

Atherectomie Orbitale

New Tool for New Results

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APPAC 2019

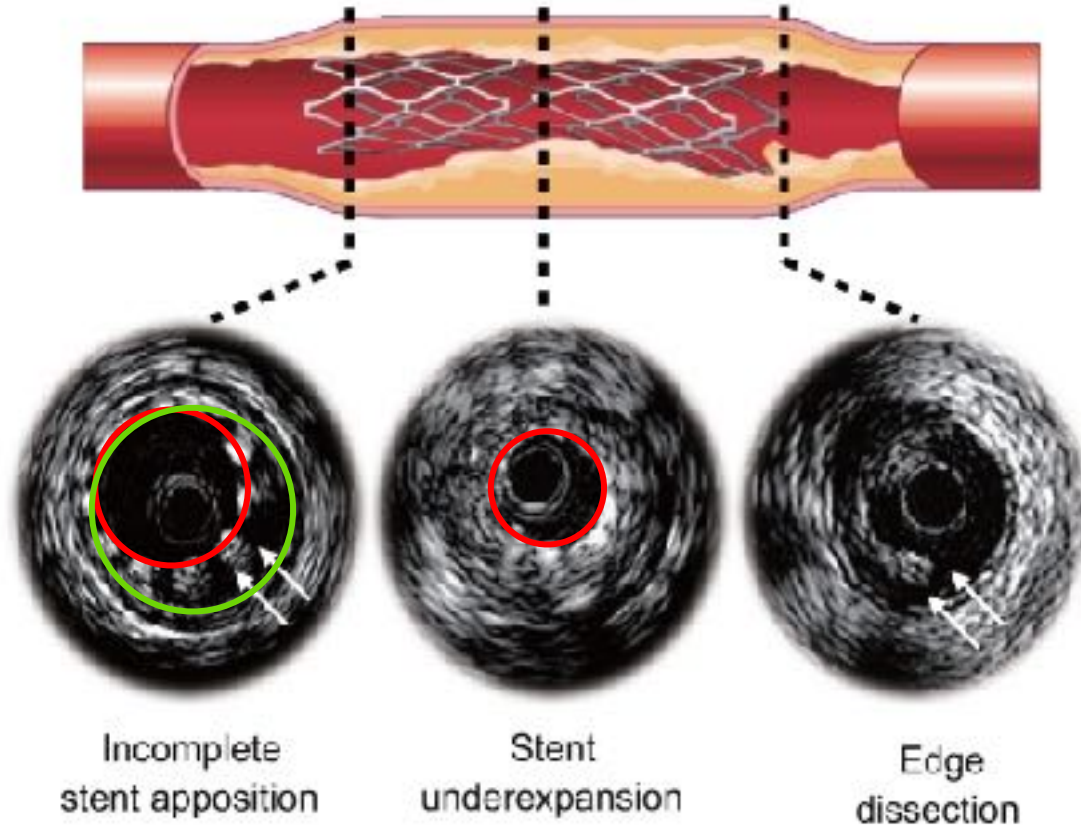
Risk Factor	Intimal Calcification	Medial Calcification
Advanced age	Yes	Yes
Diabetes mellitus	Yes	Yes
Dyslipidemia	Yes	No
Hypertension	Yes	No
Male	Yes	No
Cigarette smoking	Yes	No
Renal etiology		
Dysfunction (↓ GFR)	No	Yes
Hypercalcemia	No	Yes
Hyperphosphatemia	Yes	Yes
PTH abnormalities	No	No
Duration of dialysis	No	Yes



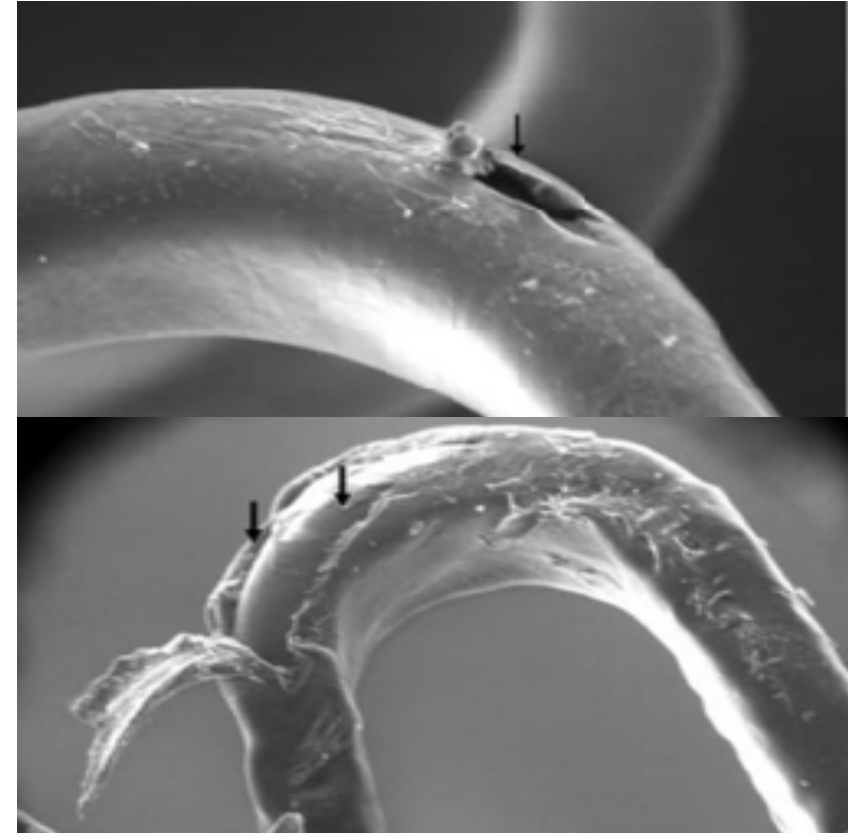
Sous estimées :
36 % en angiographie – 74% en IVUS²

¹Madhavan et al. JACC 2014

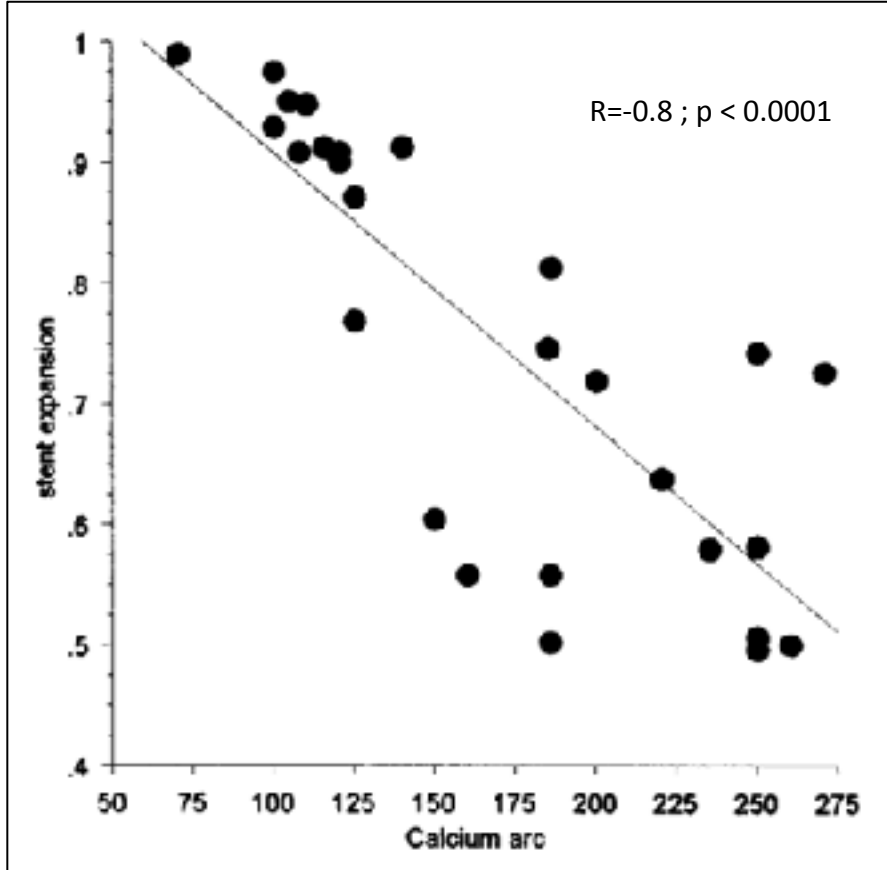
²Baht et al. Cardiovascular Revascularization Medicine 2001



