

# **Lesion Grinding with Orbital Atherectomy Is Better**

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# Disclosures

- Research Support
  - Bard, Boston Scientific, Medtronic
- Consulting
  - Boston Scientific, Medtronic
- Speakers Bureau
  - Medtronic, Spectranetics (Philips)

# How Good is Angiography at Detecting Calcium?



Calcium?



Yes!

## Angiography Underestimates Calcium By 50%<sup>1</sup>

# Worse Outcomes For Patients With Calcified Peripheral Lesions

## Increased Adverse Events

- 74% of flow limiting dissections occur in calcium<sup>1</sup>
- Dissections significantly larger in calcified vs. non-calcified plaque<sup>1</sup>

## Decreased Balloon Success

- Vessel recoil in the presence of severe calcium<sup>3</sup>
- As circumferential calcium increases, the effectiveness of DCB decreases<sup>2</sup>

## Decreased Stent Success

- Inadequate Expansion
- Presence of calcium is predictor of stent fracture<sup>4</sup>
- 41% patency at 12 months with stent fracture<sup>5</sup>

1. Fitzgerald PJ, Ports TA, Yock PG. *Circulation*. 1992; 86(1):64-70

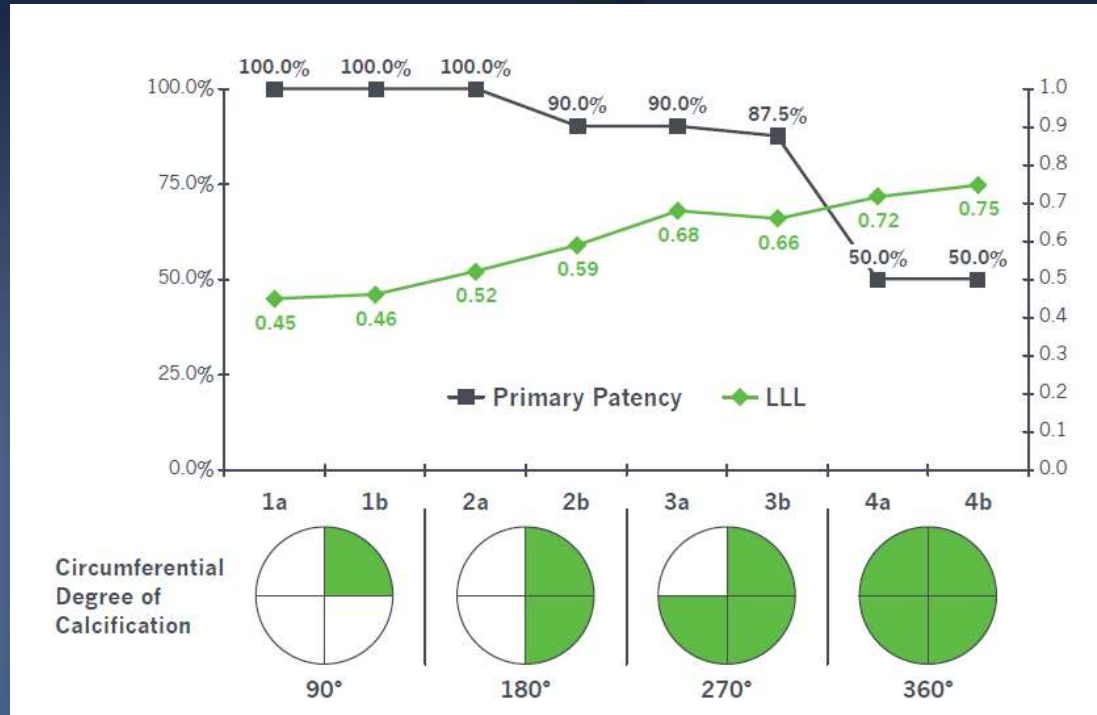
2. Fanelli, F.; Cannavale, A.; Gazzetti, M.; et al. *Cardiovasc Intervent Radiol Soc of Europe (CIRSE)*. 2014; 37:898-907.

3. Cioppa A, et al. *Cardiovasc Revasc Med*. 2012; 13:219-223.

4. Scheinert D. TCT 2008, Presentation: Calcification in the SFA: Clinical Relevance for Acute and Long-Term Outcomes and Treatment Approaches.

