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Toolbox for Severe Coronary Calcification: Device, Indication and Tips

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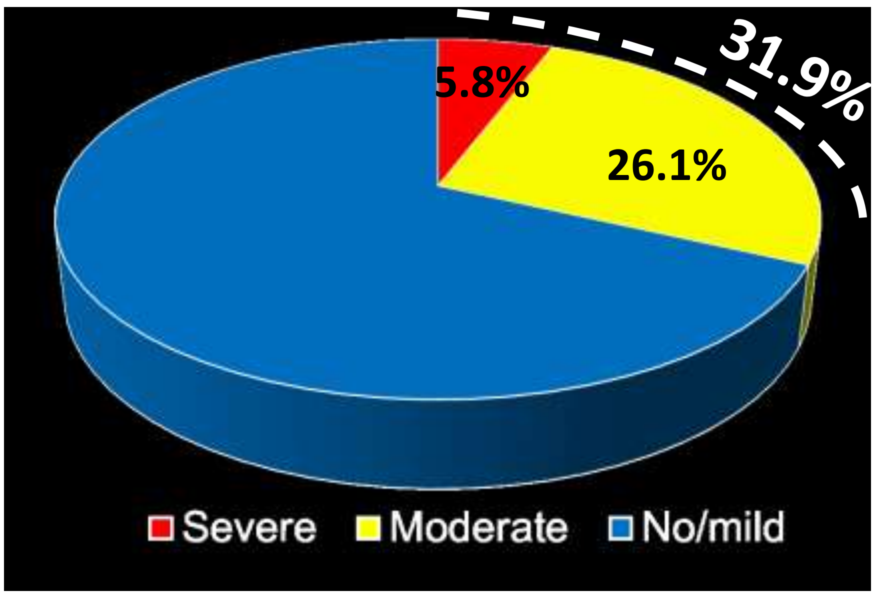
Key issues

- Frequency of coronary calcified lesions
- Clinical Implications
- Detection of coronary calcifications
- Tools for the treatment of calcified lesion

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

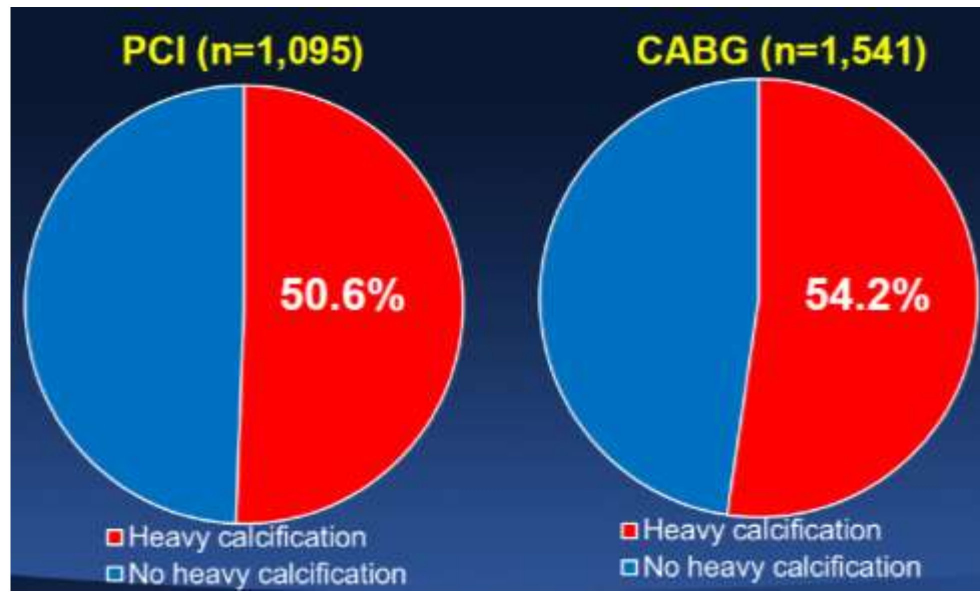
RAVEL	23.3% (27/116)
SIRIUS	17.1% (91/531)
E-SIRIUS	16.1% (28/174)
C-SIRIUS	12.0% (6/50)
TAXUS IV	18.3% (121/660)
TAXUS V	32.5% (185/570)
TAXUS VI	29.7% (65/219)
ENDEAVOR II	23.7% (140/590)
ENDEAVOR III	17.9% (78/436)
ENDEAVOR IV	33.2% (513/1546)
SPIRIT II	31.4% (91/290)
SPIRIT III	27.8% (277/997)
COMPARE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

Frequency of Mod/Sev Calcification in NSTE-ACS and STEMI PCI population: Core lab analysis from ACUITY and HORIZONS-AMI



Généreux, P. et al. J Am Coll Cardiol 2014 13;63 (18):1845-54

Frequency of "heavy" calcification in the SYNTAX trial: Randomized + Registry



Farooq et al. J Am Coll Cardiol 2013;61:282–94

Clinical Implications

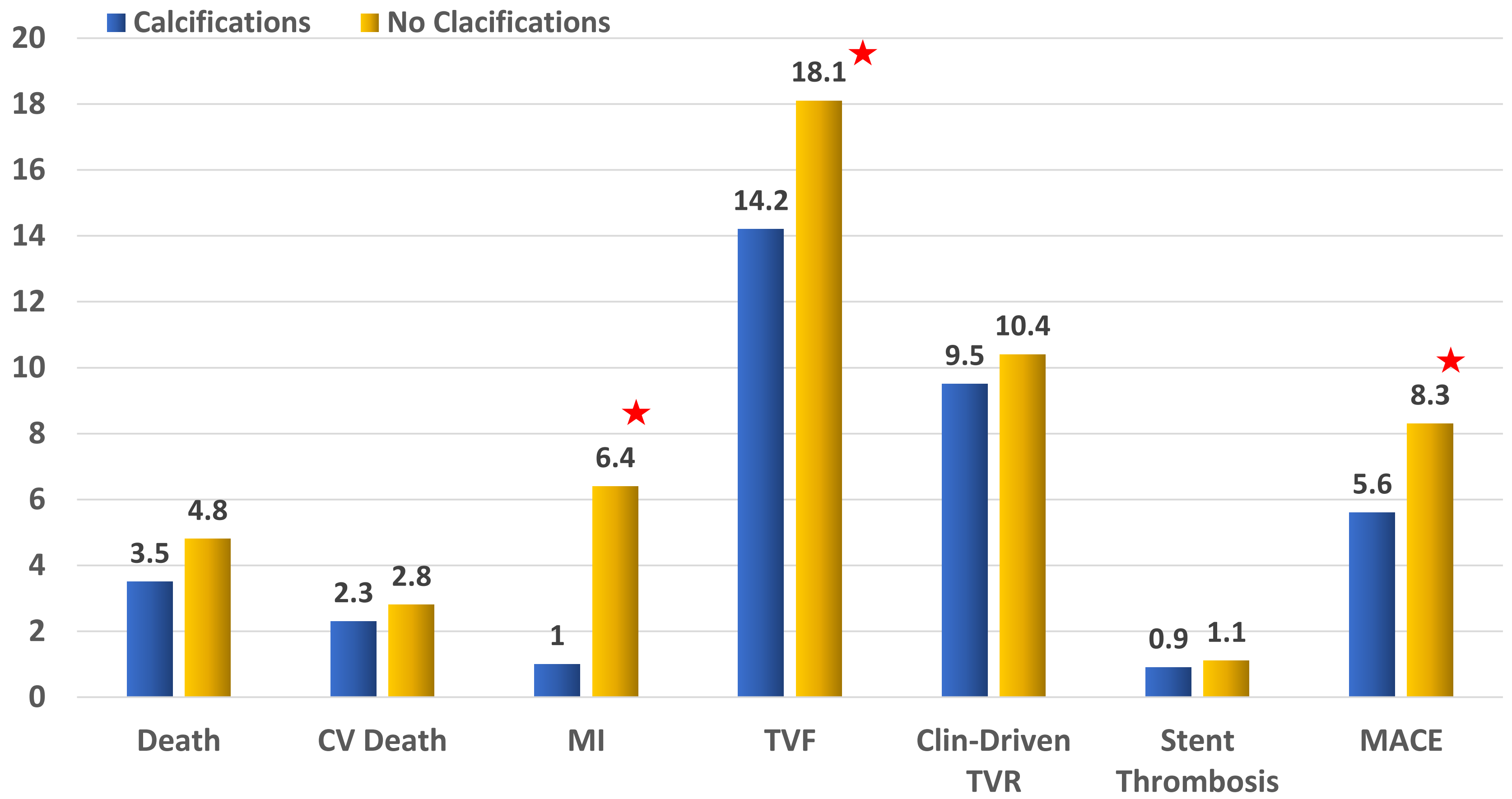
Coronary calcification results in:

- **Impaired stent delivery, decreased stent expansion, increased malapposition and stent asymmetry**
- **Increased procedural complications (edge dissections and perforations)**
- **Increased rates of stent thrombosis and restenosis**

IVUS stent expansion is the strongest predictor of early ST and restenosis after BMS or DES

	Stent Thrombosis	Restenosis
BMS	• *Cheneau et al. Circulation 2003;108:43-7*	• *Kasaoka et al. J Am Coll Cardiol 1998;32:1630-5* • *Castagna et al. AHJ 2001;142:970-4* • *de Feyter et al. Circulation 1999;100:1777-83* • *Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* • *Morino et al. Am J Cardiol 2001;88:301-3* • *Ziada et al. Am Heart J 2001;141:823-31* • *Doi et al. JACC Cardiovasc Interv. 2009;2:1269-75*
DES	• *Fujii et al. J Am Coll Cardiol 2005;45:995-8)* • *Okabe et al., Am J Cardiol. 2007;100:615-20* • *Liu et al. JACC Cardiovasc Interv. 2009;2:428-34* • *Choi et al. Circulation Cardiovasc Interv. 20011;4:239-47*	• *Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* • *Hong et al. Eur Heart J 2006;27:1305-10* • *Doi et al JACC Cardiovasc Interv. 2009;2:1269-75* • *Fujii et al. Circulation 2004;109:1085-1088* • *Hahn et al. J Am Coll Cardiol 2009;54:110-7* • *Kang et al. Circ Cardiovasc Interv 2011;4:9-14* • *Kang et al. Circ Cardiovasc Interv 2011;4:562-9* • *Choi et al. Am J Cardiol 2012;109:455-60* • *Song et al. Catheter Cardiovasc Interv, in press*

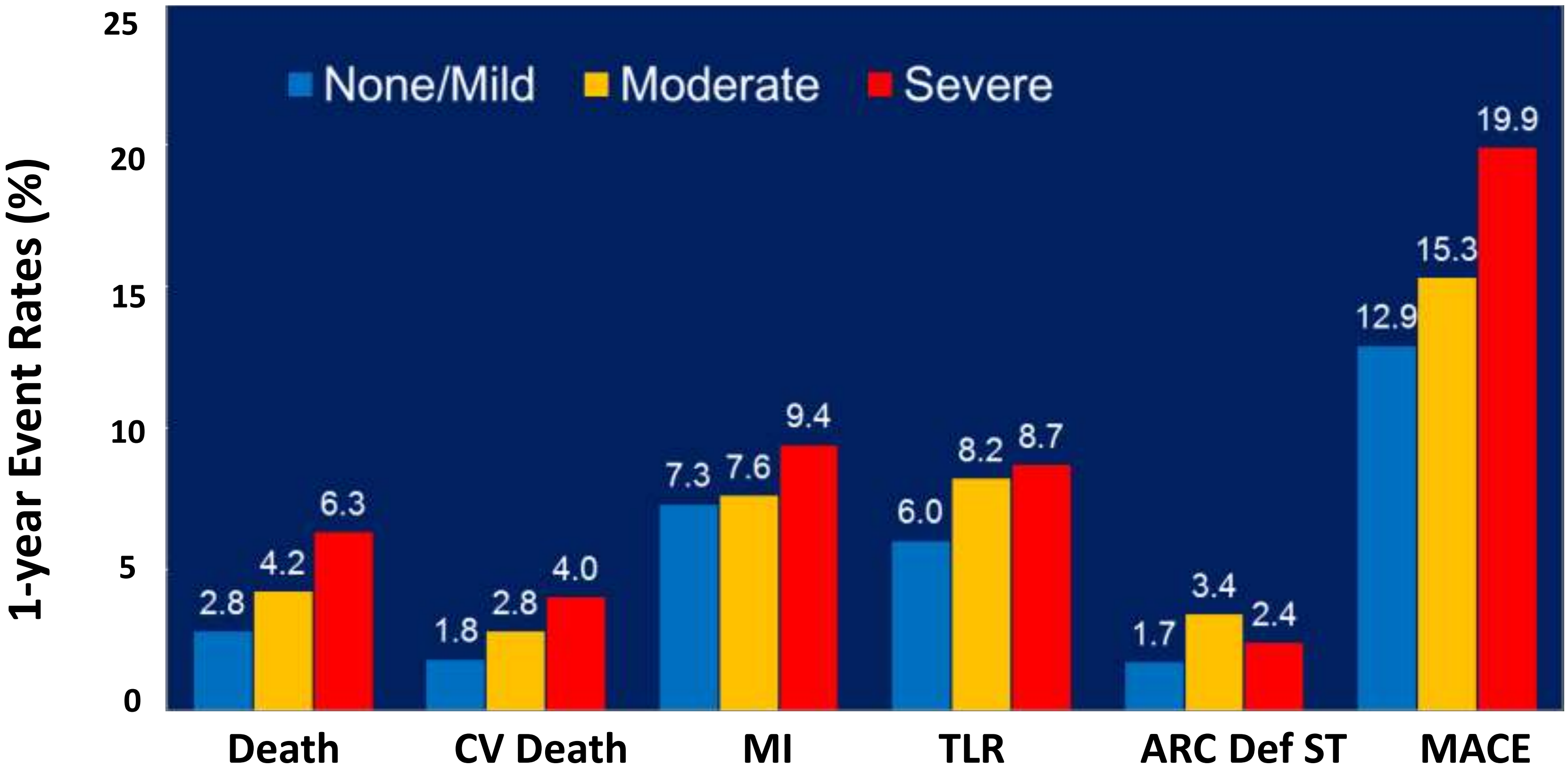
ADAPT-DES (N=8,582): Calcification and 2-Year Events



Généreux, P et al. Int. J. Cardiol 2016

ACUITY/HORIZONS-AMI: Implications of Calcified Lesions on PCI in ACS

(1-year outcomes; n=6,855 pts)