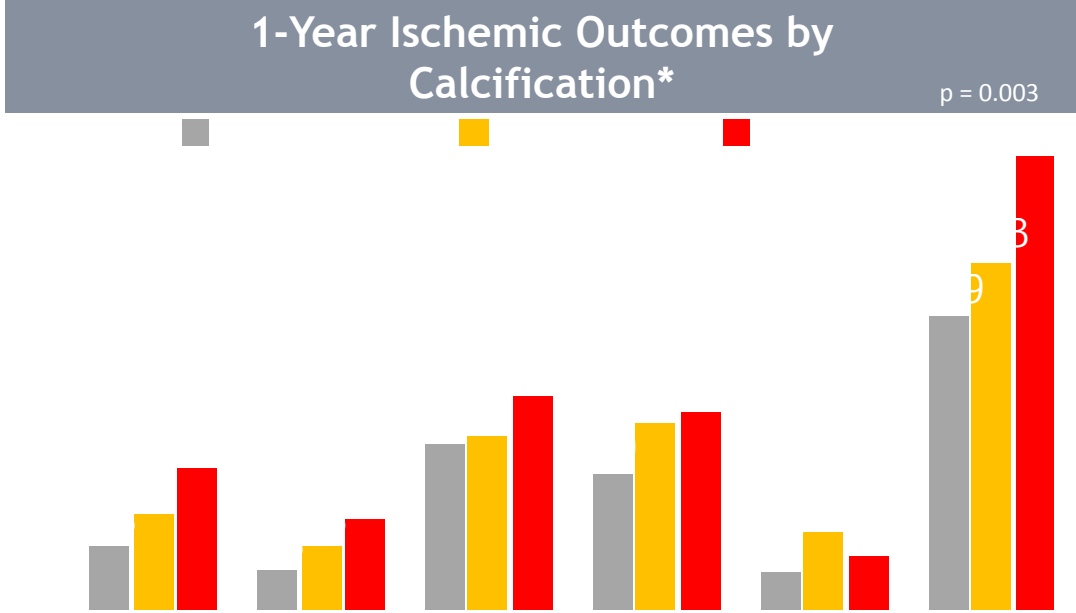
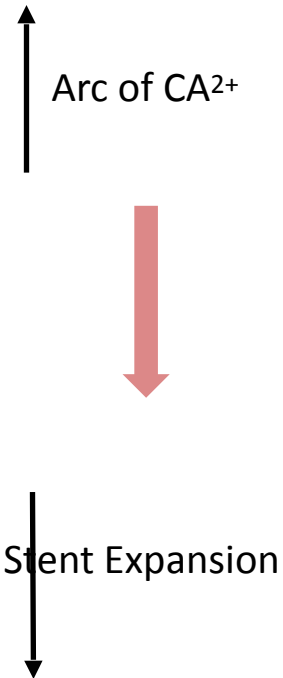
(○ depicts stent; ○ depicts lumen)



Altération du polymère



Stent Expansion after Stent inflation at 16 ATM¹



Majoration TLR – Thrombose de stent
 DC cardiaque et toute cause

¹ Vavanurakis et al. CCI 2001

² Genereux et al. J Am Coll Cardiol 2014

Atherectomie Orbitale : Materiel

Système d'athérectomie Orbitale : OAS



ViperWire Advance®
Coronary Guide Wire

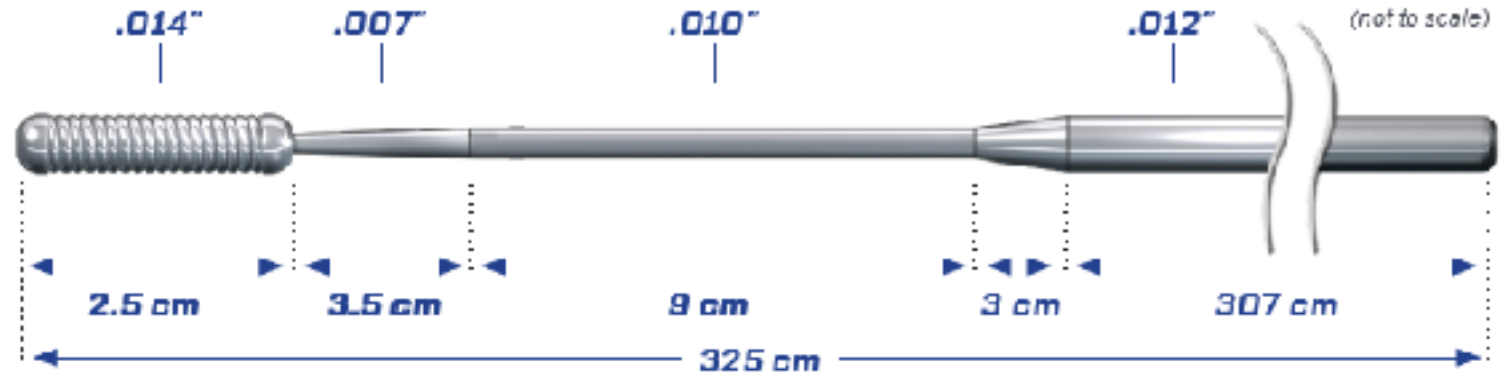
OAS Pump

Orbital
Atherectomy
OAD with
Saline Line

ViperSlide®
Lubricant

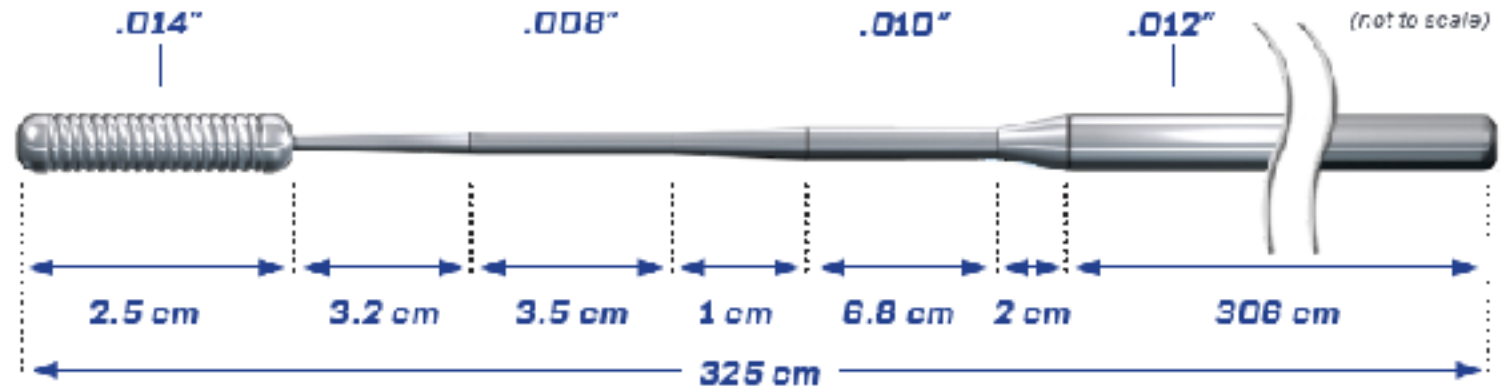
VIPERWIRE ADVANCE

Tip: Platinum/Tungsten
 Core: 304V Stainless Steel
 Spring Tip Stiffness:
 1.4 gf at 10 mm



VIPERWIRE ADVANCE WITH FLEXTIP

Tip: Platinum/Tungsten
 Core: Nitinol with Stainless Steel Support Coil
 Spring Tip Stiffness:
 1.0 gf at 10 mm



