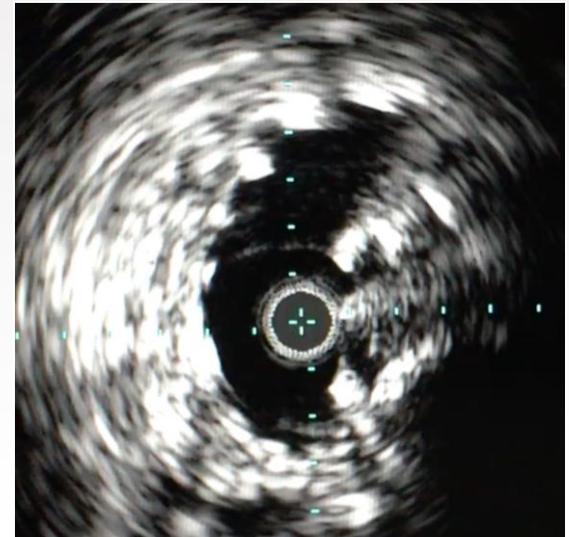
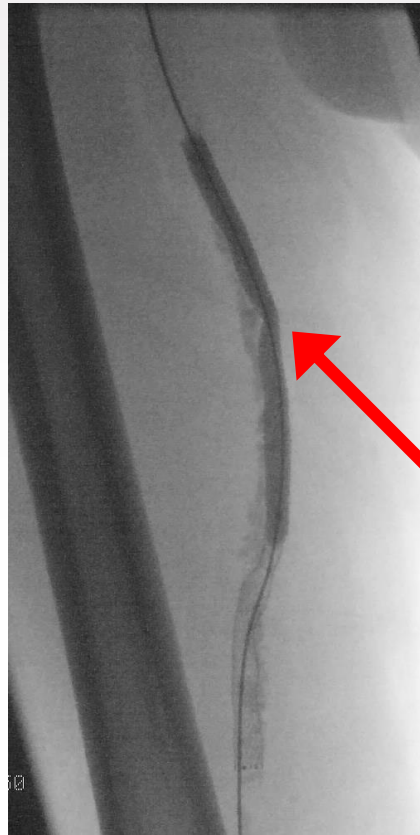
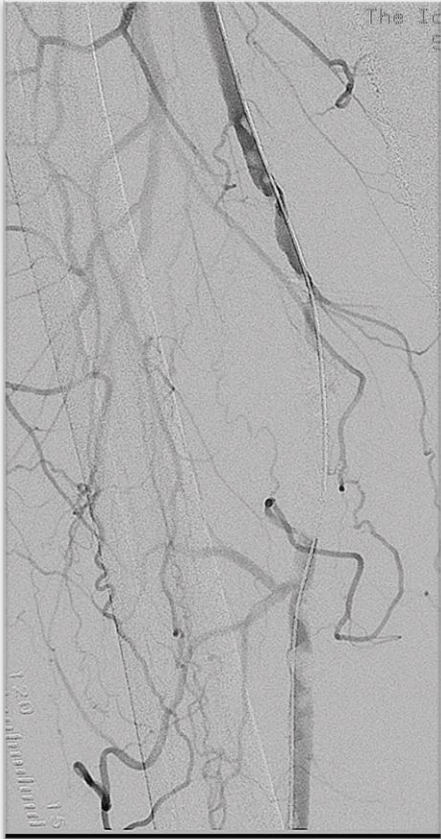


**Length expansion**  
-> longitudinal Stress



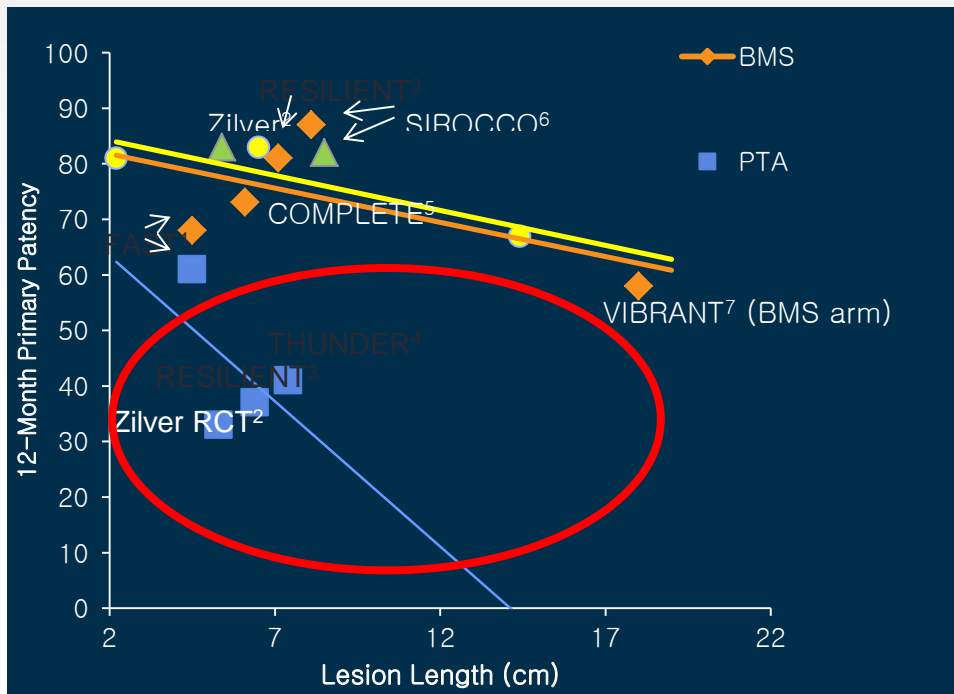
**Vessel trauma can manifest as severe dissection and elastic recoil**