5. Scheinert D, Scheinert S, Sax J, *J Am Coll Cardiol.*, 2005;45: 312-315.

# Increased Calcium Severity Worsens Outcomes with DCB

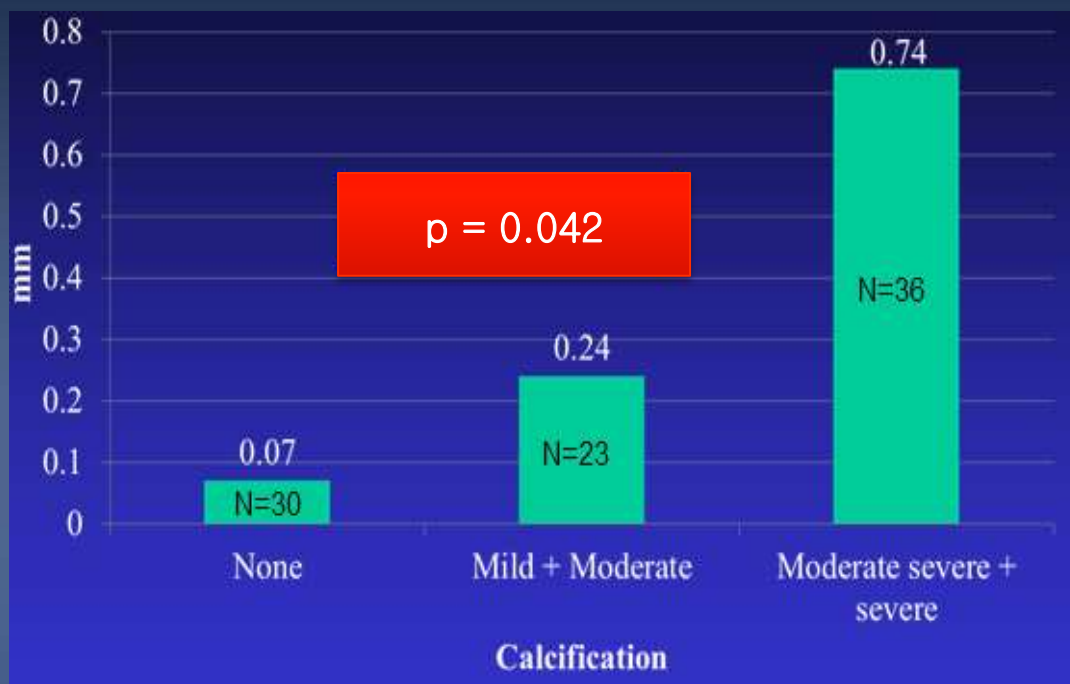


*As circumferential calcium increases, the effectiveness of drug-coated balloons decreases.<sup>1</sup>*

1. Fanelli F, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. *Cardiovasc Intervent Radiol*. 2014; 37:898-907.

# Increased Calcium Severity Worsens Outcomes

## Six Month Mean Late Lumen Loss



Retrospective  
Analysis  
91 patients  
6 month  
follow-up

*As calcium severity increases, late lumen loss at 6 months increases.<sup>1</sup>*

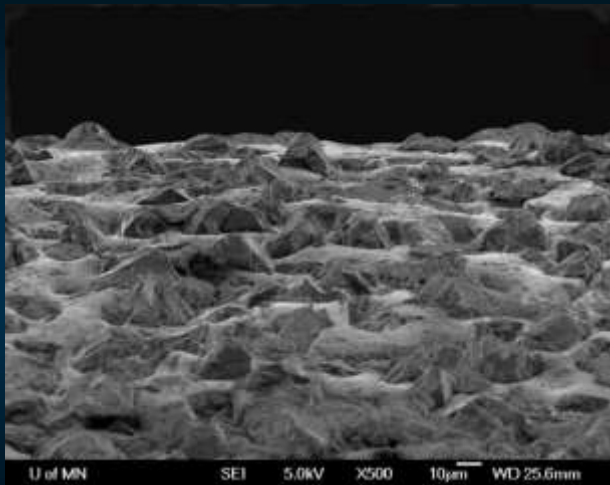
1. Tepe G. et al., Drug-Eluting Balloon Therapy for Femoropopliteal Occlusive Disease: Predictors of Outcome With a Special Emphasis on Calcium. *J Endovasc Ther.* 2015;22:727-33.

# Atherectomy in Fem-Pop Disease

- Rotational (Jetstream, Rotablator)
- Directional
- Orbital
- Laser
- Helical

# Orbital Atherectomy System (OAS)

- Asymmetric crown
- Diamond grit coated
- Creates lumen 1.75x greater than crossing profile



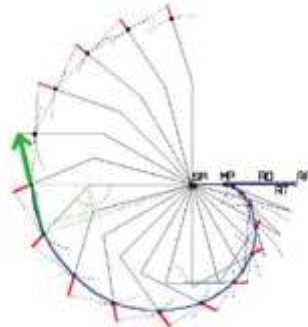


# ORBITAL TECHNOLOGY: MECHANISM OF ACTION

## DIFFERENTIAL SANDING & CENTRIFUGAL FORCE



Figure 1. The Diamondback 360° Orbital Atherectomy System eliminates plaque using a diamond-coated crown, available in two configurations — Classic Crown (shown) and Solid Crown—and a variety of sizes.



CENTRIFUGAL FORCE

$$CF = \frac{\text{mass} * \text{rotational speed}^2}{\text{radius of the orbit}}$$