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



- Réduit les frictions
- 20 ml / l de NaCl



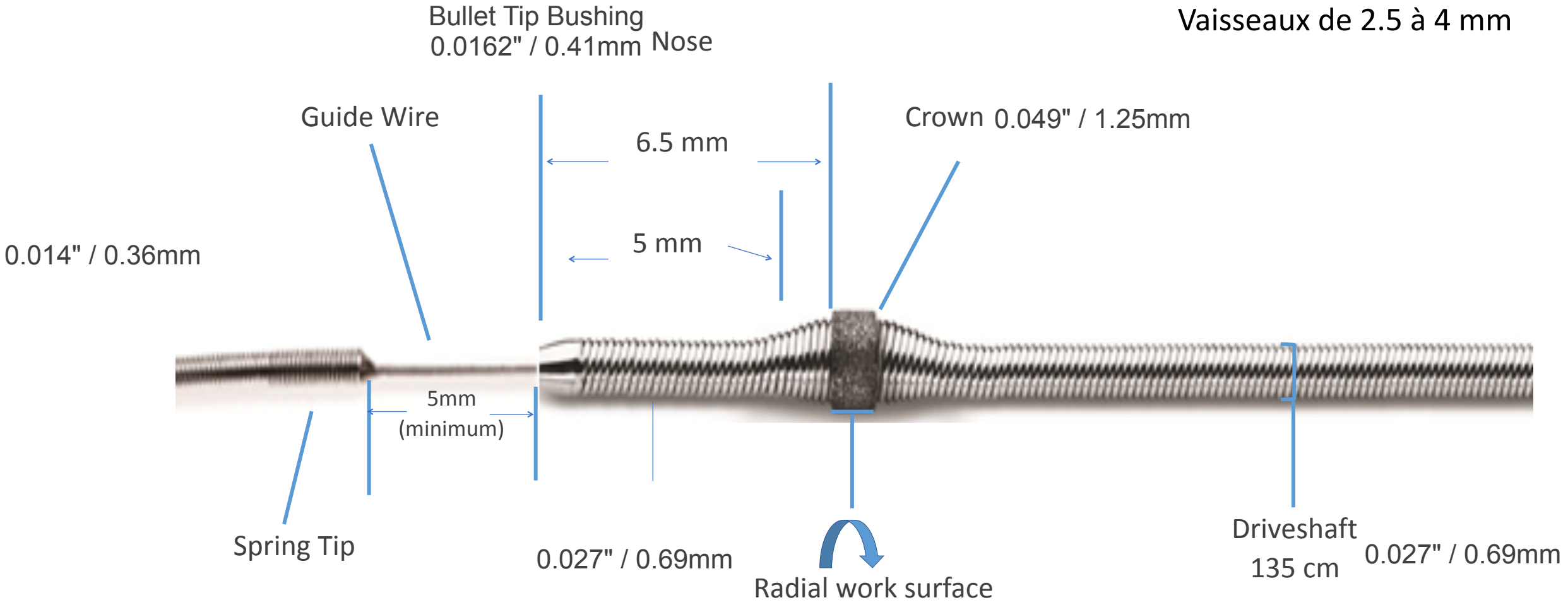
Ingredient	Amount
Soybean Oil	10%
Egg Yolk Phospholipids	1.2%
Glycerin	2.25%
Sodium Hydroxide (pH range is 6.0 to 8.9)	Quantity Sufficient
Water for Injection	Quantity Sufficient

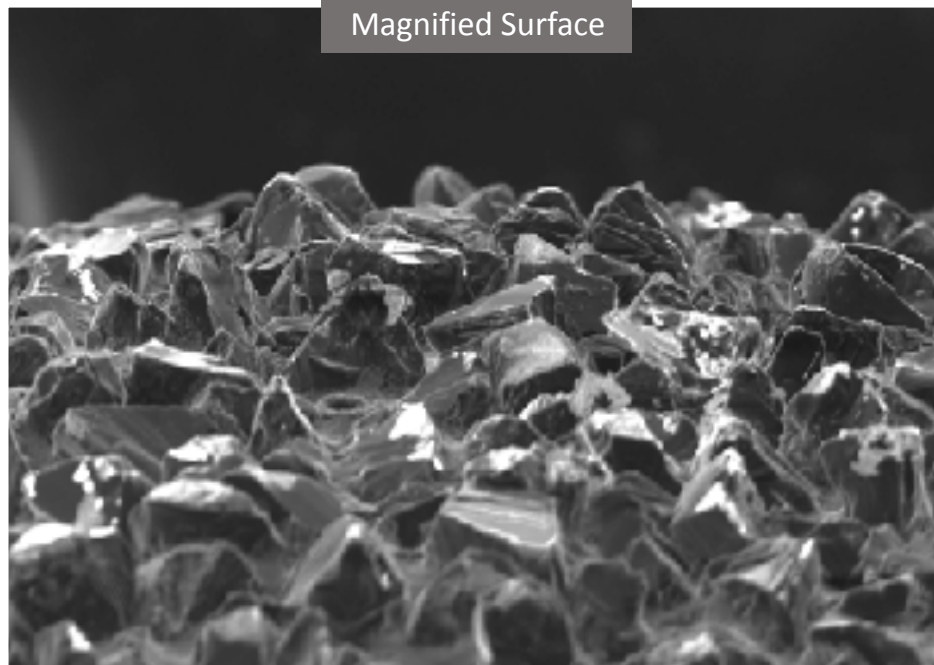
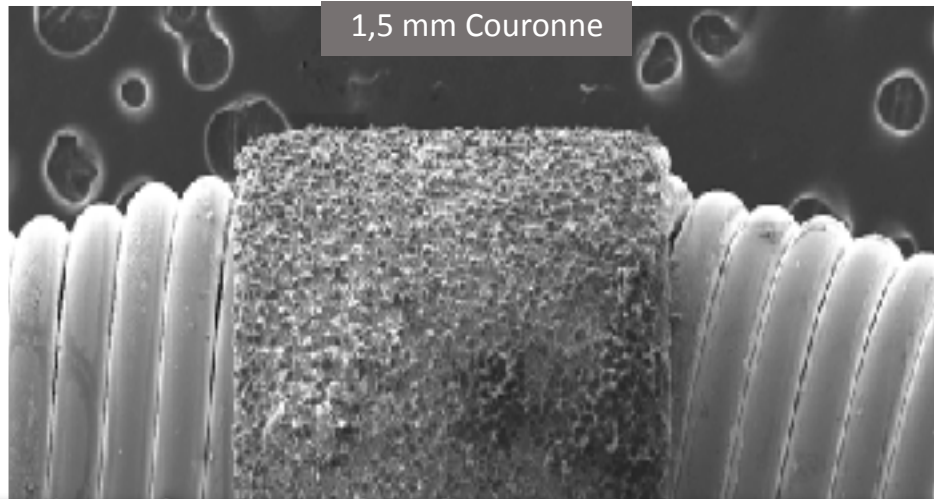
Matériel OAS : Diamondback 360[®] Coronary