Généreux P et al. J Am Coll Cardiol 2014 13;63:1845-54

Detection of Coronary Calcifications

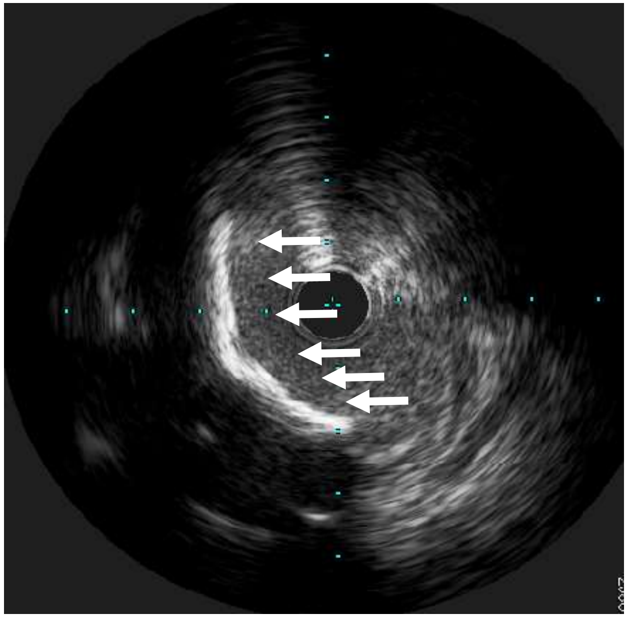
CENTRAL ILLUSTRATION Detection, Localization, and Quantification of Coronary Calcium by Various Imaging Modalities

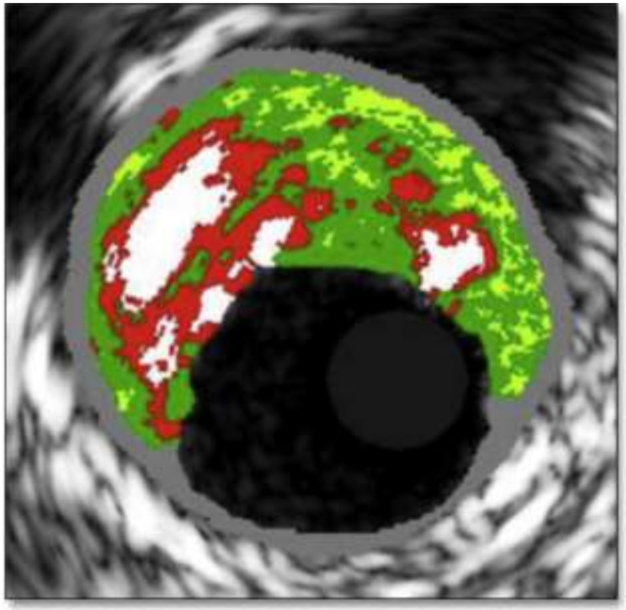
	Coronary Angiography	CT	IVUS	RF-IVUS (IVUS-VH)	OCT
IMAGING MODALITIES			Superficial calcium detection	Color coded tissue composition	Sharp delineation of calcium area is possible
Detection of coronary artery calcium	+	+++	+++	+++	++++
Localization of coronary artery calcium	+	+++	+++	+++	++++
Quantification of coronary artery calcium	+	+++	++	+++	++++

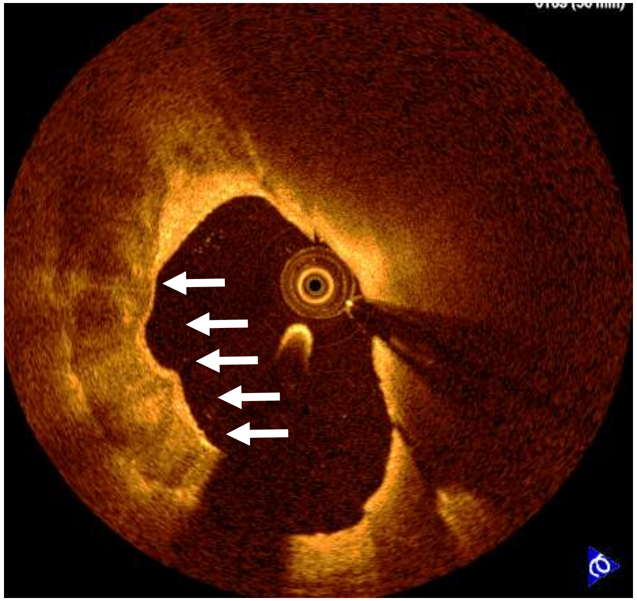
Coronary angiography, coronary computed tomography (CT), intravascular ultrasound (IVUS), radiofrequency (RF) intravascular ultrasound-virtual histology (IVUS-VH), and optical coherence tomography (OCT) can all detect and attempt to localize and quantify calcium, albeit with very different diagnostic accuracies.

GS Minz ; JACC Cardiovasc Imaging 2015;8:461-471

IVUS and OCT for Calcification detection







IVUS does not penetrate into calcium : Cannot measure thickness or mass, only arc and length

IVUS-VH (Virtual Histology)
IVUS technology incorporating radiofrequency data to assess plaque composition

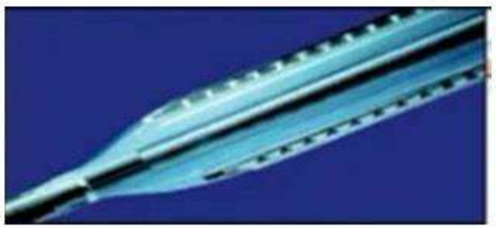
- Fibrous tissue
- Fibrofatty tissue
- Necrotic core
- Calcium

OCT penetrates calcium and is able to assess calcium thickness and area/volume as well as arc

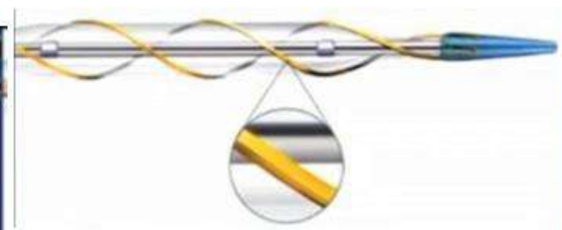
Tools for the management of coronary calcified lesions