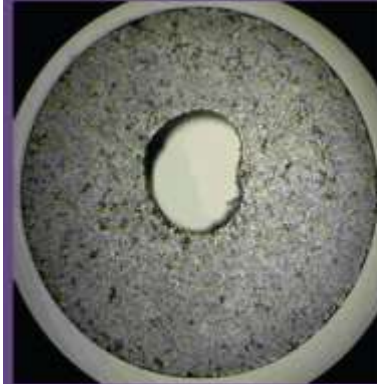
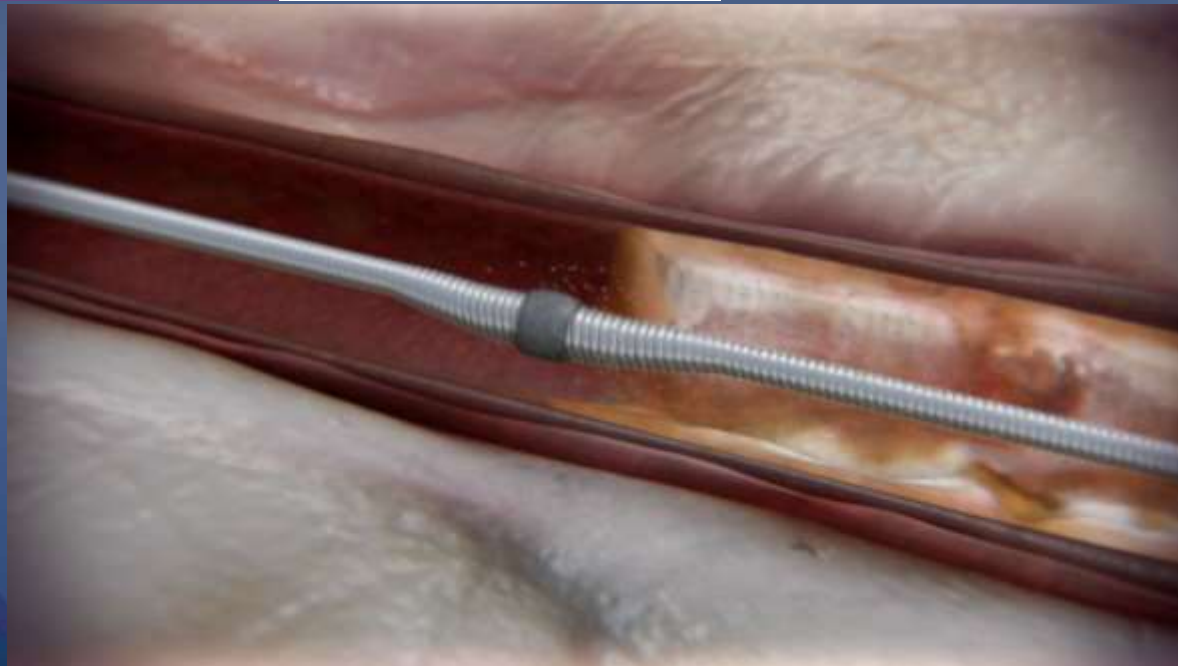


Figure 3a and 3b. The rotational speed of the Diamondback 360°, combined with the device mass ("centrifugal force"), causes the eccentrically mounted crown to "orbit", allowing creation of a progressively larger lumen.



# Goal of Orbital Atherectomy: Change Compliance >>Debulking

- **Orbital Atherectomy** with results in compliance change<sup>1,2</sup>
- **Compliance Change** enables lower-pressure balloon inflation<sup>1,2</sup>
- Compliance change and low pressure balloon inflation results in **Low Complication Rates, including Dissection**<sup>1,2</sup>

1. Shammass NW, et al. Comparison of orbital atherectomy plus balloon angioplasty vs. balloon angioplasty alone in patients with critical limb ischemia: results of the CALCIUM 360 randomized pilot trial. J Endovasc Ther. 2012 Aug;19(4):480-8.
2. Dattilo R, et al. The COMPLIANCE 360° Trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. J Invasive Cardiol. 2014 Aug;26(8):355-60.

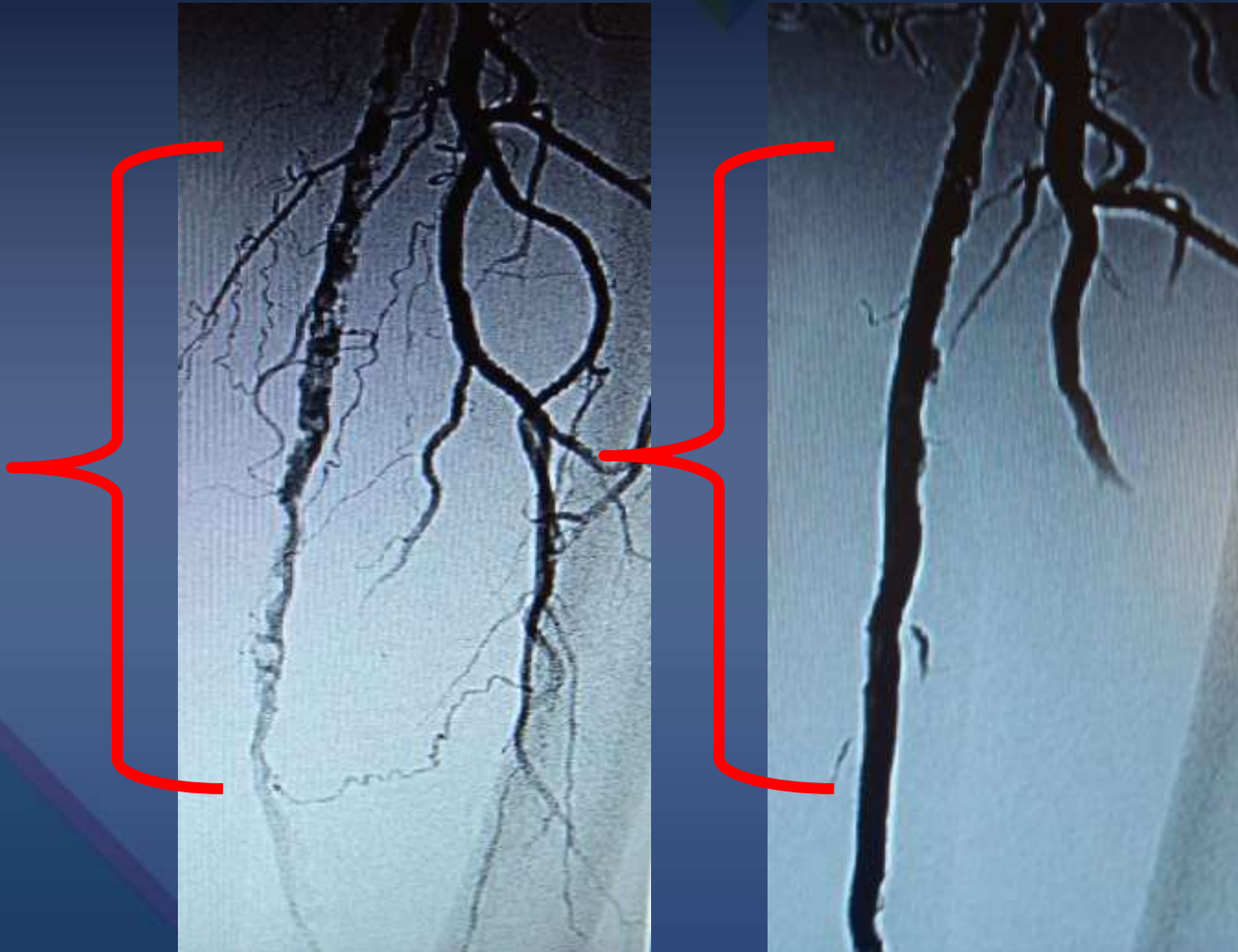
- What is the Unique Role of Orbital Atherectomy?
- Severe Diffuse Intraluminal Calcium