# Limitations of Stenting in Severe Calcium

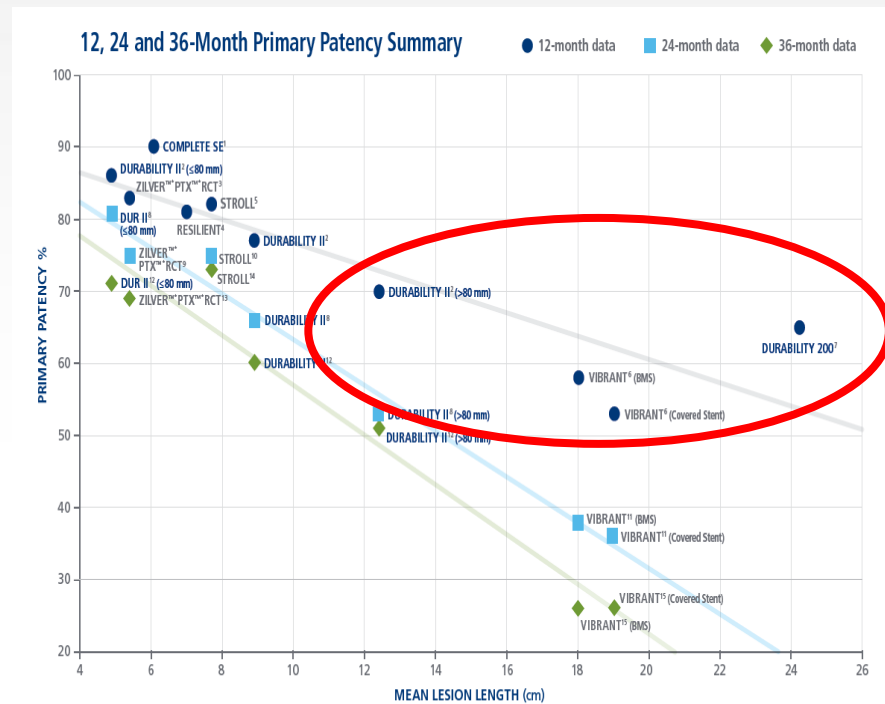


50% Residual Stenosis  
AFTER  
Angioplasty and Stenting

# Fem-Pop POBA Patency

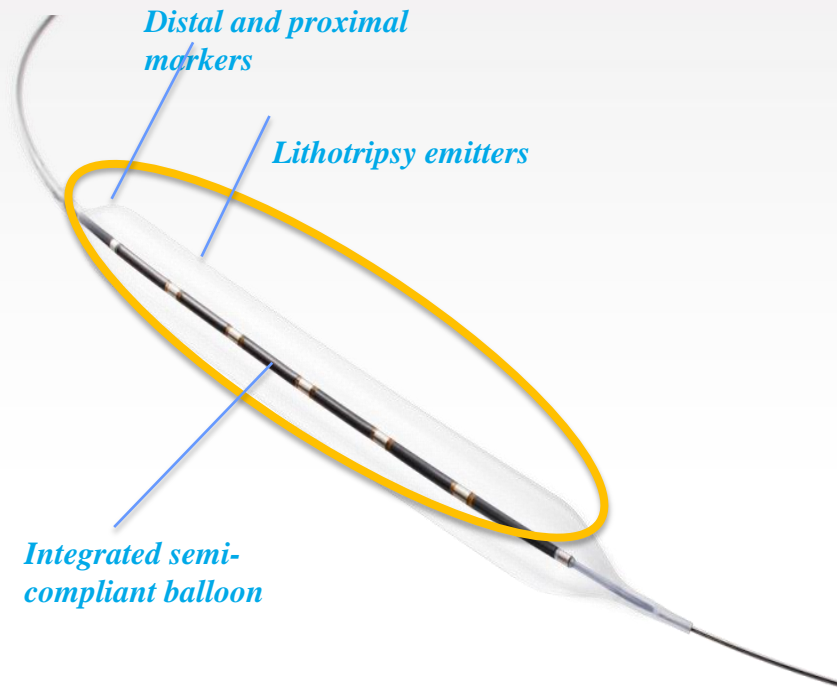


# Fem-Pop BMS Patency

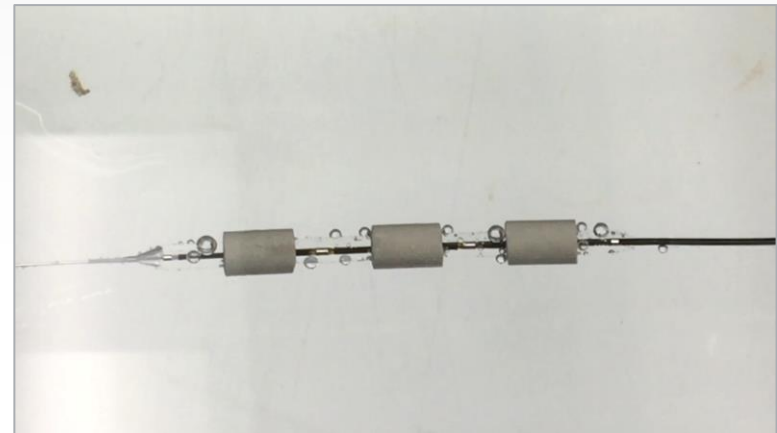




# Shockwave Peripheral IVL System



Sonic Pressure waves **crack calcium**, softening vessel compliance. Fractured calcium remains inside the vessel wall.



# Lithoplasty - Left Mid SFA

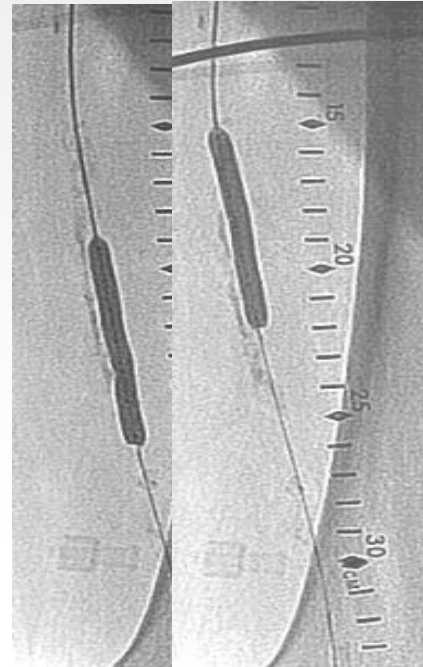
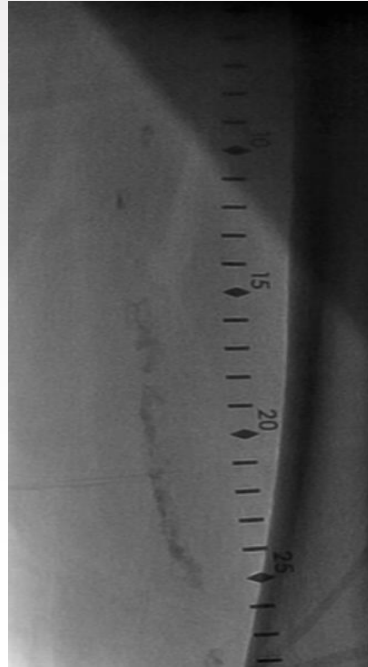
**Pre-procedure**

**Calcification**

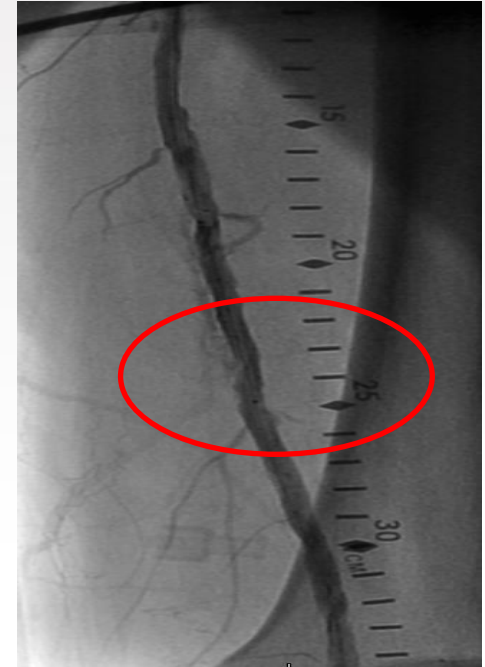
**Treatment Balloon**



**5.3mm RVD  
90.1% stenosis  
148.0mm length  
Severe Calcium**

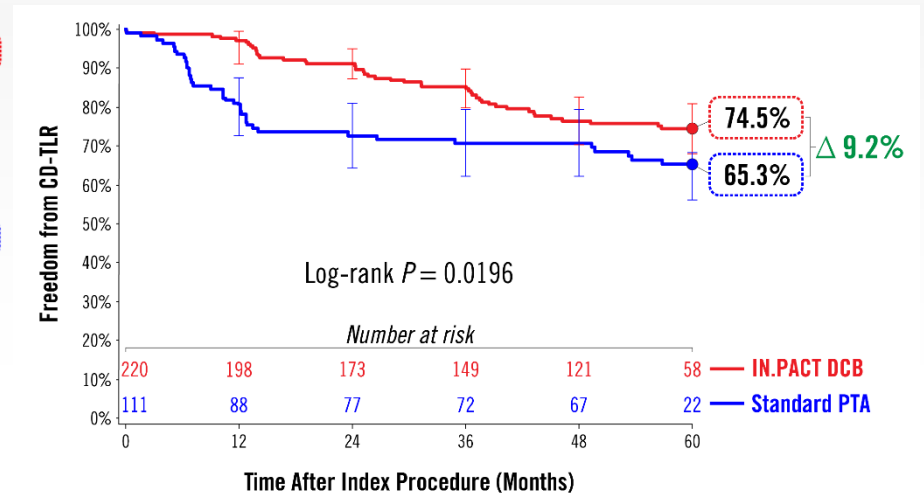
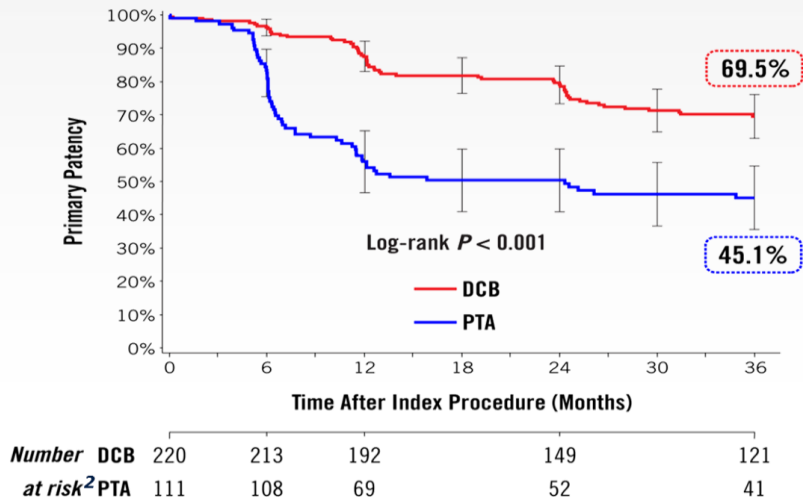


