Orbital Atherectomy for Calcified Peripheral Arterial Disease

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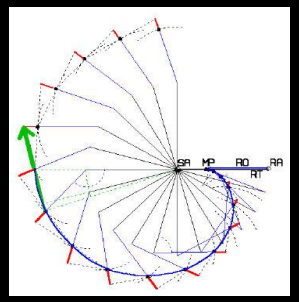
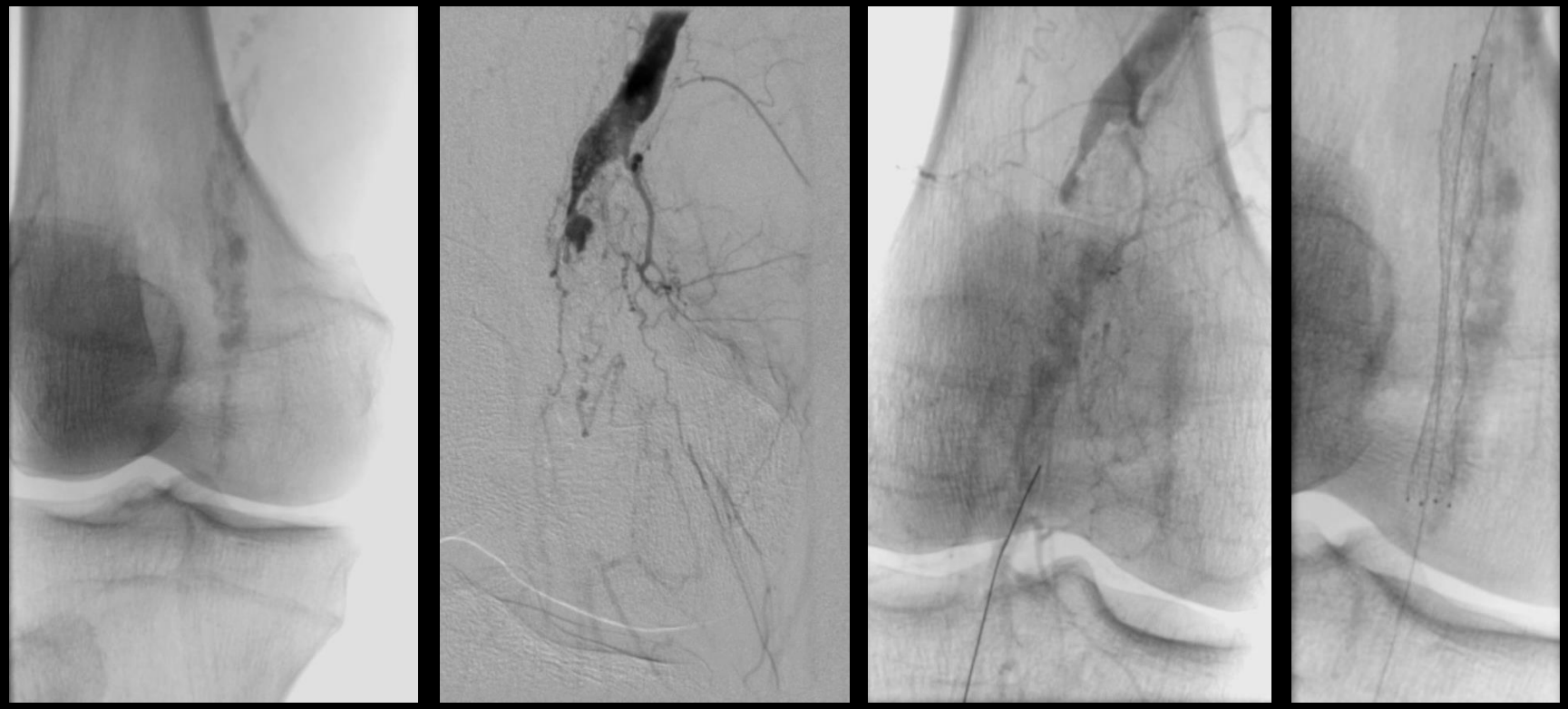
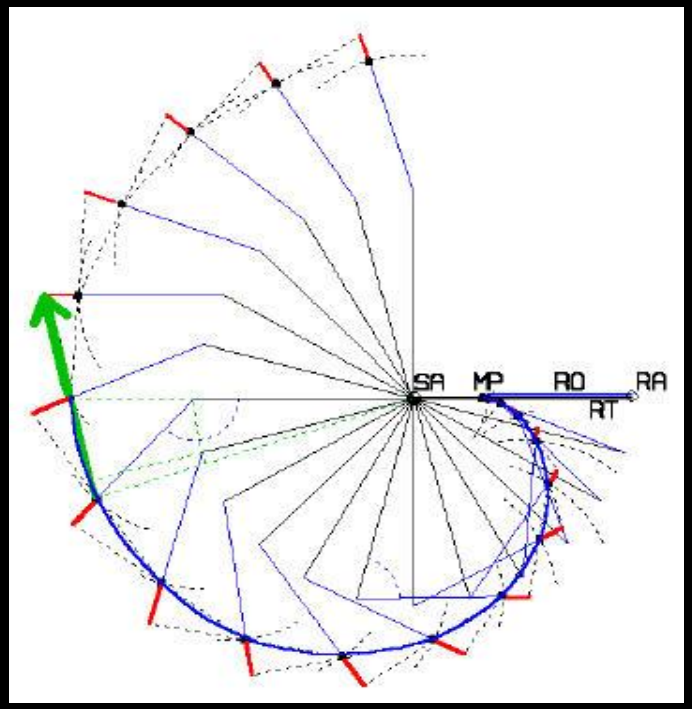