NC Balloons

Cutting Balloon

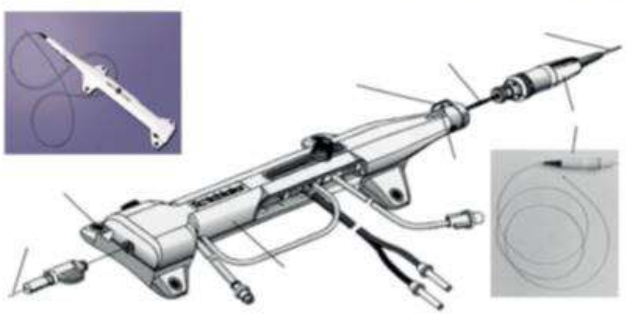


Anguiosculpt



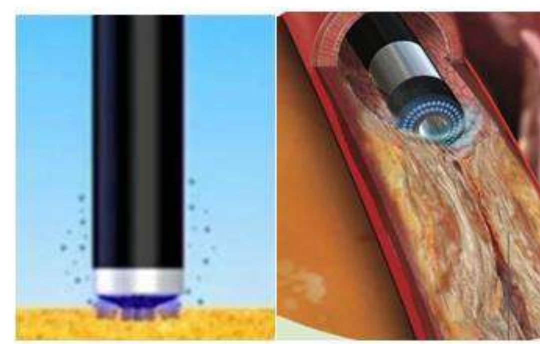
ShockWave Lithoplasty

Rotational-Ablation Atherectomy

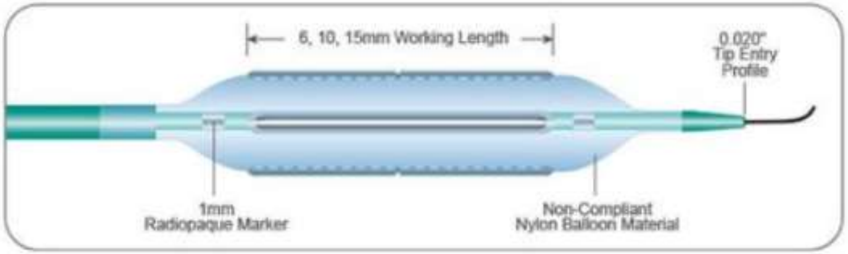


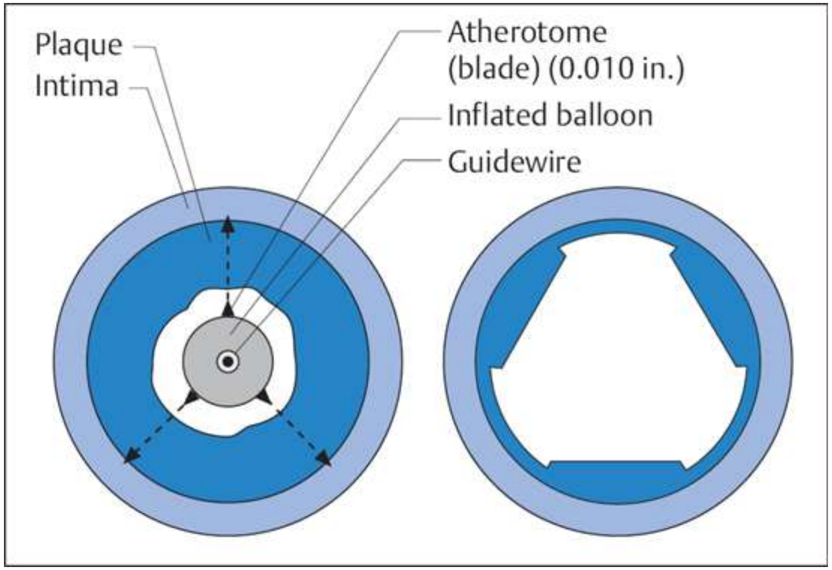
Orbital Atherectomy

Laser

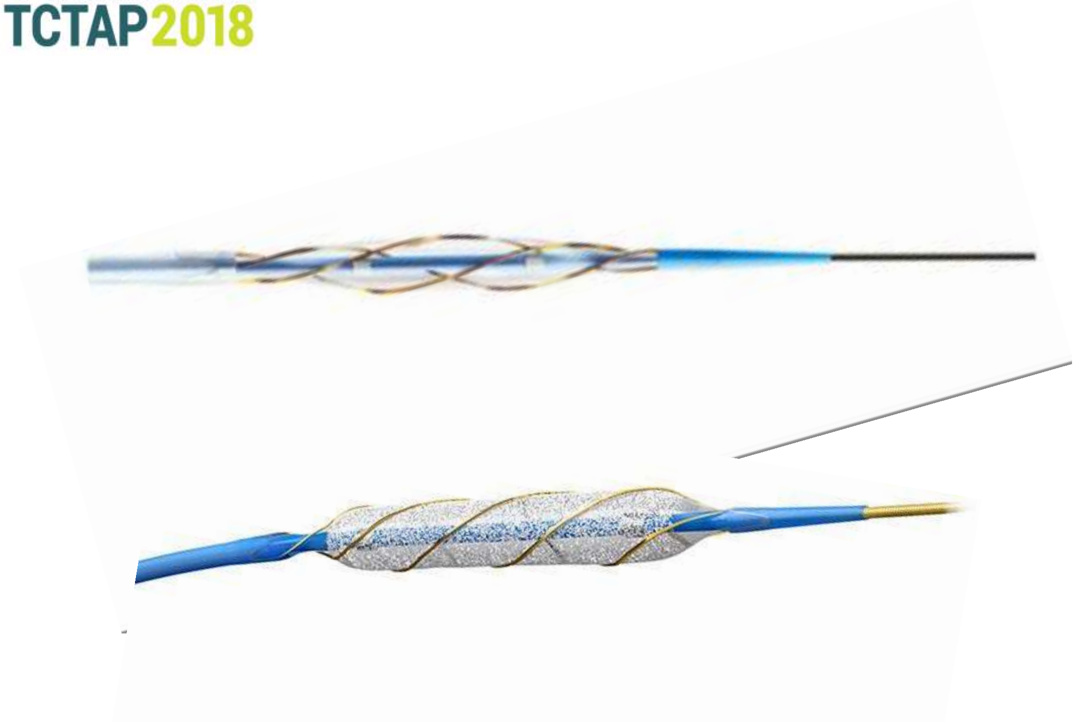


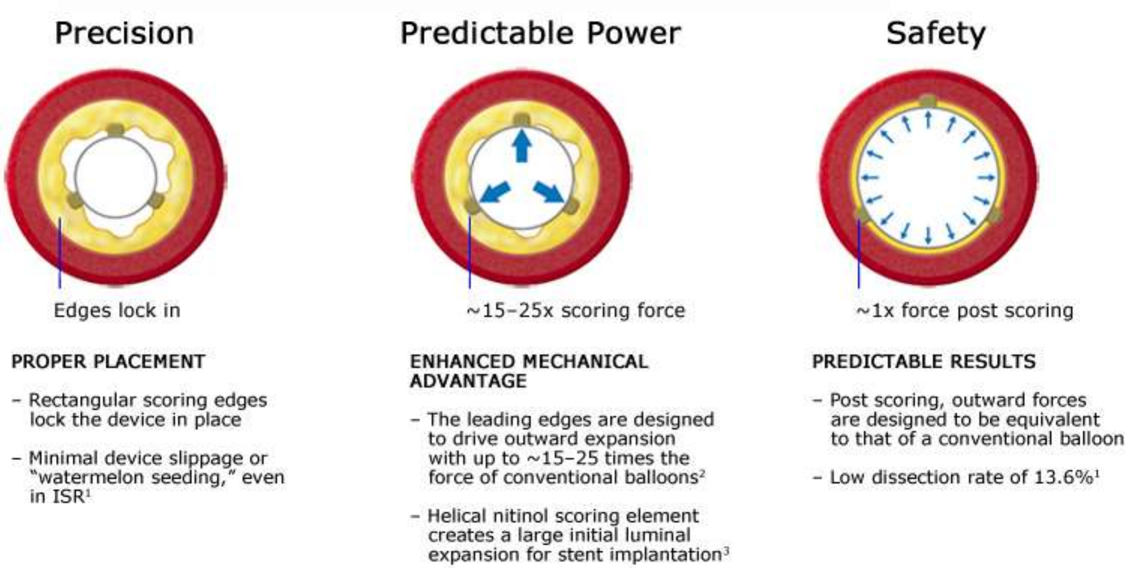
Cutting Balloon





4 blades (~0.25 mm in height), mounted longitudinally on the surface of a non-compliant balloon. During dilation, Cutting Balloon creates three or four endovascular radial incisions through the fibrocalcific tissue (controlled dissection), thus allowing further expansion with conventional balloons.