**5.5 x 60 Lithoplasty  
120 pulses**



- **Appears to Improve Compliance**
- **No Removal of Plaque**
- **Calcium Remains in Vessel**

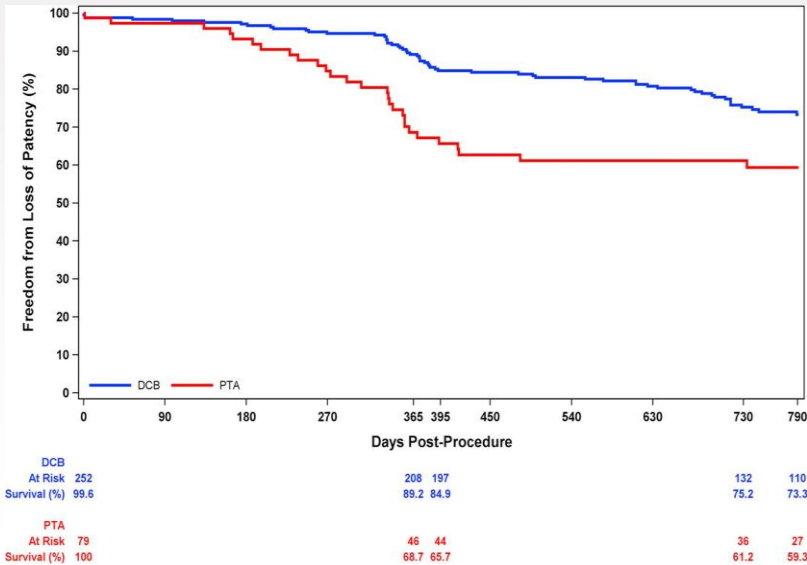
# DCB: Proven superiority over PTA for Fem-pop Disease



**In.Pact Pivotal 3 yr. Patency**

**5 yr. Freedom from cdTLR**

# The ILLUMENATE European Randomized Clinical Trial 2-Year Results

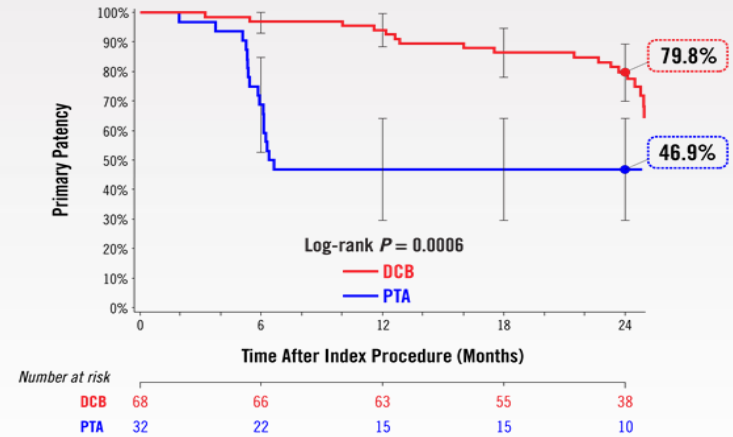


Iida et al LINC 2018

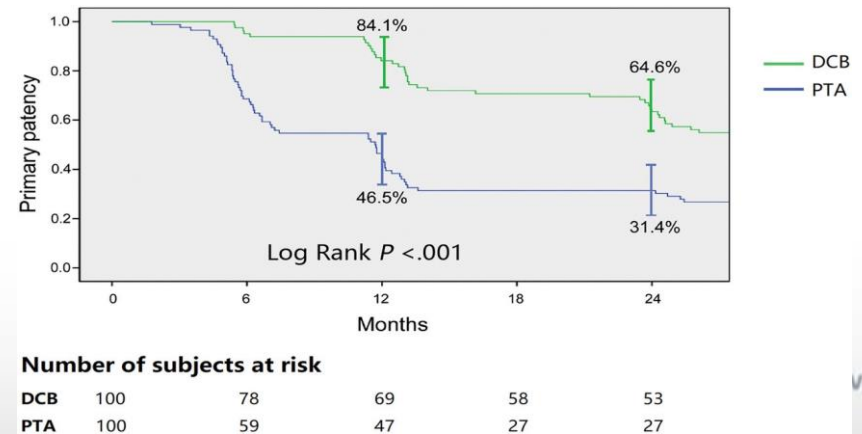
Brodmann M et al. ACC: Cardiovascular Interventions. Volume 11, Issue 23, December 2018

Yongle Xu et al. JACC: Cardiovascular Interventions Volume 11, Issue 23, December 2018

# In. Pact SFA Japan Trial Primary Patency through 2 Years



# The AcoArt1 Chinese Randomized Clinical Trial 2-Year Results



# Limitations of Randomized Trials of Anti-Restenotic Therapies

- Residual stenosis > 70% after PTA – NOT INCLUDED
- Residual dissection after PTA – NOT INCLUDED
- Severe Calcification – NOT INCLUDED
- IS THERE A HIGHER MORTALITY WITH PACLITACEL???

# IN.PACT SFA Trial

## Independent Predictors of CD-TLR in All ITT Patients Cox Regression Multivariate Analysis<sup>1</sup>

Predictors of CD-TLR to 4-Year Multiple Cox Proportional Hazards Regression		
	Hazard Ratio [95%CI]	P-Value
Gender (Male vs. Female)	0.497 [0.310, 0.797]	0.004
Lesion length (cm)	1.070 [1.022, 1.120]	0.004
Severe Calcification	2.412 [1.210, 4.811]	0.012
Treatment Group (DCB vs. PTA)	0.574 [0.358, 0.920]	0.021
Previous Ipsilateral Revascularization (SFA/PPA)	1.872 [1.040, 3.371]	0.037
Inflow Treatment Pre-procedure(core lab-reported)	0.291 [0.089, 0.953]	0.041
Number of Runoff Vessels Pre-procedure(2/3 vs. 0/1)	1.591 [0.946, 2.675]	0.080

**Calcification is a predictor of CD-TLR**

# Should We Remove Calcium in Complex Femoral Popliteal Disease?

- Plaques associated with arterial dissections commonly have significant calcium deposits<sup>1</sup>
- Presence of calcium necessitates greater balloon pressures<sup>2,3</sup>
- Calcium might influence drug-coated balloon efficacy<sup>4</sup>

1. Fitzgerald, et al. *Circulation*. 1992;86(1):64-70.

2. Demer. *Circulation*. 1991;83:2083-2093.

3. Makam. *J Invasive Cardiol*. 2013;25(2):85-8.

4. Fanelli F, et al. *Cardiovasc Intervent Radiol*. 2014 ;37(4):898-907.

# Atherectomy For Vessel Preparation In Heavily Calcific Disease

Vessel prep is improving the local environment of the vessel prior to leaving something behind, whether that something is a stent or an anti-proliferative agent

