28th Annual Scientific Congress

VIRTUAL

3 – 5 July 2020

Hong Kong College of Cardiology

Allied Cardiovascular Health Professional Symposium

New Tools for Calcified Coronary Lesions Part II: Coronary Orbital Atherectomy System

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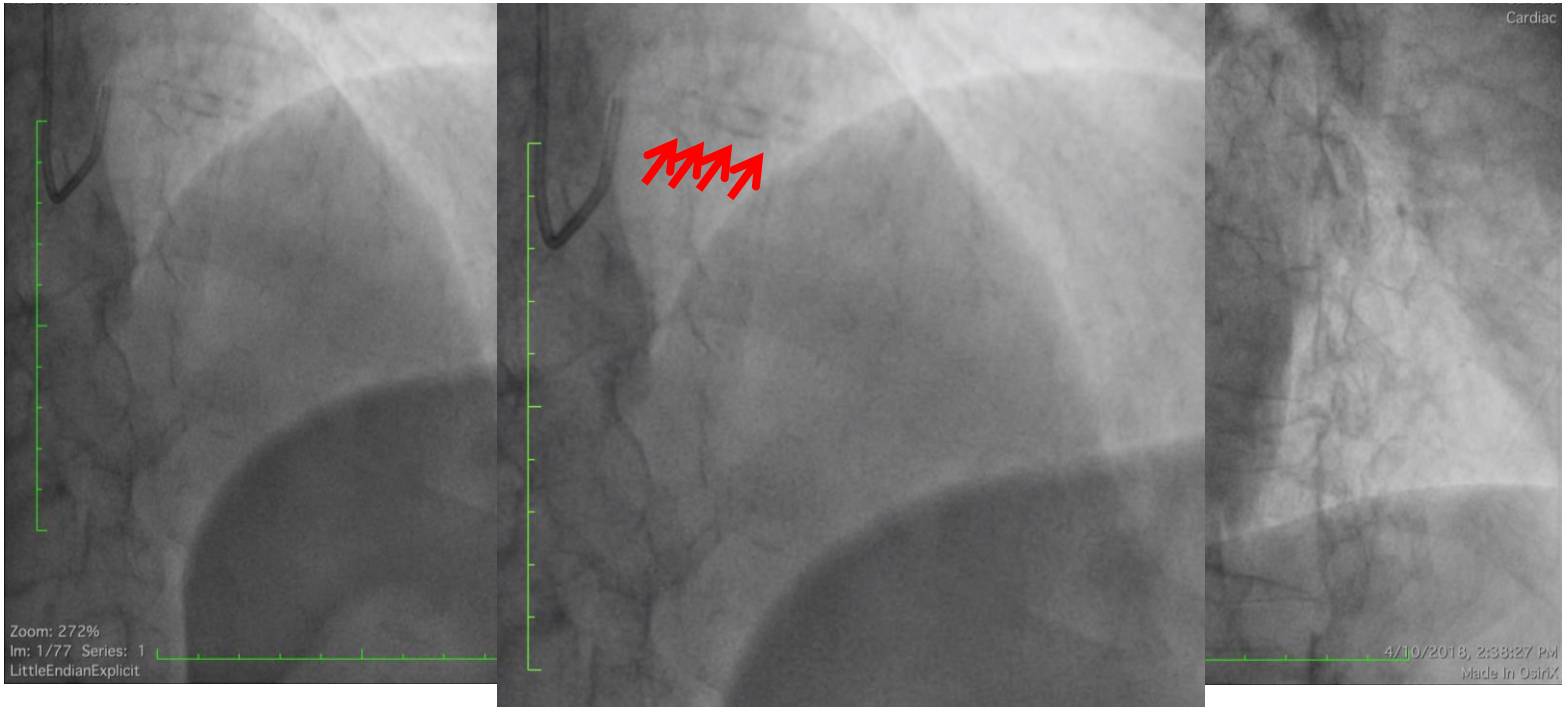
Our case

- 76/F
- Hx of DM, HT, hyperlipidemia
- Stable angina with positive Thallium perfusion scan over anterior wall
- Echo showed LVEF 50-55%, hypokinetic anterior and anteroseptal wall, mild to moderate MR, mild AR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Coronary calcification
- Why is it important?

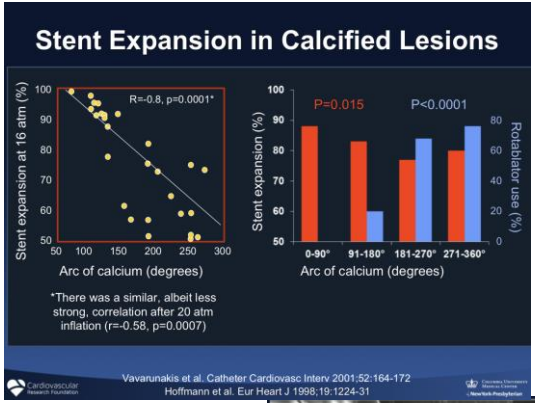
Frequency of angio core lab moderate-severe calcification in 13 DES studies

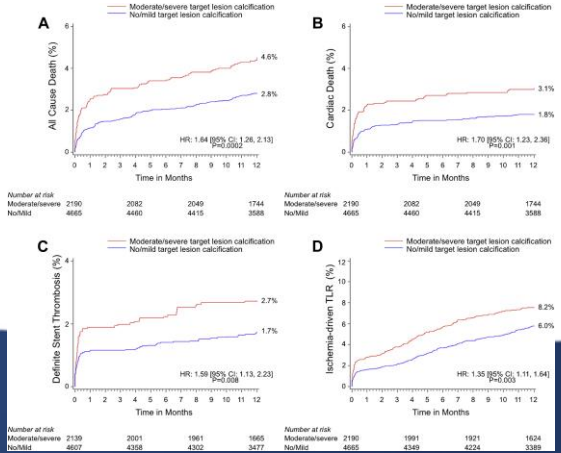
(despite being an exclusion criterion in most studies)

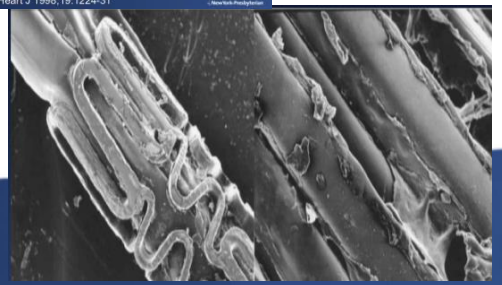
RAVEL	23.3% (27/116)
SIRIUS	17.1% (91/531)
E-SIRIUS	16.1% (28/174)
C-SIRIUS	12.0% (6/50)
TAXUS IV	18.3% (121/660)
TAXUS V	32.5% (185/570)
TAXUS VI	29.7% (65/219)
ENDEAVOR II	23.7% (140/590)
ENDEAVOR III	17.9% (78/436)
ENDEAVOR IV	33.2% (513/1546)
SPIRIT II	31.4% (91/290)
SPIRIT III	27.8% (277/997)
COMPARE	38.5% (693/1799)
Pooled	**29.0% (2,315/7,978)**

Impact of heavy calcification

- Difficult stent delivery, risks of stent under-expansion
- May abrade polymers off DES
- Increase procedural complications
- Increase long-term event rates