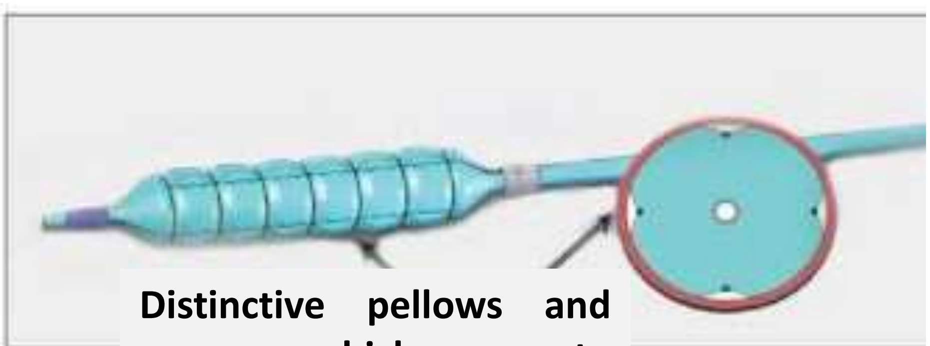




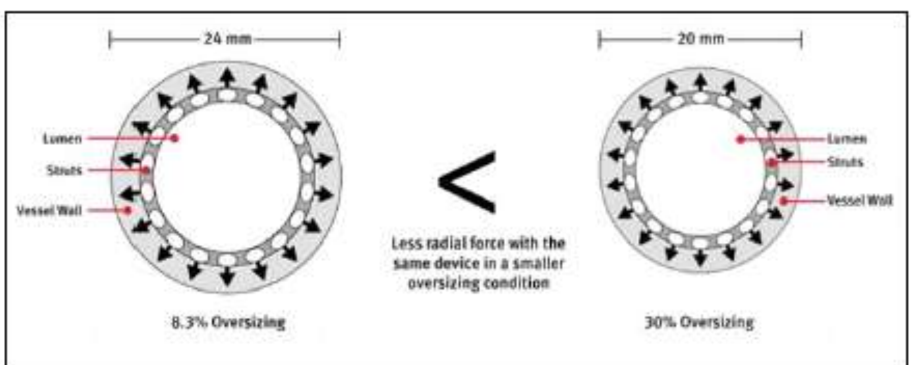
AngioSculpt

- **Consists of a semi-compliant nylon balloon, surrounded by three external nitinol spiral scoring wires**
- **This device is more flexible and deliverable than the cutting balloon (the crossing profile of the smallest device is 0.036”).**
- **Mechanism of action similar to Cutting balloon**
- **Preferentially utilised in preparing *de novo* lesions and ostial lesions**

Chocolate Balloon

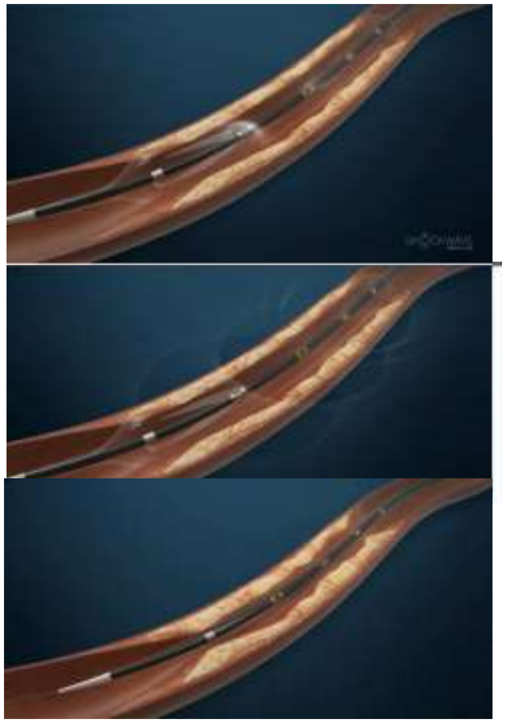


Distinctive pellows and grooves which serve to reduce vessel wall trauma



- A novel balloon catheter with a mounted nitinol constraining structure specifically designed for uniform, controlled inflation and rapid deflation resulting in atraumatic dilatation
- The nitinol-constraining structure of the Chocolate creates balloon segments or “pillows” that make contact with the vessel and functions to minimize local forces. The “grooves” facilitate plaque modification without cutting . The distinctive pillows and grooves serve to minimize vessel trauma, reduce the rate of dissection

Shockwave Balloon



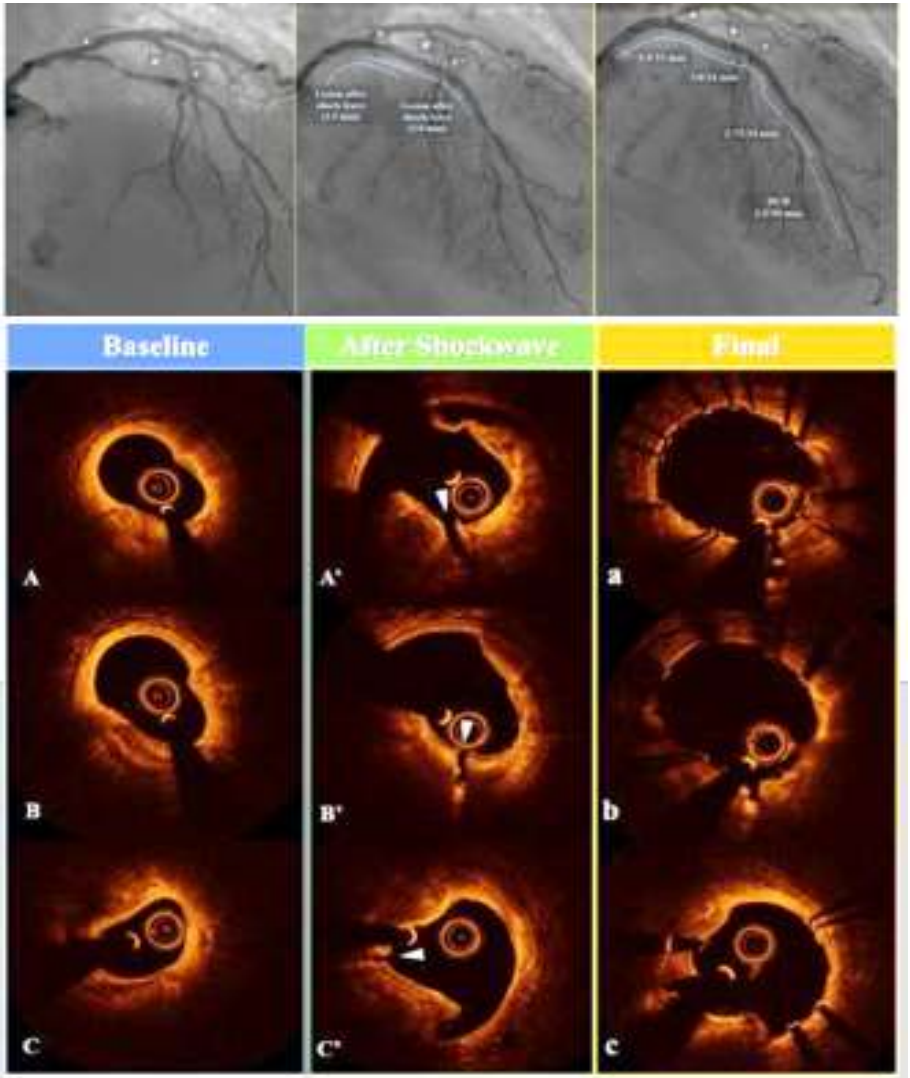
Lesion modification using lithotripsy in a balloon

Tissue-selective:

- **Hard on hard tissue, Soft on soft tissue**
- **Lithotripsy waves travel outside balloon**
- **Designed to disrupt both superficial, deep calcium**

Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation

- **Effective lesion expansion with minimized impact to healthy tissue**
- **“Front-line” balloon-based Rapid Exchange .014 platform**



Lithoplasty with Shockwave Balloon

- **Initial clinical experience**
- **Promising data in small studies**

Non Atherectomy Devices (Cutting and scoring balloons)

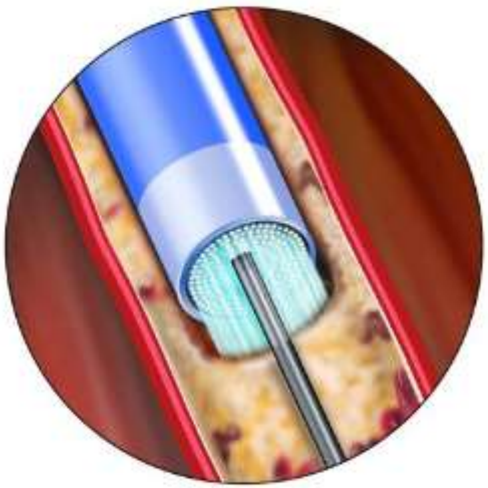
Advantages :

