

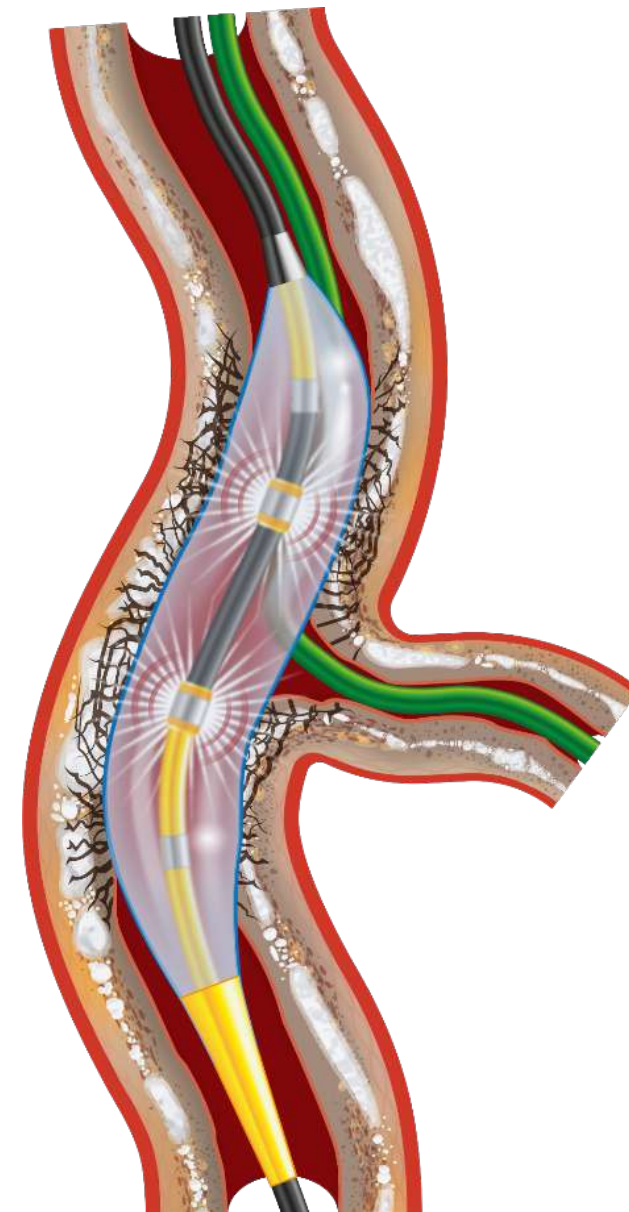
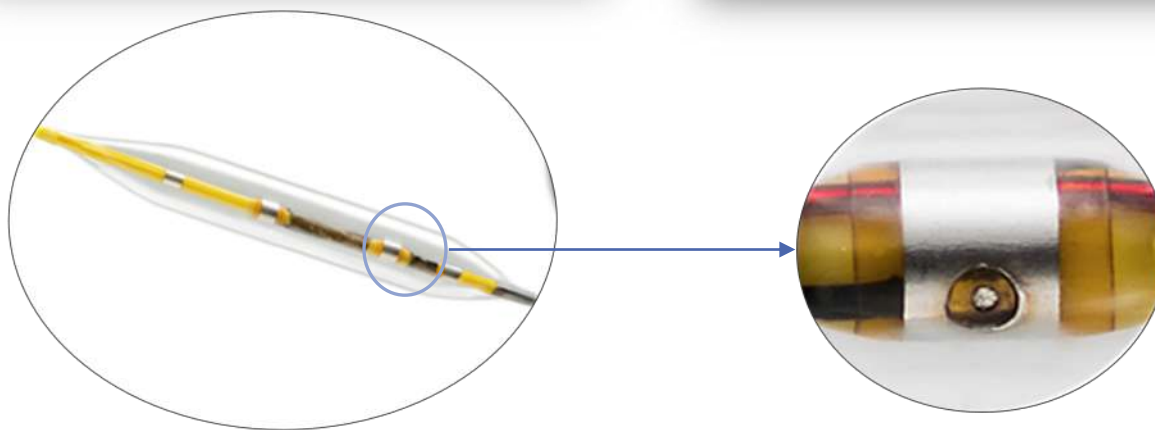
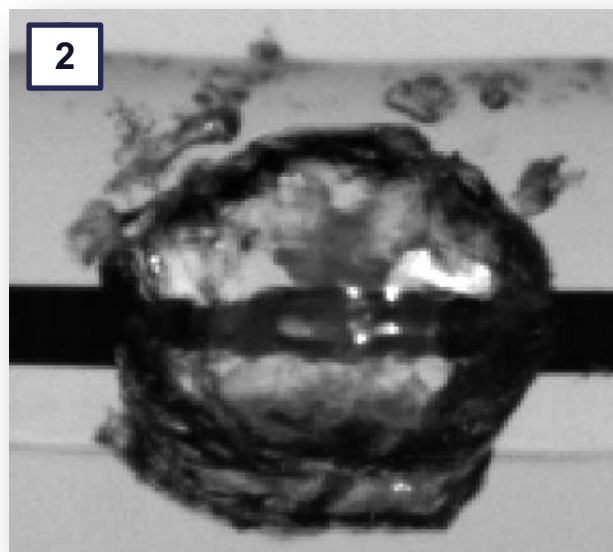
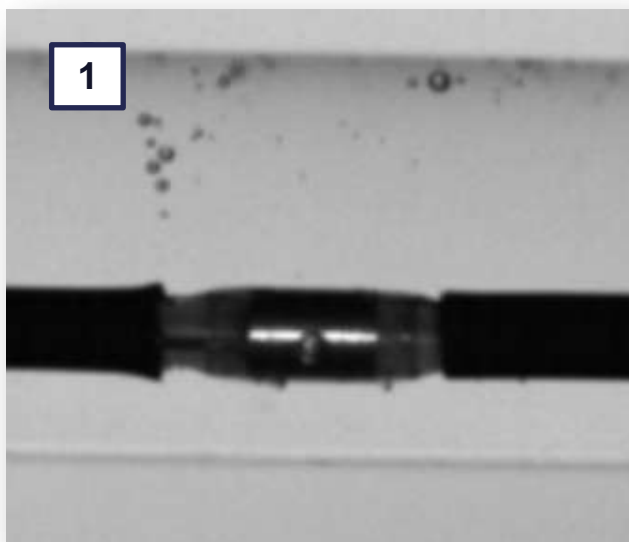