The Challenges of Calcified Lesions



Retrograde Pedal CTO Recanalization and Stenting

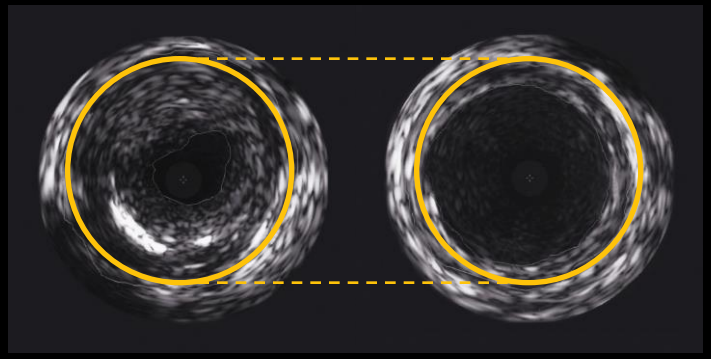
CSI Diamondback 360



Orbital Atherectomy

2.25 mm crown can achieve up to a 4.5 mm smooth, concentric lumen

before after



70% SFA lesion < 10% residual

CSI's Unique MOA: Changing Compliance using Centrifugal Force

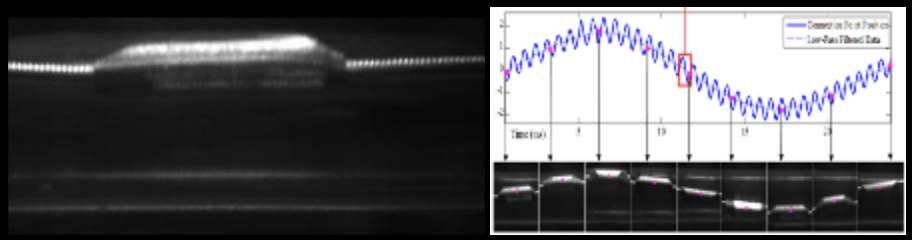
360° crown contact with the vessel wall creates a smooth, concentric lumen
Eccentric crown facilitates blood flow and particulate flushing during orbit

30 µm diamond coating | eccentric-mounted mass

Differential Sanding

- Average particulate size[1] = 2 µm
- Bi-directional sanding of superficial calcium
- Healthy elastic tissue flexes away from the crown, minimizing damage to the vessel

Pulsatile Forces[2]



- Low frequency (18-40 Hz) represents crown orbit inside vessel*
- High frequency (1000-1900 Hz) represents rotation of eccentric crown over the wire, producing pulsatile mechanical forces*
- These pulsatile forces may affect deeper plaque and contribute to compliance change**

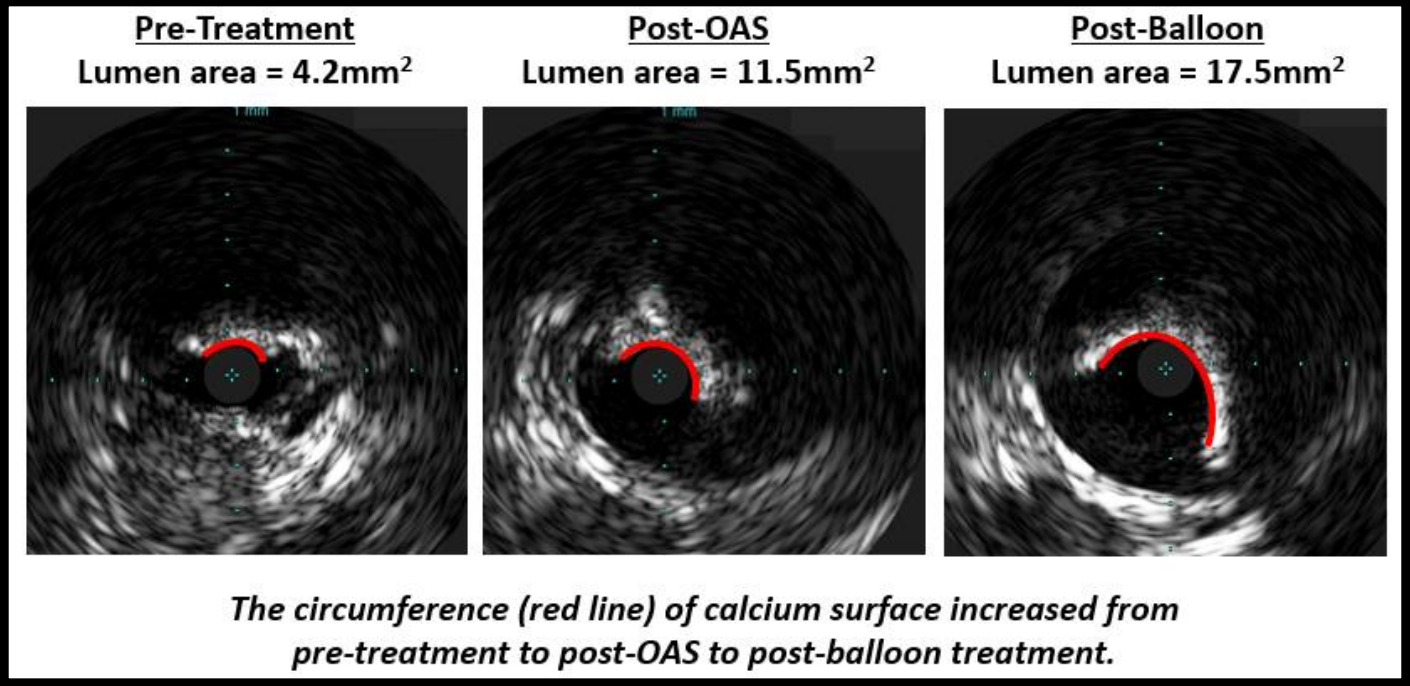
* In a phantom non-diseased popliteal artery
**Results vary based upon plaque morphology, calcification, and anatomy

1. Based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite block test models:
2. Zheng et al., 2016. Med Eng Phys. 2016 Jul;38(7):639-47.

TRUTH IVUS Study

Prospective, single-center study of IVUS to assess OAS-related plaque modification of femoral-popliteal lesions (N=25 subjects)

- MLA increased from 4.0 mm^2 to 9.1 mm^2 post-OAS+BA ($p<0.0001$)
- Calcium reduction was responsible for 86% of the luminal gain



The circumference (red line) of calcium surface increased from pre-treatment to post-OAS to post-balloon treatment.