# Severely Calcified Disease – Right SFA stenosis

2.0 Solid Crown



# SFA Diffuse Disease With Intraluminal Calcium

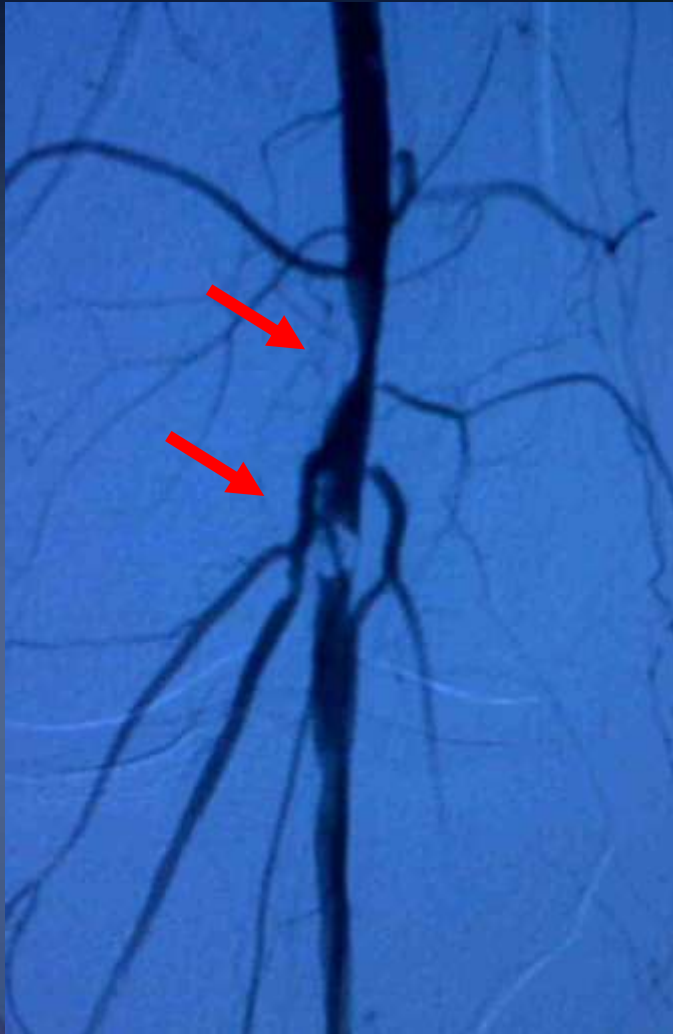


## Initial Angio

## 2.0 Classic Crown and PTA



**Popliteal (focal 99%)**



**Post 2.0 Solid**



# Popliteal Occlusion



# Stealth 360

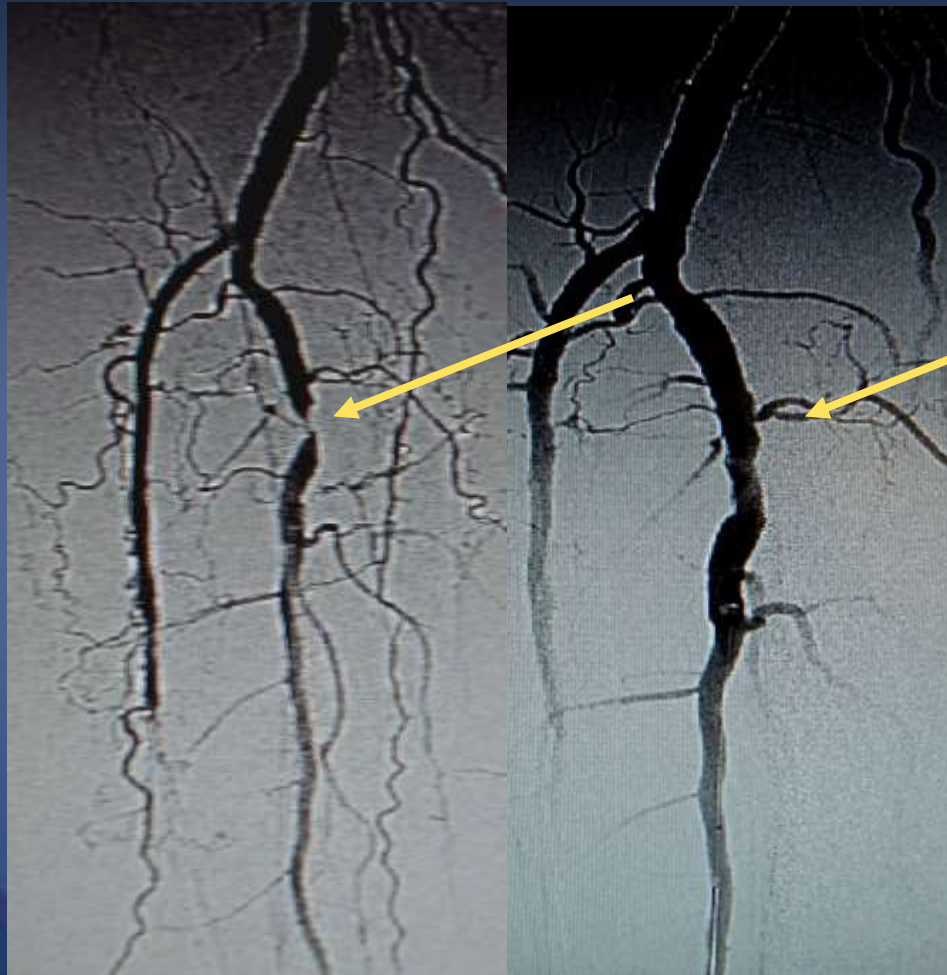


# Post





# TP Trunk with 1 vessel runoff

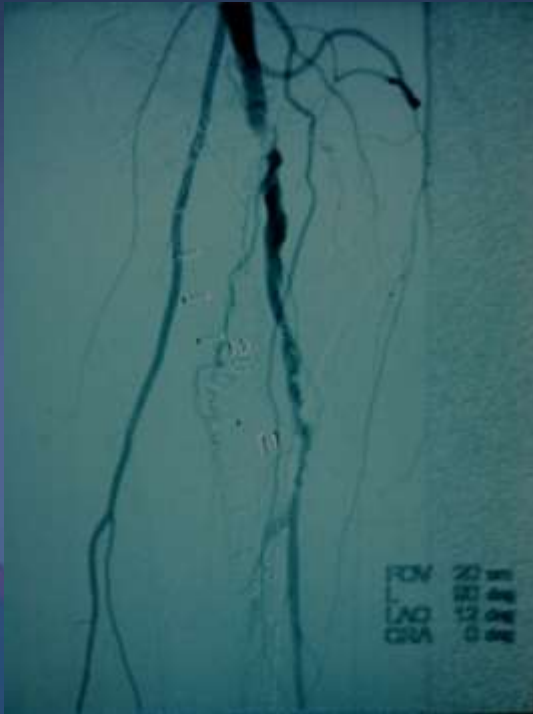


2.0 Classic Crown

**PRE**

**2.0 Stealth in Popliteal**

**POST**



# Completed Prospective Peripheral Studies Focused On Calcified Lesions

Study Name	Number Patients	# of Lesions	% BTK	% DM	Renal Insufficiency	Severe, Moderate Calcium
OASIS <sup>1</sup>	124	201	86%	55%	11%	55%
CONFIRM I <sup>2</sup>	733	1146	36%	61%	36%	76%
CONFIRM II <sup>2</sup>	1127	1734	30%	60%	37%	82%
CONFIRM III <sup>2</sup>	1275	1886	41%	59%	35%	83%
CALCIUM 360 <sup>3</sup>	50	64	100%	64%	24%	*93%