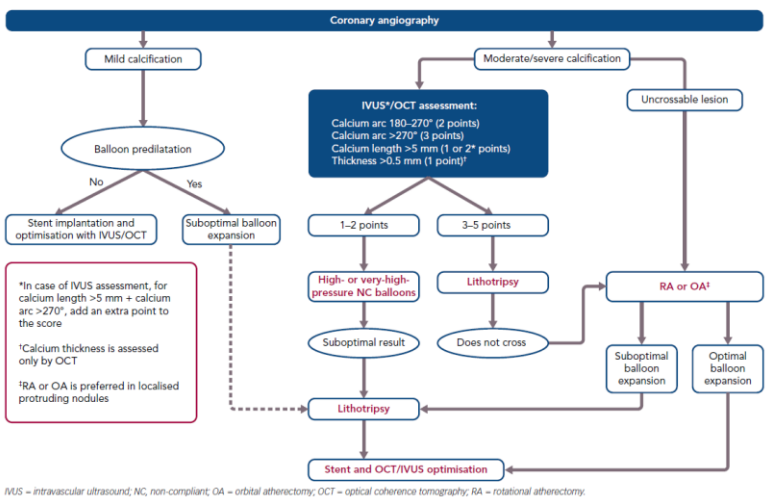




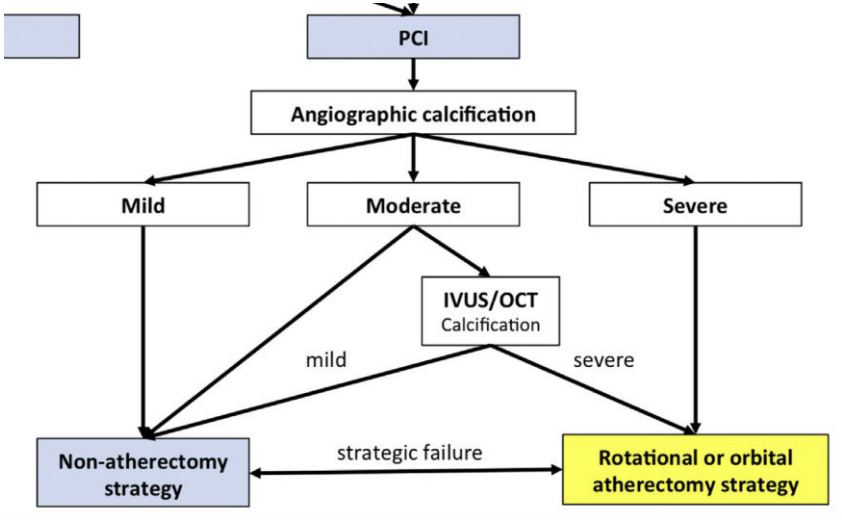


Approach for calcified lesion

Figure 2: Decision Algorithm for the Treatment of Calcified Coronary Lesions



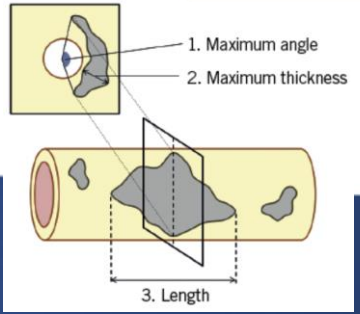
Interventional Cardiology Review 2019;14(3):154–63.

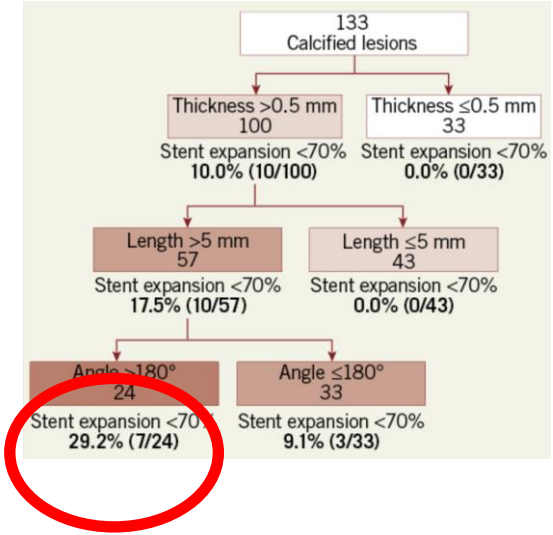


JACC CV Intervention; 2014: 345-353

How to definite severe calcification?

OCT-based calcium score		
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points	
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point	
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point	
Total score	**0 to 4 points**	

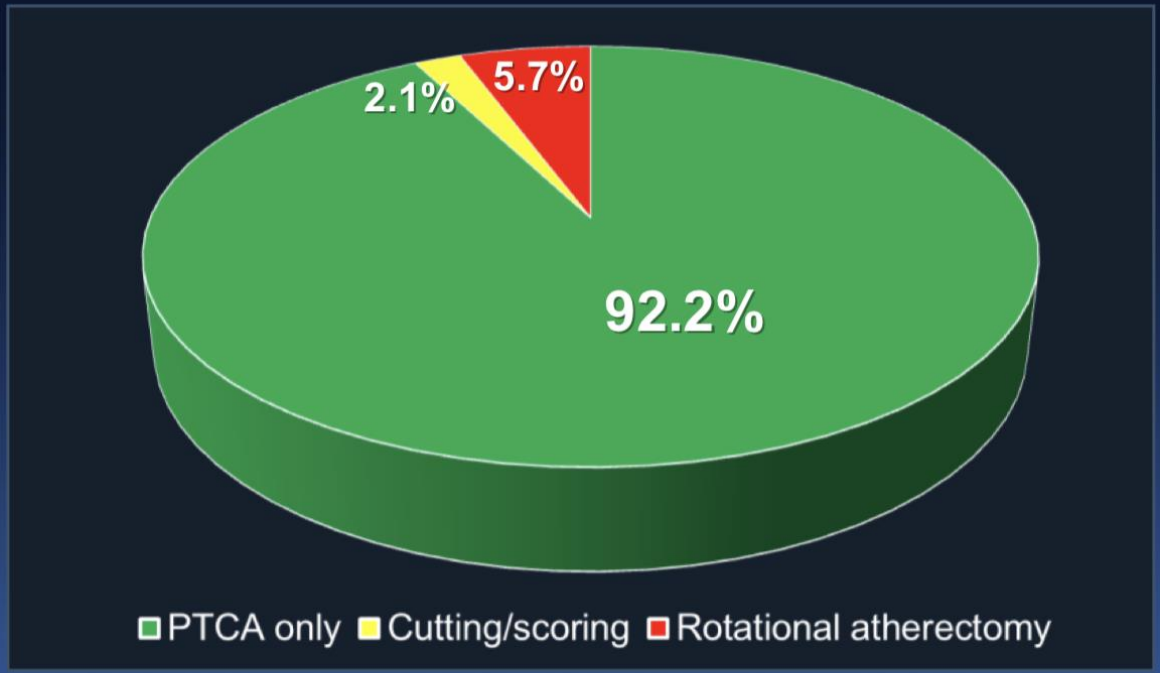




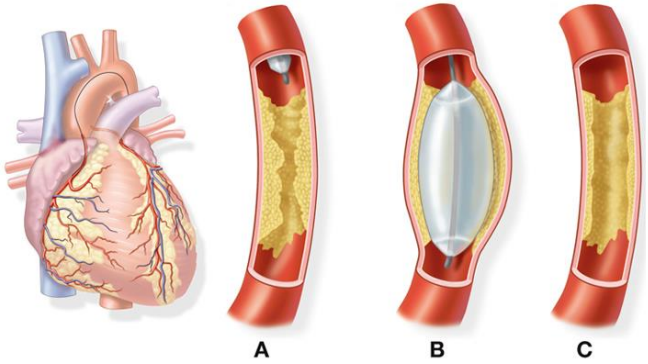
A Fujino, G Mintz, et al. EuroIntervention 2018; 13:e2182-23189