↑ Vessel Compliance  
and Lumen Gain

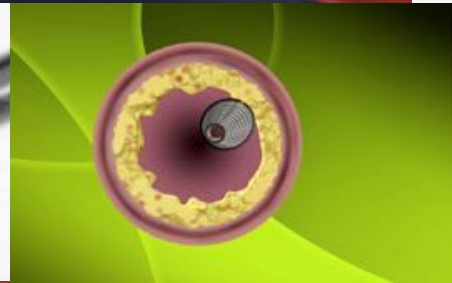
↑ Drug Transfer and  
Uptake

↓ Reduced Risk of  
Dissection/ Stenting



# Atherectomy

- Directional
- Rotational
- Orbital
- Athero-ablative
- Helical



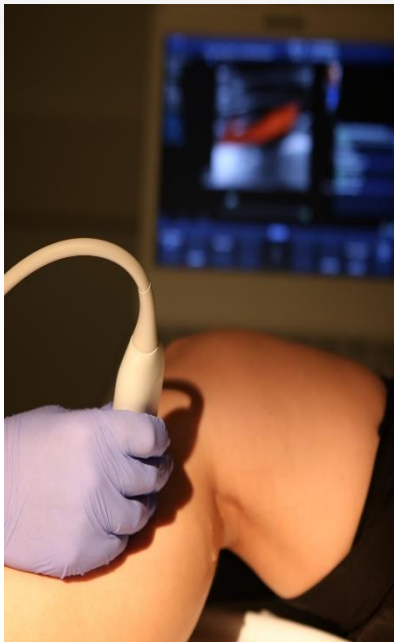
# Evidence: Published Atherectomy Trials

Study (* Core Lab)	Type	Patients	Lesions	Dissection (≥Grade D)	Patency			
					BO Stent	30-day MAE	1-year	>1-year
*DEFINITIVE LE <sup>1</sup>	DA	598 (RCC 1-3) 201 (RCC 4-6)	743 279	2.2% (13/598) 2.5% (5/201)	3.2% (33/1022)	1.0% (6/598) 3.5% (7/201)	78% 71%	?
*DEFINITIVE CA <sup>2</sup>	DA	133	168	NR	4.1% (7/169)	6.9% (9/131)	NR	?
VISION-IDE <sup>3</sup>	DA	130	130	NR	4.0%	17.6% (6-mo)	NR	?
OASIS <sup>4</sup>	OA	124	201	NR	2.5% (5/201)	3.2% (4/124)	NR	?
COMPLIANCE 360 <sup>5</sup>	OA	25	38	NR	5.3% (2/38)	NR	NR	?
CALCIUM 360 <sup>6</sup>	OA	25	29	3.5% (1/29)	6.9% (2/29)	0%	NR	?
*PATHWAY PVD <sup>7</sup>	RA	172	210	9% (15/172)	7% (14/210)	1.0% (2/172)	61.8%	?
*CELLO <sup>8</sup>	Las	65	65	NR	23.2% (15/65)	0%	54.3%	?
*EXCITE-ISR <sup>9</sup>	Las	169	169	2.4% (≥Grade C)	4.1% (7/169)	5.8% (9/155)	71.1% (6-mo)	?

1. McKinsey J, et al. JACC Cardiovasc Interv 7(8):923-33:2014.
2. Roberts D, et al. Catheter Cardiovasc Interv 84(2):236-44:2014.
3. Schwindt A. Presented at VIVA, Las Vegas 2015.
4. Safian RD, et al. Catheter Cardiovasc Interv 73(3):406-12:2009
5. Dattilo R, et al. J Invasive Cardiol 26(8):355-60:2014.

6. Shammam NW, et al. J Endovasc Ther 19(4):480-8:2012.
7. Zeller T, et al. J Endovasc Ther 16(6):653-62:2009.
8. Dave R, et al. J Endovasc Ther 16(6):665-75:2009.
9. Dippel EJ, et al. JACC Cardiovasc Interv 8(1 Pt. A):92-101:2015.

# DEFINITIVE LE



Patency (PSVR $\leq$  2.4)

78%

Lesions

743

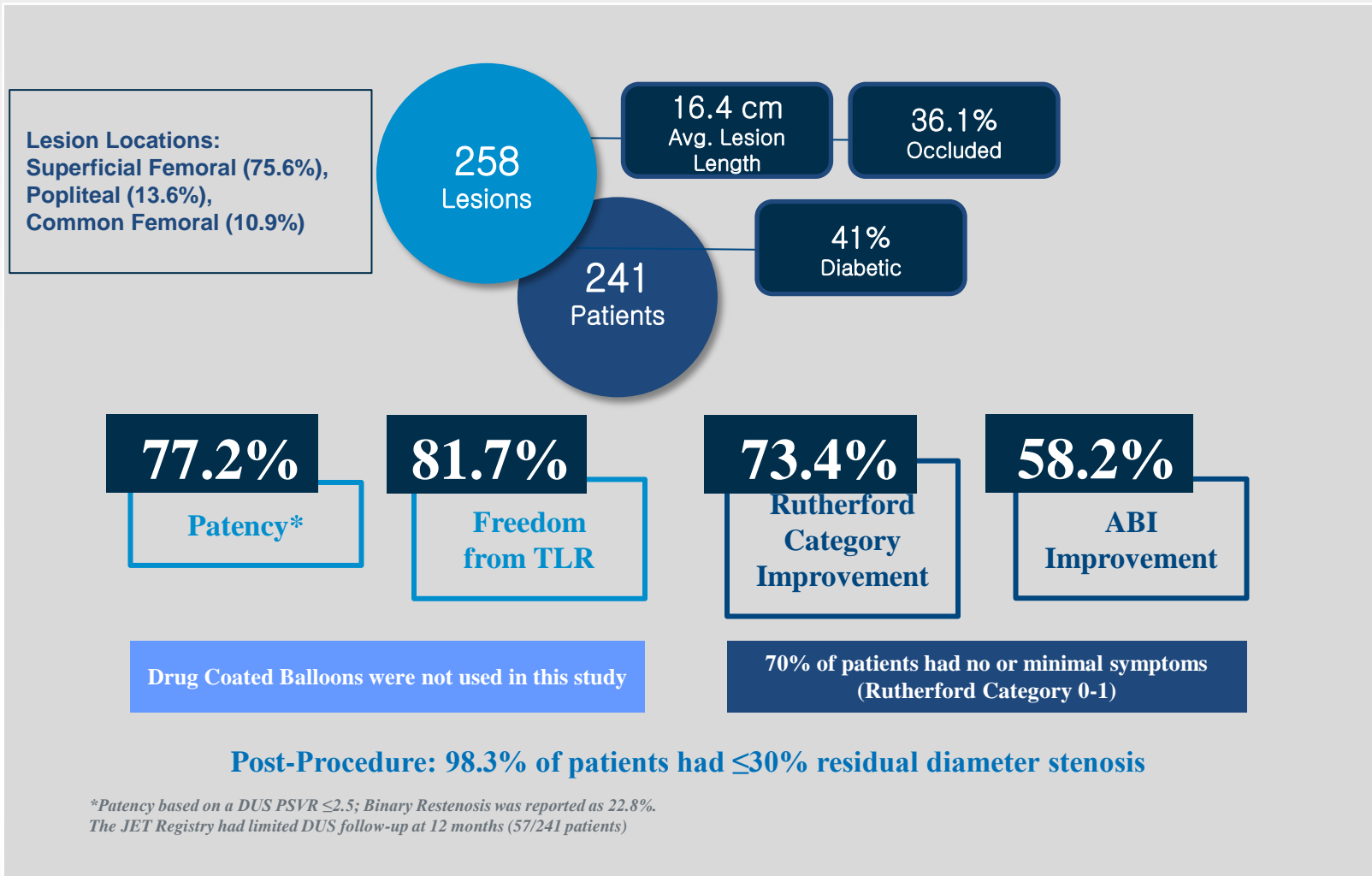
Mean Lesion Length

7.5cm

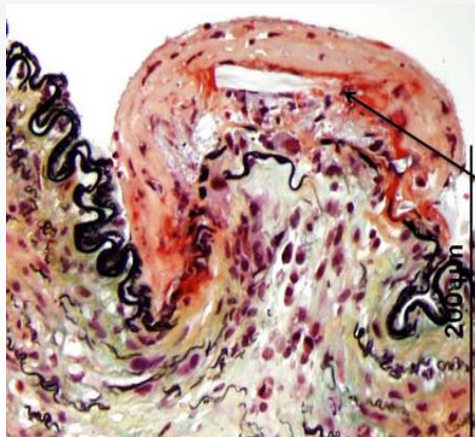
Mean Baseline Stenosis

73%

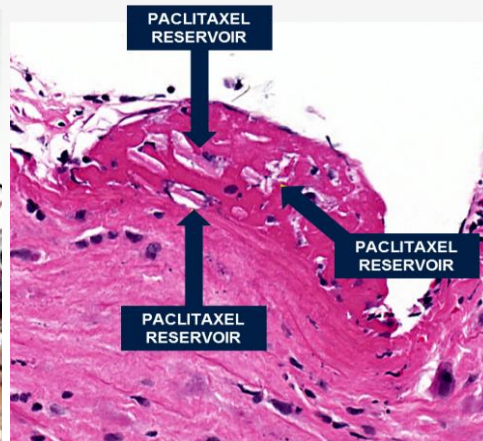
# Jet Registry: 12 Month Efficacy and Outcomes