Nouvelles options dans le traitement des lésions calcifiées

Une lésion idéale pour la Lithotripsie intra coronaire

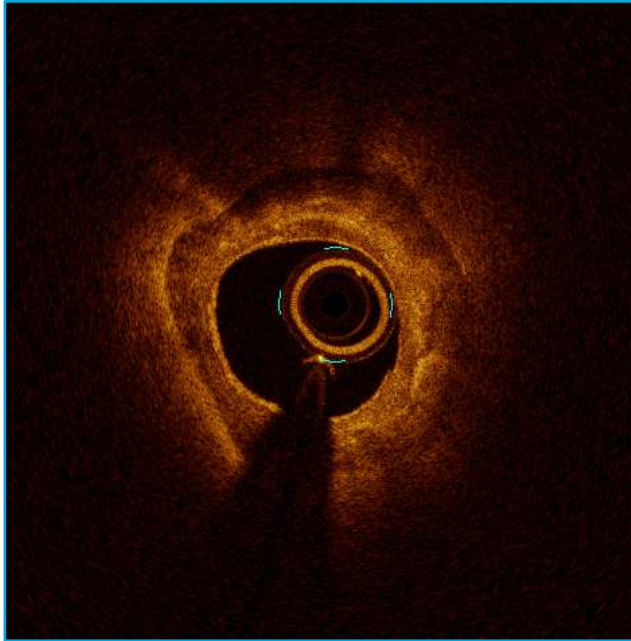
*B.Honton
Clinique Pasteur
Toulouse – France*