Matériel OAS : Couronne de 1.25 mm

6F guiding Catheter
Vaisseaux de 2.5 à 4 mm





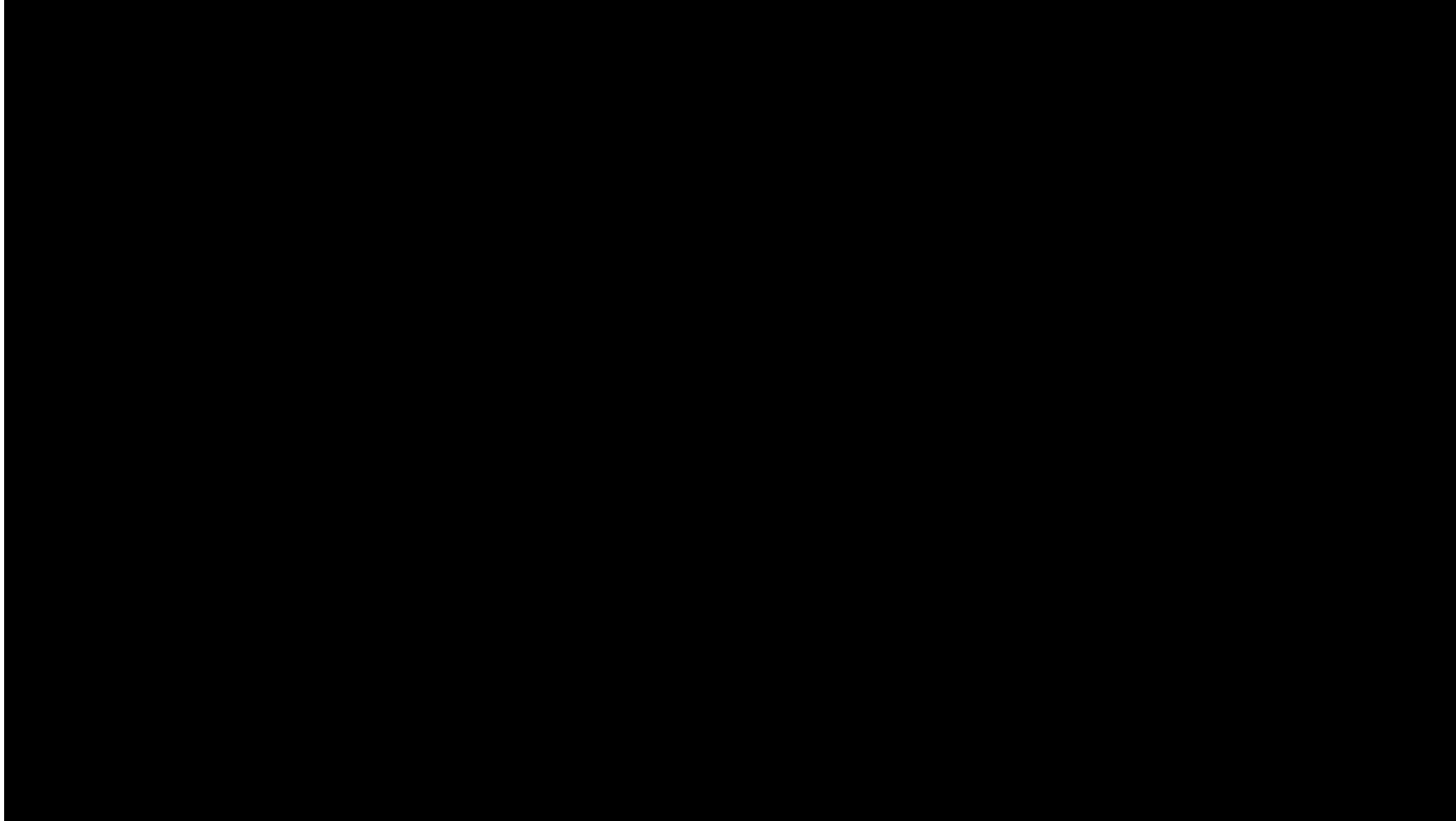
Revêtement Diamant :

30 microns de longueur
10 microns exposé pour abrasion

Atherectomie Orbitale : Mécanisme d'Action

5 6 7
JUN 2019

OAS : Mécanisme d'action



OVERVIEW

System mechanics can be better understood with the following formula:

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

F_c

CENTRIFUGAL FORCE

Pulls the crown outward from its axis allowing it to treat lesions in vessels of varying size

m

MASS

- The mass of the crown
- Directly proportional
 - As mass increases, centrifugal force increases



v

VELOCITY

- OAD rotational speed
- Directly proportional
- Exponential relationship

Classic Crown

Speed	Force Multiplier
80k RPM	Baseline
120k RPM	2.25X

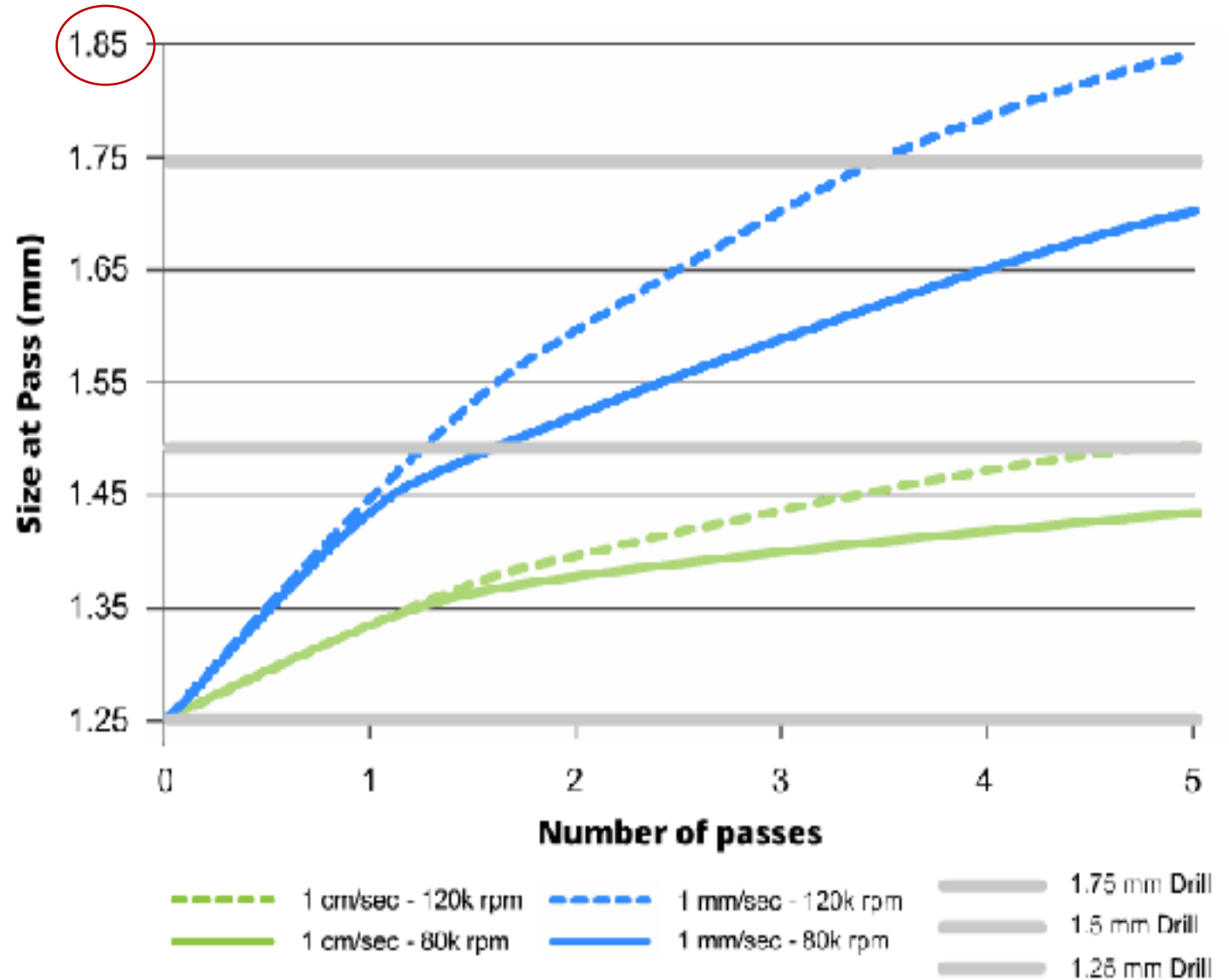
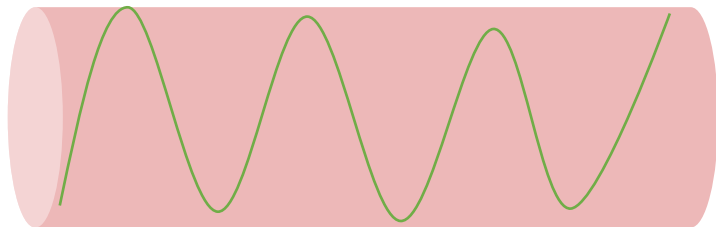
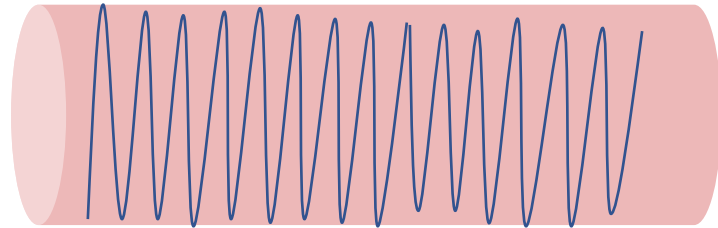
R