- Easy use
- Relatively less complications
- Work on conventional wires

Disadvanteges :

- Often difficult to reach target lesion (High profile)
- Reduced efficacy in moderate / severe calcification

Main indications : lesion preparation in mild calcification & de novo and ostial lesions



Excimer Laser Atherectomy

Tissue ablation mechanisms:

Vaporization of tissue (photothermal effect)
Ejection of debries (photoacustic effect)
Direct breakdown of molecules(photochimical dissociation

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AHEAD OF PRINT | CURRENT ISSUE | ARCHIVE | SUPPLEME

Previous Article | Vol 70. Num 02. February 2017 | Next article

Rev Esp Cardiol. 2017;70:116 - Vol. 70 Num.02 DOI: 10

Effects of Excimer Laser Coronary Atherectomy Assessed by OCT

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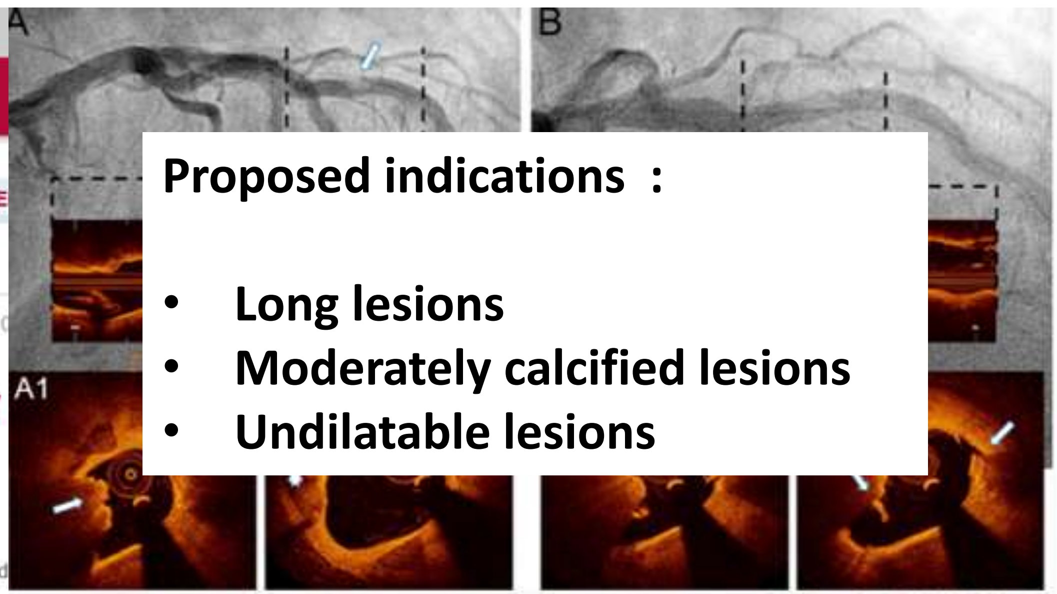
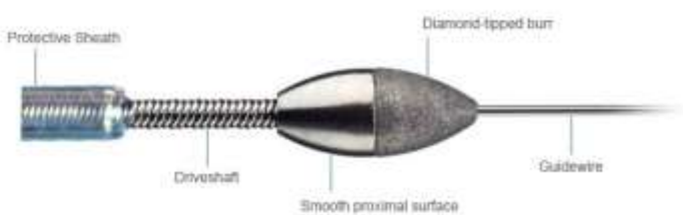


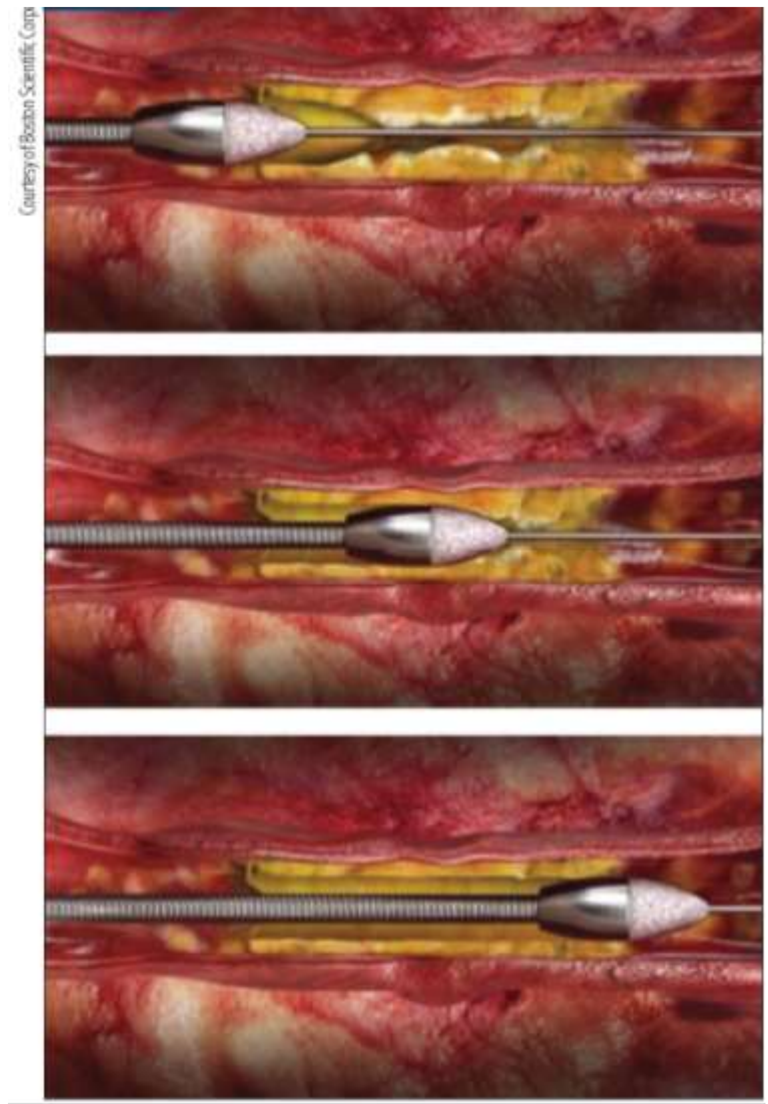
Proposed indications :

- **Long lesions**
- **Moderately calcified lesions**
- **Undilatable lesions**

Rev Esp Cardiol. 2017;70:116

Rotational Atherectomy (Rotablator)





Rotational Atherectomy (Rotablator)

Mechanism of action

- **Differential cutting : cuts more rigid ,inelastic material**
- **Orthogonal friction displacment : reduces friction between vessel wall and entering device**

Technical considerations

- **Burr /artery ratio 0.5-0.6**
- **Rotational speed up to 200.000 rpm**
- **Lower rpm 140.000 ; less heat generation and platlet activation**
- **Runs should be limited to 20 seconds**
- **Deceleration of > 5000 rpm should be avoided**

Rotational Atherectomy (Rotablator)

OPERATOR TECHNIQUE

- **Gradual burr advancement using a pecking motion**
- **Short ablation runs of 15 – 30 sec**
- **Avoidance of decelerations > 5,000 rpm**
- **Keep under control distal edge of rotawire**
- **Avoidance of pushing in angled lesions**
- **If not crossing , try with lower burr size**
- **Final polishing run**

Rotational Atherectomy (Rotablator)