Mécanisme d'action de l'IVL



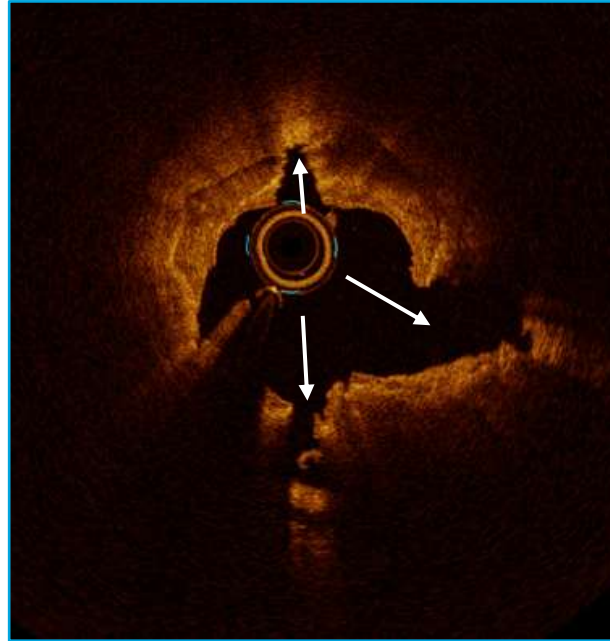
Mécanisme d'action de l'IVL

Pre-procedure



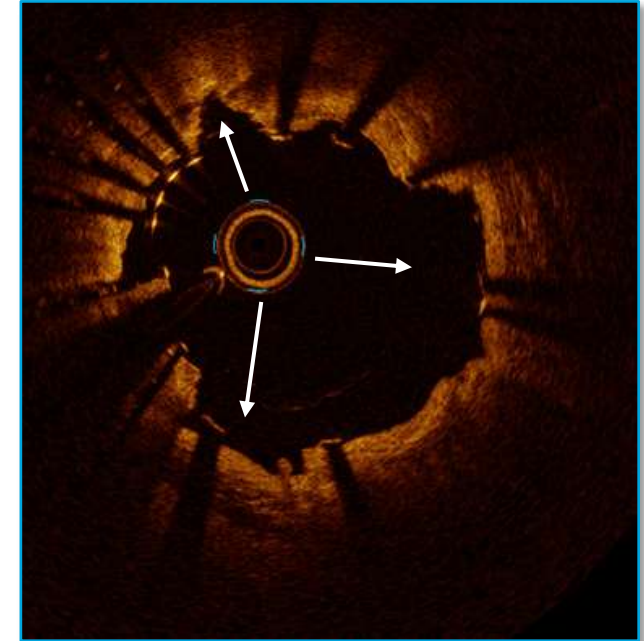
Lumen Area: 1.69 mm²

Post-IVL



Lumen Area: 4.58 mm²

Post-stent



Lumen Area: 9.51 mm²

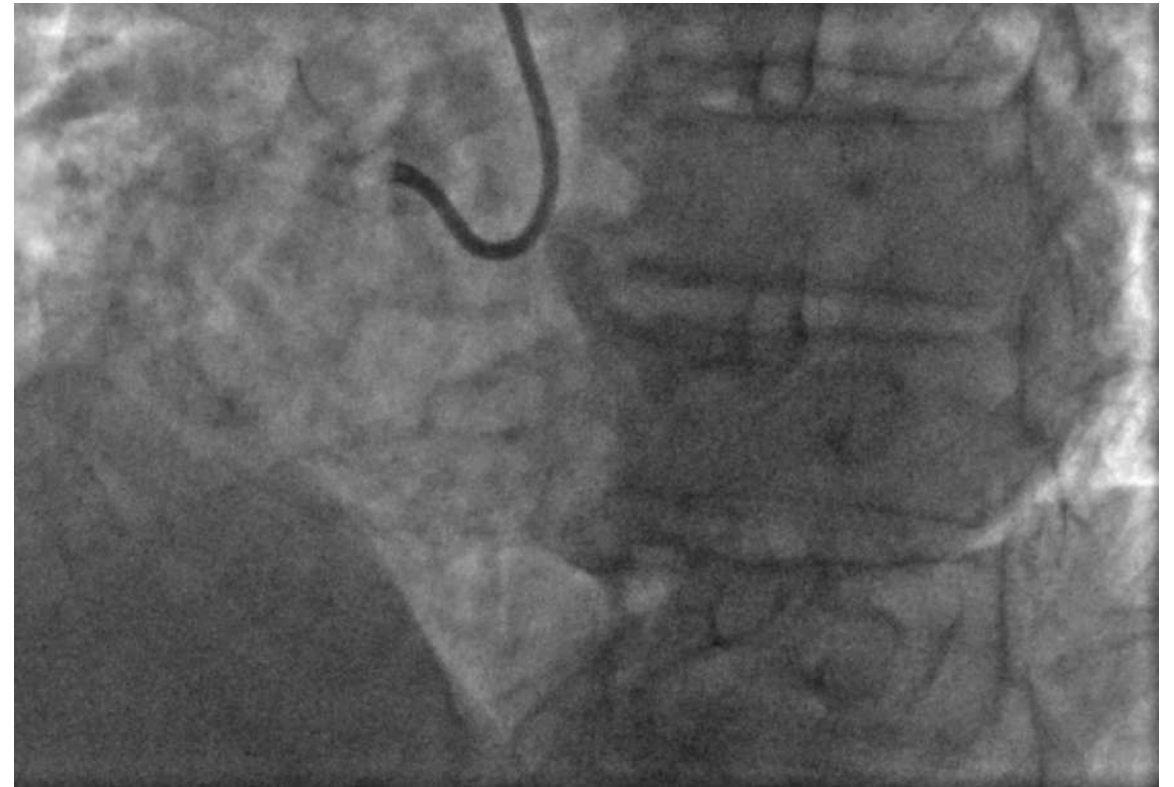
Stent Area: 8.01 mm²

Fractures multiplanes / longitudinales dans la plaque calcique
Absence de production de débris

Monsieur C, 65 ans

D2 – HTA – Obésité (IMC à 31)

