

**The use of orbital atherectomy and lithoplasty in fem-pop disease –  
What is the concept, and how to  
best select the cases?  
The “Sand Blasting” technique for  
vessel preparation**

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# Disclosures

- None pertaining to this talk

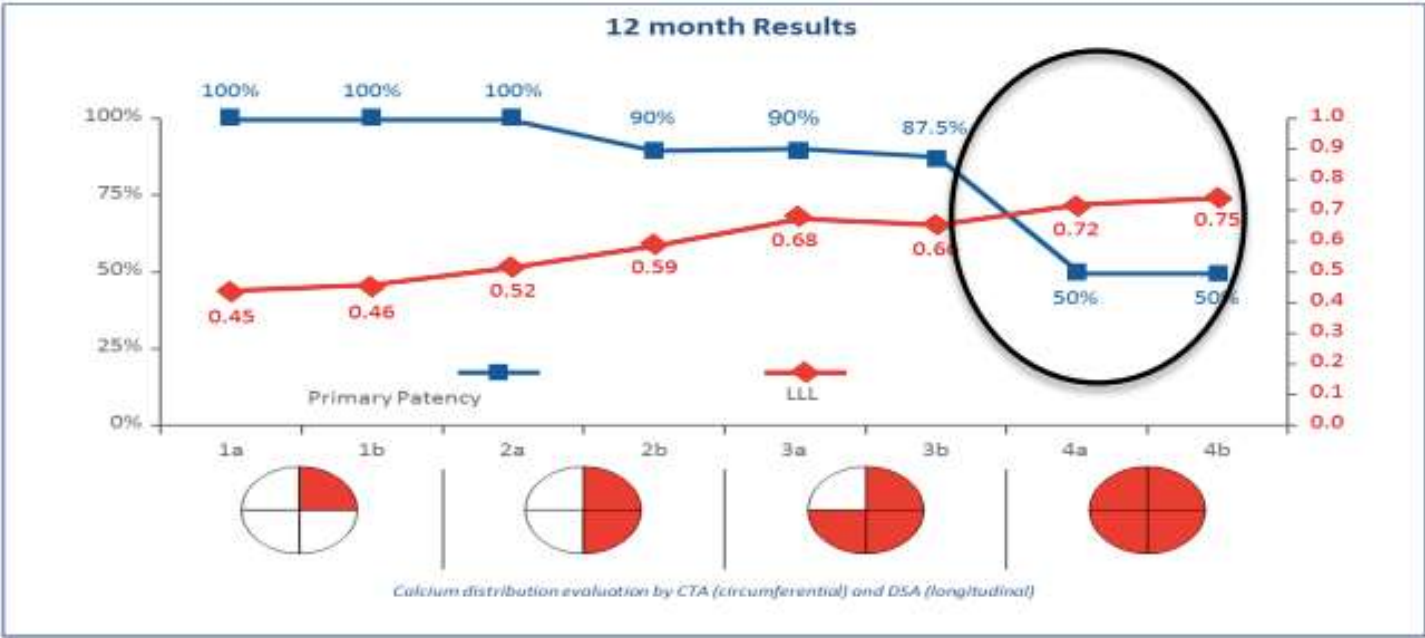
# The Problem...



# Severe Calcification

- Disruptor for therapeutic delivery
- Vessel wall resists balloon remodeling
  - Impede drug delivery
  - Increase dissection/complications
  - Inadequate stent expansion
- No gold standard for vessel preparation

# Severe Calcium Acts as a Barrier to DCB



Fanelli F et al. Calcium Burden Assessment and Impact on Drug-Eluting Balloons in Peripheral Arterial Disease. *Cardiovasc Intervent Radiol* (2014) 37:898–907

# Severe Calcification in DE Trials

	Zilver PTX RCT	IN.PACT SFA II	LEVANT 2
Severe Calcification	37.7%	8.1%	10.4%

Imperial (Eluvia): >60% patients with moderate to severe calcification

# Classification

## PACSS:

Proposed Fluoroscopy/DSA based Peripheral Arterial Calcification Scoring Systems (**PACSS**): Intimal and medial vessel wall calcification at the target lesion site as assessed by high intensity fluoroscopy and digital subtraction angiography (DSA) assessed in the AP projection.

**Grade 0:** No visible calcium at the target lesion site

**Grade 1:** unilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 2:** unilateral calcification  $\geq$  5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 3:** bilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 4:** bilateral calcification  $\geq$  5cm; a) intimal calcification; b) medical calcification; c) mixed type