- **Indications**

  - Moderate/ severe calcified lesion
  - Undilatable lesion

- **Contraindications :**

  - Dissections
  - Angulated lesions > 70° - 90°
  - Thrombus cantaining lesions
  - SVG
  - Acute MI

Rotational Atherectomy (Rotablator)

Copmplications

- Slow flow , no reflow
- Non Q MI
- Coronary perforation
- Dissection
- Bradycardia & AV block
- Vasospasm

Rotablator Failure :

- Burr enrapment
- Burr detushment
- Burr Stalling
- Rotawire fracture

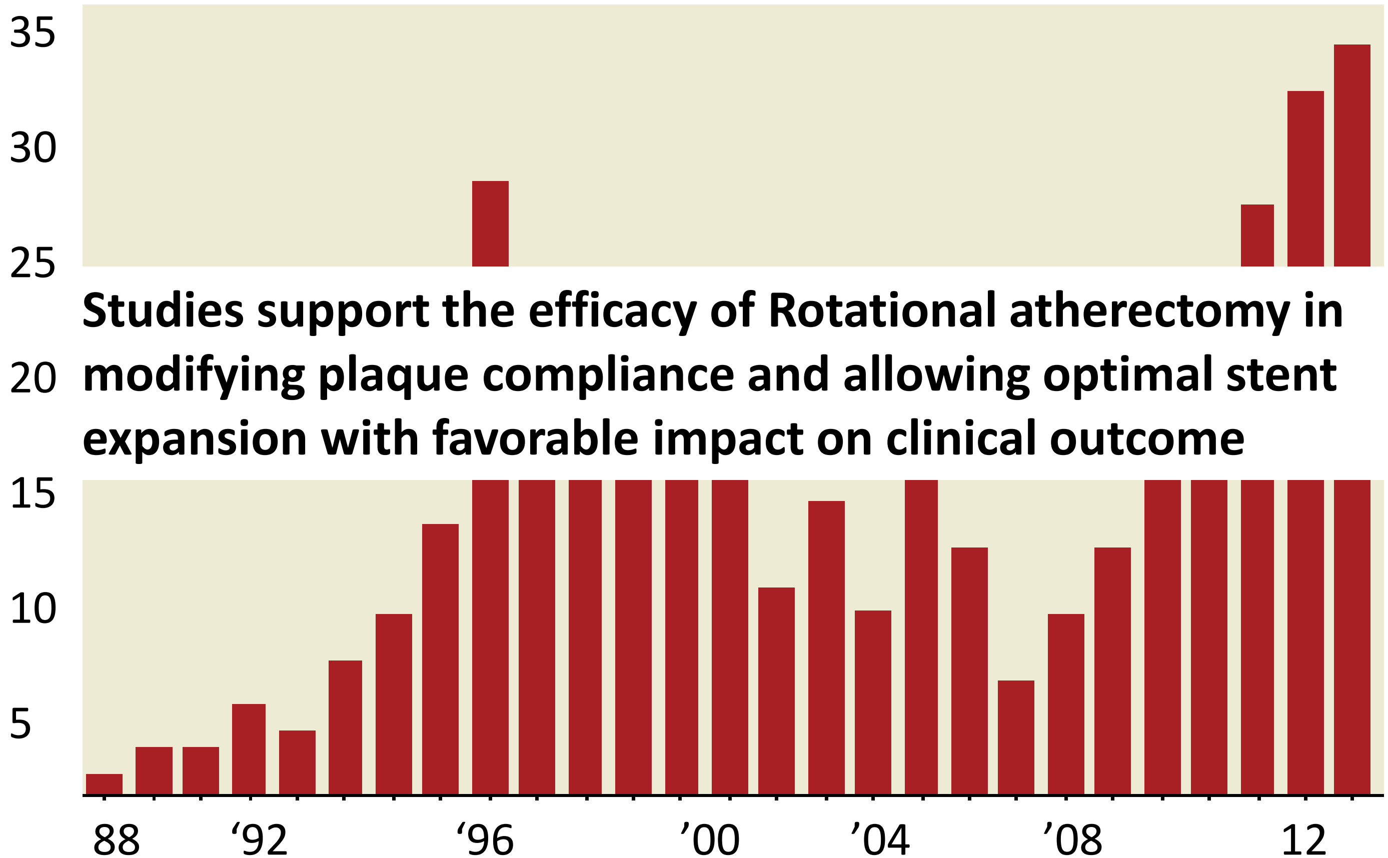
ROTAPRO™ Rotational Atherectomy System

Currently in Development

Design Goals:

- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use

Rotational Atherectomy (Rotablator)



Studies support the efficacy of Rotational atherectomy in modifying plaque compliance and allowing optimal stent expansion with favorable impact on clinical outcome

Publications over the years on coronary rotational atherectomy (Pubmed)

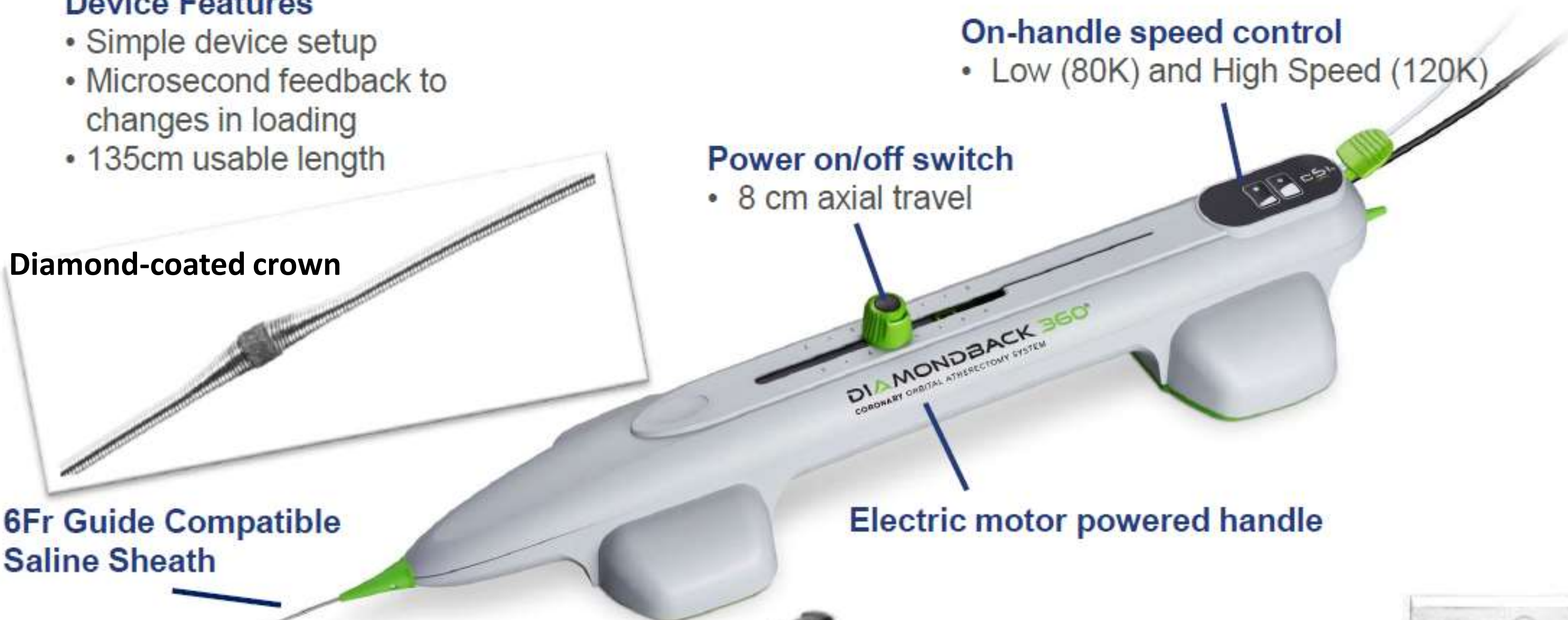
Renewed interest in Rotational Atherectomy …..