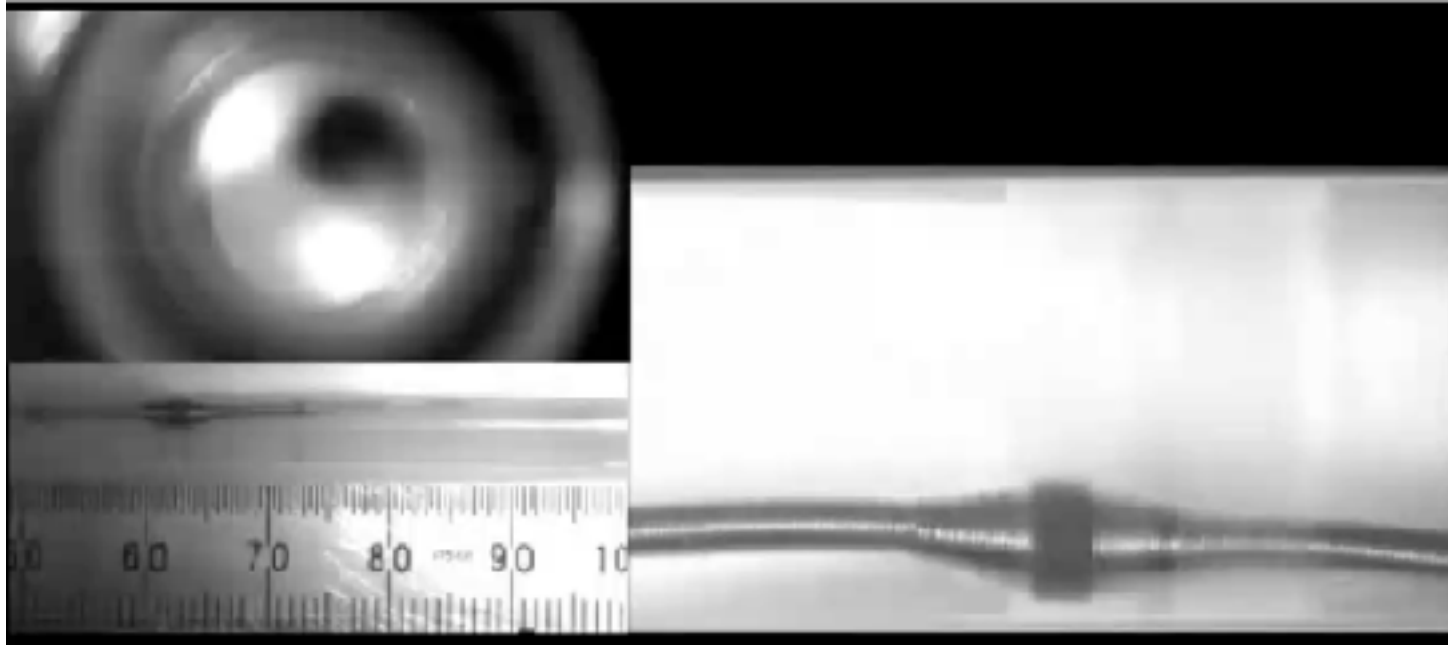
RADIUS OF ROTATION

- Inversely proportional
- As radius increases, centrifugal force decreases

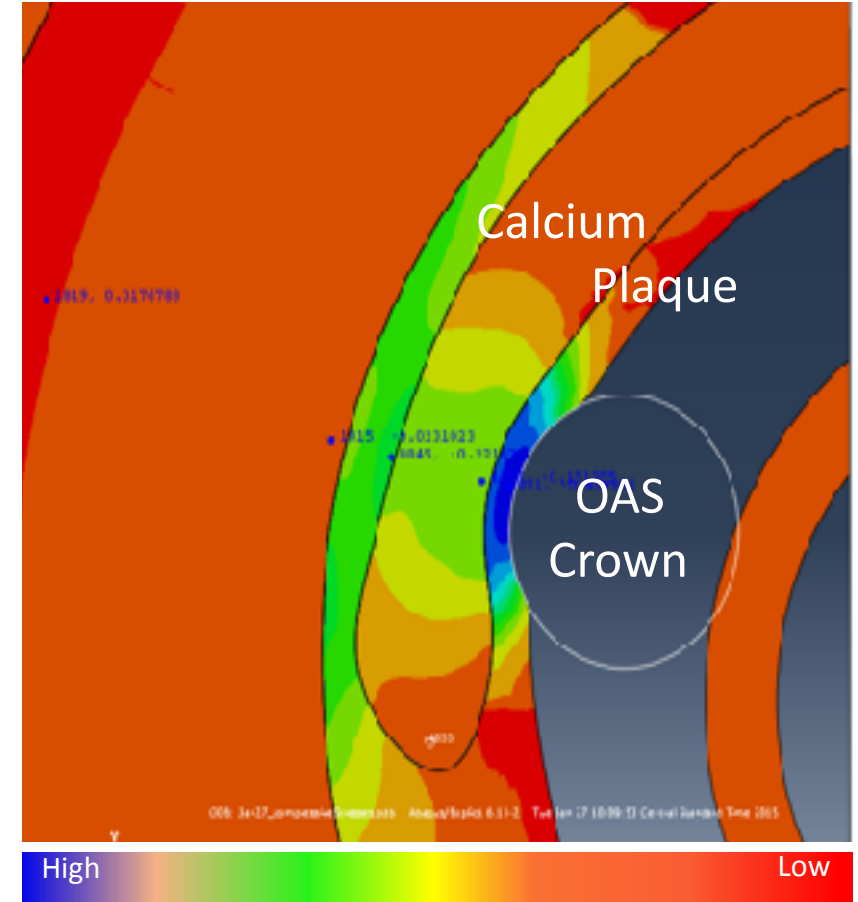


Orbital Sanding action : « Time Dependant »