## PARC:

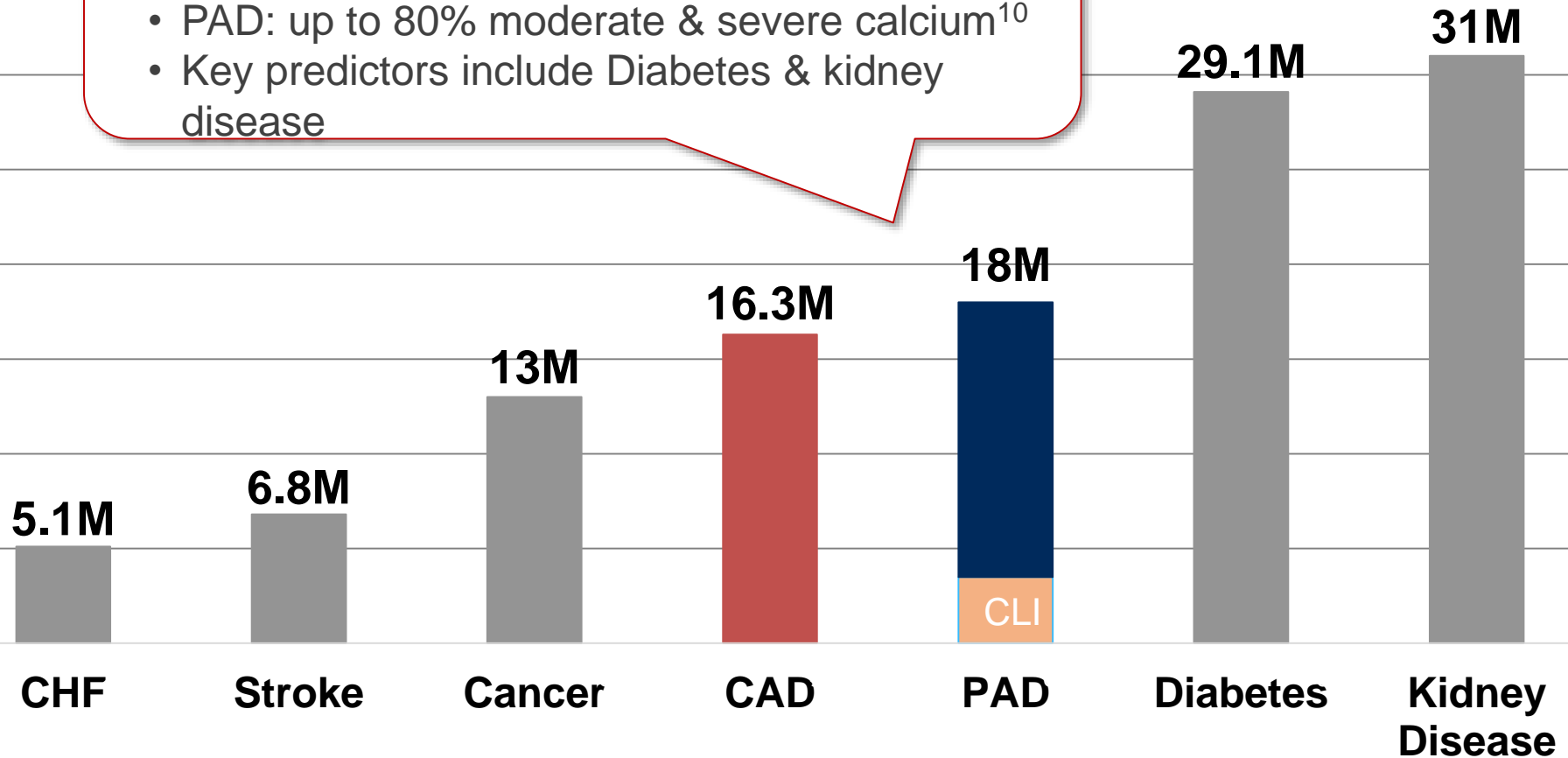
Degree of lesion calcification (34,26)	Focal	<180° (1 side of vessel) and less than one-half of the total lesion length
	Mild	<180° and greater than one-half of the total lesion length
	Moderate	$\geq$ 180° (both sides of vessel at same location) and less than one-half of the total lesion length
	Severe	>180° (both sides of the vessel at the same location) and greater than one-half of the total lesion length

# Disease State Prevalence

*PAD patients with calcium => large and growing problem in the U.S.*

## Incidence of Arterial Calcium:

- CAD: 6-20% severe calcium<sup>8,9</sup>
- PAD: up to 80% moderate & severe calcium<sup>10</sup>
- Key predictors include Diabetes & kidney disease



1. Dolor RJ, et al. Comparative Effectiveness Review No. 66. Agency for Healthcare Research and Quality. August 2012. [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm). 2. Go AS, et al. Circulation. 2014;129(3):e28-e292. 3. American Diabetes Association 2015 Fast Facts—Data and Statistics About Diabetes <http://www.diabetes.org/diabetes-basics/statistics/> (Accessed December 8, 2015). 4. American Kidney Fund Website. Accessed July 30, 2013. 5. Howlander N, et al. SEER Cancer Statistics Review, 1975-2010. Accessed April 17, 2014. 6. Schiravetta A, et al. Stem Cells Transl Med. 2012;1(7):572-8. 7. Sage Report 2010. 8. Genereux P, et al. J Am Coll Cardiol. 2014;63(18):1845-54. 9. Bourantas CV, et al. Heart. 2014;100(15):1158-64. 10. Das T, et al. Catheter Cardiovasc Interv. 2014;83(1):115-22.



# Current methods of treatment

- Scoring/cutting balloon
- Atherectomy
  - Front-cutting
  - Excisional
  - Orbital
- Lithoplasty

# “Sand Blasting” Vessel Prep

- **DIAMONDBACK 360° Peripheral Orbital Atherectomy System**
  - Solid crown (1.5 or 2.0)
    - 5-6 passes total
    - 30 sec between each
    - +/- Embolic protection
- **Shockwave balloon**
- Deliver therapy

# DIAMONDBACK 360° Peripheral Orbital Atherectomy System

## Sleek Electric-Powered Handle

- Simple device set-up
- Optimum torque transfer to the shaft and crown
- Short overall treatment times