Angor d'effort – Ischémie inférieure scintigraphique : 15%



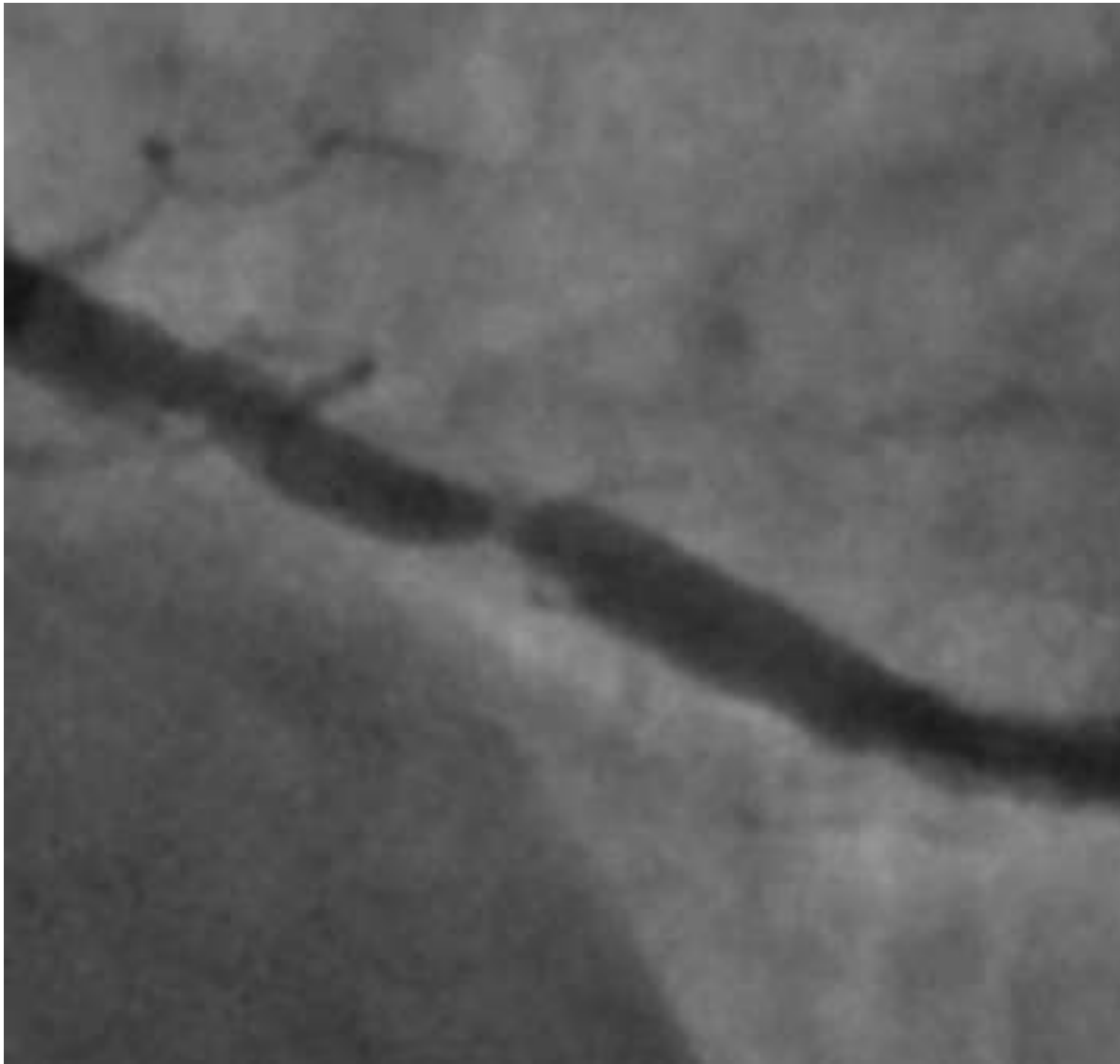
Sténose critique et focale de la CD3

Monsieur C, 65 ans



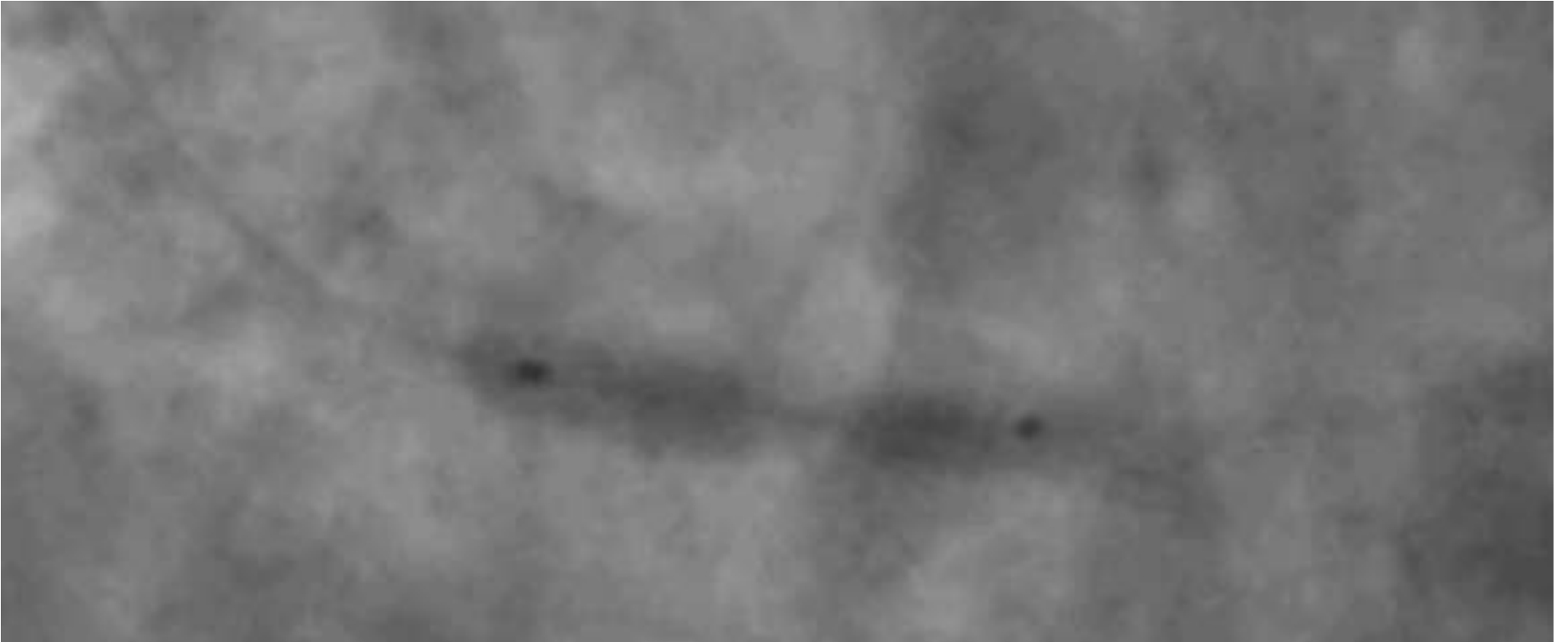
Tortuosité de la CD2

Monsieur C, 65 ans



Calcifications massives
et circumférentielles

Monsieur C, 65 ans



Predilatation NC 3.5x20 mm - 18 ATM

Monsieur C, 65 ans