COMPLIANCE 360 <sup>4</sup>	50	65	0%	56%	N/R	*82%
TRUTH <sup>5</sup>	25	29	7%	72%	24%	90% <sup>7</sup>
LIBERTY 360 <sup>6</sup>	1204	1503	52% <sup>8</sup>	61%	35%	44% <sup>9</sup>

\*OAS arm

**OASIS:**

**CONFIRM SERIES:**

**CALCIUM 360:**

**COMPLIANCE 360:**

**TRUTH:**

**LIBERTY 360:**

**IDE Study**

**Real World, Complex Patients, No Exclusion Criteria**

**BTK Head-to-Head Trial Comparing OAS+PTA and PTA alone**

**ATK Head-to-Head Trial Comparing OAS+PTA and PTA alone**

**ATK IVUS Analysis**

**Real World, All-Comers, All-Treatment Options PAD Study**

1. Safian RD, et al. Catheter Cardiovasc Interv. 2009;73(3):406-12.
2. Das T, et al. Catheter Cardiovasc Interv. 2014;83(1):115-22. CSI Data on File.
3. Shammam NW, et al. J Endovasc Ther. 2012;19(4):480-8.
4. Dattilo R, et al. J Invasive Cardiol. 2014;26(8):355-60.
5. Babaev A, et al. Vasc Endovascular Surg. 2015;49:188-94.