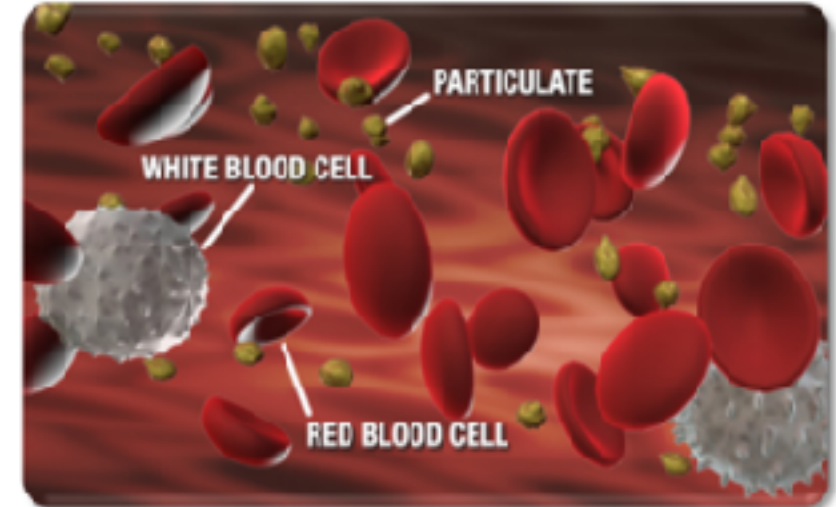
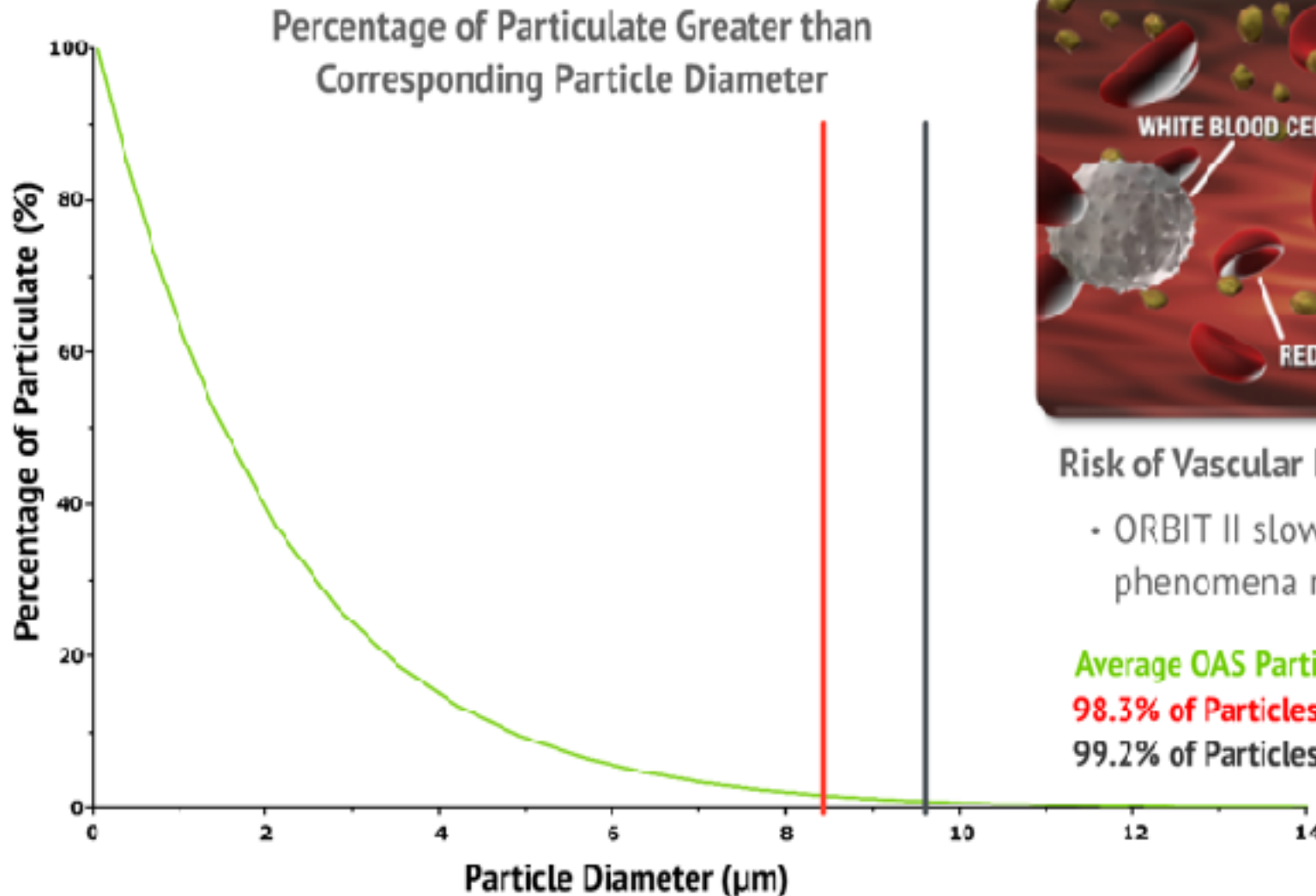




Effet mécanique sur la plaque
Fracture de la plaque calcique



Particulate Size Generated During Use in Carbon Block Model¹



Risk of Vascular Bed Overload Minimized

- ORBIT II slow flow or no reflow phenomena rate of 0.9%

Average OAS Particulate Size: 2.04 microns
98.3% of Particles < Red Blood Cell Diameter
99.2% of Particles < Capillary Diameter

1. Particulate data collected from carbon block simulation model. Curve created with a statistical regression analysis. Data on file. Particulate analysis capability range is 0.717 micron to 46.228 micron.

ROTABLATOR™
atherectomy device



Diamondback 360 OAS
Classic Crown 1.25 mm



Atherectomie Orbitale : Preuves Scientifiques

STUDY	DESIGN	CALCIUM	N	YEARS OF FOLLOW-UP					
				ACUTE	1	2	3	4	5
ORBIT I	Feasibility study, Classic Crown (India)*	Mild to severe	50	■	■	■	■	■	■
ORBIT II	IDE pivotal study of Classic Crown (US)	Severe	443	■	■	■			
COAST	IDF study, Micro Crown (US & Japan)	Severe	100	■	■				
CORONARY FLOW RESERVE (CFR)	Post-market, CFR post-OA/ stenting (US)	Severe	15	■					
ECLIPSE	Powered RCT, vs. conventional angioplasty (US)	Severe	~2000						

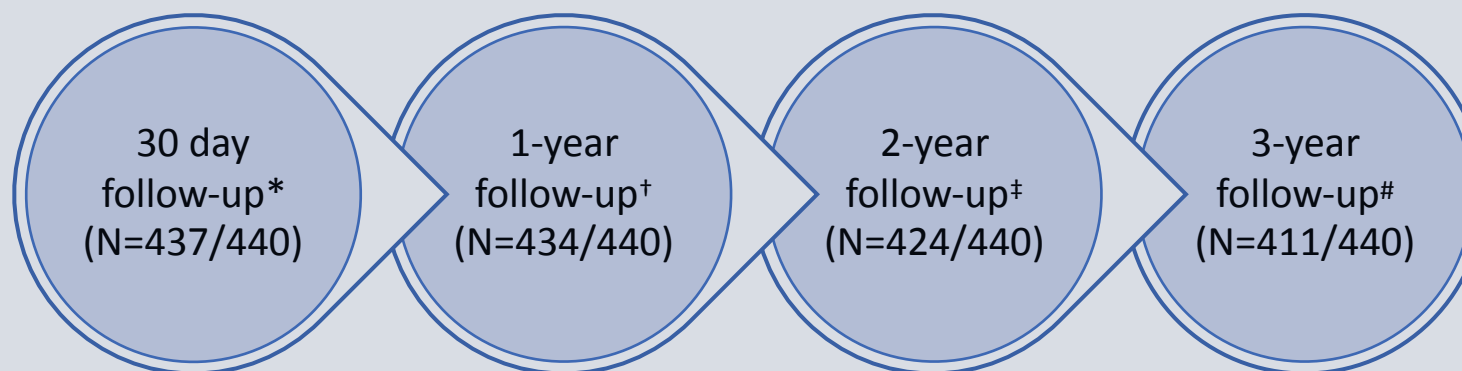
CURRENTLY ENROLLING

- **The ORBIT I Study** Prospective, non-randomized first in man trial, two centers in India
- **50 Patients** At least > 90° of calcification via IVUS treated with the OAS Classic Crown prior to stent placement

	6 Month Follow-up ¹	3 Year Follow-up Single Center ²	5 Year Follow-up Single Center ²
MACE	8% (4/49)	18.2% (6/33)	21.2% (7/33)
Cardiac Death	2% (1/49)	9.1% (3/33)	12.1% (4/33)
Q-wave MI	0	0	0
Non Q-wave MI	6% (3/49)	6.1% (2/33)	6.1% (2/33)
TLR	2% (1/49)	3.0% (1/33)	3.0% (1/33)

To evaluate safety and efficacy of the Diamondback 360[®] Coronary OAS Classic Crown* to prepare *de novo*, severely calcified coronary lesions for enabling stent placement

- Prospective, multi-center trial in the United States – Single Arm
- 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

PATIENT CHARACTERISTICS¹

Demographics	N = 443
Male	64.6%
Age (yrs)	71.4
History of Diabetes Mellitus	36.1%
History of CABG	14.7%
History of Dislipidemia	91.9%
History of Hypertension	91.6%
Smoker (current or previous)	66.1%

ACC/AHA lesion classification

Type A	0/440 (0.0)
Type B1	114/440 (25.9)
Type B2	197/440 (44.8)
Type C	129/440 (29.3)

VESSEL AND LESION CHARACTERISTICS¹ N = 440

Mean Pre-procedure Target Lesion Length	18.9 mm
Mean Pre-procedure Minimum Lumen Diameter	0.5 mm
Mean Pre-procedure Percent Stenosis	84.4%
Subjects with Severely Calcified Lesions	99.3%