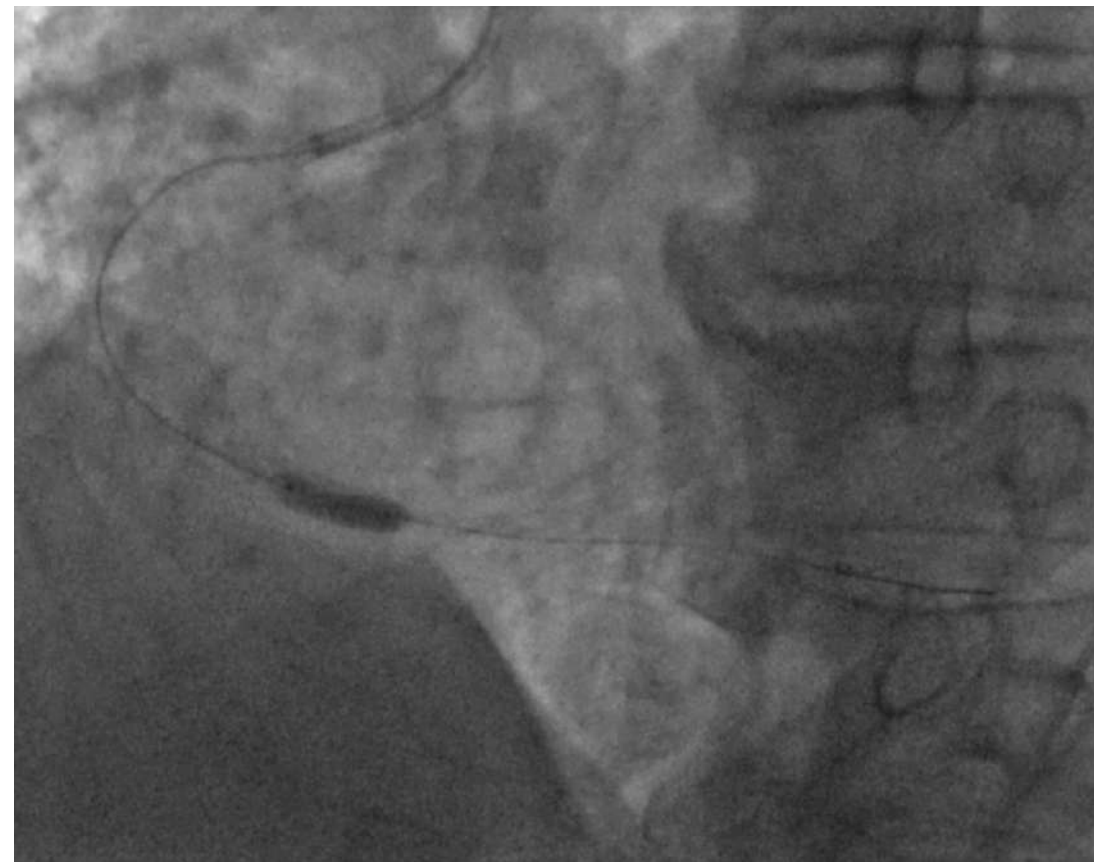


Buddy Wire / Progression Shockwave C2 catheter 4x12 mm

Monsieur C, 65 ans



Premier cycle



Sixième cycle

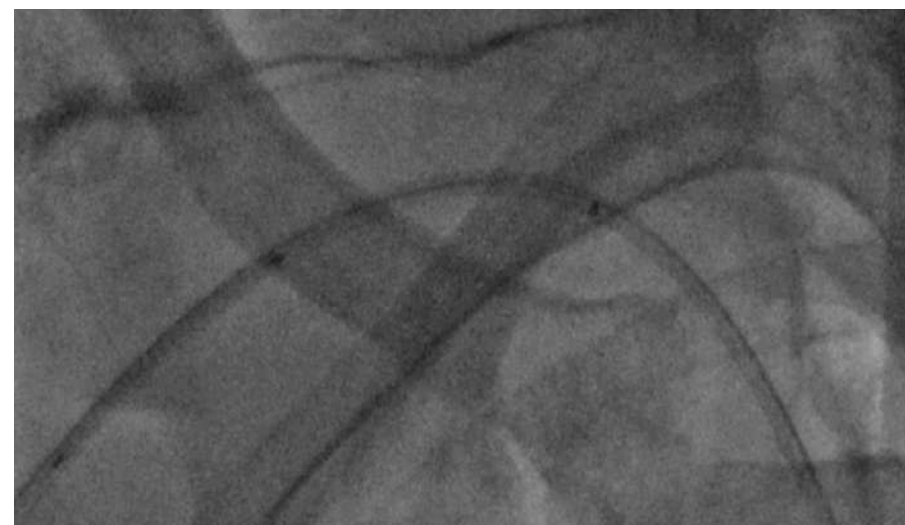
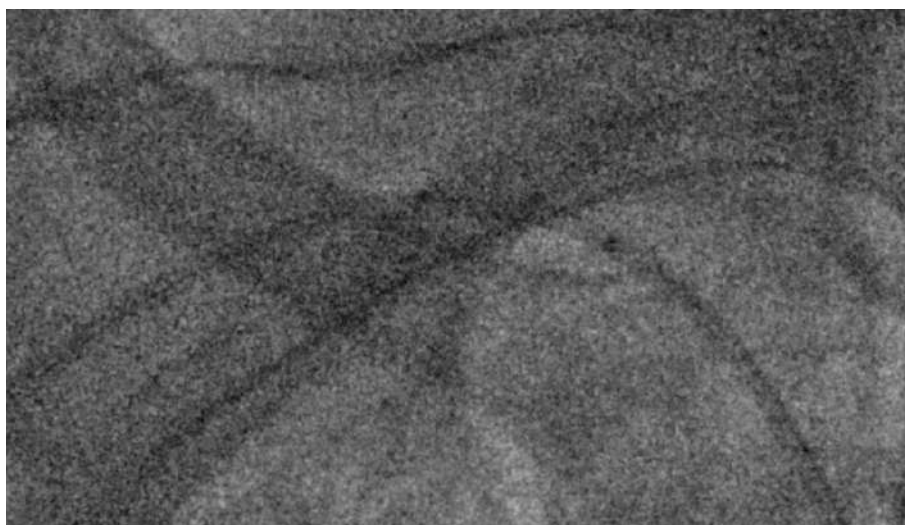
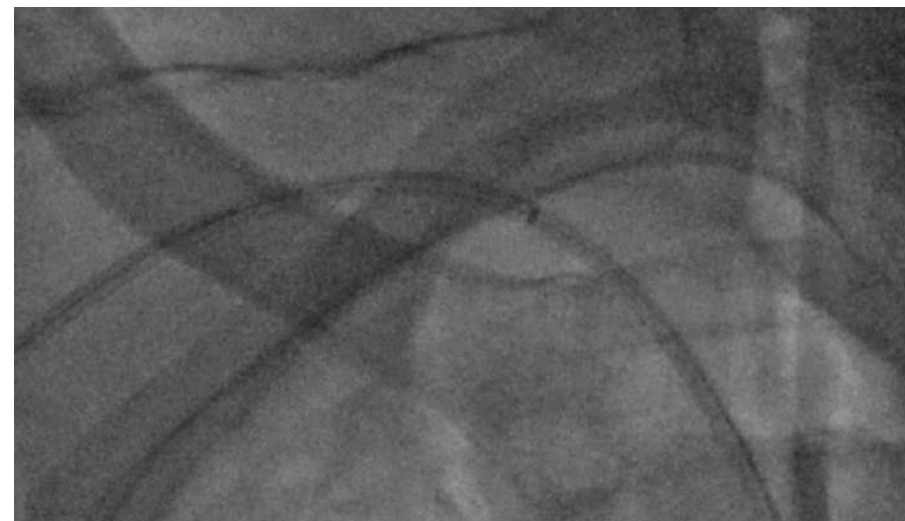
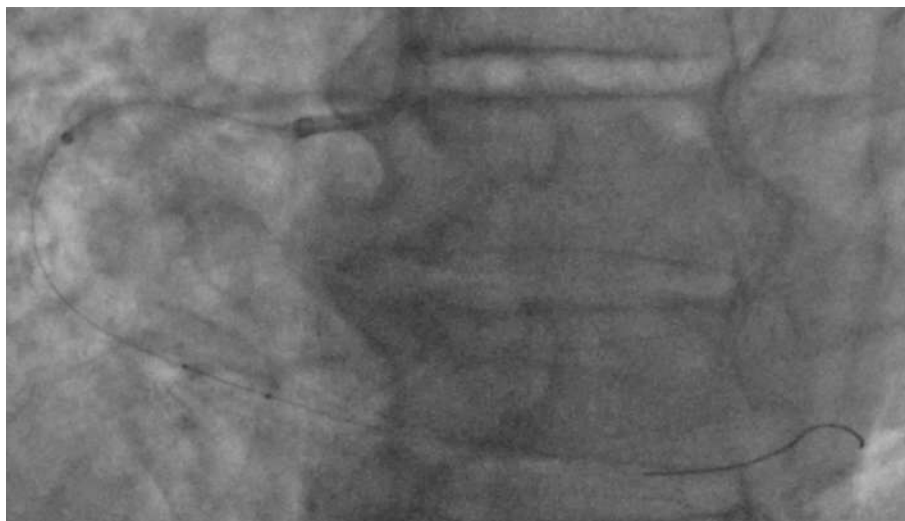
60 impulsions : 5-10% sténose résiduelle