Babaev A et al *Vasc Endovasc Surg* 2015; 49: 188-194

Lesion Complaince and Outcome
CSI 360° Changes Vessel Compliance

Compliance not changed by PTA

Post-Balloon

• 40% stenosis

Post-Balloon + Stent

• 40% stenosis

Right Leg

Compliance changed by DB 360º

Post-Diamondback 360º

• 40% stenosis

Post-Diamondback 360º

+ PTA 3 ATM

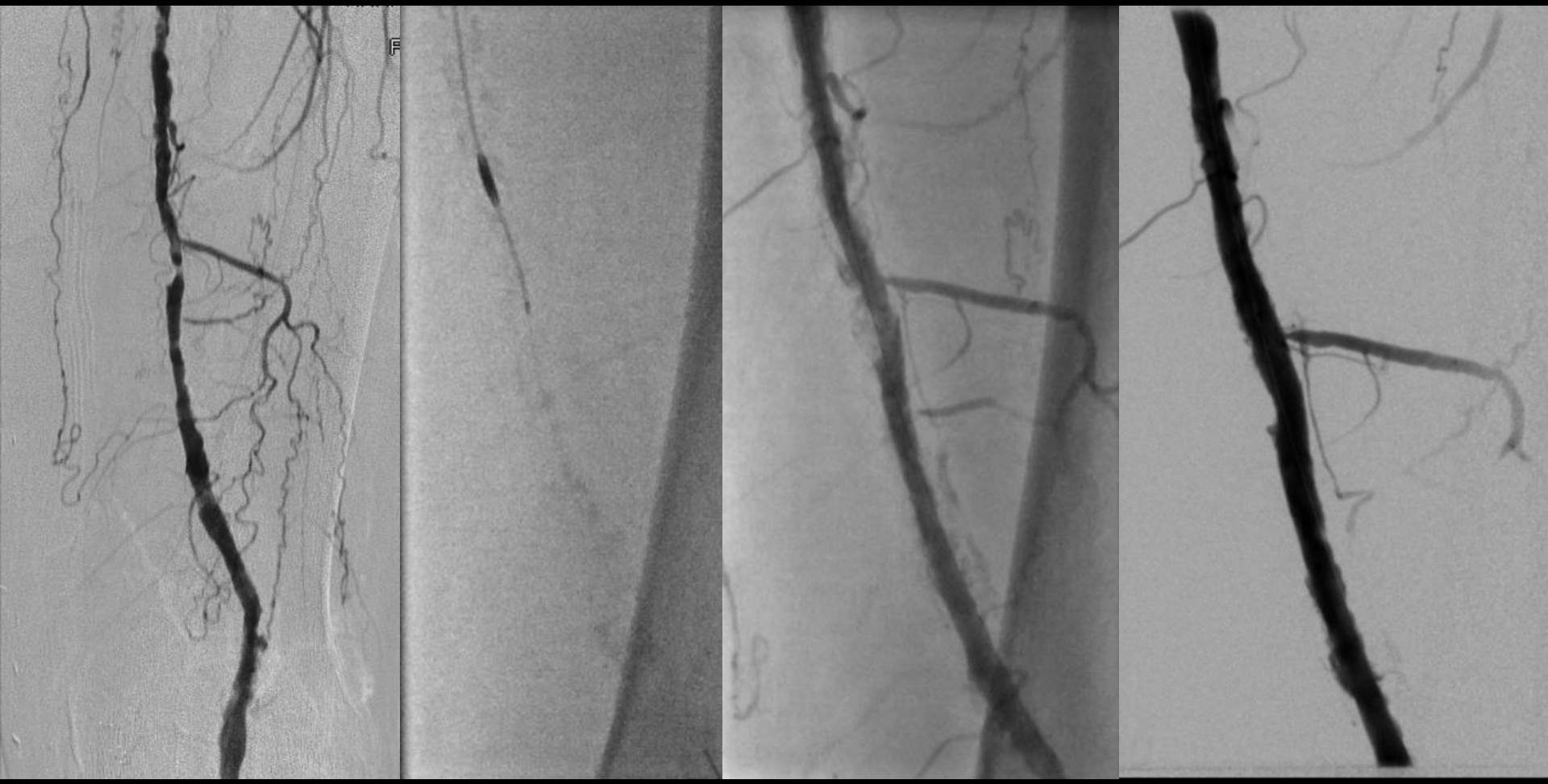
10% stenosis

Left Leg

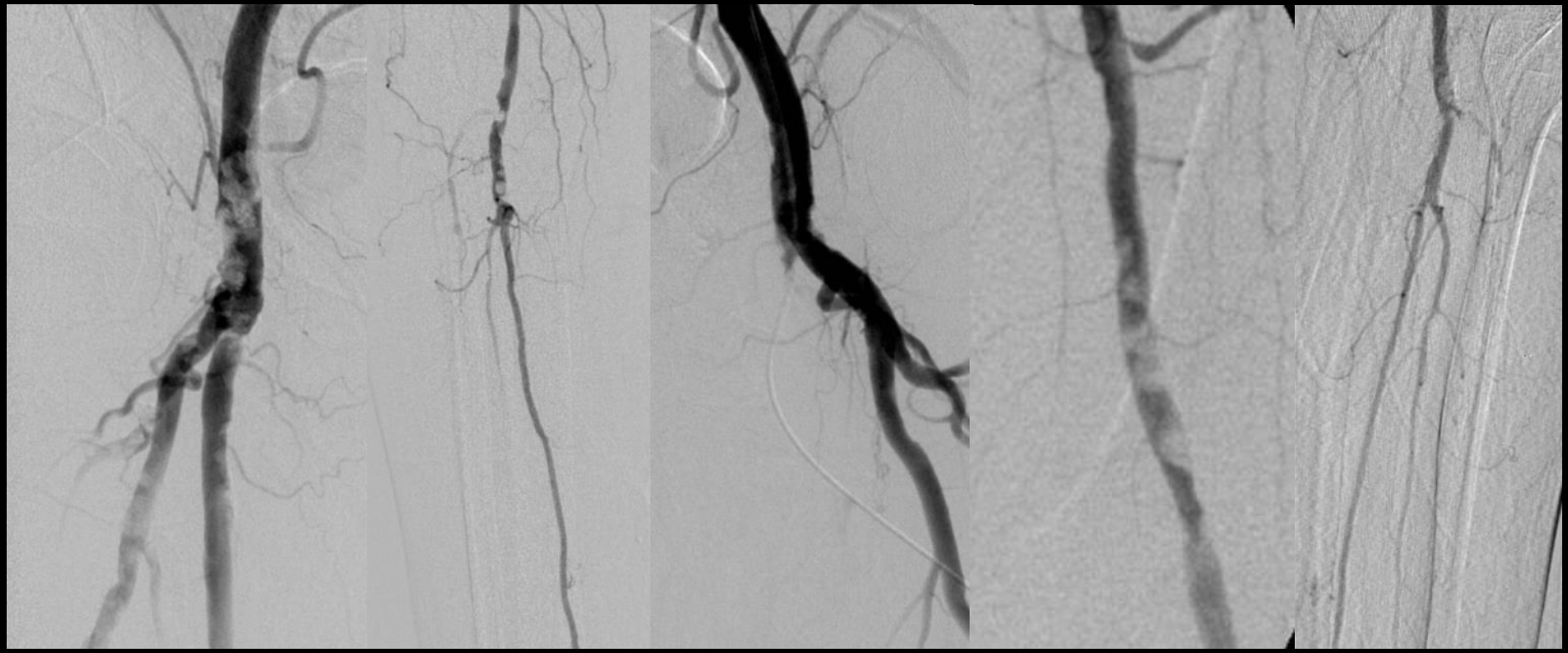
Images Courtesy of Dr. Agostino Ingraldi, Lafayette, LA

Femoral-Popliteal 2.25 mm Solid Crown

Femoral-Popliteal 2.25 mm Solid Crown

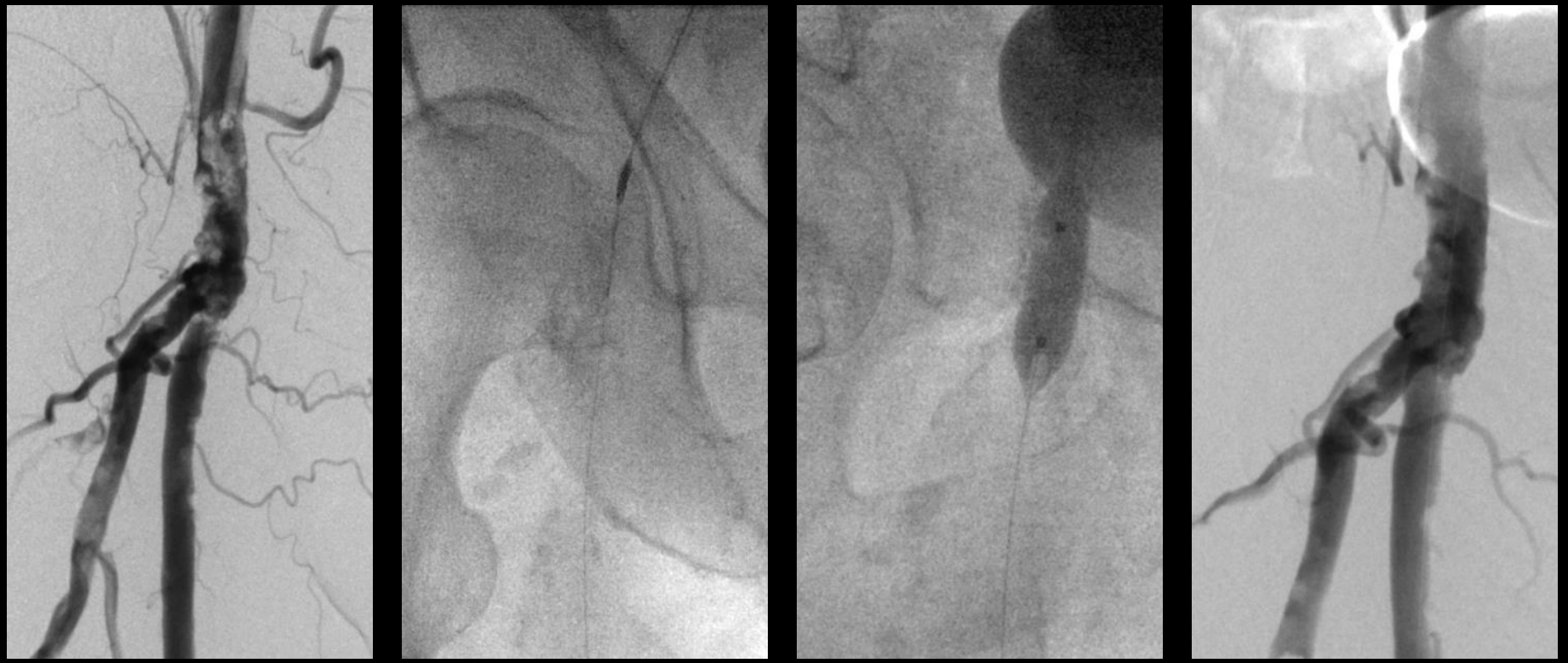


Calcified Femoral-Popliteal Disease



TASC E, F and G lesions!