ADAPT-DES (11 center all-comers registry):
Calcified lesion preparation

N = 2,644 patients



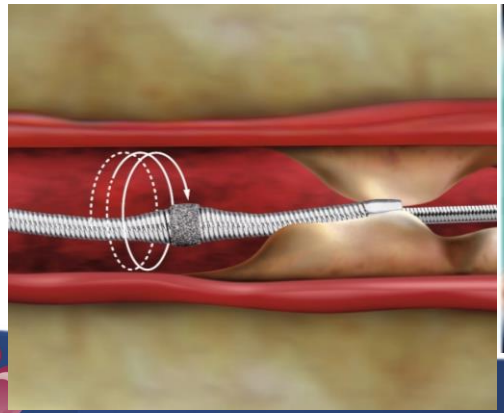
Généreux et al. Int. J. Cardiol 2017


A
B
C

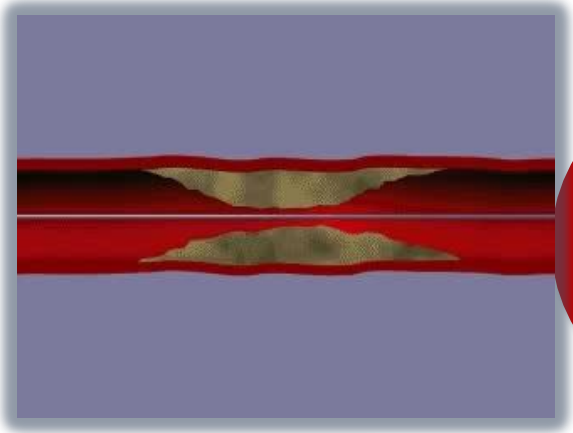

Cutting Balloon Ultra

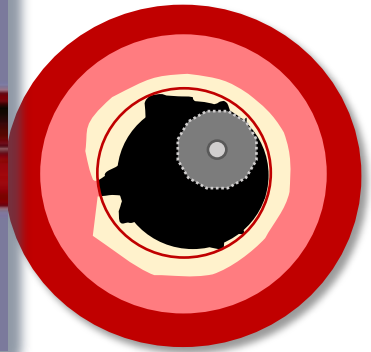

Angiosculpt

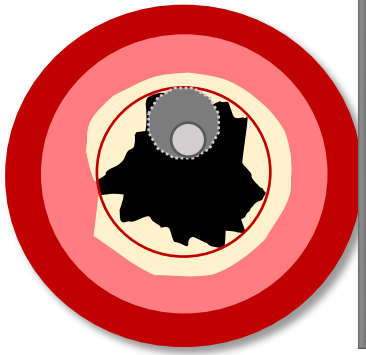

Flextome Cutting Balloon

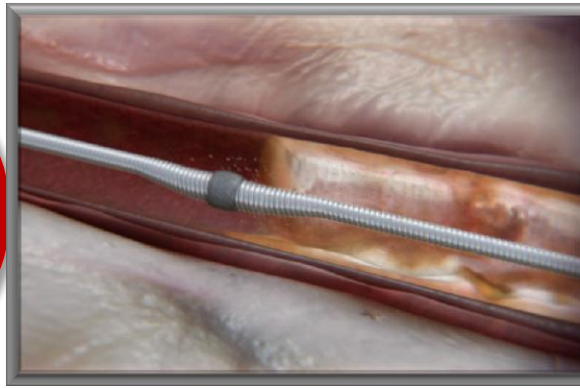


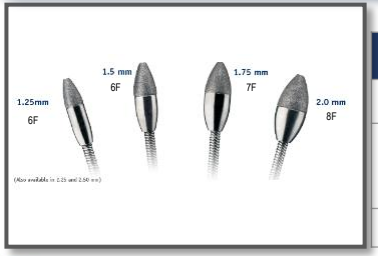
Atherectomy: Two Approaches



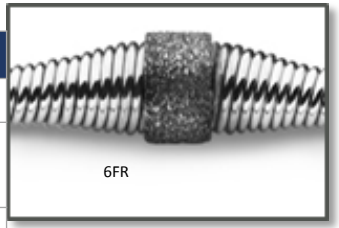








Rotational Atherectomy	Orbital Atherectomy
Uni-directional, front cutting, risk burr entrapment	Bi-directional differential sanding and pulsatile forces
Concentrically mounted burr rotates to create a lumen same size as the burr, larger vessels may require multiple burrs.	Eccentrically mounted crown creates centrifugal force: • Designed to treat 360° of the vessel for improved compliance • Treat 2.5 mm to 4 mm vessel with a single crown



Orbital Atherectomy System: Diamondback360

Device Features
- Easy setup and use <2 mins
- Control of device in operating field
- Compatible with 6 Fr approach

OAS Pump
- Mounts directly on to an IV pole
- Provides power
- Delivers fluid
- Includes saline sensor

0.012" Viper Wire Advance®

ViperSlide® Lubricant
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline

Power on/off switch
- 8cm axial travel

On-handle speed control
- Low (80K) and High Speed (120K)
- GlideAssist® (5K) for easier tracking & removal of OAD

Electric motor powered handle

Ecc

ViperSlide® Lubricant

- ViperSlide® reduces friction within the OAD
- 20 ml ViperSlide® per liter of saline

Ingredient	Amount
Soybean Oil	10%
Egg Yolk Phospholipids	1.2%
Glycerin	2.25%
Sodium Hydroxide (pH range is 6.0 to 8.9)	Quantity Sufficient
Water for Injection	Quantity Sufficient

OAS Pump

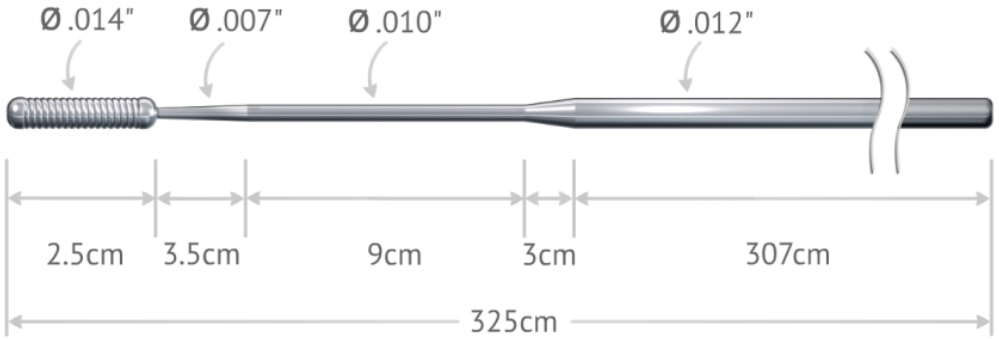
Designed to allow continuous flow of blood and saline during orbit.
Potentially minimizes thermal injury and decreases no-reflow
and cardiac enzyme elevation

Flow Rates (ml/min)*

- OAD not spinning,
  prime button pressed: 30 - 36
- Not spinning: 17 - 19
- Spinning low: 20 - 34
- Spinning high: 17 - 29

VIPERWIRE Advance® Coronary Guide Wire

- 325 cm long guide wire
- 25 mm long spring tip
- Spring tip stiffness: 1.4 grams force at 10 mm



Images are not to scale.

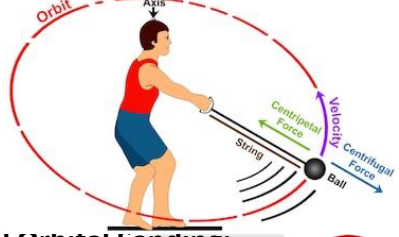
DIAMONDBACK 360° CORONARY OAS CLASSIC CROWN FEATURES

Simple OAD setup

Electric powered handle with millisecond feedback

Demonstration of Physics and Performance

High speed video (1200 fps) show Classic Crown in orbit at high speed (120k rpm)



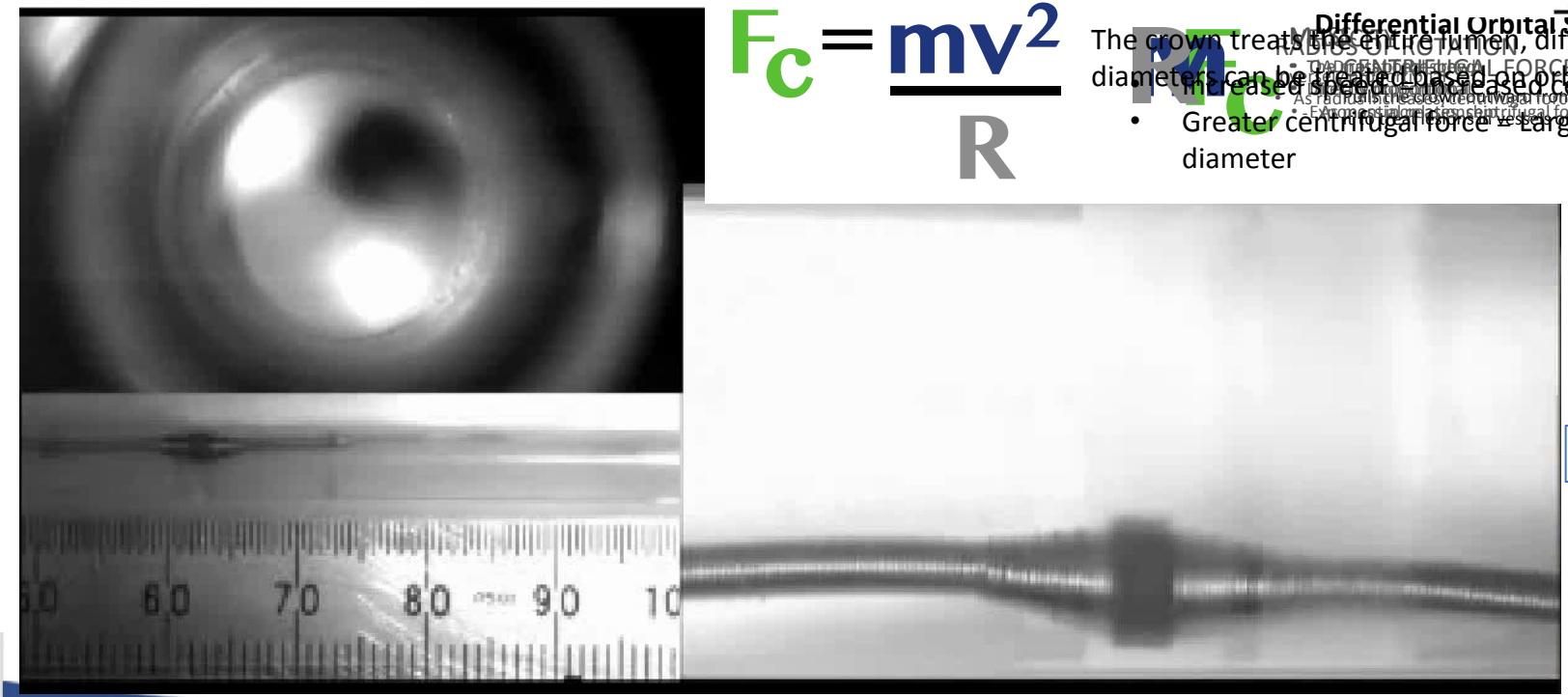
$$F_c = \frac{mv^2}{R}$$

The crown treats the entire lumen, different vessel diameters can be treated based on orbiting speed