Monsieur C, 65 ans



Contrôle angiographique post IVL

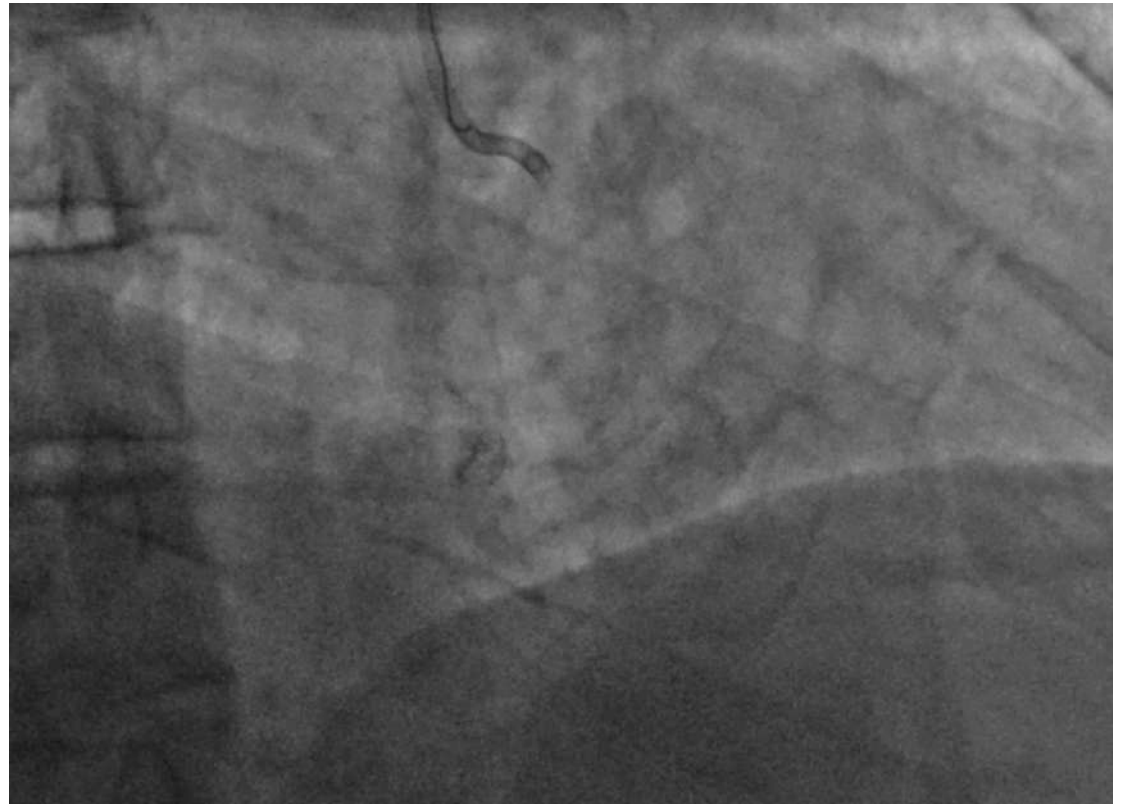
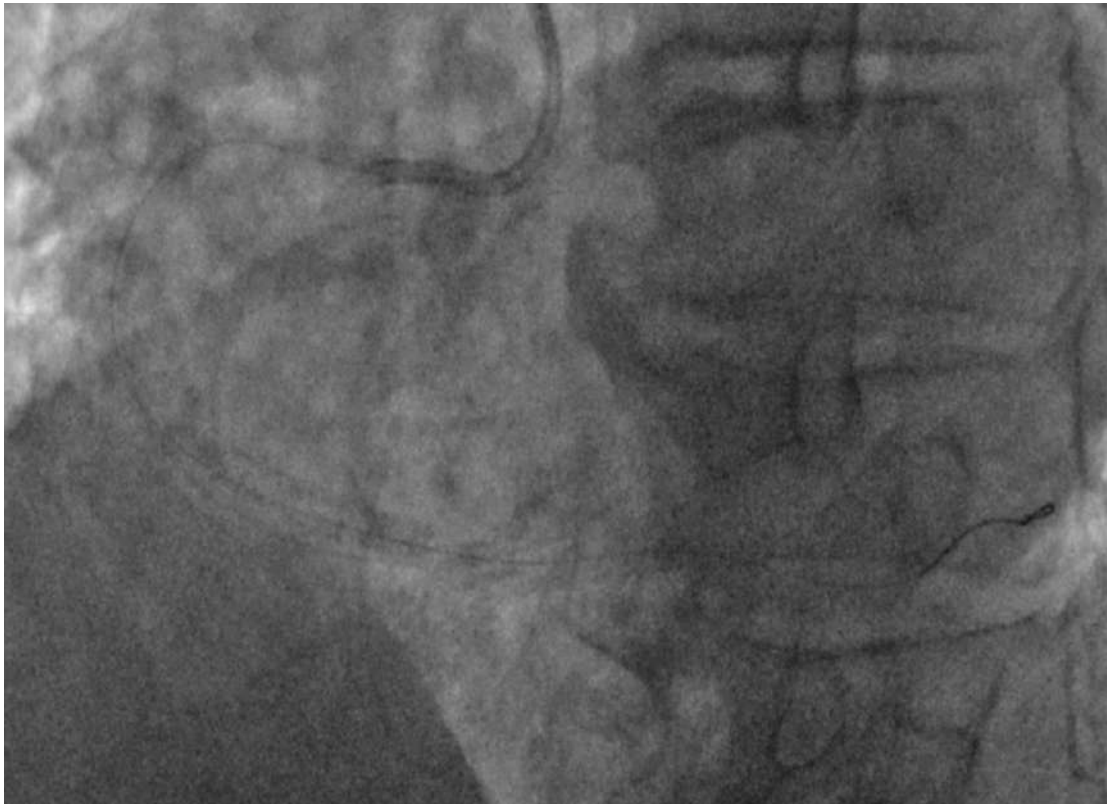
Monsieur C, 65 ans