## Crowns

- Micro Crown
- Classic Crown
- Solid Crown



## Prime Control

- Flush saline from device

## Simple Speed Settings

## Instant Response On/Off Switch

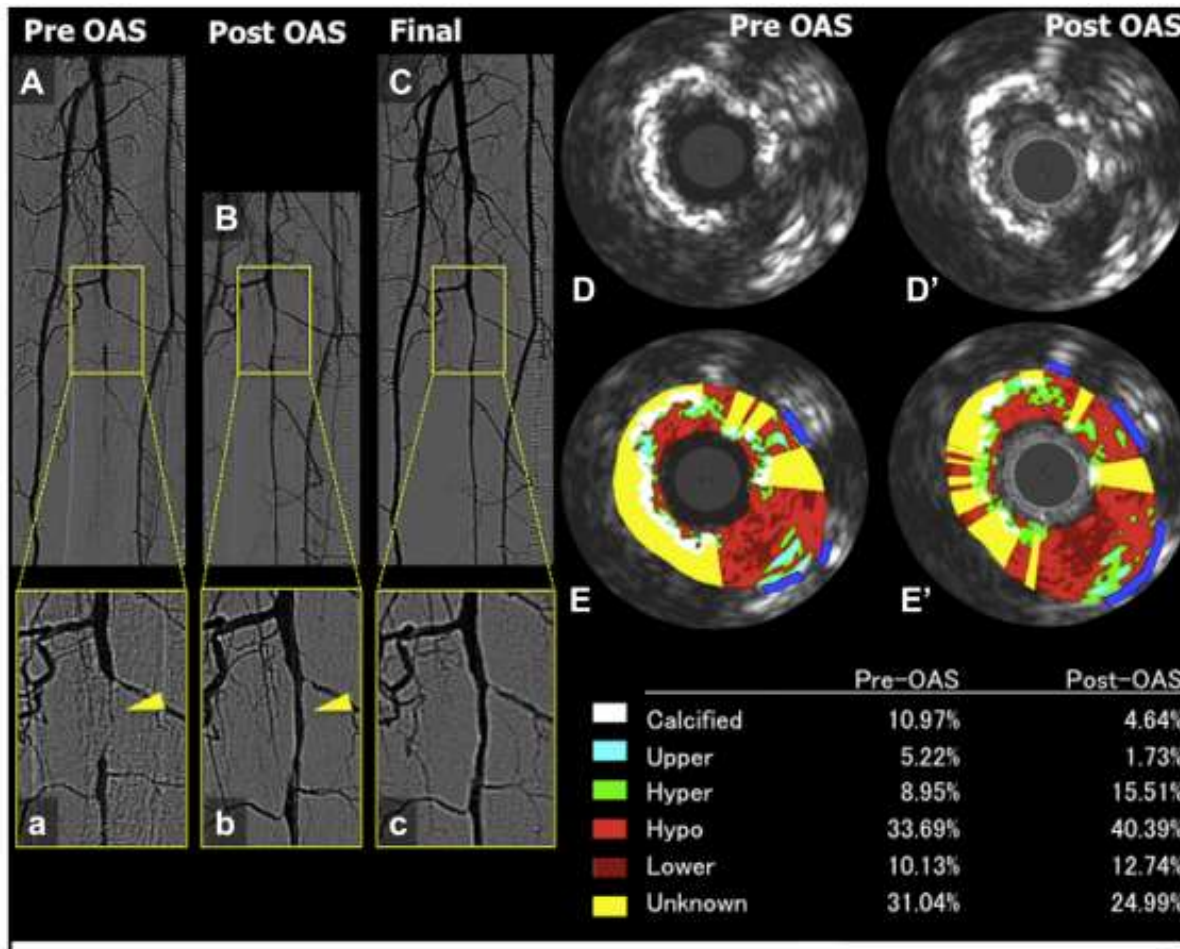
## Brake

## Saline Pump

- Mounts directly to an I.V. pole
- Bathes shaft and crown to facilitate smooth device operation



# Micro-fissures after OAS



Sotomi, Y et al. JACC Interv 2015

# Intravascular Lithoplasty (IVL)


SHOCKWAVE



- DISRUPT CALCIUM
- RESTORE FLOW
- EXPAND POSSIBILITIES

Reshape interventional therapy with the power of Lithoplasty® Technology.

Dilate to reference vessel diameter | 6 ATM



Lithoplasty®

SHOCKWAVE MEDICAL INC.



OHIOHEALTH  
VASCULAR INST

OUR SYSTEM

# IVL: Early Clinical Data

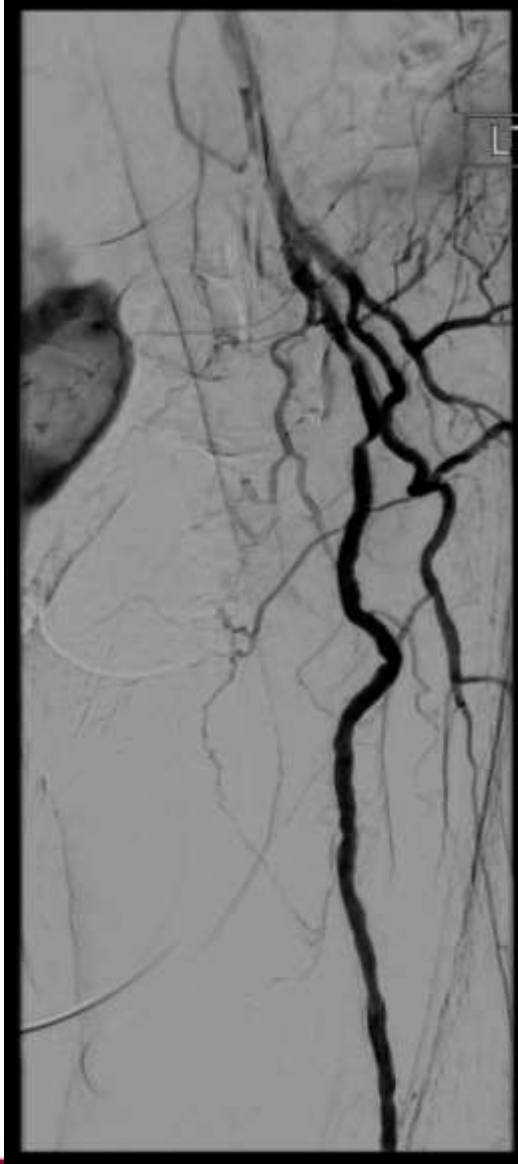
- Disrupt PAD II

- 60 pts
- 85% severe Ca++
- 98 mm length
- 12 mo primary patency: **54.5% (62.9%)**
- 12 mo C-TLR: **20.7% (8.6%)** Brodmann, M et. al. Cath Cardiovasc Interv. 2018