Calcified Femoral-Popliteal Disease



Calcified Femoral-Popliteal Disease

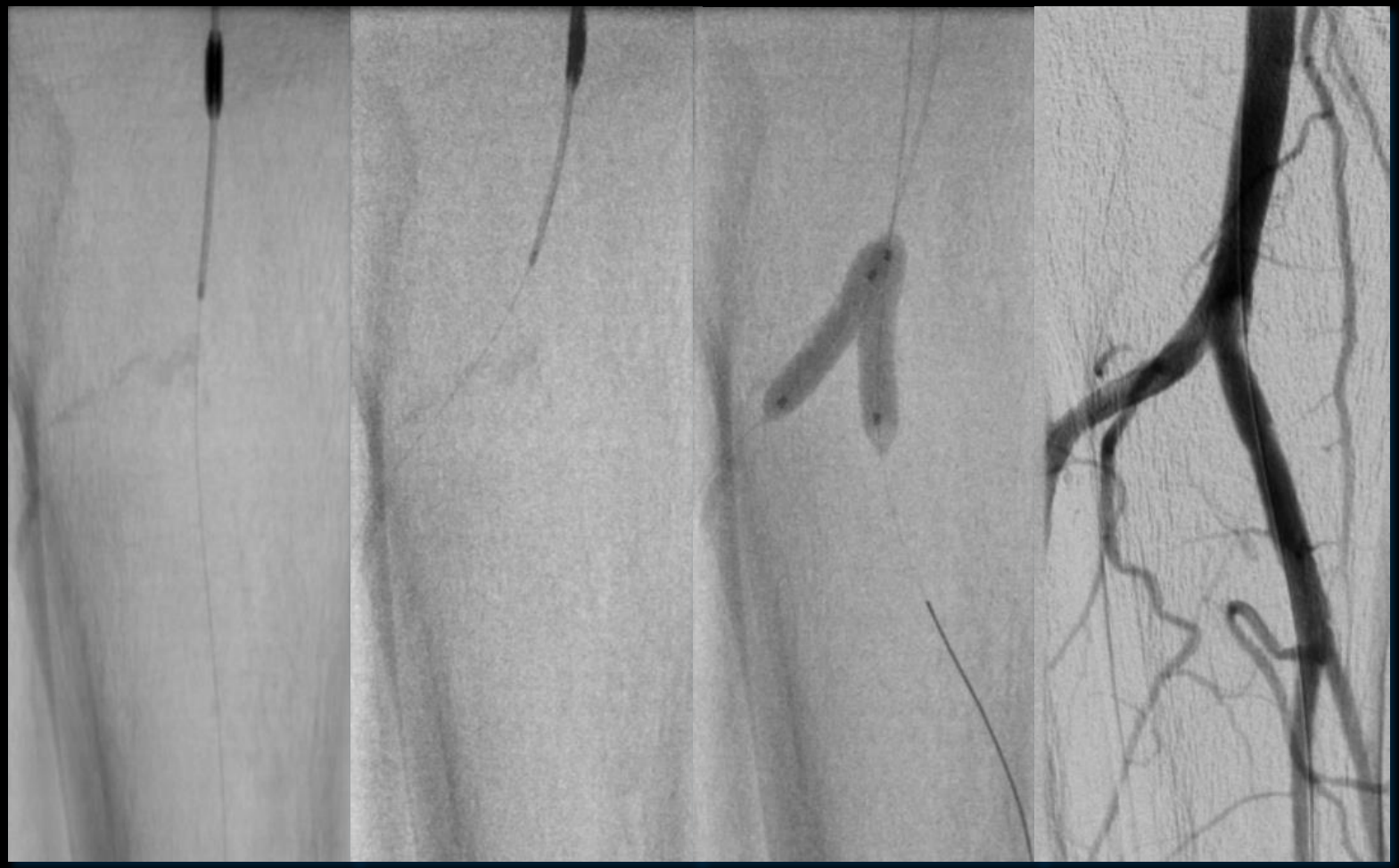
Calcified Femoral-Popliteal Disease

Calcified Femoral-Popliteal Disease

Calcified Tibial-Peroneal Disease

Calcified Tibial-Peroneal Disease

Calcified Tibial-Peroneal Disease



Safety Profile of CSI 360 in Calcified Lower Extremity Lesions

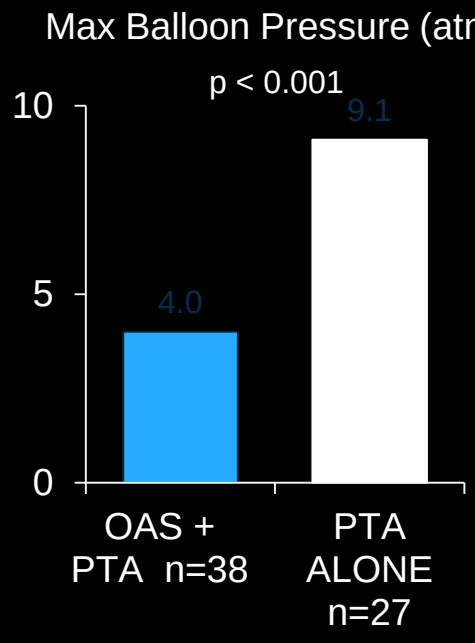
	OASIS[1] n = 201	CONFIRM I[2] n = 1146	CONFIRM II[2] n = 1734	CONFIRM III[2] n = 1886	CALCIUM[3] n = 29	COMPLIANCE[4] n = 38
Mean Max Inflation Pressure (atm)	N/R	5.7	5.4	5.9	5.9	4.0
Bail-out Stenting	2.5%	3.8%*	5.8%*	5.2%*	6.9%	5.3%‡
Perforation	1.5%	0.9%	0.6%	0.7%	0.0%	0.0%
Embolization	0.5%	N/R	2.2%	2.2%	0.0%	2.6%

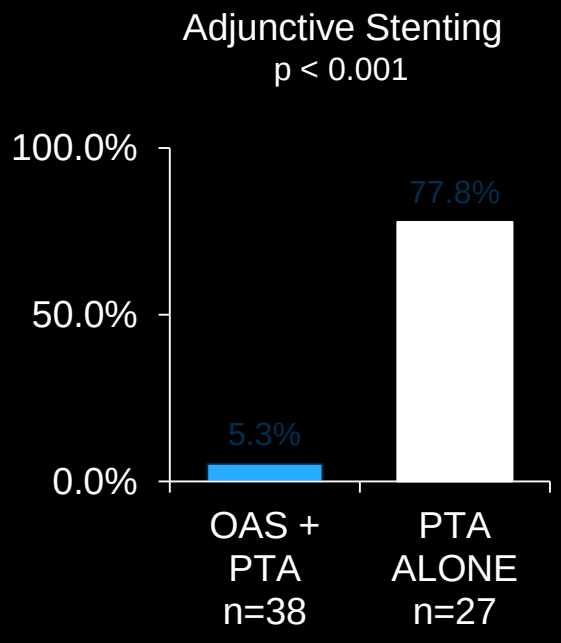
* Based on reported dissection treatments
‡ Adjunctive Stenting due to >30% residual stenosis