Monsieur C, 65 ans

Franchissement DES 4 x 34 mm

Post dilatation au ballon NC de 4 mm - 22 ATM



Disrupt Clinical Program

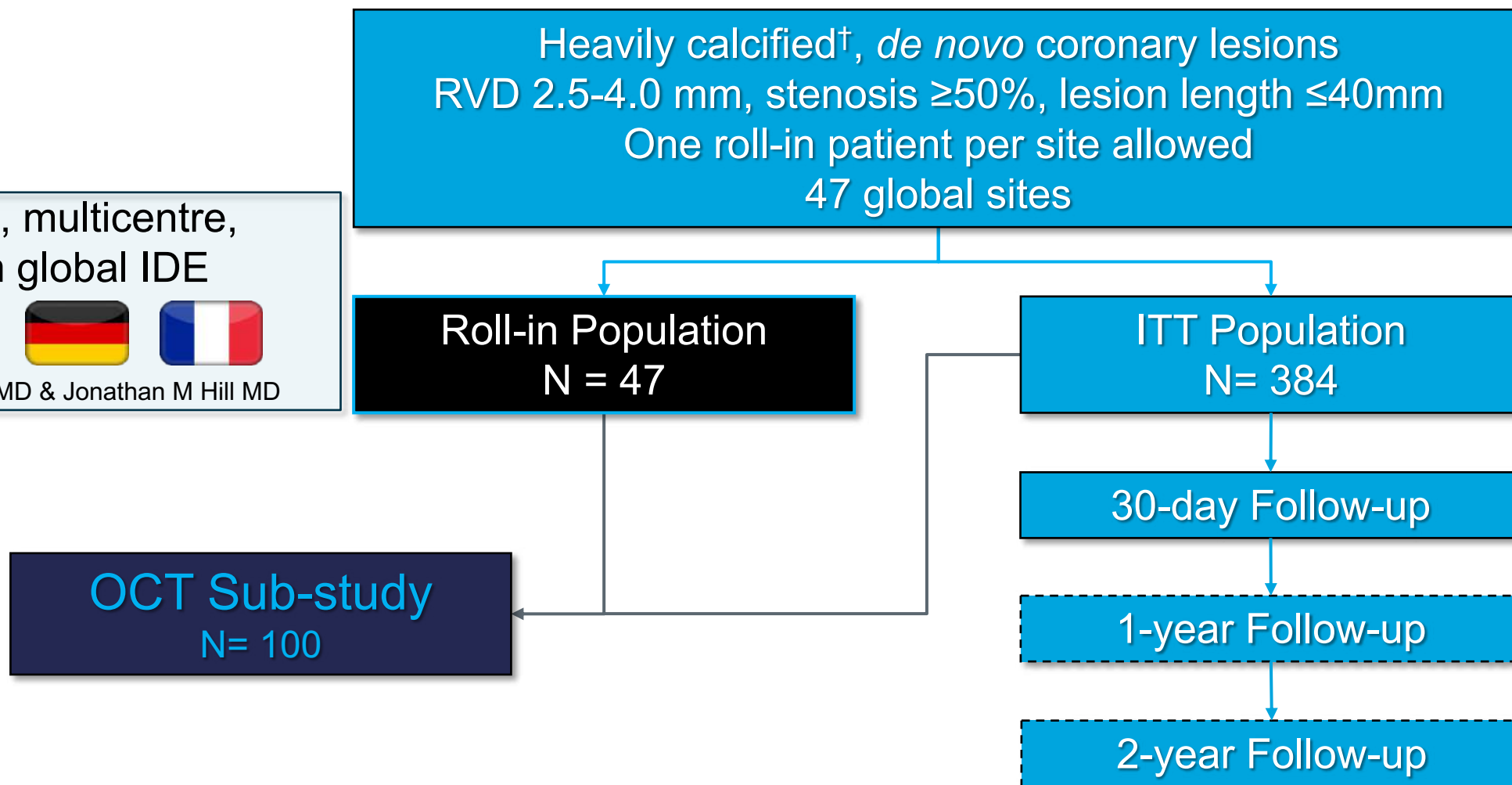
	Disrupt CAD I	Disrupt CAD II	Disrupt CAD III	Disrupt CAD IV
Status	Enrollment completed	Enrollment completed	Enrollment completed	Enrollment completed
Study design	Single arm, safety & feasibility	Single arm, post-market, safety & effectiveness	Single arm, IDE, safety & effectiveness	Single arm, pre-market safety & effectiveness
# of patients	60	120	384	64
# of sites	7	15	47	8
Regions	AU, EU	EU	US, EU	Japan
Published	Circulation 2019	Circ Interv 2019	JACC 2020	Circulation Journal 2021

Disrupt CAD III : Flow Chart

Prospective, multicentre,
single-arm global IDE



PIs: Dean J Kereiakes MD & Jonathan M Hill MD

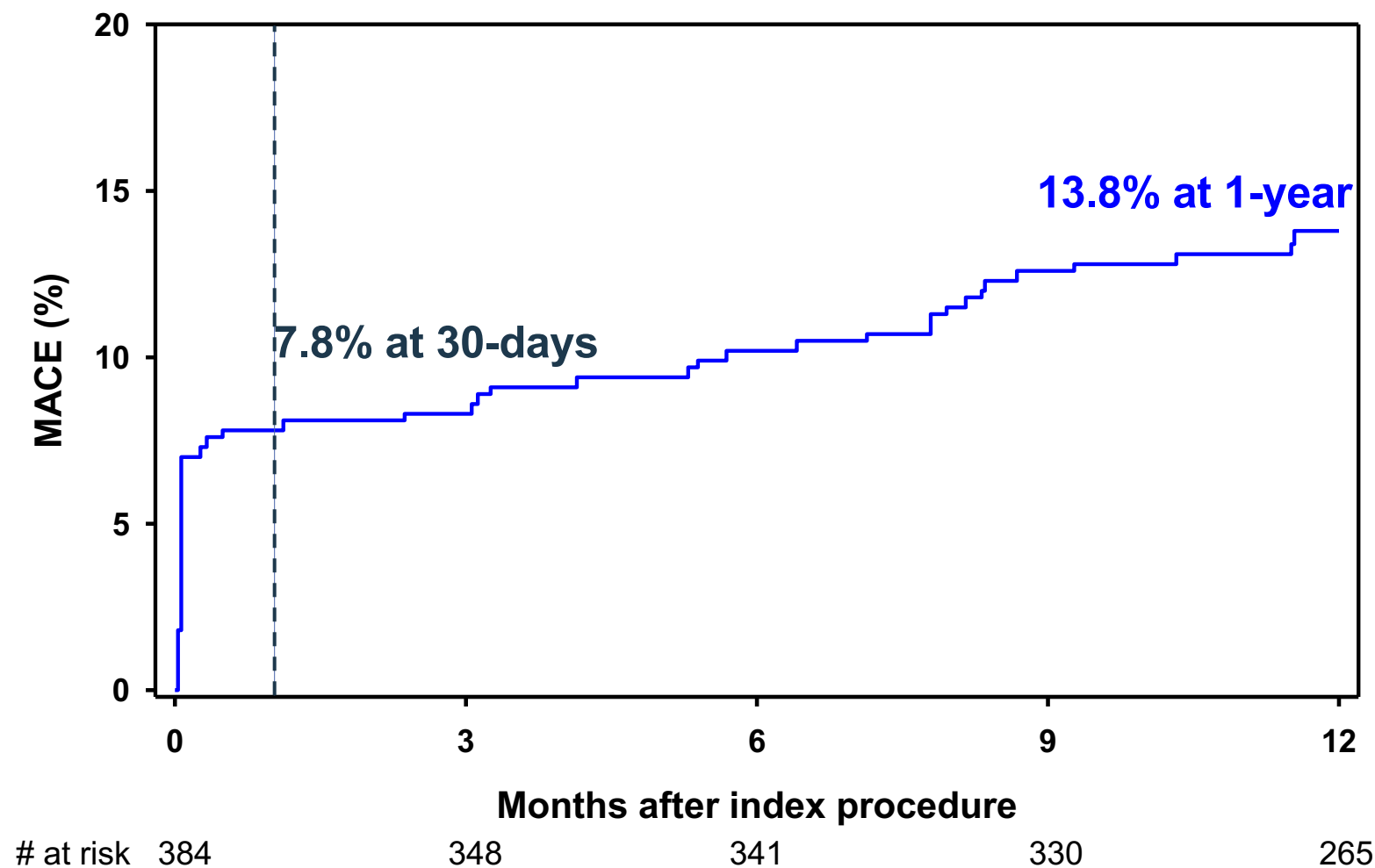


*Kereiakes D. *Am Heart J* 2020;225:10-18

†Radio-opacities both sides of vessel ≥15 mm length by angiography or calcium angle ≥270° by OCT or IVUS