- Disrupt PAD III

- IVL + DCB vs. DCB alone –currently enrolling

# 76 yo F, DM, CKD, RC V



**BLASTING, no SAND**

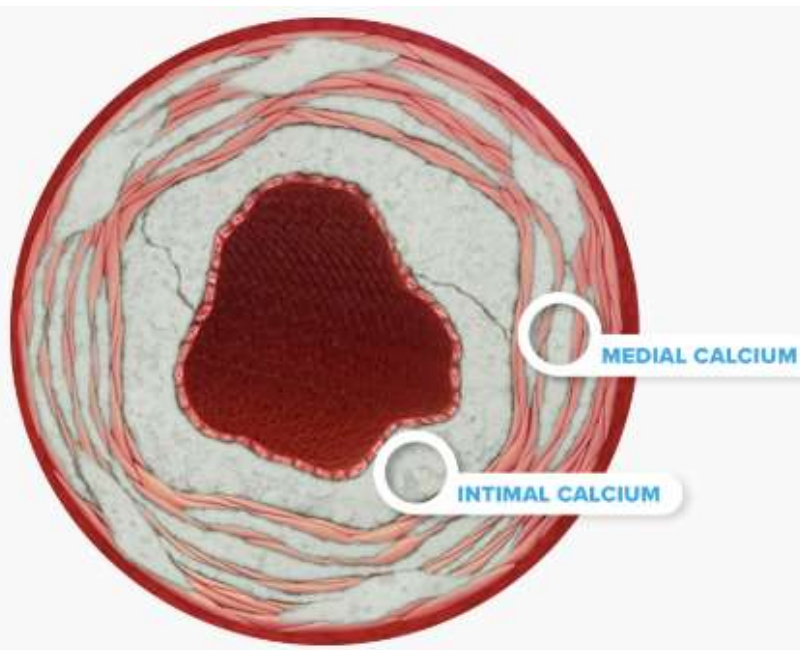
# Why both? Disrupt the 'cast' around the vessel

- OAS

- Micro-fissures
- Superficial disruption

- IVL

- Micro and Macro-fissures
- Deeper disruption



- \*Change vessel compliance, increase lumen gain
- \*Reduce recoil
- \*Reduce spiral dissection



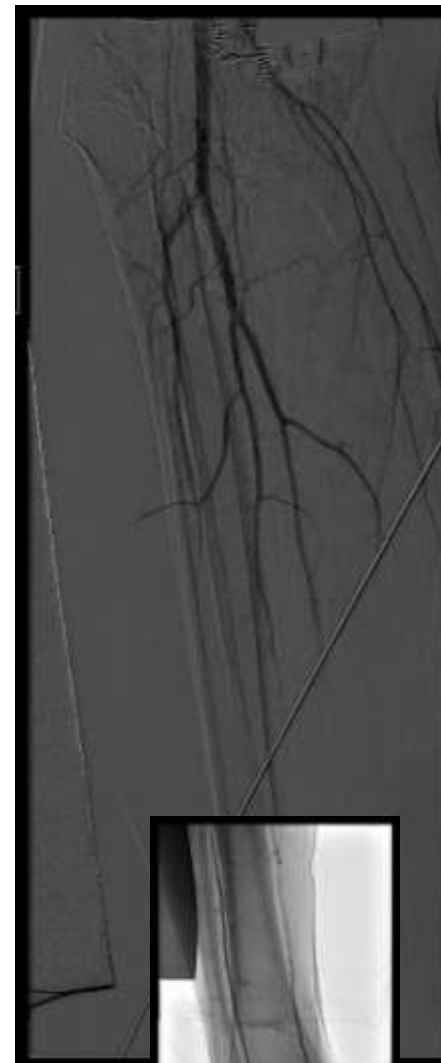
# Patient Selection

- Severe, dense calcification
  - Must maintain true lumen
  - Eccentric
  - Regions less desirable for scaffold
    - CFA
    - Across knee joint
  - In Fem-pop region\*, acceptable runoff