6. ClinicalTrials.gov NCT01855412; Adams et al. The LIBERTY Study Design. American Heart Journal. 2016;174:14-21. The LIBERTY study is ongoing; subjects will be followed for up to 5 years.
7. Calcified (severity not specified)
8. 13% of lesions located ATK + BTK
9. Grade 3 or 4 in PACSS

# Safety Profile In Peripheral Calcified Lesions

	OASIS <sup>1</sup> n = 201	CONFIRM I Diamondback <sup>2</sup> n = 1146	CONFIRM II Predator <sup>2</sup> n = 1734	CONFIRM III Outflow <sup>2</sup> n = 1886	CALCIUM <sup>3</sup> n = 29	COMPLIANCE <sup>4</sup> n = 38
Mean Max Inflation Pressure (atm)	N/R	5.7	5.4	5.9	5.9	4.0
Bail-out Stent due to complications	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%

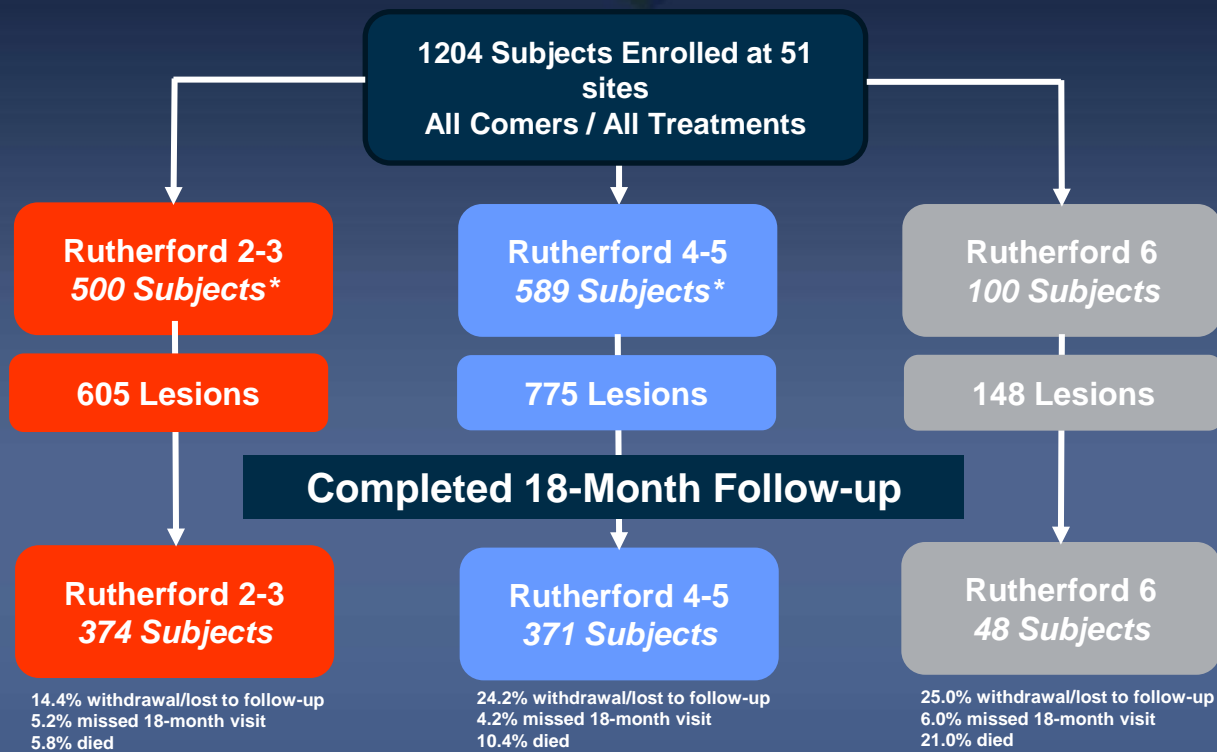
**In real-world patient populations AND the challenging lesions orbital atherectomy demonstrated successful lesion modification while maintaining low rates of procedural adverse events.**

1. Safian RD, et al. Catheter Cardiovasc Interv. 2009;73(3):406-12.
2. Das T, et al. Catheter Cardiovasc Interv. 2014;83(1):115-22. CSI Data on File.
3. Shammam NW, et al. J Endovasc Ther. 2012;19(4):480-8.
4. Dattilo R, et al. J Invasive Cardiol. 2014;26(8):355-60.

## LIBERTY 360:

Procedural and 18–Month Outcomes of Endovascular Device Intervention in Patients with Symptomatic Lower Extremity PAD

# Enrollment and 18-Month Follow-up



*\*Due to site closure and lack of PI signature, baseline & procedure data from 15 subjects were excluded. Rutherford 2, N=97; Rutherford 3, N=403; Rutherford 4, N=285; Rutherford 5, N=304. Core Lab reported lesions. 30-Oct-2017 Data*

# Subanalysis: Orbital Atherectomy (OAS)

## 18-Month Freedom from MAE and Amputation Free Survival

High freedom from MAE in all groups with similar MAE outcomes in RC4-5 and RC6. High freedom from major amputation in all Rutherford Classes (RC2-3, 100%; RC4-5, 95.3%; and RC6, 91.3%).