- Greater centrifugal force = Larger orbital diameter

Differential Orbital Sanding:

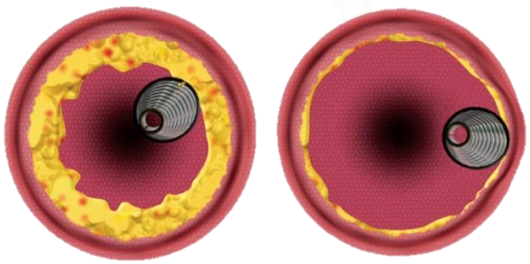
- Increase of speed increased centrifugal force



1.25 mm Classic Crown orbiting in a 3 mm glass tube at 120k rpm

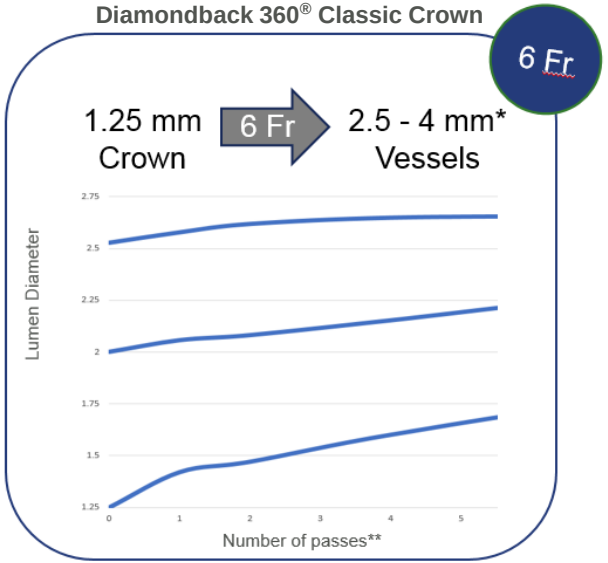
Crown orbiting to tube diameter

ORBITAL ATHERECTOMY



Advantage of eccentrically mounted, orbiting crown:

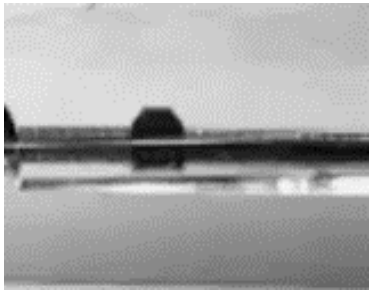
- Single **1.25mm crown (6F) treats 2.5 to 4.0mm** vessels
- Orbiting crown **enables constant blood flow** and reduces heat
- **Bi-directional treatment** can reduce passes



OAS Orbit curve data represented is from testing using a carbon block model system with Classic Crown

1. Data on file.
2. *Based on minimum reference vessel diameter as determined by orbit testing in a carbon block model system

GLIDE ASSIST FEATURE



No orbiting observed in glide mode

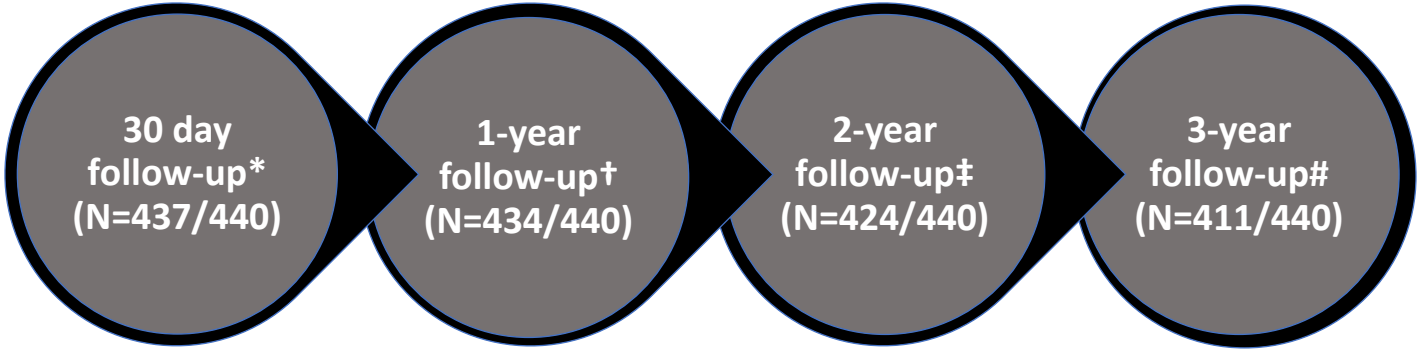
- Glide Assist feature: slow spinning at 5K RPM’s to reduce guidewire friction

ORBIT II

Prospective, multi-center trial in the United States

Single arm - As there were no FDA-approved percutaneous treatments specifically for patients with severely calcified coronary lesions.

443 subjects enrolled at 49 U.S. Sites



Primary Safety Endpoint: MACE (MI= CK-MB>3x ULN, TVR, Cardiac Death)

Primary Efficacy Endpoint: Procedural Success

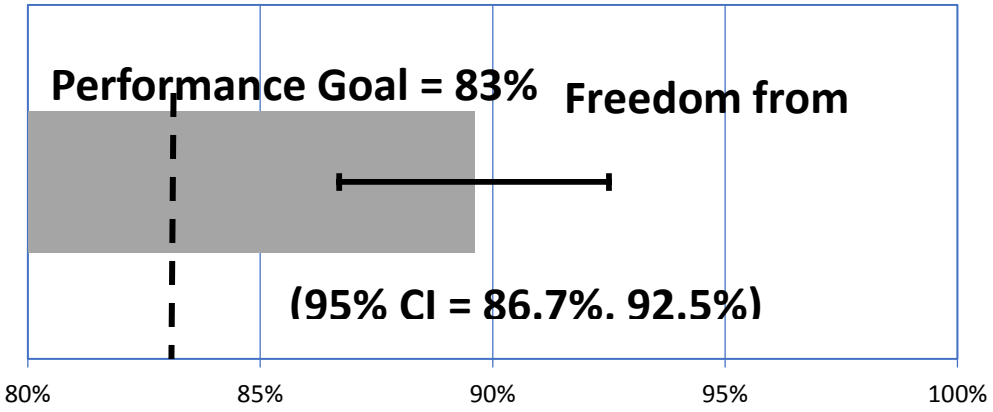
- Success in facilitating stent delivery with a final residual stenosis of <50% (as determined by Angiographic Core Lab) and free from in-hospital MACE

ORBIT II: Primary Safety Endpoint

Prospective, single arm, multi-center trial to evaluate the safety and efficacy of OAS to prepare de novo, severely calcified coronary lesions for enabling stent placement (N=443)

30 Day MACE Rate Components:

MI (CK-MB >3x ULN):	**9.7%**
Non Q-wave	8.8%
Q-wave	0.9%
TVR/TLR:	**1.4%**
Cardiac death:	**0.2%**



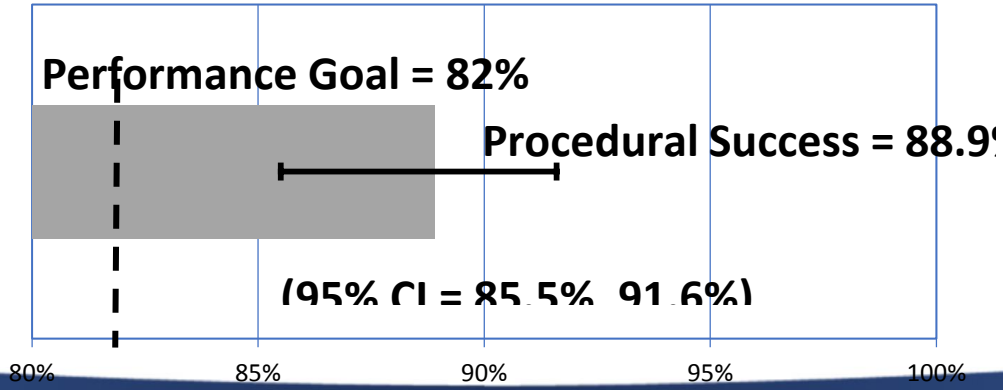
Chambers JW, et al. JACC Cardiovasc Interv. 2014;7:510-8.