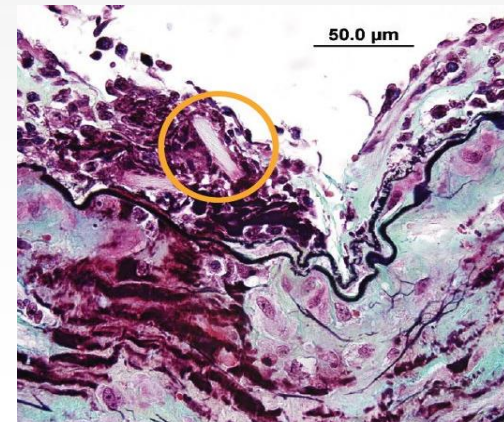
# Atherectomy + DCB: Is Two Better Than One



PACCOCATH (2009)  
Granada JF. Open Heart. 2014



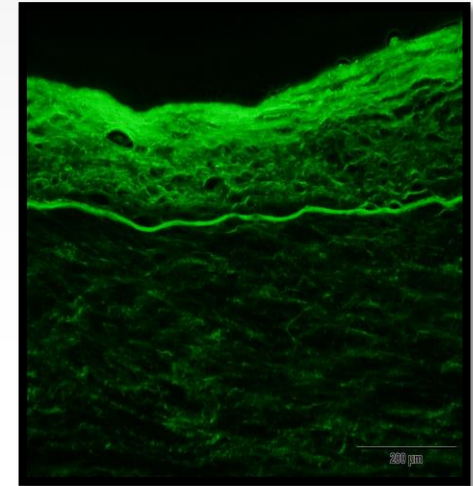
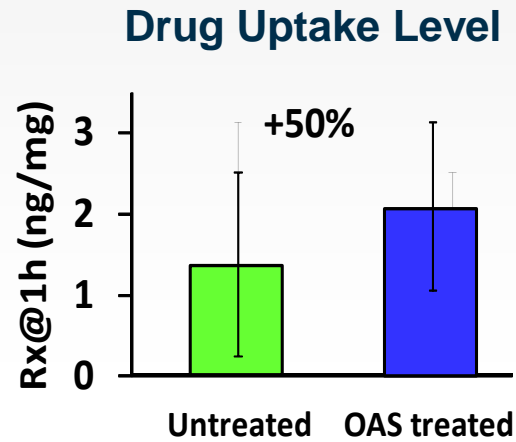
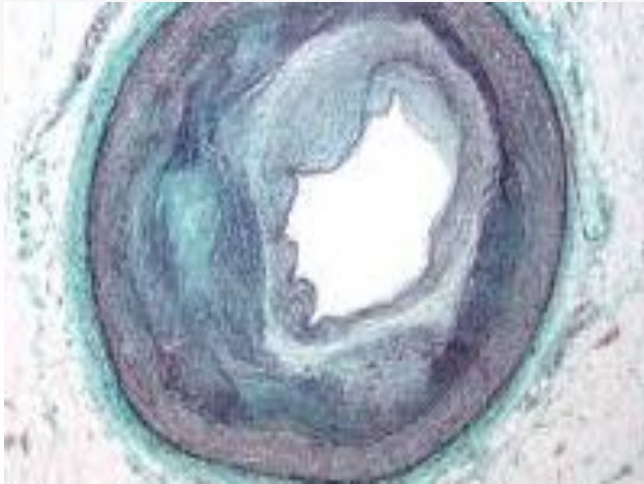
IN.PACT



STELLAREX

DCB Mechanism of Action:  
Solid Phase Drug Delivery to Media/Adventitia

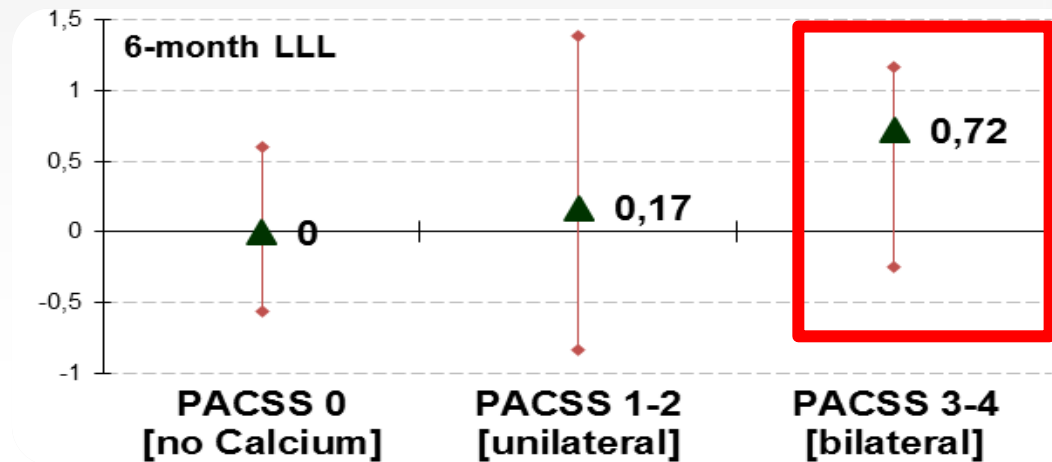
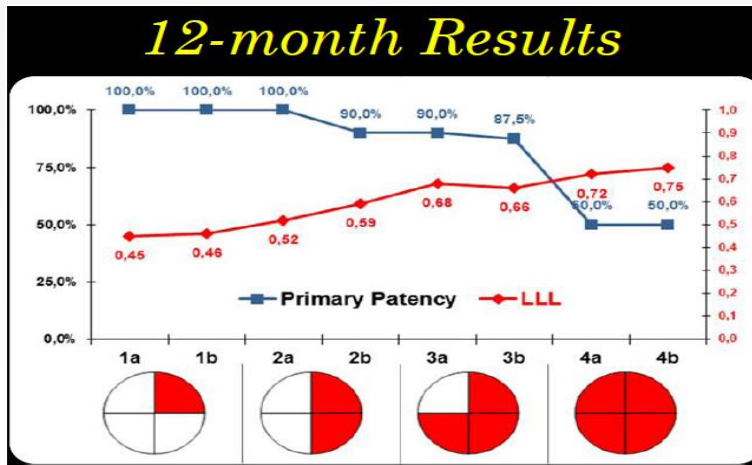
# Cadaveric Study with Orbital Atherectomy + DCB