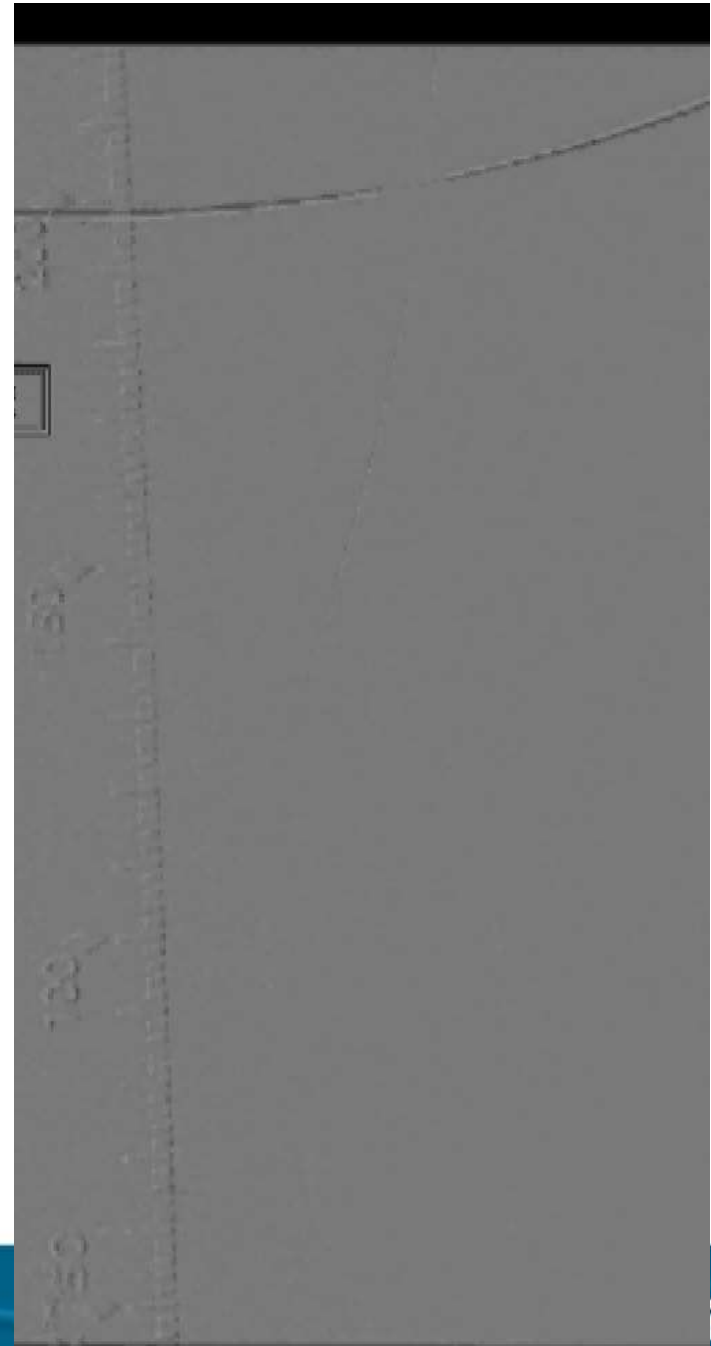
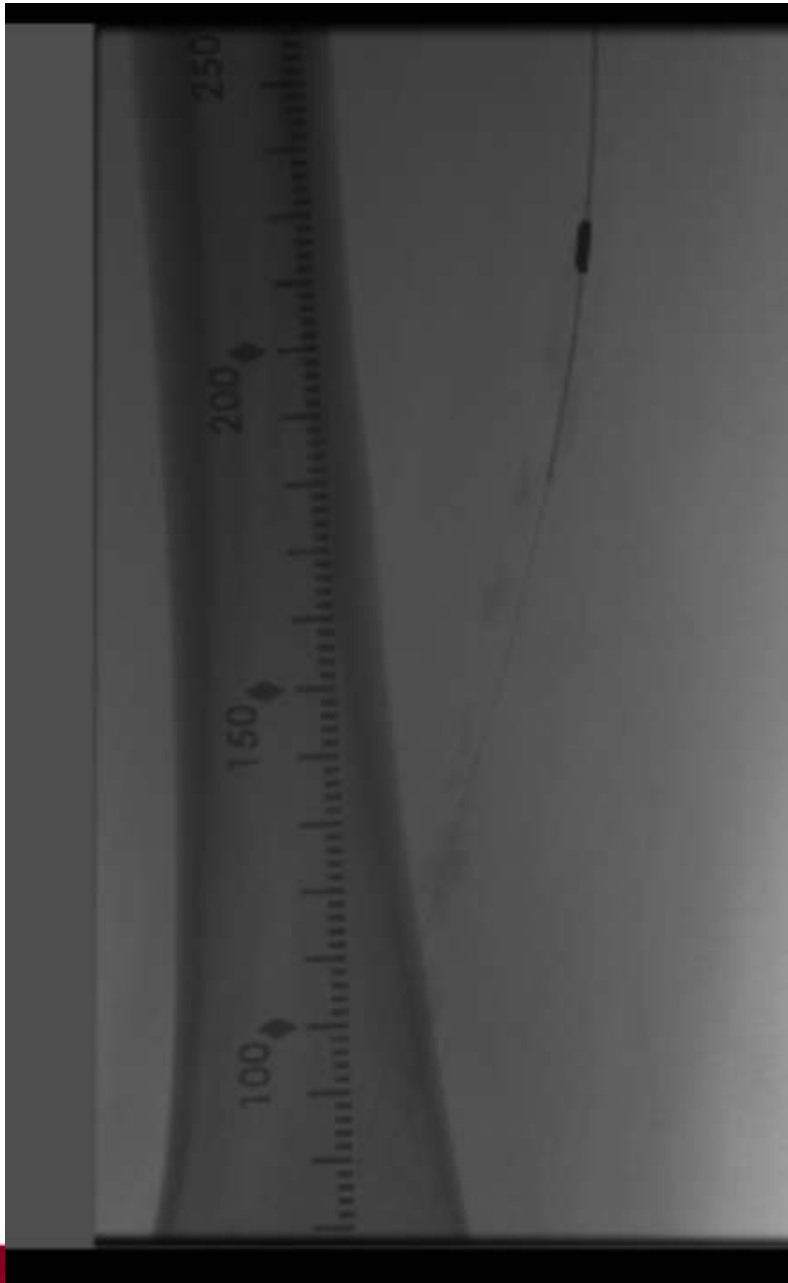
\*Smaller diameter lithoplasty balloons for tibials now available

# Patient #1: 63 yo M, DM, tobacco abuse

- RC II claudication, life-style limiting
- Abnormal resting ABI on Right (0.69), Left normal
- Abnormal pulse exam on R, normal L