ORBIT II: EFFICACY OUTCOMES¹

Procedural Success Components:

Successful Stent Delivered:	97.7%
Less than 50% Residual Stenosis:	98.6%

49 US Site

	30-day	1-year	2-year	3-year
Major adverse cardiac events	46 (10.4)	74 (16.9)	87 (20.0)	101 (23.5)
Death	2 (0.5)	19 (4.4)	34 (7.9)	52 (12.4)
Cardiac death	1 (0.2)	14 (3.2)	20 (4.7)	28 (6.7)
Myocardial infarction	43 (9.7)	47 (10.6)	48 (10.9)	49 (11.2)
Q wave myocardial infarction	4 (0.9)	4 (0.9)	4 (0.9)	5 (1.2)
Non-Q wave myocardial infarction	39 (8.8)	43 (9.7)	44 (10.0)	44 (10.0)
Target vessel revascularization	6 (1.4)	25 (5.8)	34 (8.1)	42 (10.2)
Target lesion revascularization	3 (0.7)	20 (4.7)	26 (6.2)	32 (7.8)
Target vessel revascularization (non-TLR)	3 (0.7)	8 (1.9)	11 (2.6)	14 (3.4)

MACE : MI - TVR -CARDIAC DEATH

**SEVERE ANGIOGRAPHIC
 COMPLICATIONS¹**

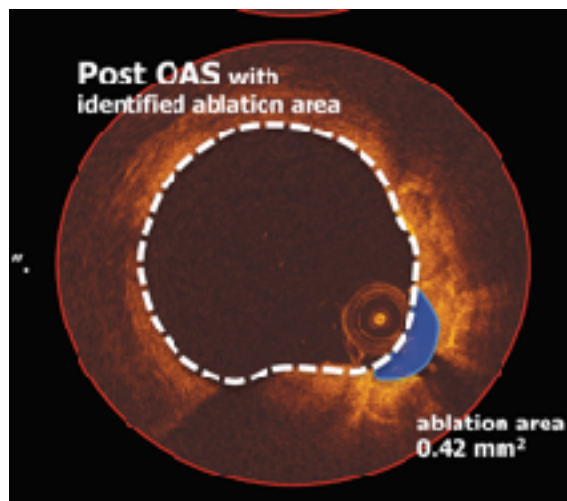
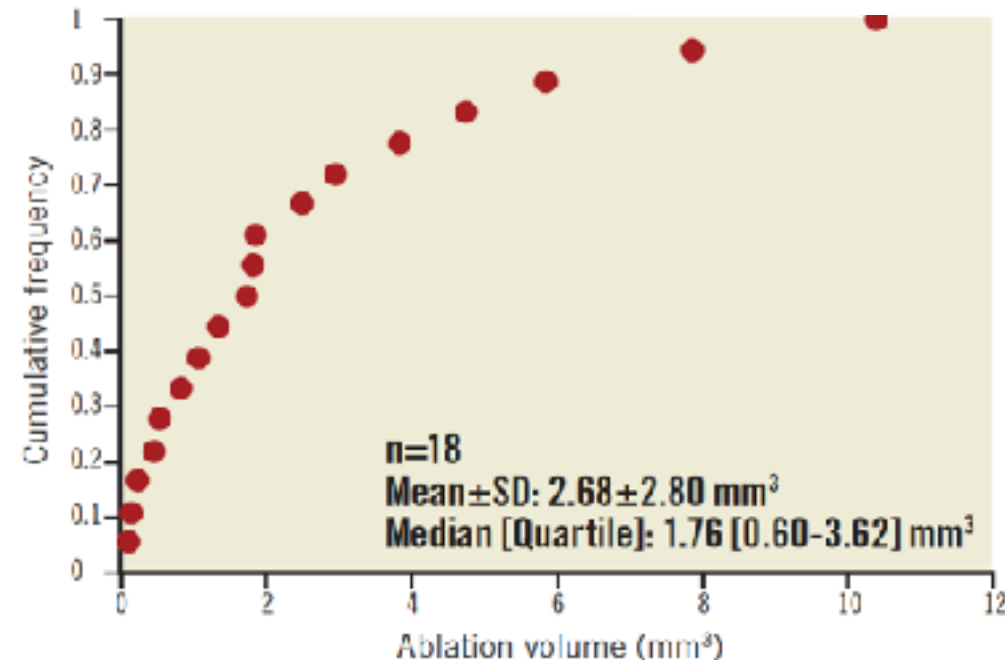
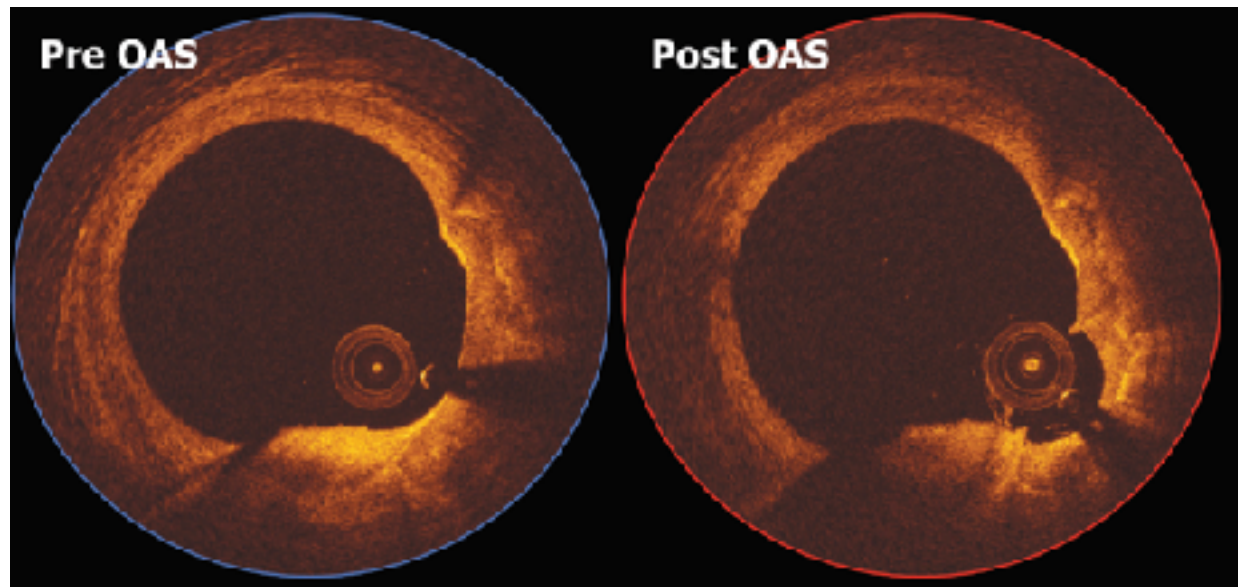
Criteria	Prior to OAS	Post OAS	Post Balloon/ Stent	Unknown	Overall
Dissection Type C-F	0.2%	2.3%	0.9%	0.0%	3.4%
Perforation	0.0%	0.9%	0.9%	0.0%	1.8%
Persistent Slow Flow/No Reflow	0.2%	0.2%	0.5%	0.0%	0.9%
Abrupt Closure	0.2%	0.9%	0.2%	0.5%	1.8%

To evaluate safety and efficacy of orbital atherectomy (OA) in real-world patients with severe coronary artery calcification (CAC)

Retrospective, multi-center registry at 3 U.S. Sites

- 458 consecutive patients with severe CAC who underwent OA followed by stenting
- Registry included patients that were excluded from the ORBIT II trial
- Primary Endpoint: 30-day major adverse cardiac and cerebrovascular events (MACCE), as defined as all-cause death, myocardial infarction, TVR, and stroke