### 18-Month Freedom from MAE – OAS

#### Rutherford 2-3

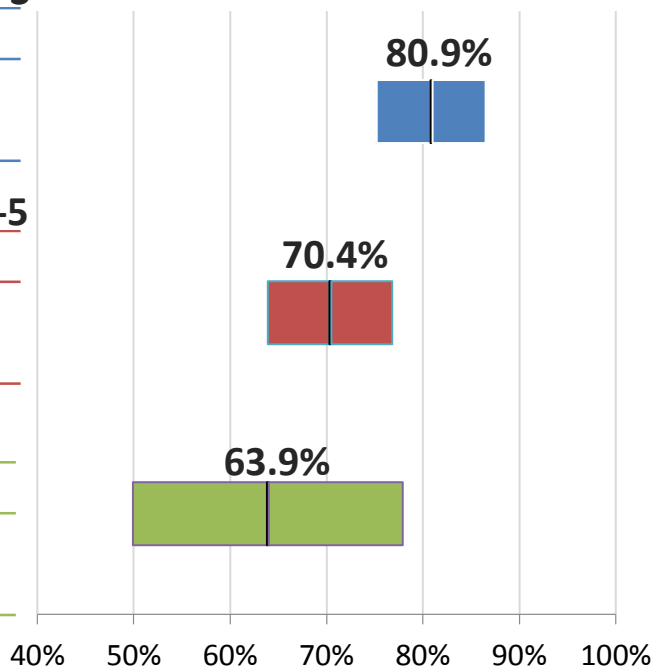
At Risk	127
Events	36
Censored	51

#### Rutherford 4-5

At Risk	97
Events	59
Censored	77

#### Rutherford 6

At Risk	25
Events	17
Censored	14



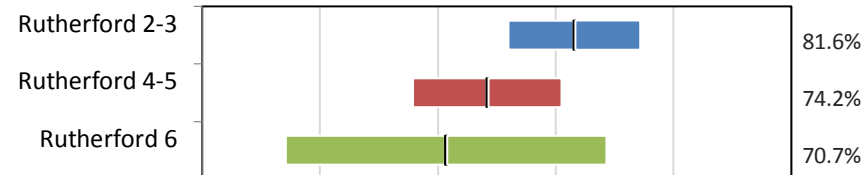
18 Month	RC2-3 vs. RC4-5		RC2-3 vs. RC6		RC4-5 vs. RC6	
	Hazard Ratio	P	Hazard Ratio	P	Hazard Ratio	P
MAE	0.56 [0.37, 0.84]	0.006	0.46 [0.26, 0.81]	0.008	0.82 [0.48, 1.41]	0.479

MAE rate differences assessed via Cox Proportional Hazards model [MAE: Death to 30 days, Major amputation, TVR]. Kaplan-Meier method used to obtain estimate rates. Greenwood's method used to obtain the 95% confidence interval for the estimate.  
30-Oct-2017 Data

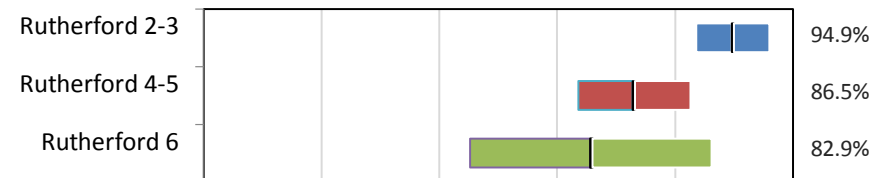
### FF Major Amputation 18-Month Rates – OAS



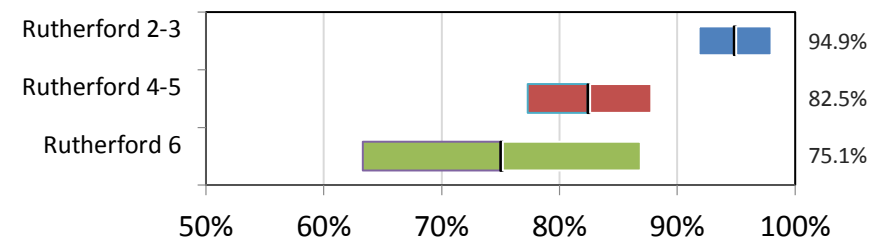
#### FF TVR



#### FF All Death\*



#### Amputation Free Survival



FF = Freedom From. \* All Death rate shown here is at 18 months, but the Freedom from MAE (shown on left) only includes death within 30-days of the procedure. Amputation free survival defined as freedom from death and target limb major amputation.