# Post procedure & 6 mo follow up

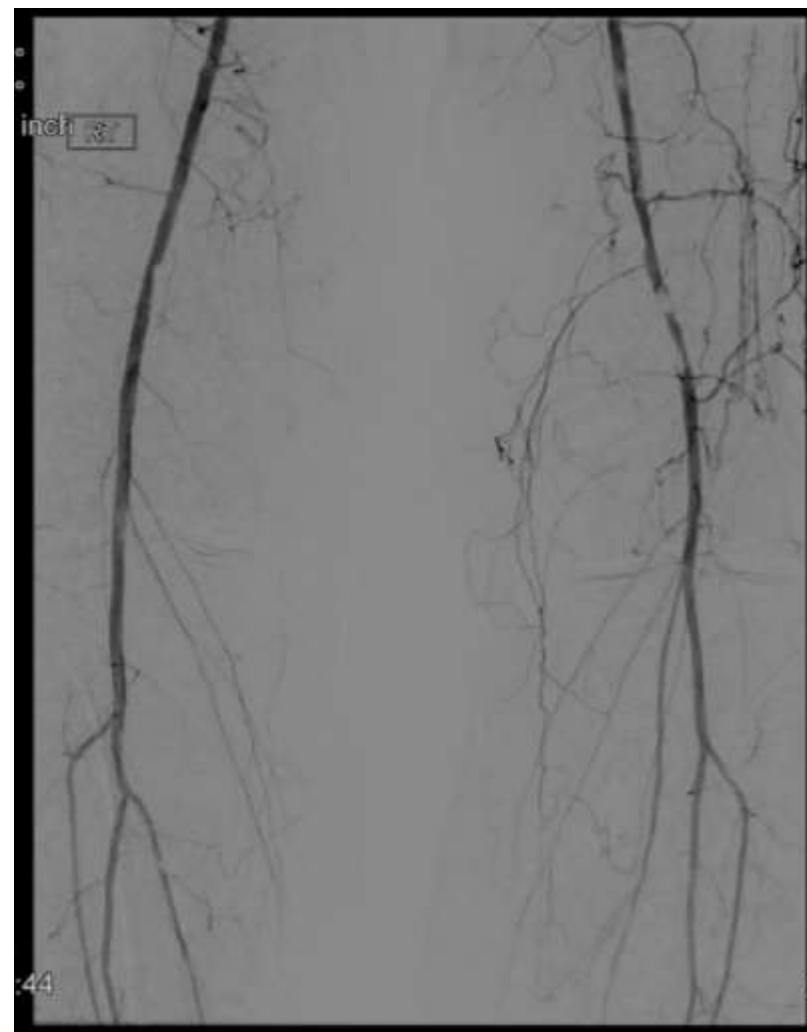
- 2+ palpable pulses end of procedure, no distal embolization
- 6 mo ABI: R: 1.01 L:0.96
- 6 mo Arterial Duplex: <50% stenosis R SFA

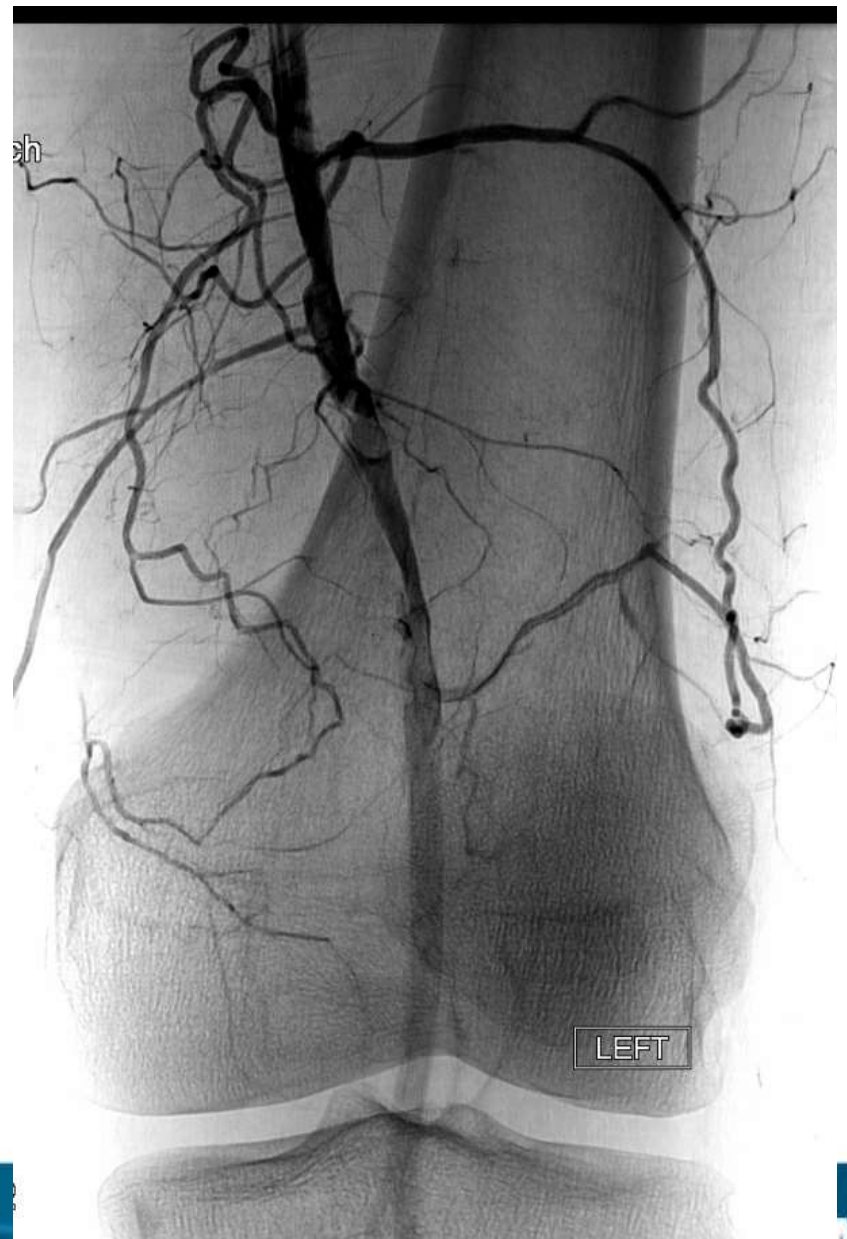
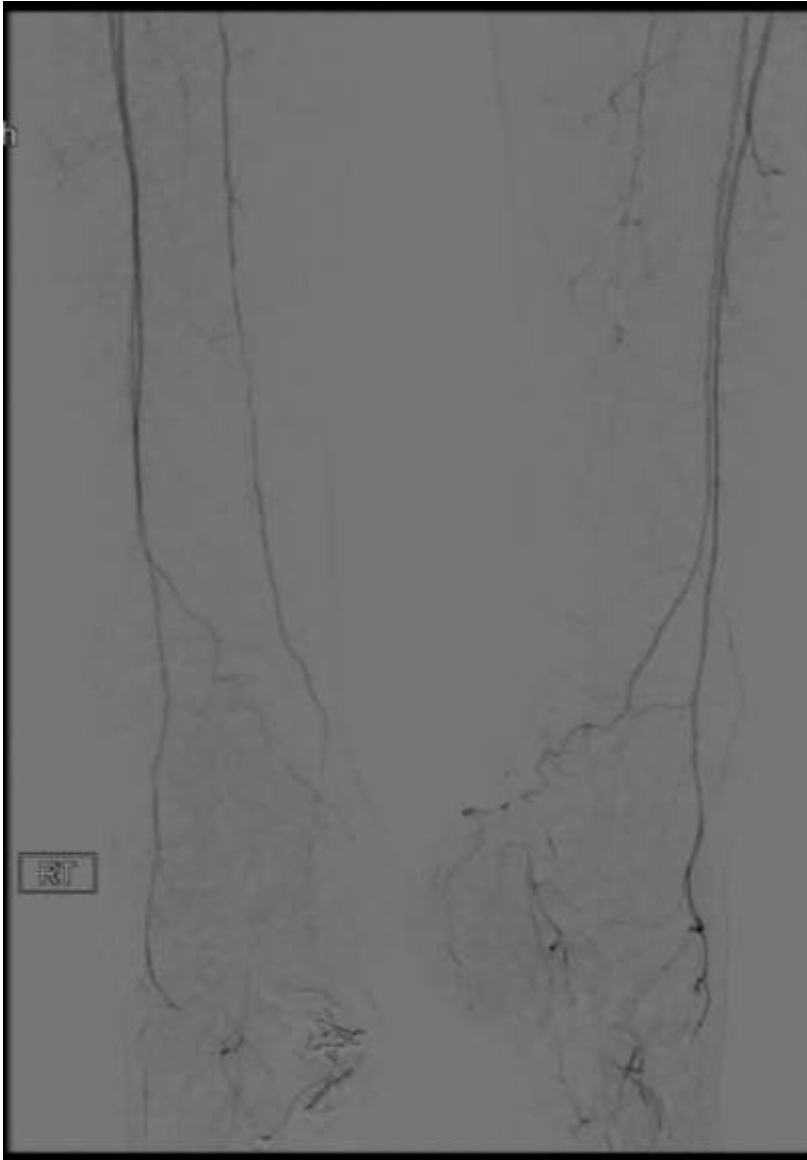
# 12 Mo Follow up