ORBIT II: Primary Efficacy Endpoint

Prospective, single arm, multi-center trial to evaluate the safety and efficacy of OAS to prepare de novo, severely calcified coronary lesions for enabling stent placement (N=443)

Procedural Success Components:

Successful Stent delivered:	**97.7%**
Less than 50% residual stenosis:	**98.6%**
In hospital MACE:	**9.8%**
MI (CK-MB >3x ULN):	**9.3%**
Non Q-wave	8.6%
Q-wave	0.7%
TVR/TLR:	**0.7%**
Cardiac death:	**0.2%**



Chambers JW, et al. JACC Cardiovasc Interv. 2014;7:510-8.

COAST Study Design

- To evaluate the performance of the Coronary OAS Micro Crown in treating *de novo*, severely calcified coronary lesions
  - Prospective, single-arm, multi-center Investigational Device Exemption (IDE) study conducted in the US and Japan
  - Harmonization by Doing (regulatory collaboration between US and Japan)

100 patients enrolled

US: 74 patients
12 sites

Japan: 26 patients
5 sites

1-year follow-up completed* (93/100)

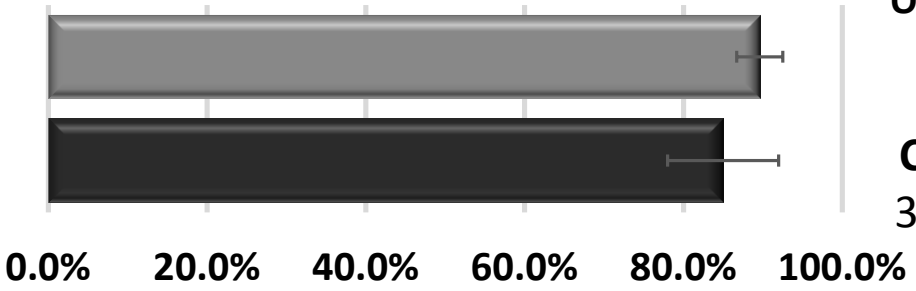
- Same Primary Endpoints as ORBIT II

Sharma S. Treatment of Severely Calcified Coronary Lesions with the Coronary Orbital Atherectomy System Micro Crown: 1-year Results from the COAST Trial. Presented at CRT; February 20, 2017; Washington, DC.

COAST Primary Safety Endpoint

30-Day MACE Rate Components:

MI (CK-MB >3x ULN):	**14.0%**
Non Q-wave	12.0%
Q-wave	2.0%
TVR/TLR:	**1.0%**
TLR	1.0%
Cardiac death:	**1.0%**



ORBIT II Freedom from 30-Day MACE[1] = **89.6%**
(95% CI = 86.7%, 92.5%)

COAST Freedom from 30-Day MACE = **85.0%**
(95% CI = 78.0%, 92.0%)

1. Chambers JW, et al. JACC Cardiovasc Interv. 2014;7:510-8.

COAST Primary Efficacy Endpoint

Procedural Success

Components:

Successful Stent delivered:

99.0%

Less than 50% residual stenosis:

99.0%

In-hospital MACE:

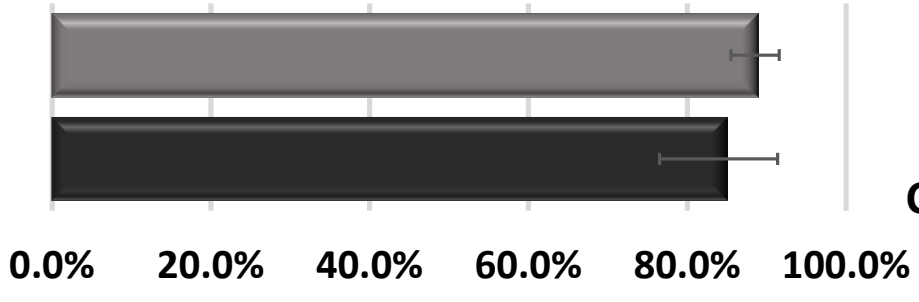
14.0%

TVR/TLR:

0%

Cardiac death:

1.0%



ORBIT II Procedural Success[1] = **88.9%**

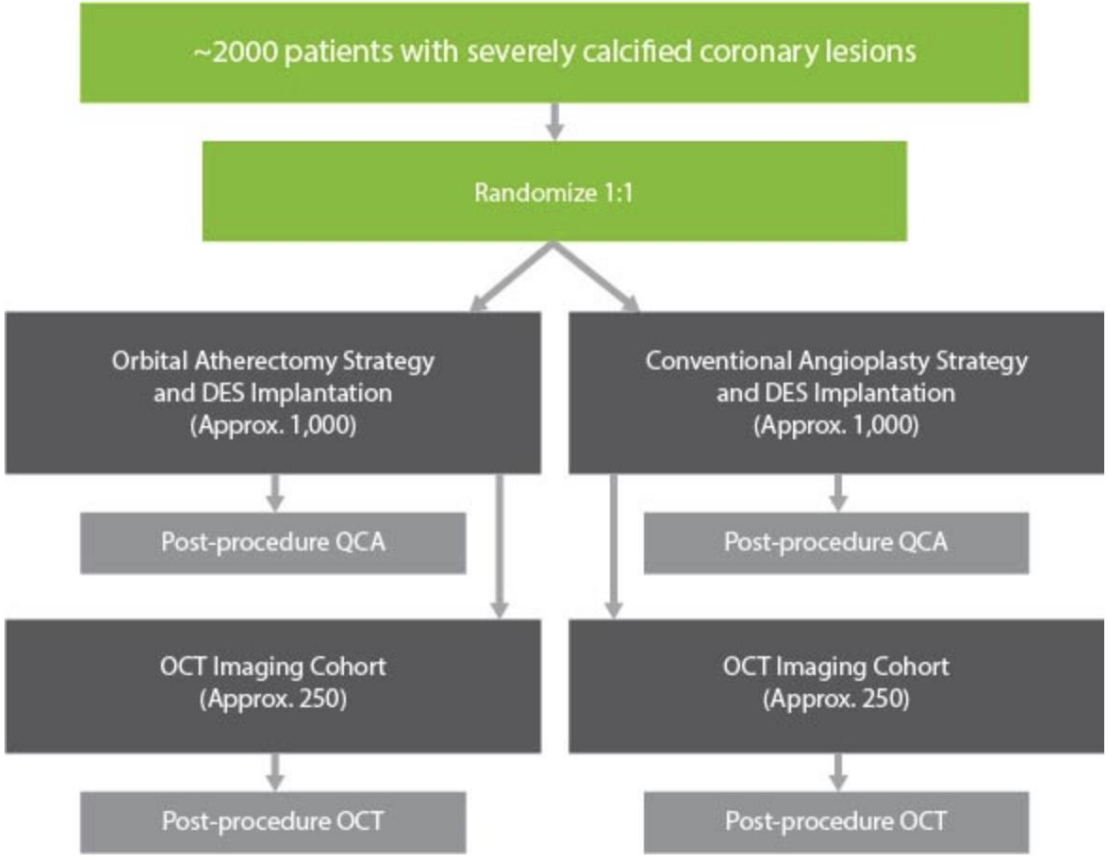
(95% CI = 85.5%, 91.6%)

COAST Procedural Success = **85.0%**

(95% CI = 76.5%, 91.4%)

Chambers JW, et al. JACC Cardiovasc Interv. 2014;7:510-8.