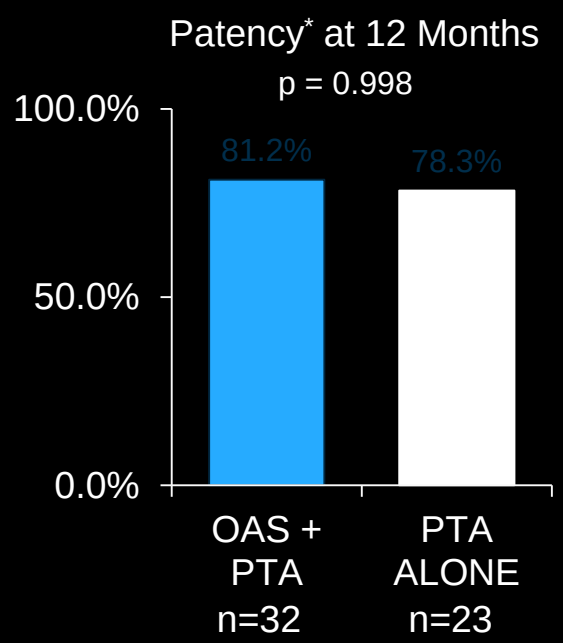
1. Safian RD, et al. *Catheter Cardiovasc Interv*. 2009;73:406-412.
2. Das T. et al. *Catheter Cardiovasc Interv*. 2014;83:115-22 & CSI Data on file.
3. Shammas NW, et al. *J Endovasc Ther*. 2012;19:480-488.
4. Dattilo R, et al. *J Invasive Cardiol*. 2014;26:355-360.

COMPLIANCE 360° Results

Prospective, randomized, multi-center study comparing OAS+PTA vs. PTA alone in calcified ATK lesions





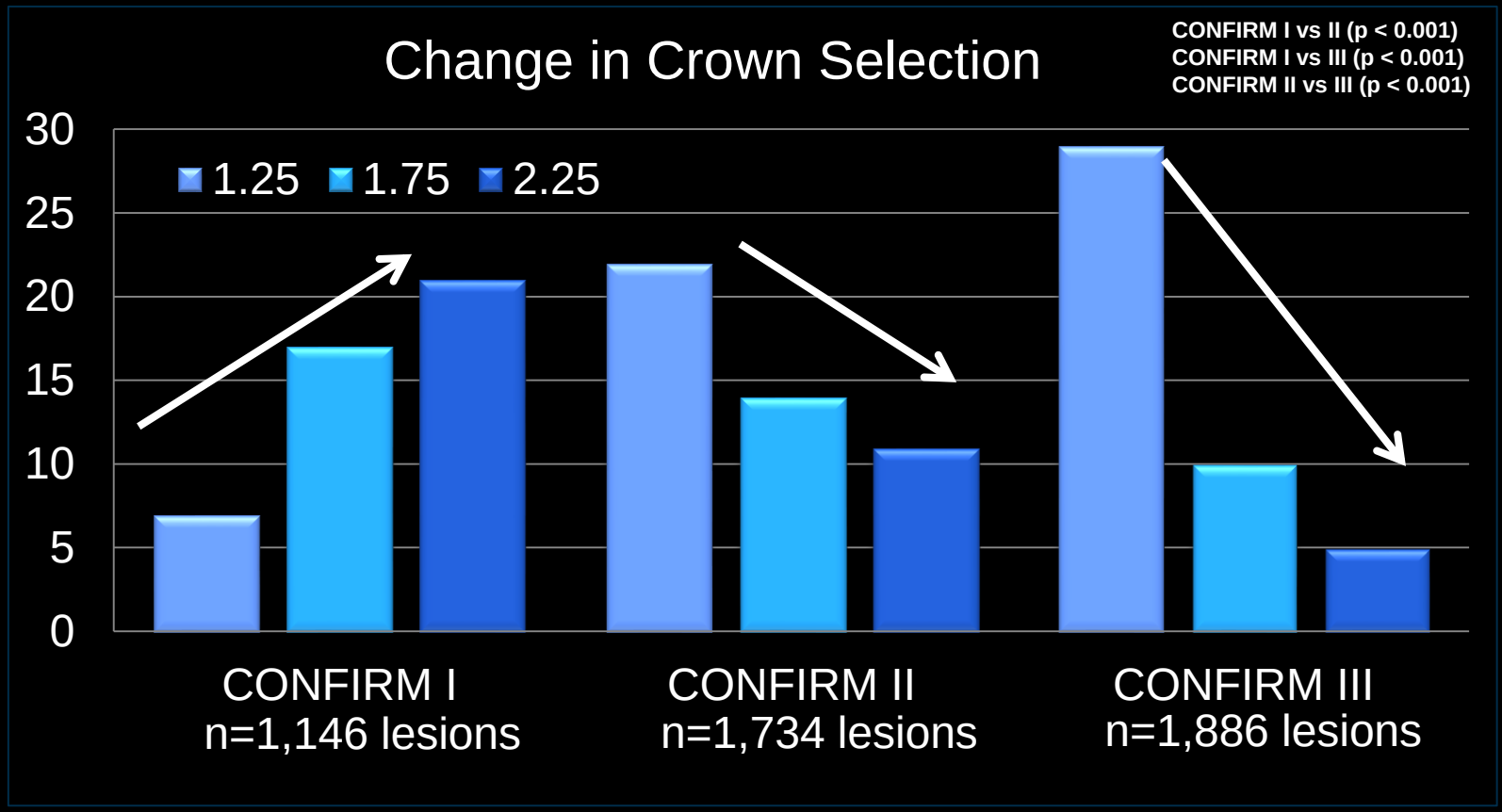


Same patency rate despite large differences in adjunctive stenting

*Patency definition: Freedom from TLR or restenosis (Peak Systolic Velocity Ratio (PSVR) ≥2.5)