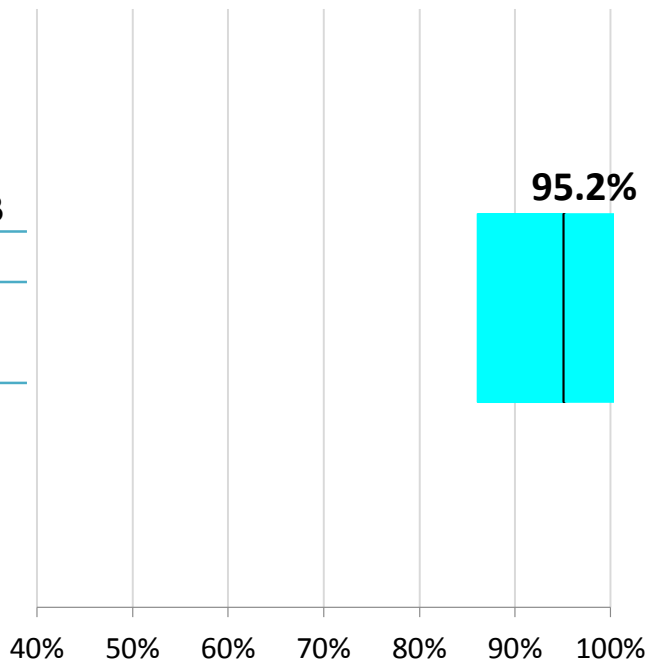
# Subanalysis: OAS+DCB

## 12 Month Freedom from MAEs

For vessel prep with OAS prior to DCB therapy, high freedom from MAE (95.2%) at 1 year with no major amputations reported.

### 12 Month Freedom from MAE – OAS+DCB

OAS + DCB	
At Risk	17
Events	1
Censored	6



### 12 Month Freedom from Rates – OAS+DCB

#### FF Major Amputation

No events

100%

#### FF TVR

95.2%

#### FF All Death\*

95.0%

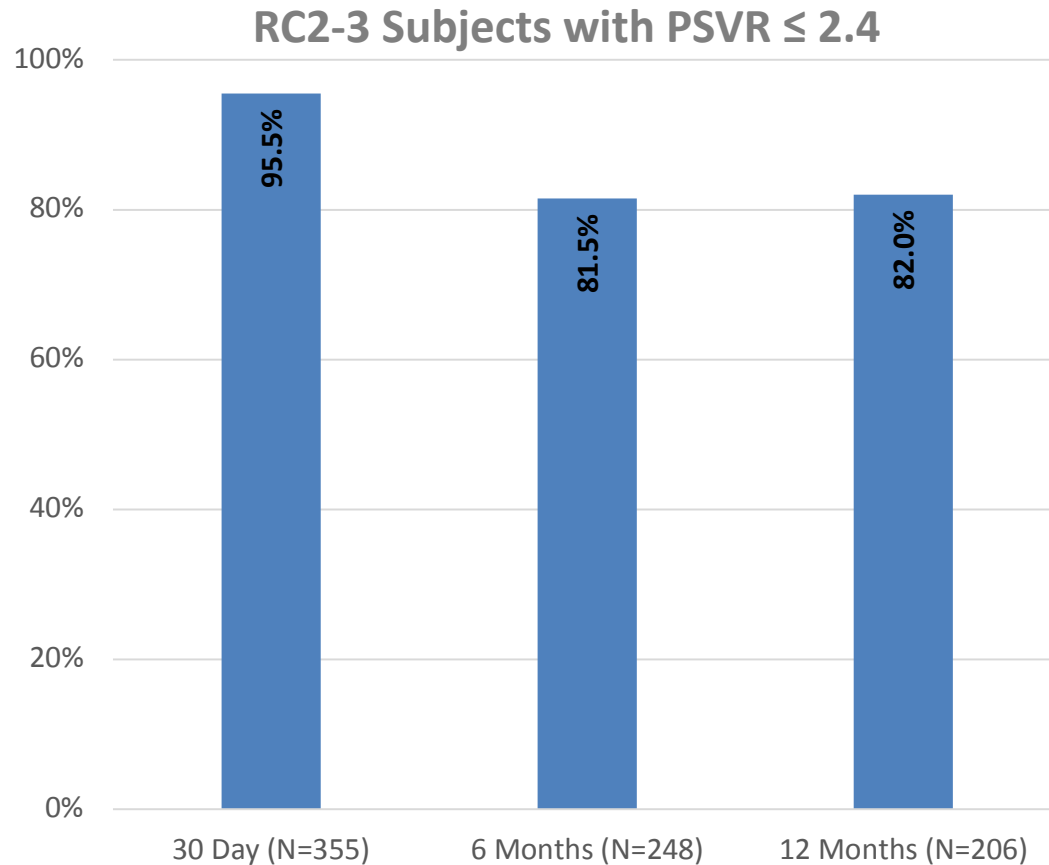
FF = Freedom From. \* All Death rate shown here is at 12 months, but the Freedom from MAE (shown on left) only includes death within 30-days of the procedure.

On-label DCB use only. Of subjects treated with OAS prior to DCB: 61.9% in RC2-3; 28.6% in RC4-5, 9.5% in RC6.  
 MAE: [Death to 30 days, Major amputation, TVR]  
 Kaplan-Meier method used to obtain estimate of freedom from MAE.  
 Greenwood's method used to obtain the 95% confidence interval for the estimate.  
 30-Oct-2017 Data



# 12 Month Duplex Ultrasound (DUS)

High long-term patency rate in RC2-3 subjects.



Duplex Ultrasound was not performed at 18 months as the visit was conducted over the telephone  
VasCore Core Lab Assessed (Patients with reported values may be less than total number of patients enrolled in each arm).  
DUS required only for RC2-3 Subjects  
At baseline, previous Peripheral Vascular Intervention on target limb in 30% of RC 2-3 subjects  
30-Oct-2017 Data

# Conclusion

- Orbital Atherectomy is safe and effective
- Mechanism of action is differential sanding which results in improved vessel compliance
- Well suited for several types of infrainguinal disease
- Has unique advantages in severe diffuse intraluminal calcific disease