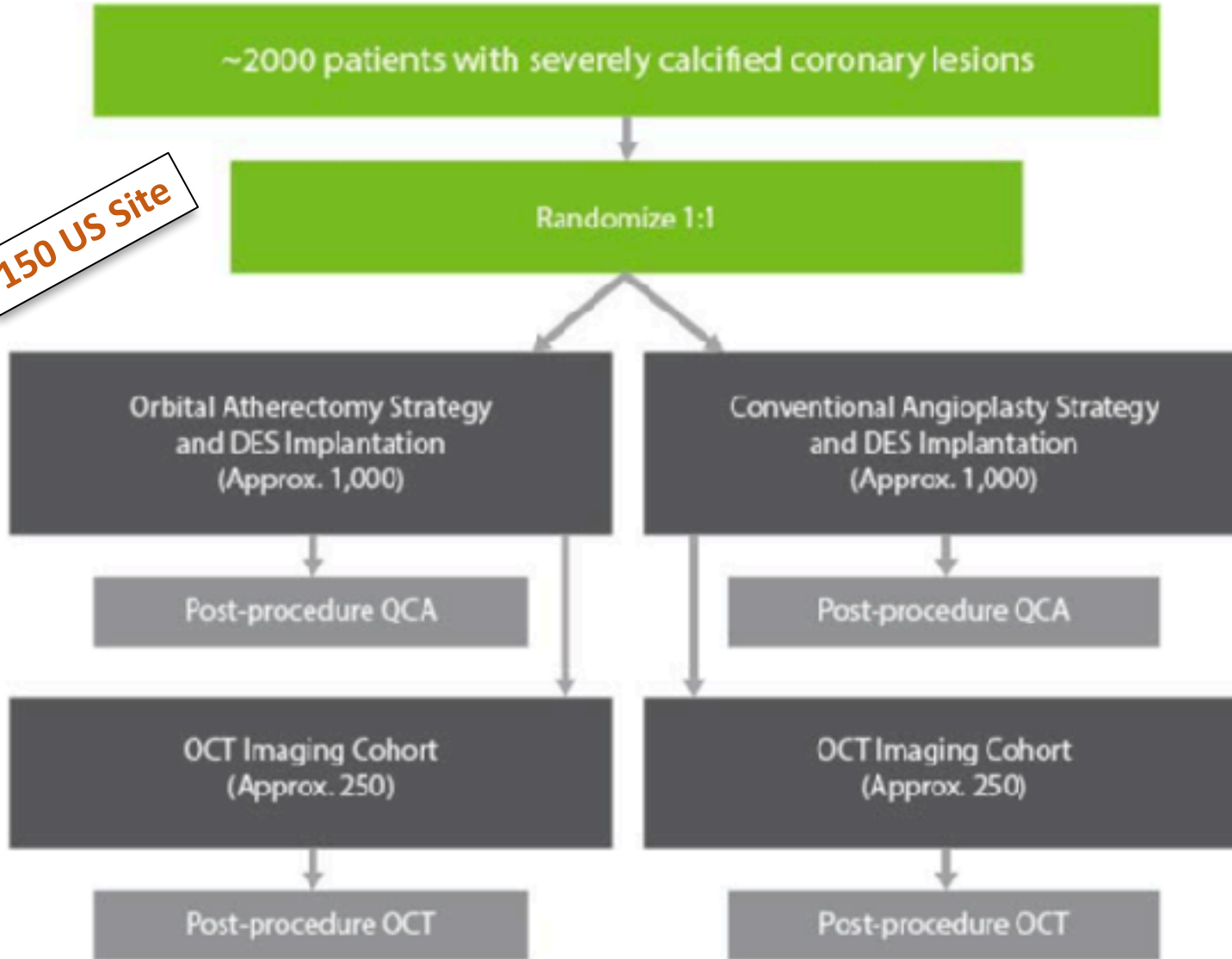
30-day Clinical Event Rates	n=458
MACCE	1.7%
Death	1.3%
Myocardial infarction	1.1%
Target vessel revascularization	0.0%
Stroke	0.2%
Angiographic Complications	
Perforation	0.7%
Dissection	0.9%
No-reflow	0.7%
Successful Stent Delivery	99.1%



Dissection		8 (44)
	Flap	7 (39)
	Cavity	0 (0)
	Double lumen cap	2 (11)
	Fissure	3 (17)



150 US Site



Co-Primary Endpoints

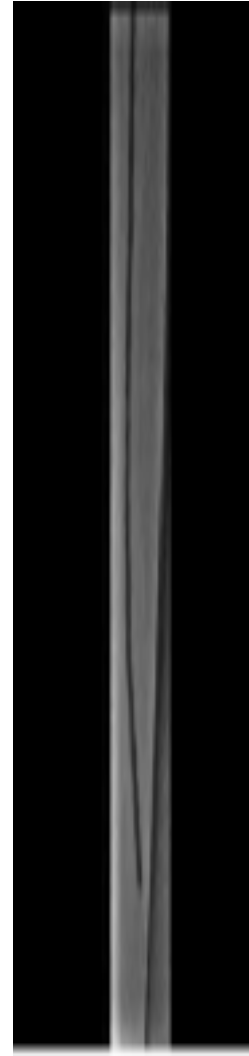
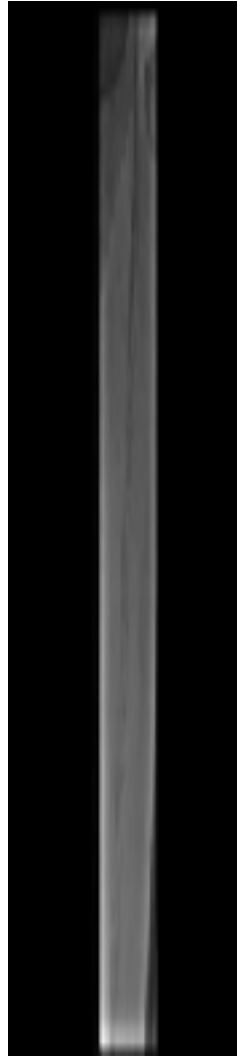
- * MLA Stent / OCT lors de l'implantation
- * Target vessel failure (TVF) à 12 mois :
Critère composite associant décès d'origine cardiaque, Revascularisation du vaisseaux cible (Myocardial infaction ou ischemia driven)

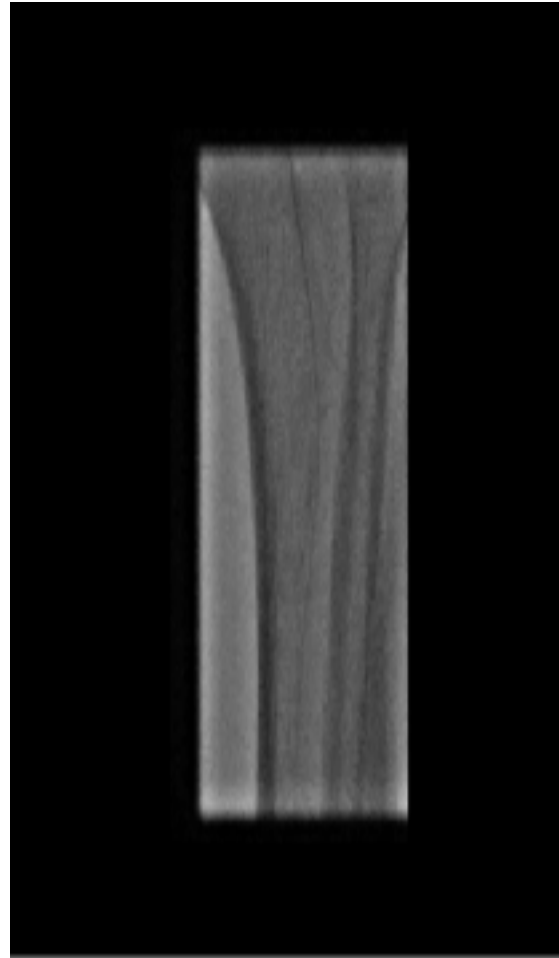
Environ 700 inclusions USA
Ouverture en EUROPE...

Atherectomie Orbitale : Retour d'expérience

Clinique Pasteur depuis 15 avril 2019 : 9 patients traités par OAS pour AMI

1 dissection de type D couvert par stent







Conclusion

Nouveau device d'athérectomie en EU : Marquage CE sous peu (juin 2019)

Mécanistique différente de l'athérectomie rotationnelle

Programme clinique ambitieux

Nombreuse preuves scientifiques dans le champ périphérique