Dattilo R et al *J Invasive Cardiol* 2014; 26(8): 355-360

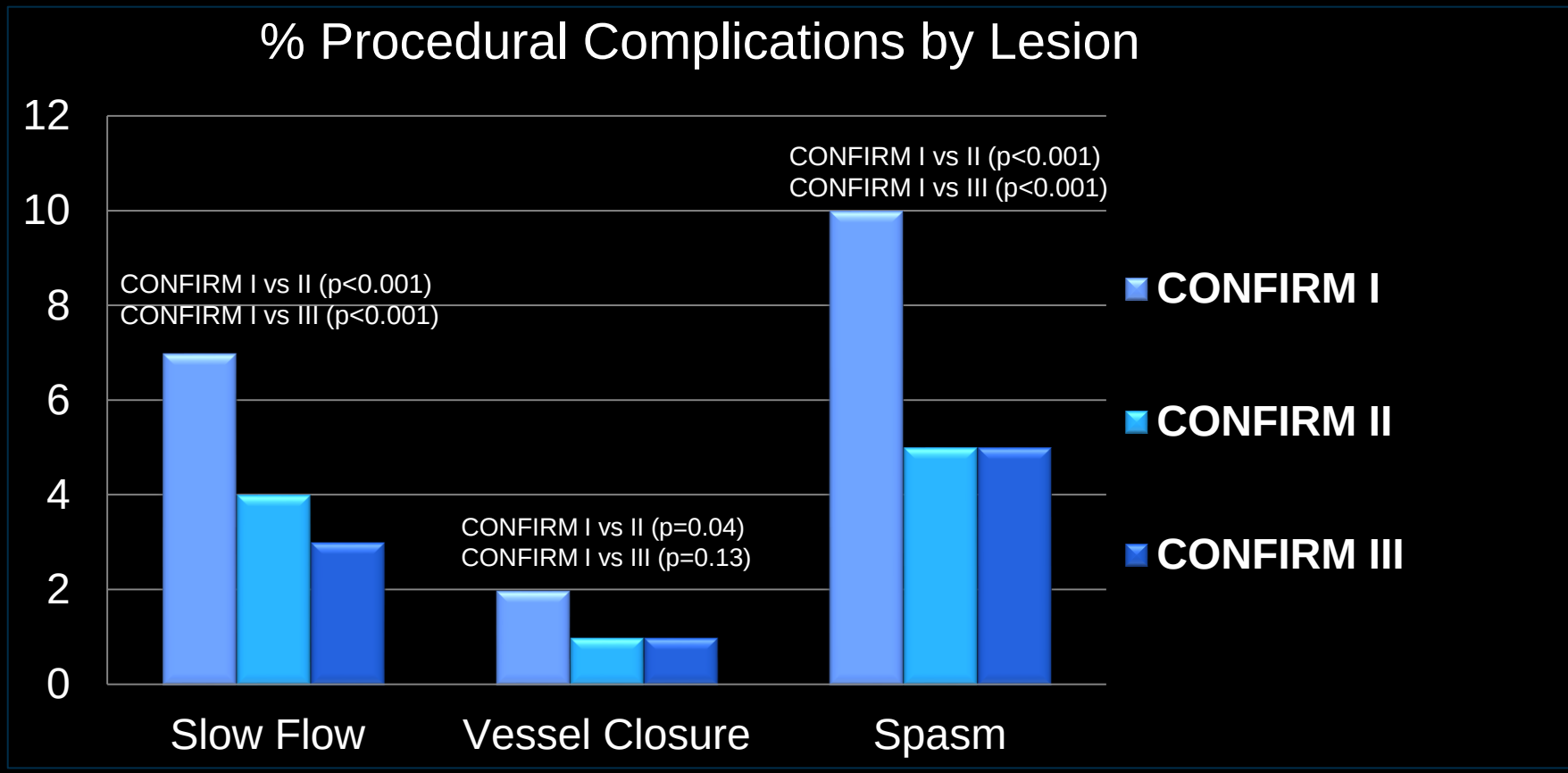
Trend to Select Smaller Crown Size Over the CONFIRM 360° Series



Prospective, multi-center, acute registries to evaluate the use of OAS in patients with infra-inguinal PAD (n=4,766 lesions)

Das T et al *Catheter Cardiovasc Interv* 2014; 83: 115-122

Improved Safety with Smaller Crowns in the CONFIRM 360° Series



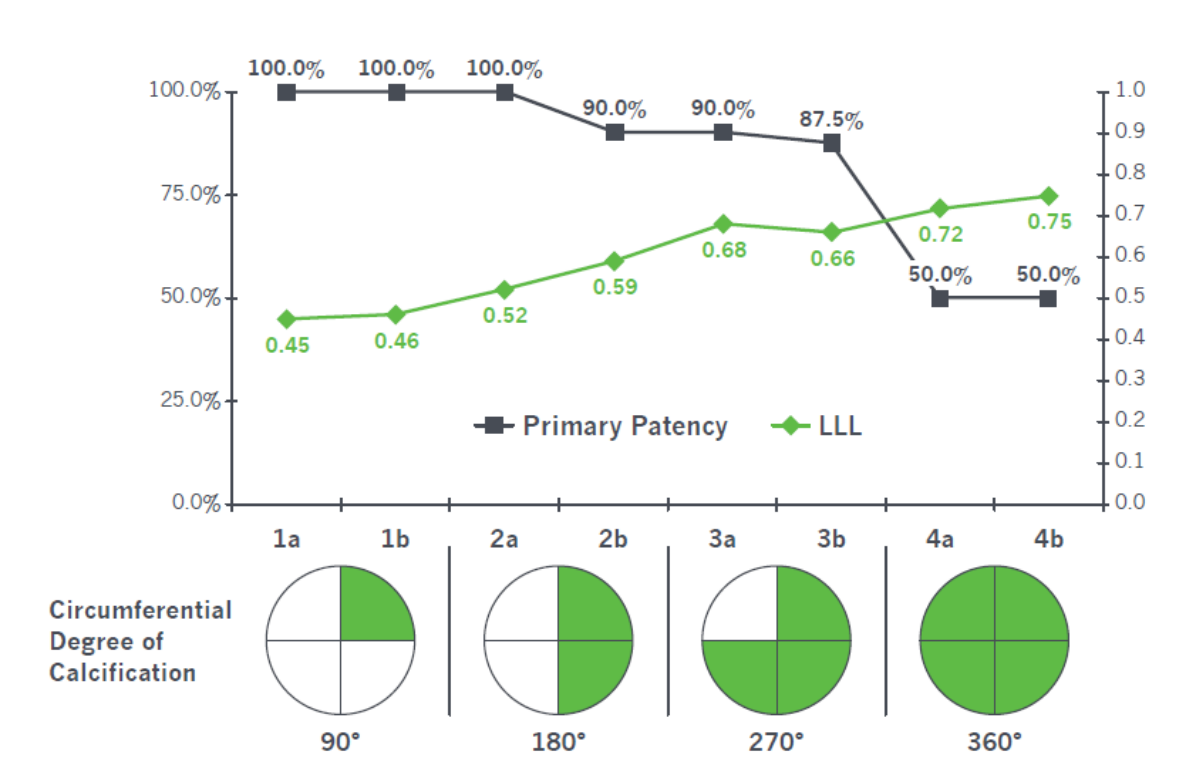
Prospective, multi-center, acute registries to evaluate the use of OAS in patients with infra-inguinal PAD (n=4,766 lesions)