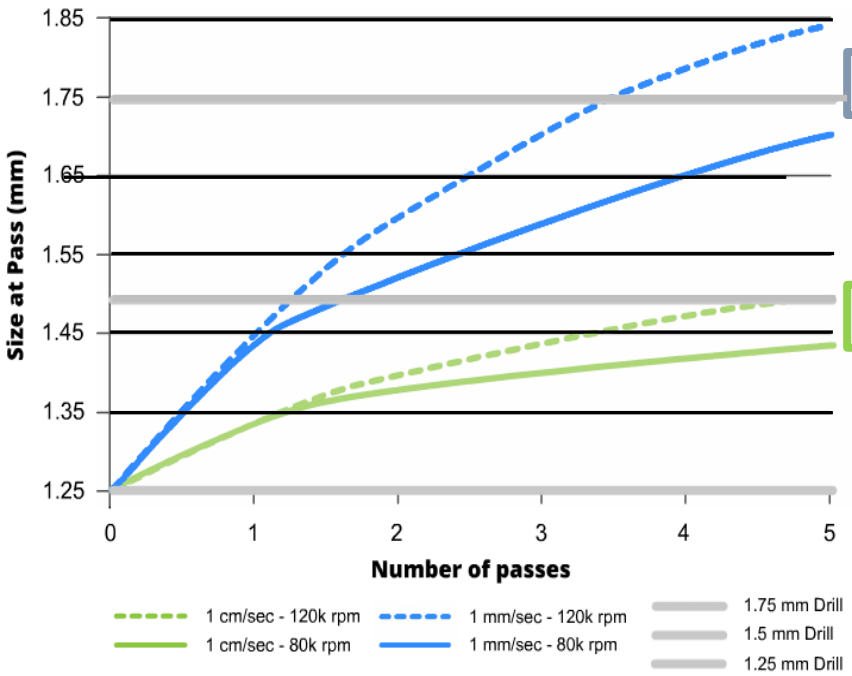
ECLIPSE Trial Design

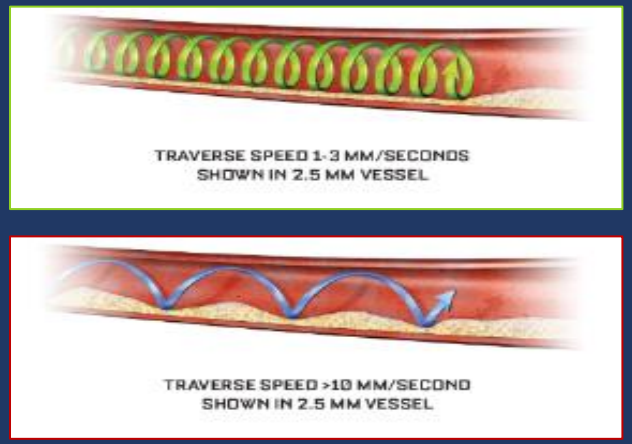


Practical considerations

Orbital Atherectomy is a Time Dependent Therapy

A breakdown of the physics that drive the system

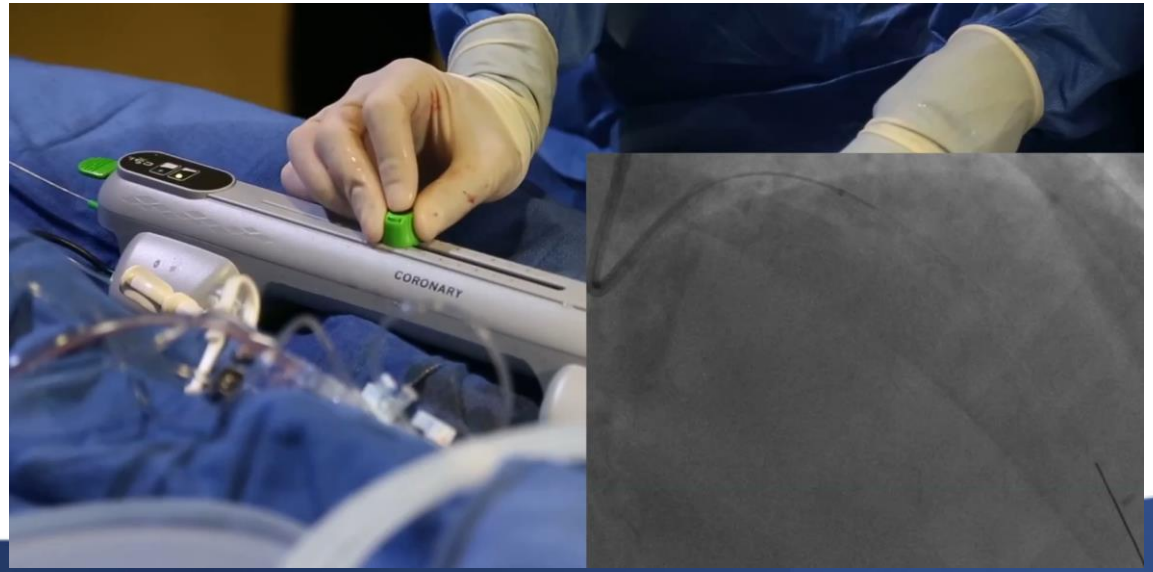




*Orbit chart data is from carbon block testing.

No rush

- Slow transverse speed
  - Target at 1mm/sec



Leverage Low Treatment Speed

$$F_c = \frac{mv^2}{R}$$

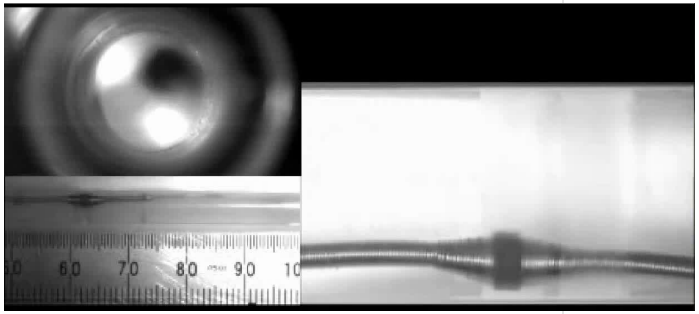
Insights –

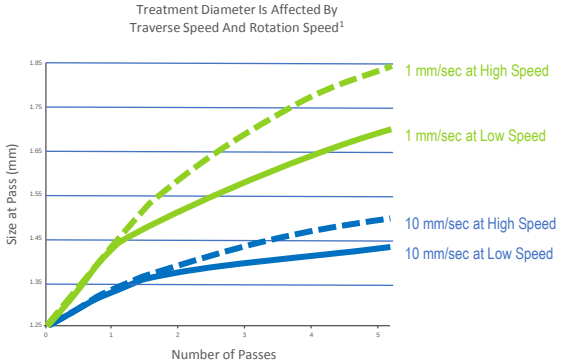
- Always begin treatment on low speed.
- Low speed is appropriate to treat most lesions. If additional treatment is required, consider use of high speed. High speed may be more suitable in larger and less tortuous anatomy.

Rationale –

- Orbital atherectomy is a time dependent therapy; time and contact determine treatment effect.
- Because of the increased centrifugal force, high speed may be more suitable in larger and less tortuous anatomy.

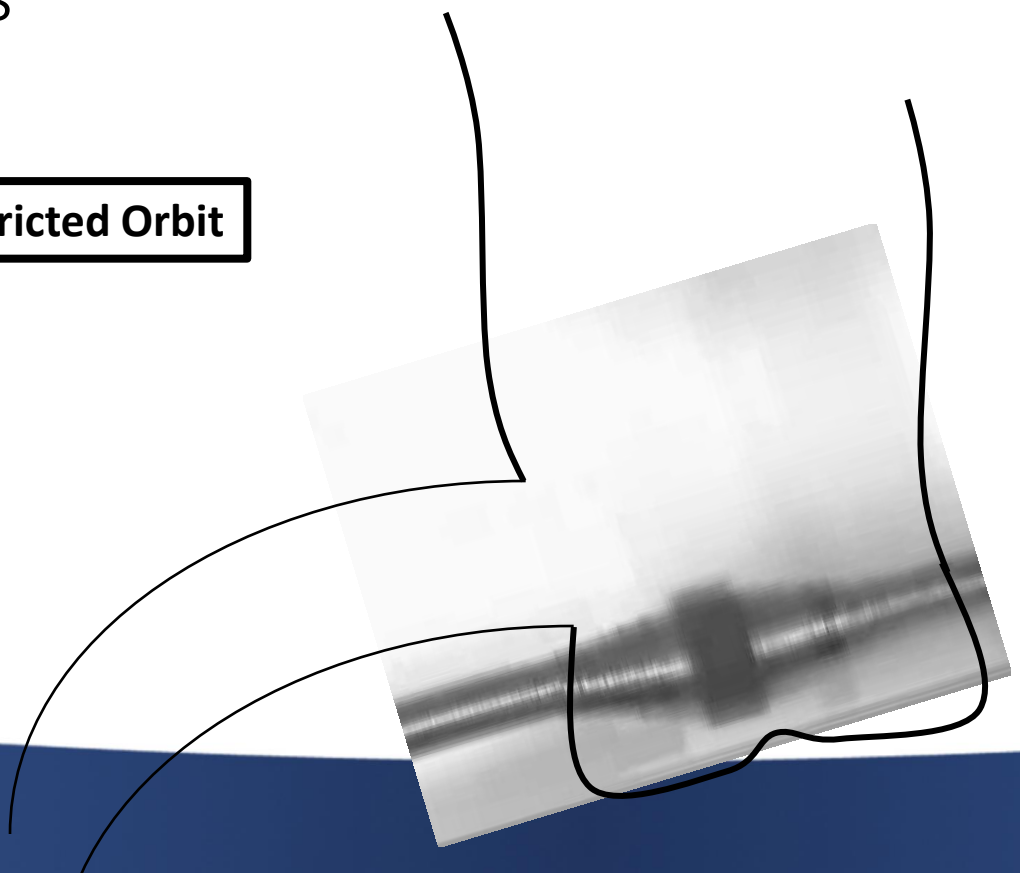
- 1.25 mm Classic Crown orbiting in a 3 mm glass tube
- Crown orbiting to tube diameter