**6 X deeper penetration with OAS**

Edelman E. EuroPCR 2015

# Calcium: Barrier to Drug Penetration?



1. Fanelli F et al Cardiovas Interv Radiol 2014
2. Tepe G. ISET 2014
3. Tepe G. J Vasc Surgery 2015

# Evidence: Published Studies of Atherectomy + DCB

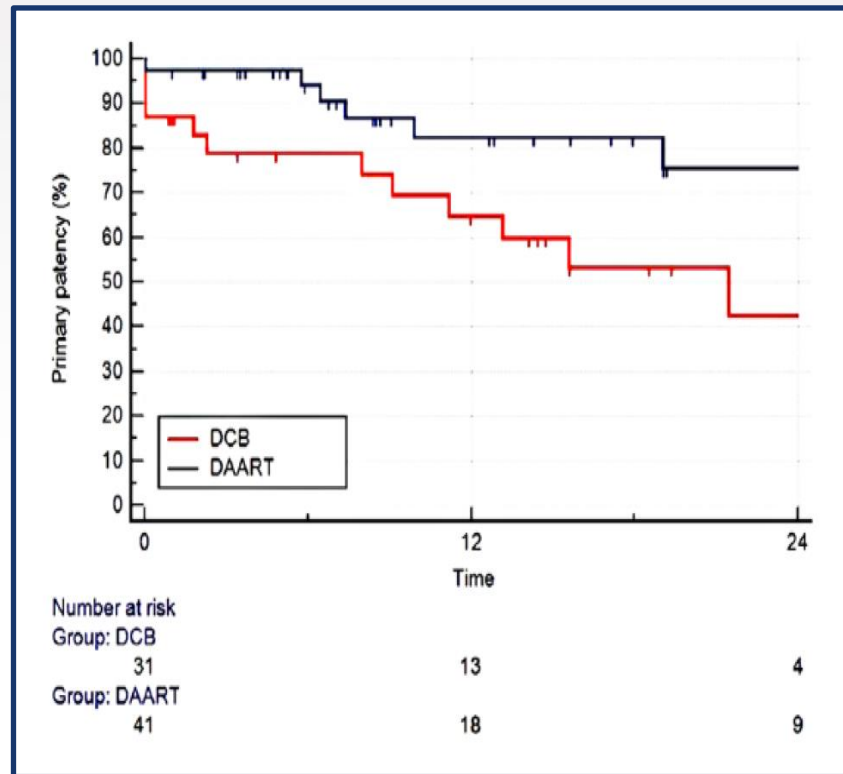
Study (* Core Lab)	Type	Patients	Dissection (≥Grade C)	Patency			
				BO Stent	30-day MAE	1-year	>1-year
*DEFINITIVE AR <sup>1</sup>	DA + DCB	48 (DA+DCB) 54 (DCB alone)	2% (1/48) 18.5% (10/54)	0% (0/48) NR	2.1% (1/48) 1.9% (1/54)	84.6% 81.3%	?
STAVROULAKIS <sup>2</sup>	DA+DCB	41 (DA+DCB) 31 (DCB alone)	NR	5% (2/41) 16% (5/31)	NR	85% 65%	?
CIOPPA <sup>3</sup>	DA+DCB	30 (DA + D)	NR	6.5% (2/30)	NR	90%	?
SIXT <sup>4</sup>	DA+DC B	29 (DA+DCB) 60 (PTA)	NR	12.4%(11/89)	NR	84.7% 43.8%	?
GANDINI <sup>5</sup> ISR	Laser+ DCB	24 (Laser+DCB) 24 (DCB alone)	0% 0%	8% (2/24) 0% (0/24)	NR	66.7% 37.5%	?
KOKKINIDIS <sup>6</sup> I SR	Laser+ DCB	62 (Laser+DCB) 50(Laser+POBA)	1.6% (1/62) 0% (0/50)	32% 19/60 58% (29/50)	NR	86.7% 56.9%	?

1. Zeller J, et al. Circ Cardiovasc Interv 10 doi: 10.1161:2017.  
 2. Stavroulakis K, et al. J Endovasc Ther 24(2):181-88:2017.  
 3. Cioppa A, et al. Cardiovasc Revasc Med 13(4): 219-223:2012

4. Sixt S, et al. J Vasc Surg 58(3): 682-86:2013  
 5. Gandini R, et al. J Endovasc Ther 20: 805-14: 2013  
 6. Kokkinidis D., et al. J Endovasc Ther 25(1):81-88 :2017..