Das T et al *Catheter Cardiovasc Interv* 2014; 83: 115-122

Calcium is a Barrier to Drug Absorption

Prospective 60 patient trial to assess the impact of calcium on the efficacy of DCB druing revascularization of SFA lesions.

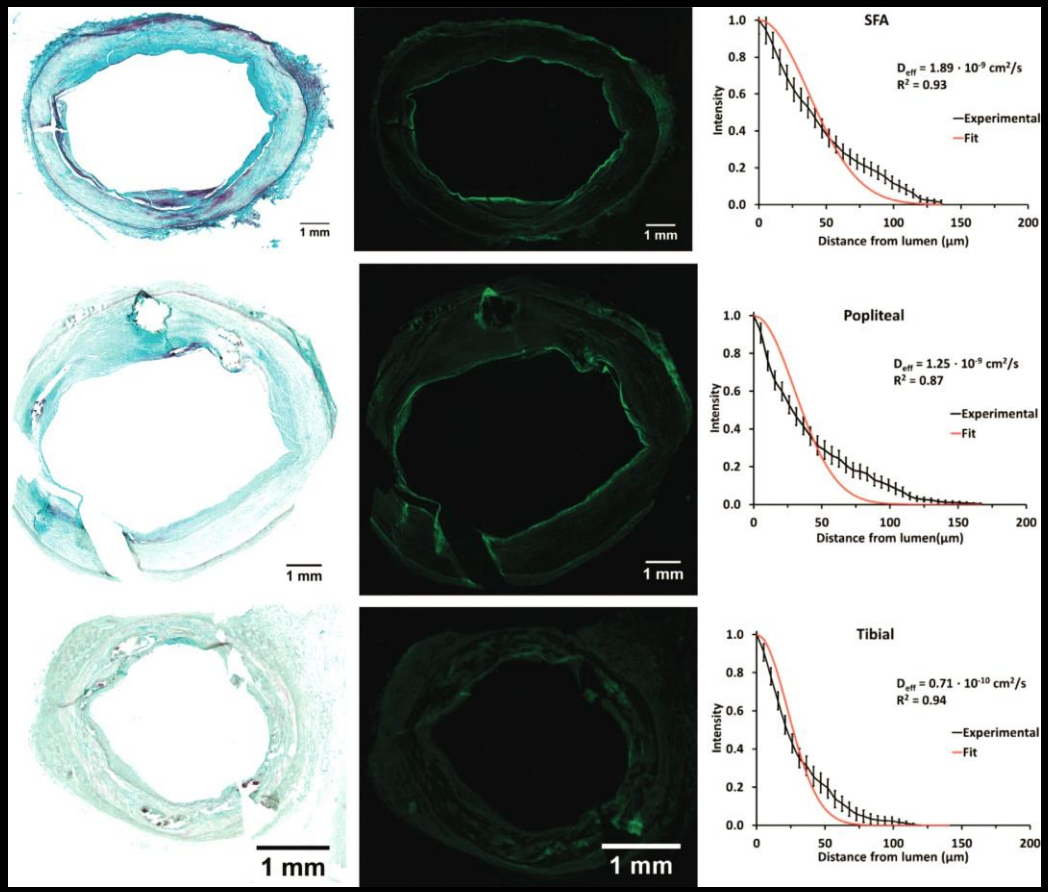
- Calcium represents a barrier to optimal drug absorption
- Late Lumen Loss increased and primary patency decreased with increasing calcium severity



As circumferential calcium increases, the effectiveness of drug-coated balloons decreases.[1]

Fanelli F et al *Cardiovasc Intervent Radiol* 2014; 37: 898-907

CSI 360 Facilitates Drug Absorption in Femoral-Popliteal Lesions



"fluorescent paclitaxel penetrated 26% deeper in OAS treated femorpopliteal segments compared to controls ($p < 0.001$)"

Tzafriri AR et al *J Controlled Release 2017;* 264: 203–210

OPTIMIZE-BTK
OAS+DCB vs. PTA+DCB in BTK Lesions

Trial Design:

- Pilot study, prospective, 1:1 Randomization
- Non-powered, hypothesis generating
- Calcified, below the knee lesions
- Study devices:
  - Peripheral Orbital Atherectomy System (Cardiovascular Systems, Inc.)
  - Lutonix® 014 Drug Coated Balloon (C.R. Bard, Inc.)
- 2-year follow-up

Active Sites:

- Austria (Prof. Brodmann/Deutschmann, Dr. Werner)
- Germany (Prof. Zeller, Prof. Tepe, Prof. Andrassy, Prof. Blessing, Prof. Scheinert)