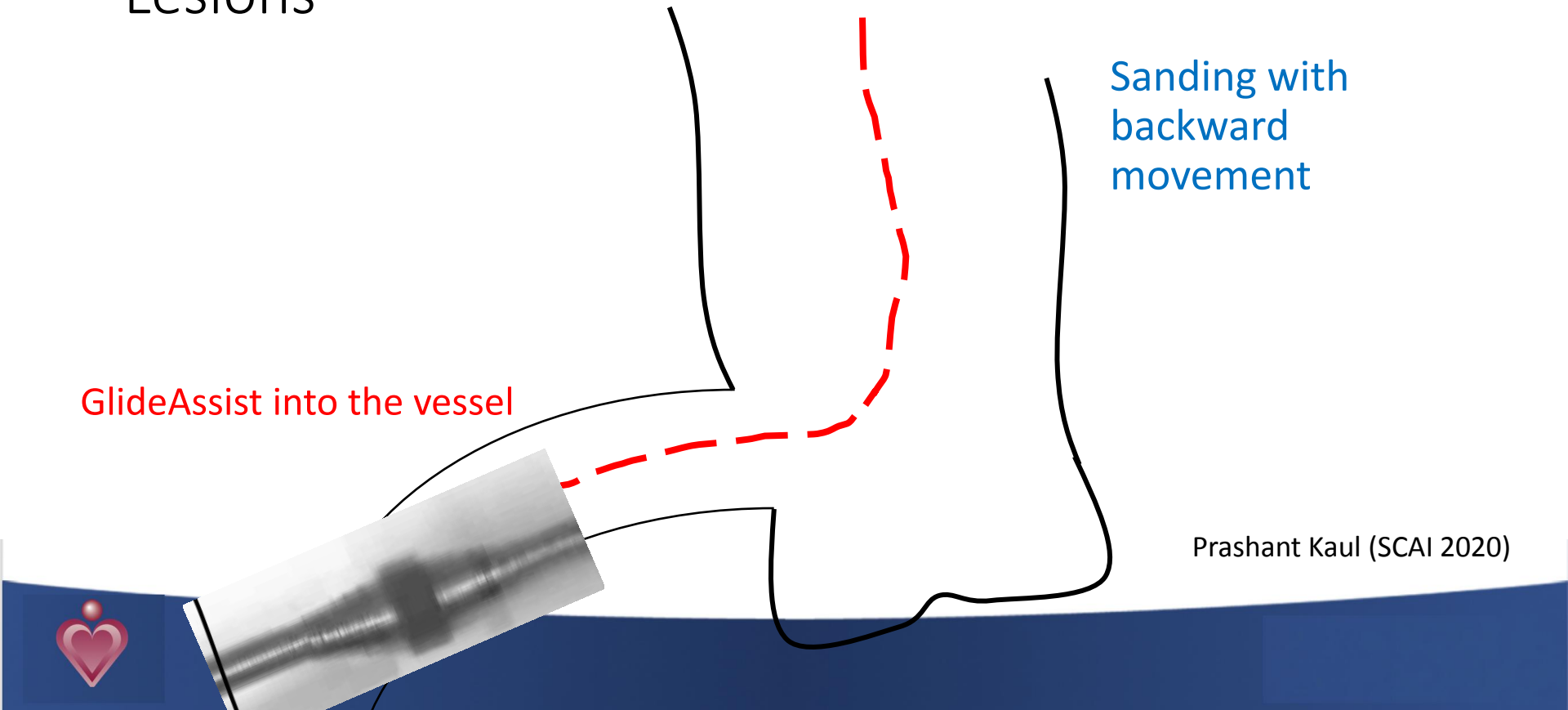
Technical Considerations: OAS in Aorto-Ostial Lesions

Unrestricted Orbit



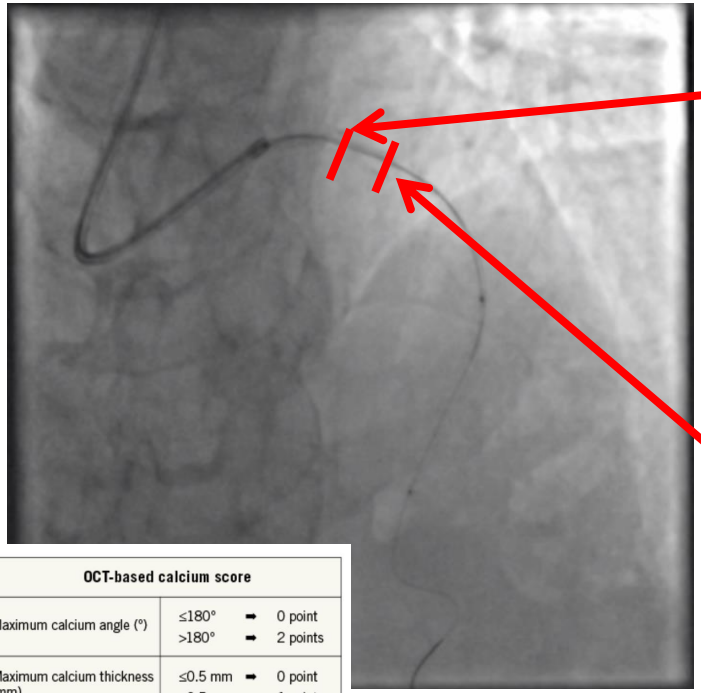
Prashant Kaul (SCAI 2020)

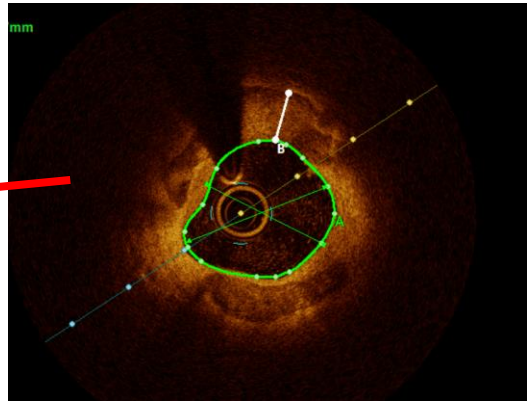
Technical Considerations: OAS in Aorto-Ostial Lesions

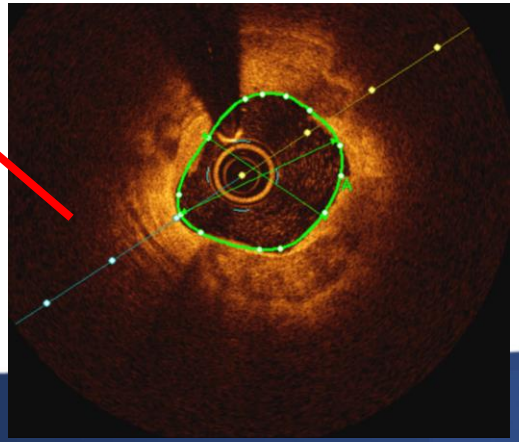


Prashant Kaul (SCAI 2020)