# Calcium Diminishes Acute and Long-Term Outcomes Single Center Randomized Study n=72 Patients



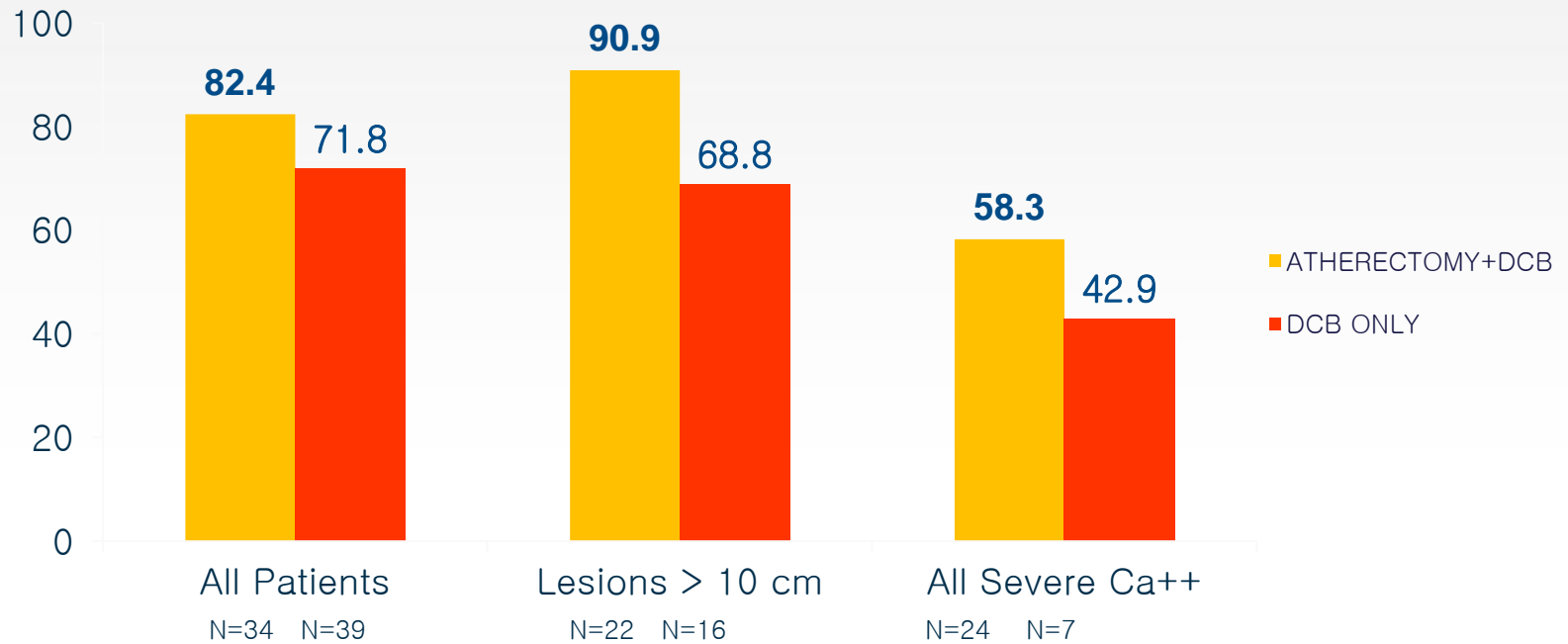
**Atherectomy + DCB**

**DCB**

24-month Results

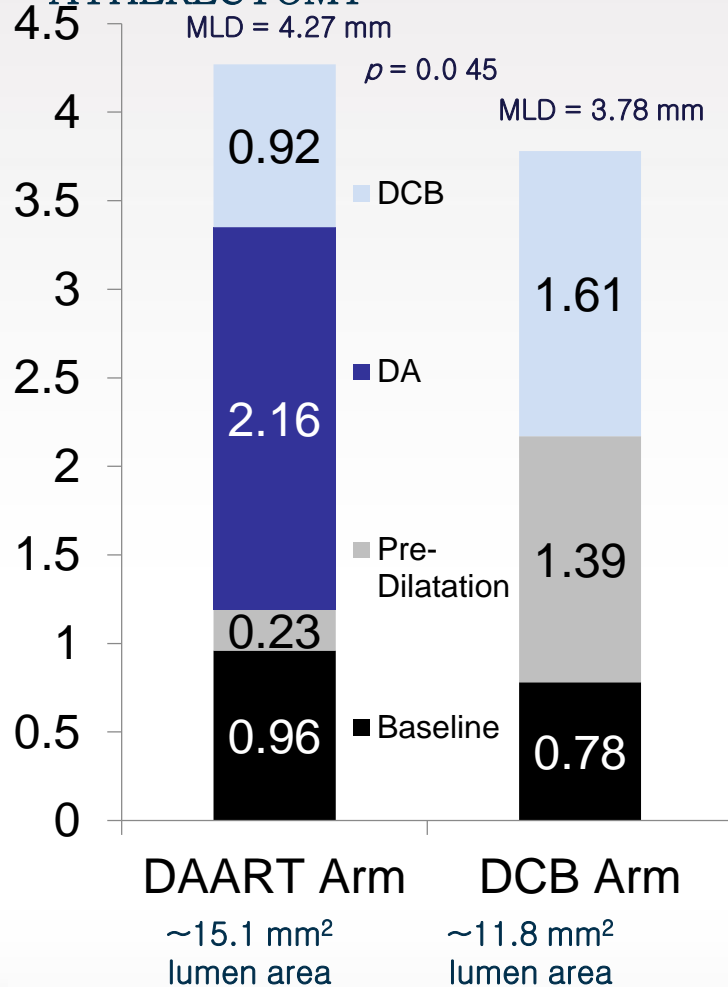
# DEFINITIVE AR

## ANGIOGRAPHIC PATENCY



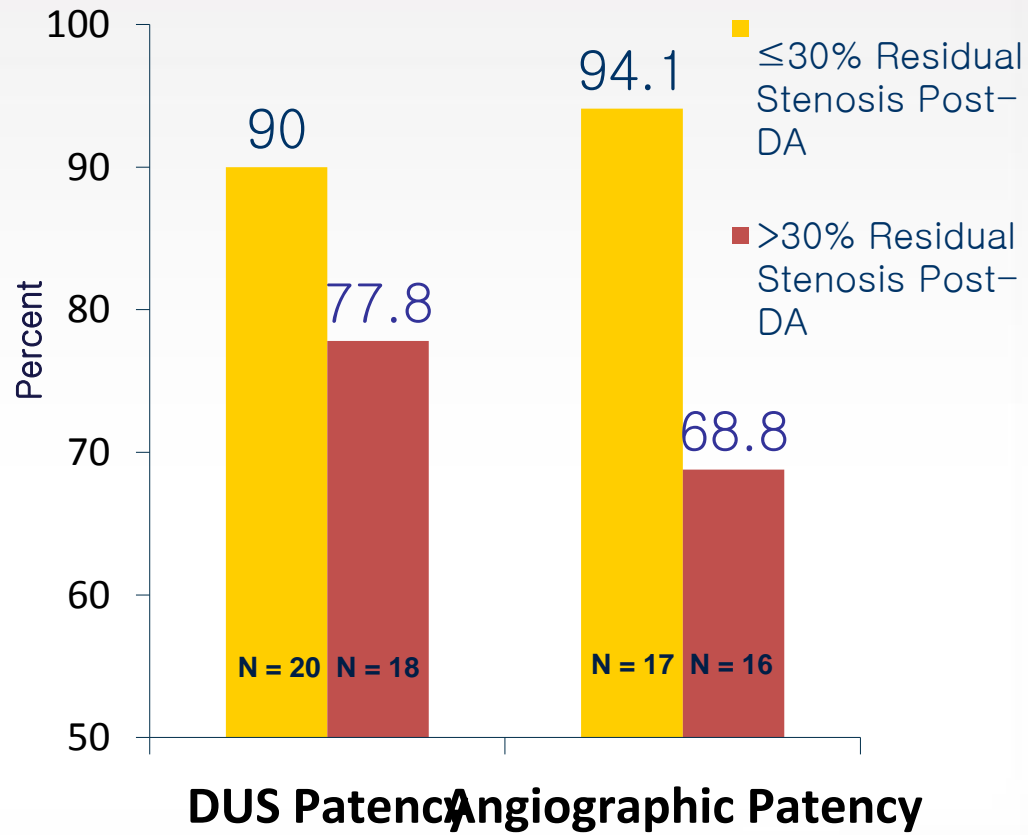
# DEFINITIVE AR

## GREATER MLD AFTER ATHERECTOMY

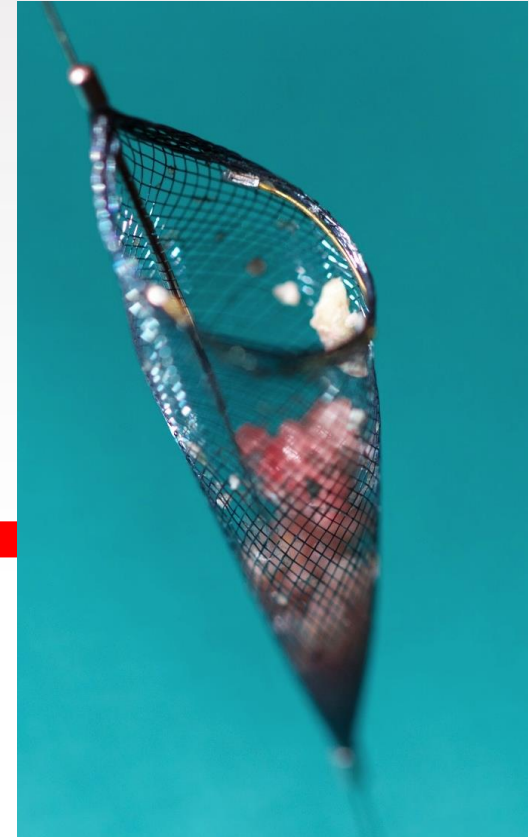
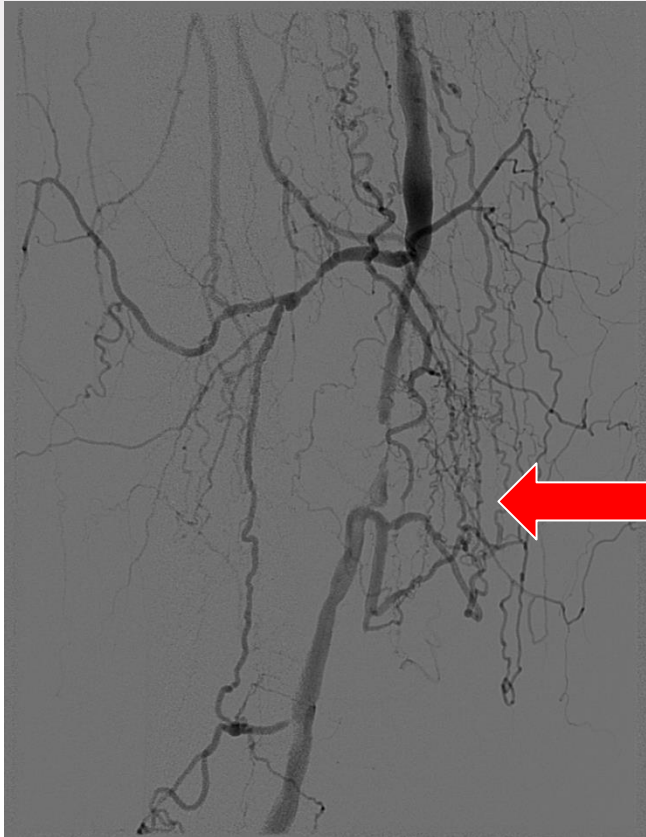