- Procedure date: 10/2017
- Last visit: 10/2018
  - RC O, doing well.
  - ABI 10/2018: R: 1.57      L: 1.57, normal bilateral PVRs
  - Arterial duplex 10/2018: <50% R SFA by arterial duplex



# 55 yo M, HTN, DM, RC III

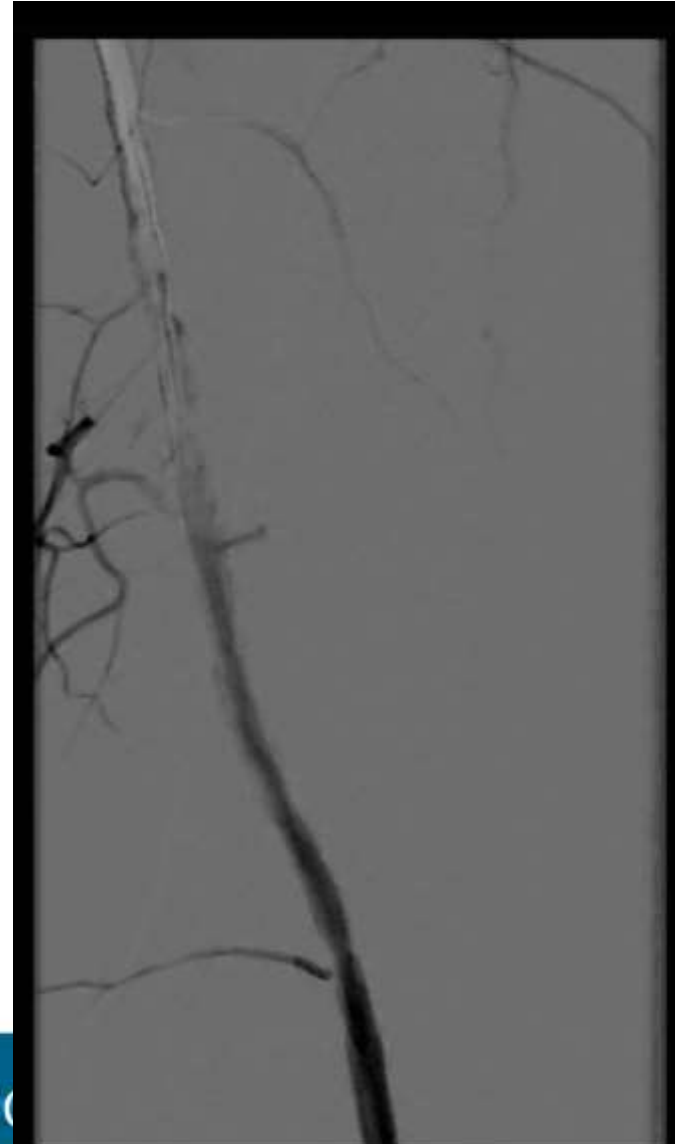
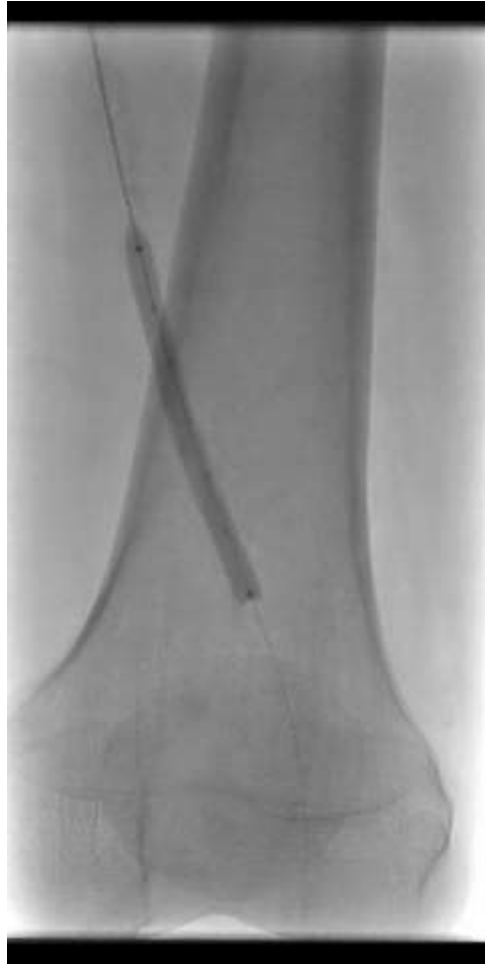