Back to our case

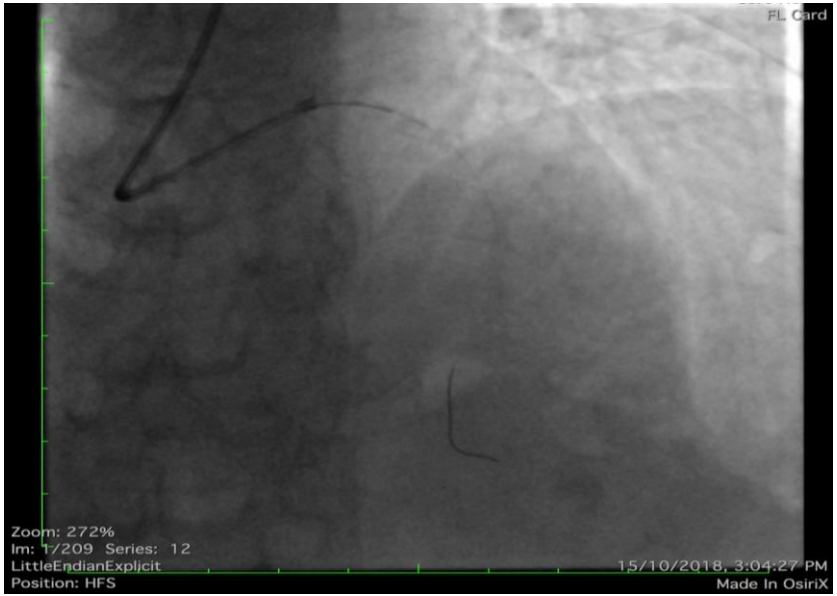




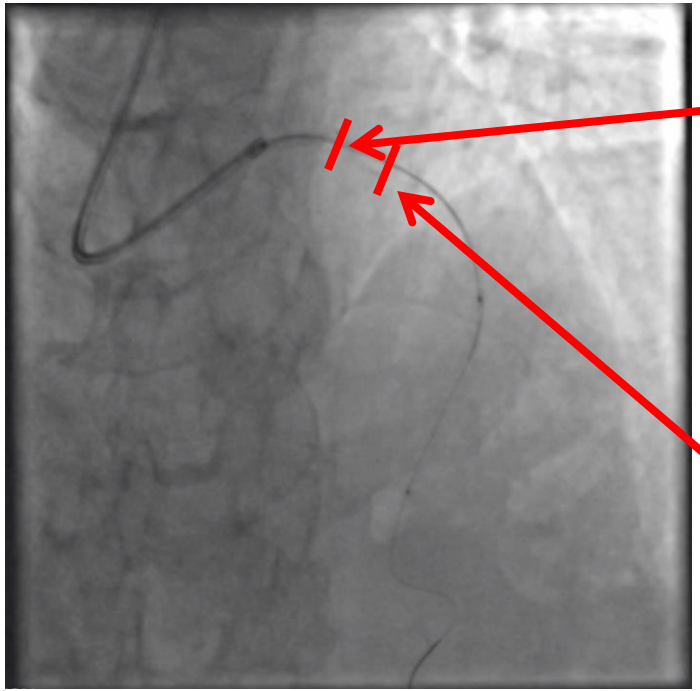


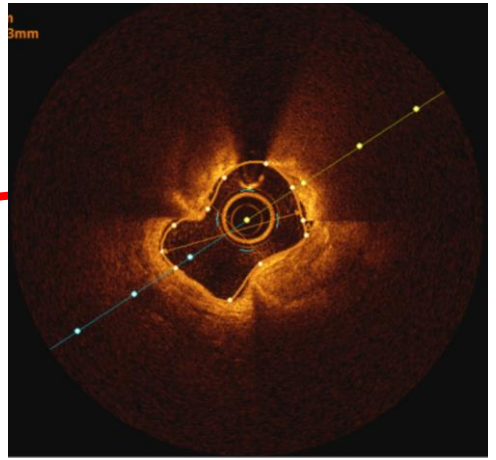
OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	**0 to 4 points**

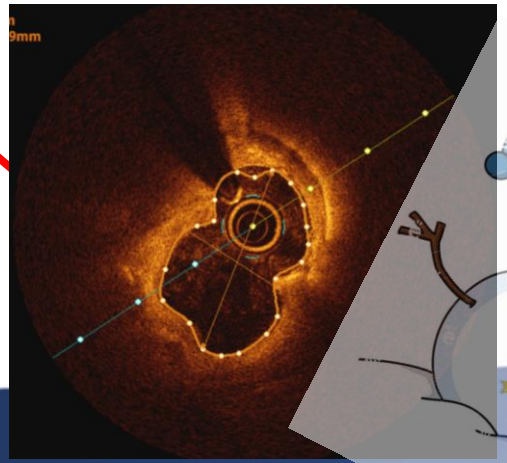
OCT Score : 4

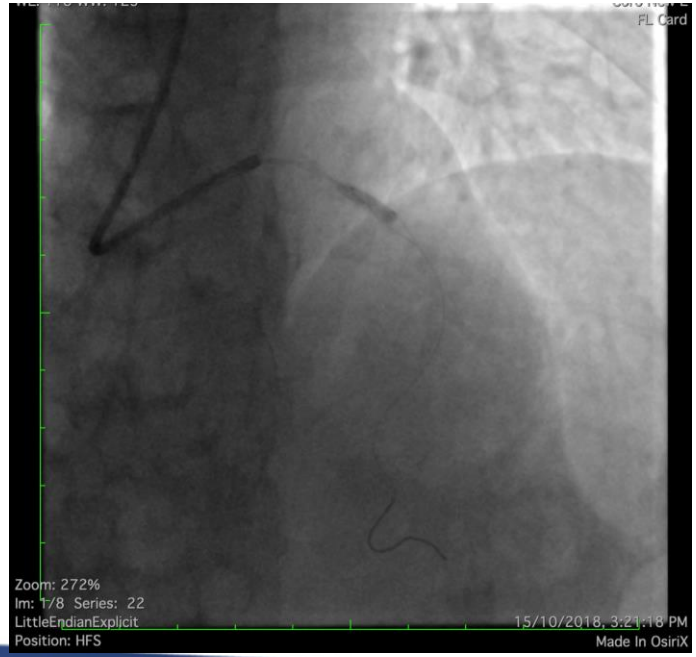


Orbital atherectomy performed

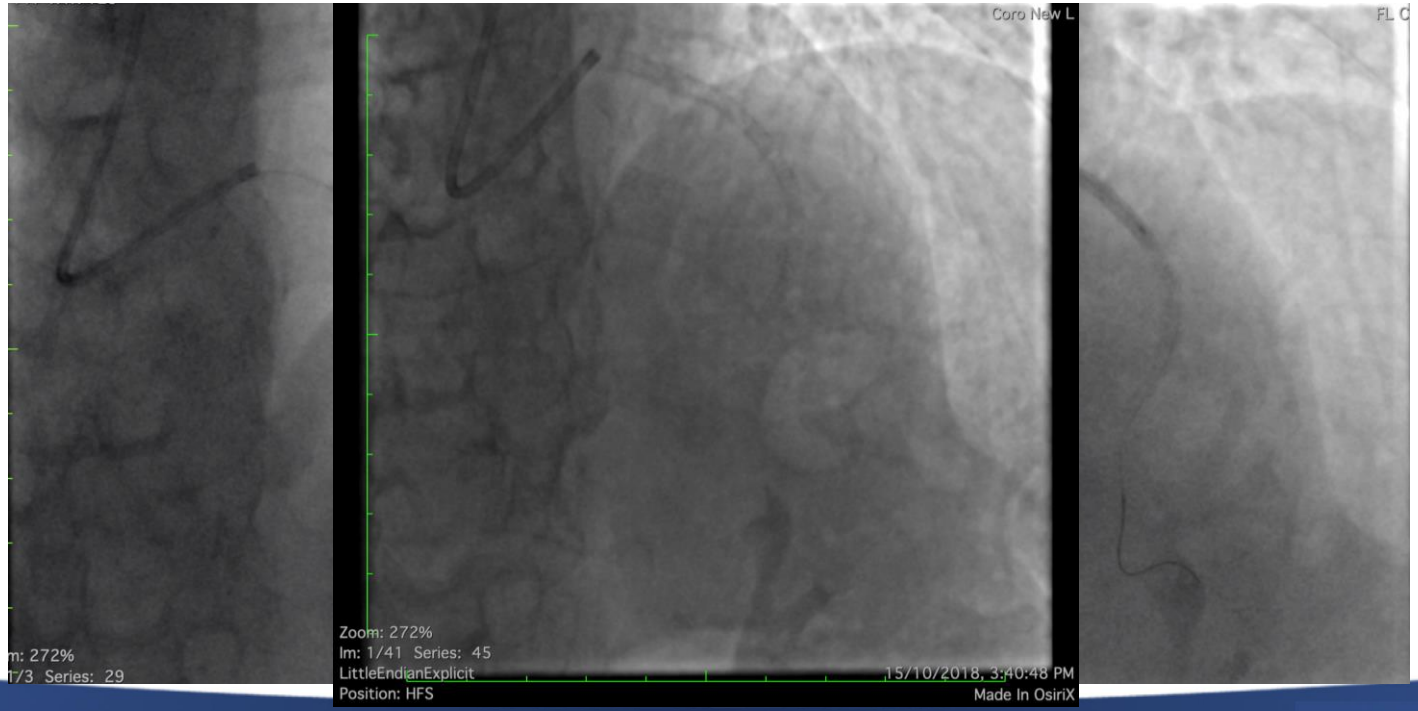








2.5x10mm and 3.5x10mm NC Balloon at 6atm



2.5x38mm and 3.5x18mm DES

Conclusion

- Coronary calcification is very common among patients with ischemic heart disease, which can increase risks of procedural complications and later ischemic events
- Advanced imaging modalities are necessary for better visualization and quantify the degree of calcification
- For those heavily calcified lesion, use of orbital atherectomy can address calcification and vessel compliance for better stent expansion

Thank you