## IMPACT OF LUMINAL GAIN

ATHERECTOMY ARM: INCREASED LUMEN GAIN MAY IMPROVE 12-MONTH PATENCY



# Calcified Lesion: Directional Atherectomy with DCB



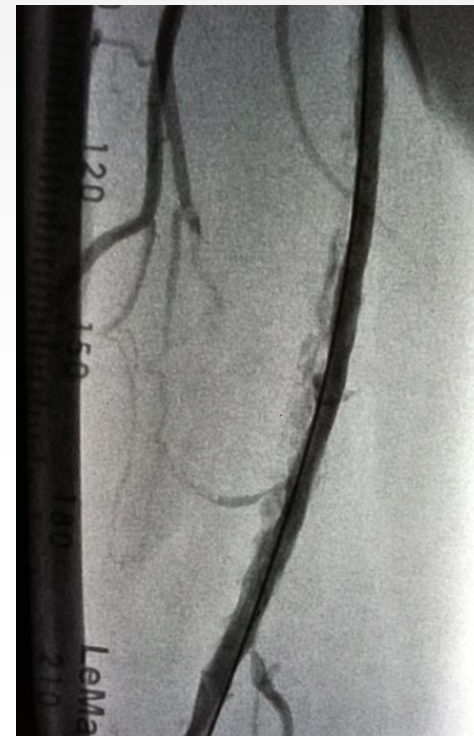
# Severely Calcified Right SFA disease Jetstream + DCB



Pre-treatment



Post Jetstream™ 2.1/3.0 mm



Post DCB Treatment

# Left CFA Stenosis

## Orbital Atherectomy

### 7/40 InPact Admiral DCB



# REALITY STUDY –

Does the Use of DA prior to DCB improve long term outcomes in patients with *long lesions and calcified lesions*

- Multi-center, prospective, single-arm observational
- 250 subjects in several sites across the U.S. and EU
- Stopped at 100 patients
- Angiographic and duplex ultrasound core lab
- Primary patency assessed by duplex ultrasound at 12-months.
- 24 months CD-TLR.
- REALITY study will help answer this question more definitively

The logo for the REALITY study, featuring a stylized blue 'R' followed by the word 'REALITY' in bold black capital letters. Below 'REALITY' is the text 'Sponsored by VIVA' in a smaller font.

Sponsored by VIVA

# JET-RANGER Clinical Study

## Clinical Study Overview: JET-RANGER (Investigator sponsored IDE)\*

Title	JETStream Atherectomy With Adjunctive Paclitaxel-Coated Balloon Angioplasty vs Plain Old Balloon Angioplasty Followed by Paclitaxel-Coated Balloon in Treating Complex De novo Femoropopliteal Arterial Disease (JET-RANGER)
Study Chairman/ Co-PI Sponsor	Nicolas W. Shammass, MD/Co-PI: Lawrence Garcia, MD Midwest Cardiovascular Research Foundation
Objective	Test the hypothesis that Jetstream atherectomy followed by DCB (Ranger or IN.PACT Paclitaxel Drug Coated Balloon) improves target lesion revascularization at 1 year follow-up when compared to balloon angioplasty followed by DCB in the treatment of femoropopliteal arterial de novo disease
Study Design	Prospective, multicenter, randomized study Jetstream + DCB vs PTA + DCB (2:1 randomization)
Patients	255 patients at up to 25 US sites Rutherford category 2-4 and $\geq 70\%$ de novo stenosis with: lesion length $\geq 10$ cm, or chronic total occlusion (any length) in the SFA and/or popliteal artery, or calcification of $\geq$ grade by PACCS
Endpoints	Effectiveness: Target Lesion Revascularization at 1 Year: intra-procedural bail out stenting of the index lesion is considered meeting a TLR endpoint. Safety: Major Adverse Events (MAE) at 30 days: unplanned amputation, total mortality or TLR at 30 days (TLR includes bail out stenting)

ClinicalTrials.gov Identifier: NCT03206762

Enrolling



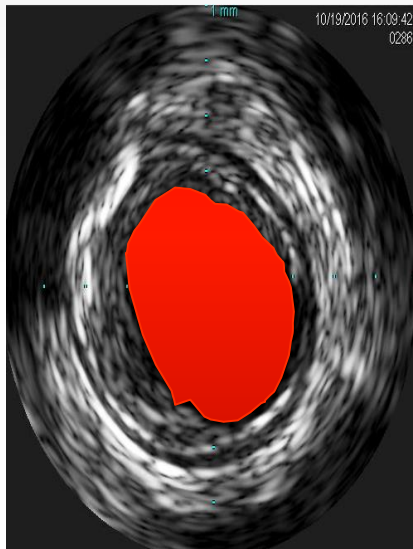
# SUMMARY

- Many options for treating patients with Fem-Pop Disease
- Severe calcium can result in adverse acute and long-term outcomes if not treated appropriately
- Atherectomy plays an important role to remove calcium which cannot be achieved by other modalities
- Standard of care in my practice
- Several small single center studies and one randomized study so far show promise
- Await results of larger/randomized trials

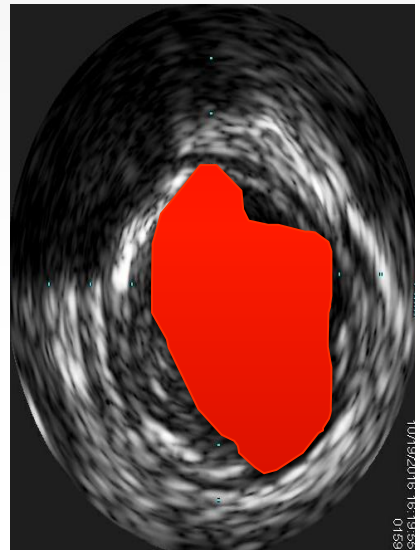
*Thank you!*

# REALITY: IVUS Plaque Burden Analysis

Baseline IVUS



Post-DA

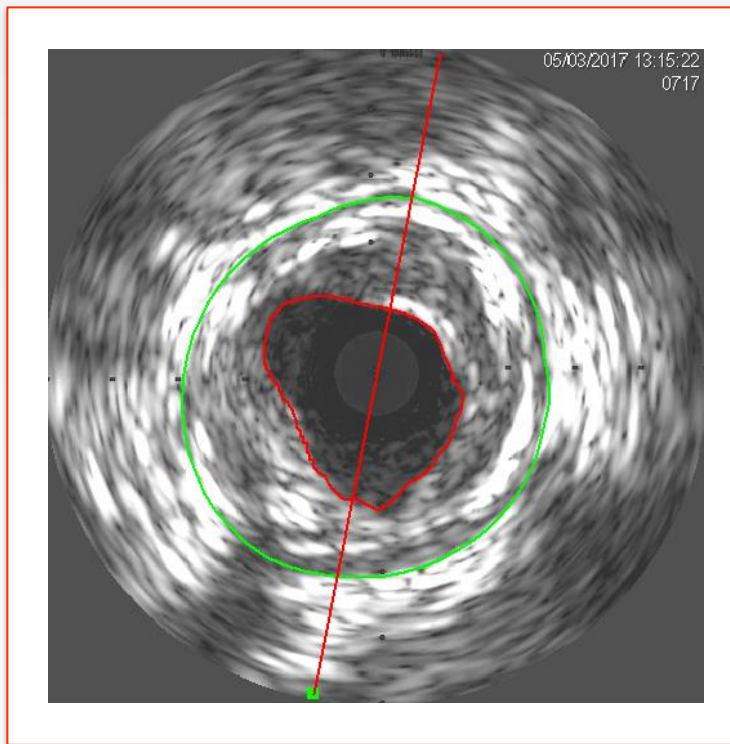


Post-DCB

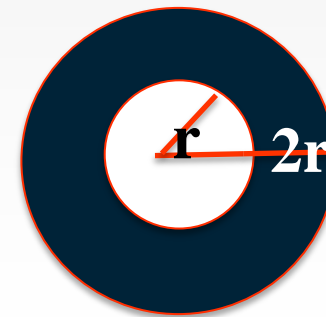


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# The Benefit of Lumen Gain is Exponential



**Plaque Burden:**  
An area-based calculation and percentage



**Vessel Area:  $4\pi r^2$**

**Lumen Area:  $\pi r^2$**

**Plaque Burden(Area) =  $3\pi r^2$**

**Percent: 75**

# Benefits of Atherectomy + DCB

- May provide added benefit in lesions  $\geq 10\text{cm}$  & severely calcified lesions
- Good atherectomy ( $< 30\%$  stenosis after DA alone) may improve patency