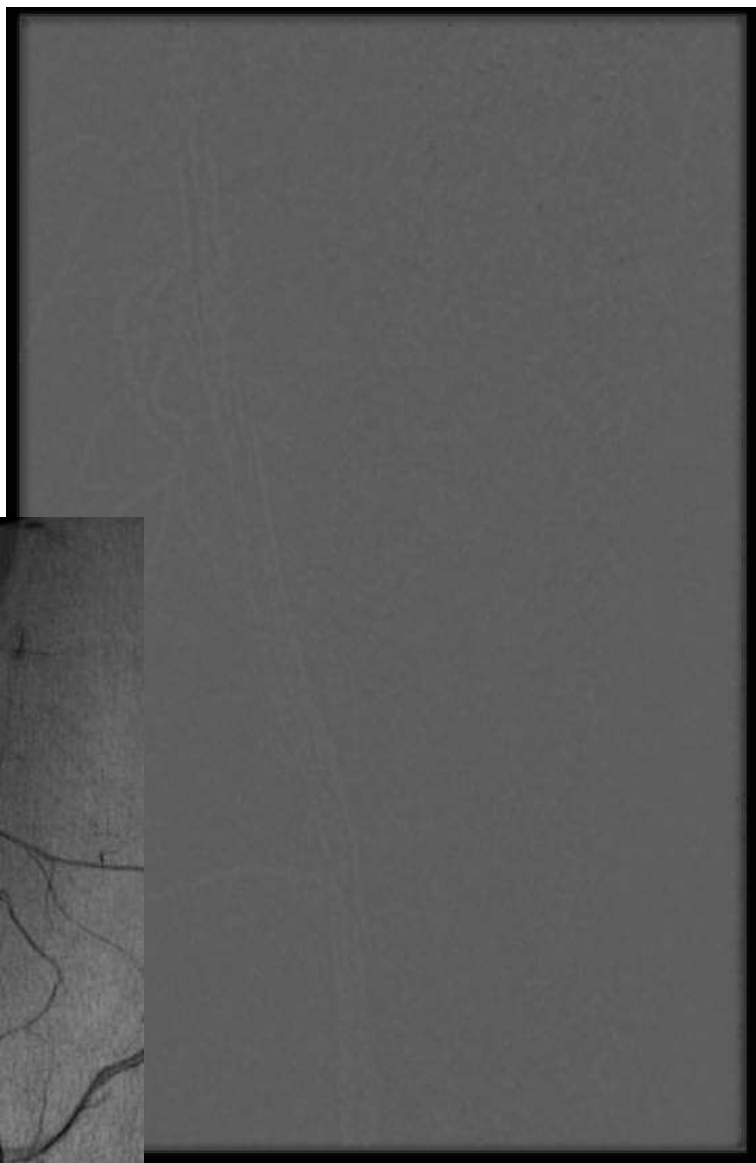
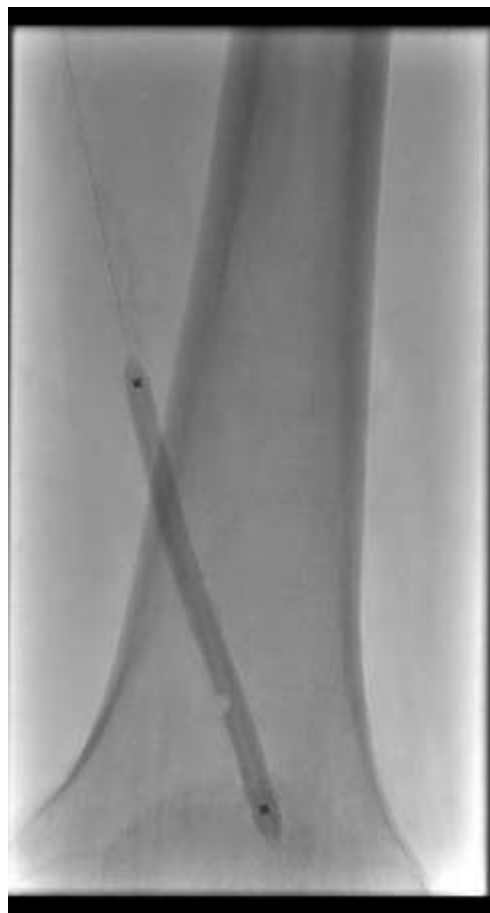
# Popliteal After CSI



# After IVL



# Popliteal after DCB



# SFA- after CSI and Lithoplasty, DES



# Limitations

- **\$\$\$\$**
  - Atherectomy device
  - Lithoplasty
  - Orbital atherectomy + lithoplasty ≠ standalone treatment
  - Need for DCB, DES
- **Small sample size: 5 patients**
  - 100% technical success, 0% complications
  - 2 pts followed 18 months, TLR 0%, Duplex <50% stenosis, normal ABI

# Moving Forward

- Registry of patients with severe calcifications
  - OAR + lithoplasty vs. lithoplasty alone using IVUS
  - End points
    - Patency, TLR
  - Cost analysis
    - Initial, longitudinal









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