Barbato, et al. "European expert consensus on rotational atherectomy." EuroIntervention 2015;11:30-36.

Diamond Back 360® Orbital Atherectomy System

Device Features
- Simple device setup
- Microsecond feedback to changes in loading
- 135cm usable length

Diamond-coated crown



On-handle speed control
- Low (80K) and High Speed (120K)

Power on/off switch
- 8 cm axial travel

Electric motor powered handle

6Fr Guide Compatible Saline Sheath

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

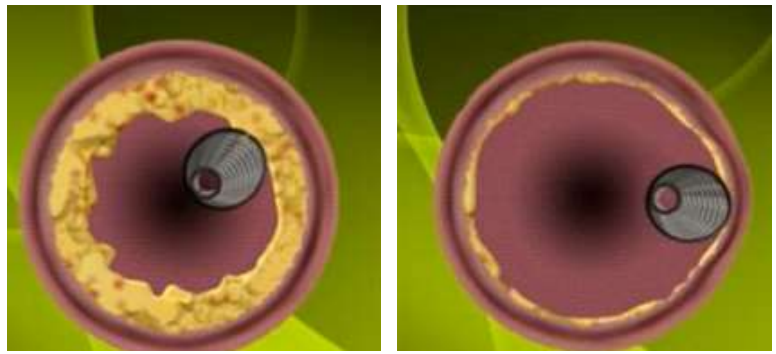
ViperSlide® Lubricant
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline

Works on Specific guidewire (Viper-Wire™)

Orbital Atherectomy : mechanism of action

Differential Orbital Sanding

Crown sands the hard component of the plaque



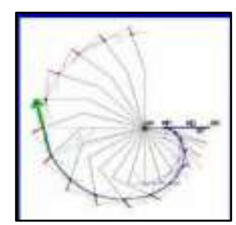
Soft componenent (plaque / tissue) flex away from the crown

Orbital Mechanism :

- **Increased speed = increased centrifugal force**
- **Greater centrifugal force = larger orbital diameter**
- **Different vessel diameters can be treated based on orbiting speed**

Diamond-coated crown

Size 1.25mm



$$CF = \frac{\text{Mass} \times \text{Rotational speed}^2}{\text{Radius of the orbit}}$$

Available for clinical use only in USA and Japan

ORBIT II Study Design

- To evaluate safety and efficacy of the Diamondback Coronary OAS to prepare *de novo*, severely calcified coronary lesions for enabling stent placement
  - Prospective, multi-center trial
  - Single arm - FDA recommendation as there are no FDA-approved percutaneous treatments for patients with severely calcified lesions.

N=443 enrolled
in 49 U.S. sites

↓

30 days follow-up
(N=437/440)

↓

1 year follow-up
(N=433/440)

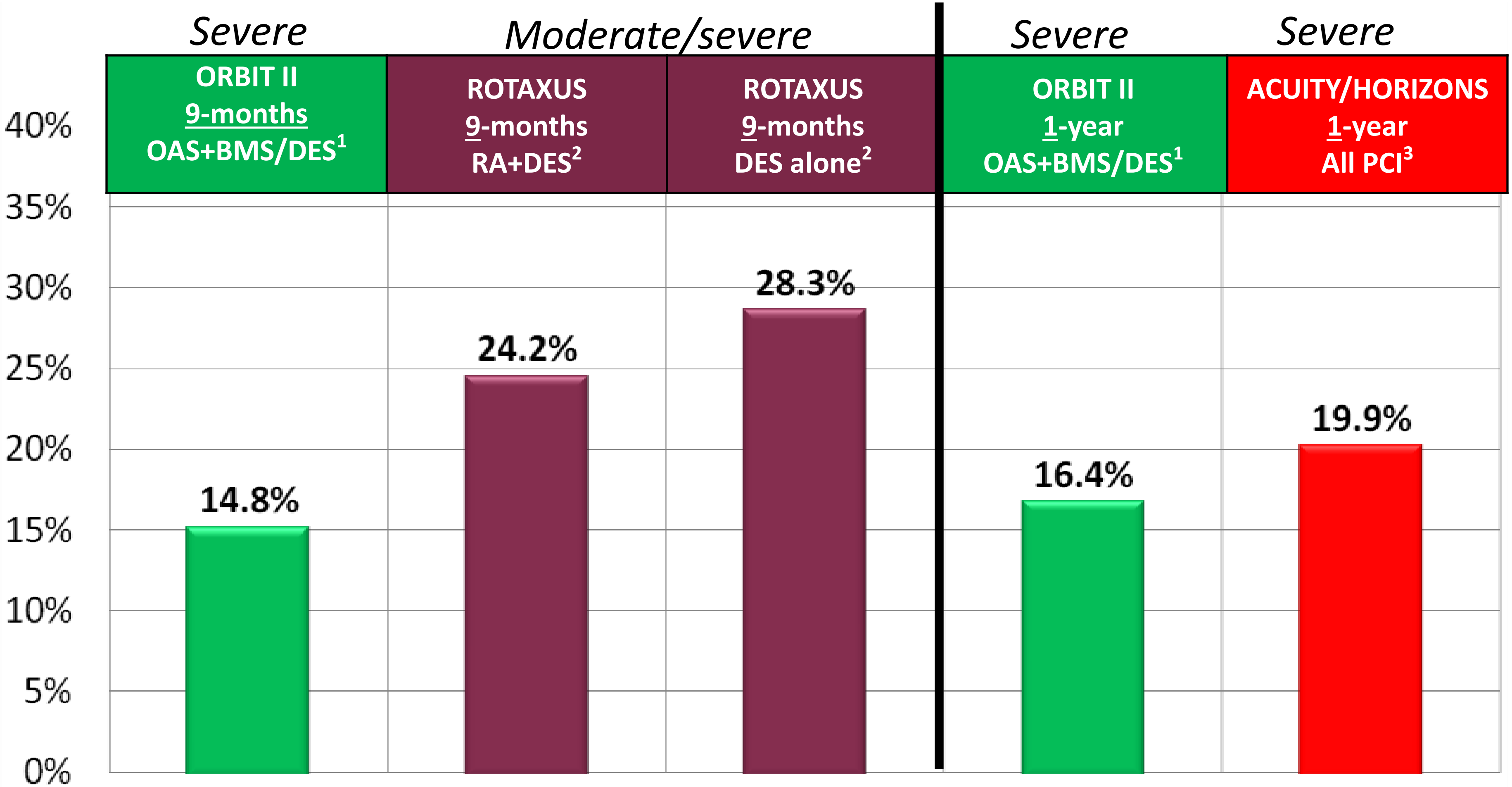
ORBIT II Study Objective 1
EFFICACY

Demonstrate that the OAS successfully facilitates stent deployment in severely calcified coronary lesions

Successful Stent delivered: **97.7%***

Less than 50% residual stenosis: **98.6%**

9-12 Months MACE in Patients with Severe Coronary Calcium



1. Chambers, 2014, Data on file at CSI, ORBIT II, 100% severely calcified lesions
2. Abdel-Wahab 2013, EuroPCR, ROTAXUS, ~50%/50% moderate/severely calcified lesions, and Abdel- Wahab, 2013 JACC:CI
3. Genereux, 2013, TCT, ACUITY/HORIZONS Subanalysis, 100% severely calcified lesions

Algorythm for Calcified Coronary Lesions Management