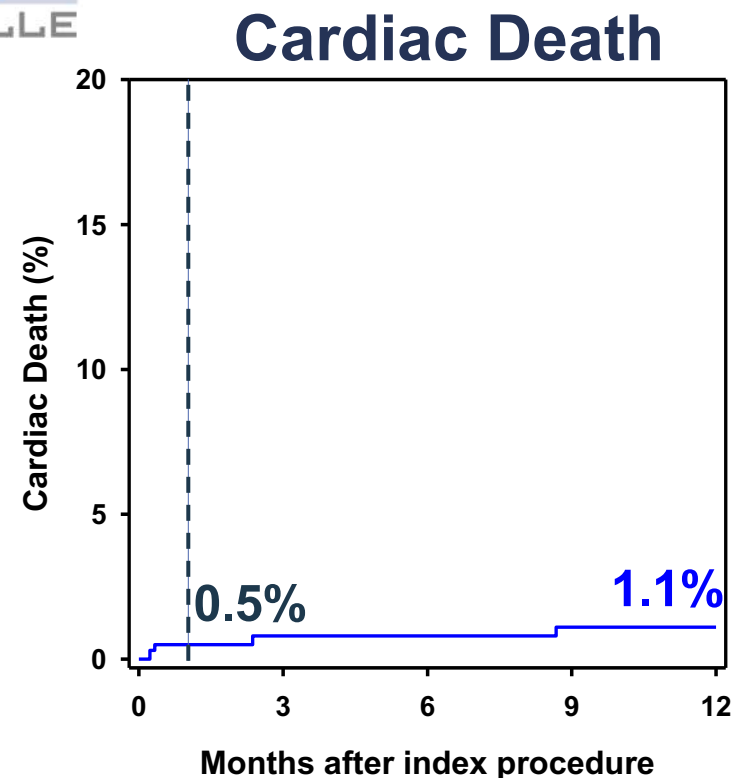
Disrupt CAD III : 12 month FU

Overall MACE

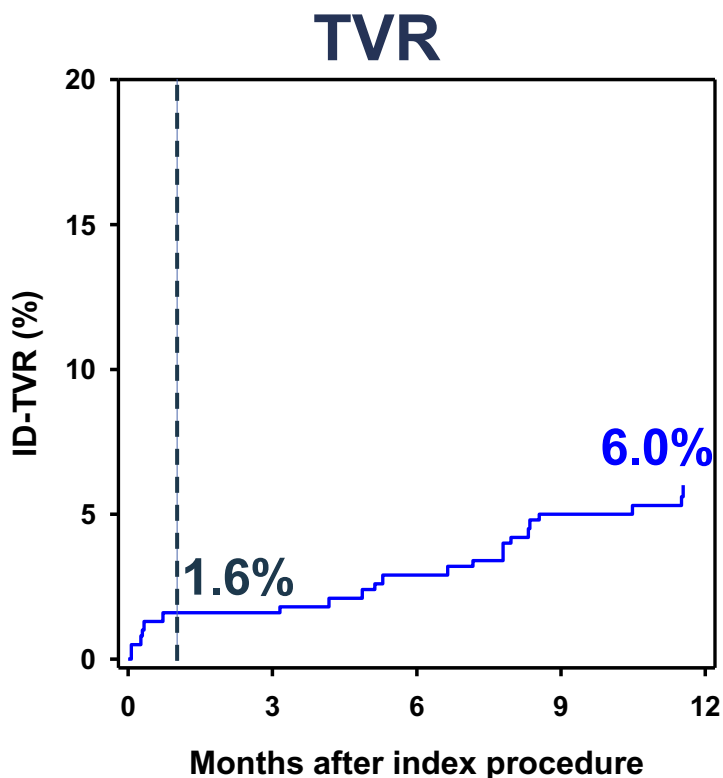


Disrupt CAD III : 12 month FU

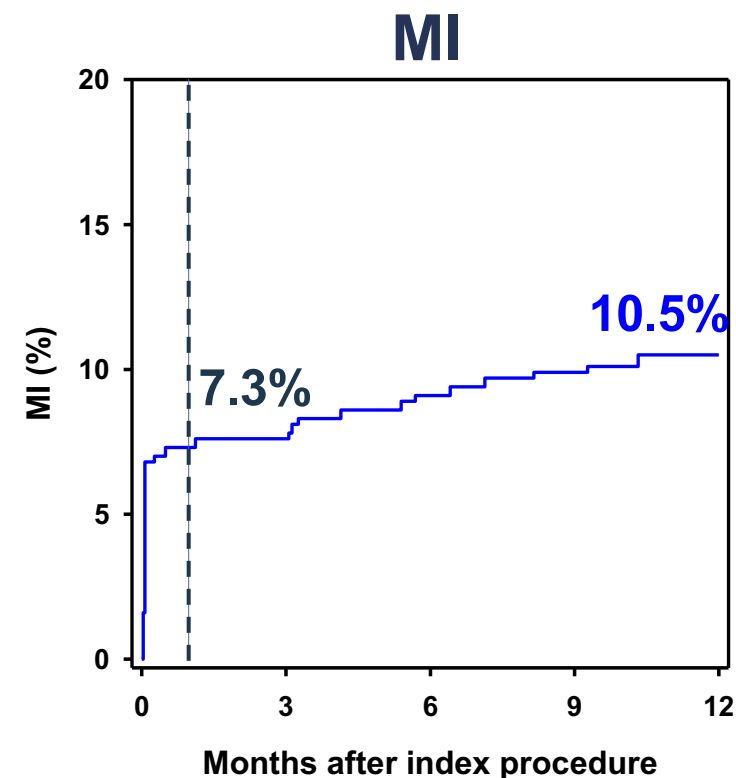
MACE distribution



at risk 384 377 377 372 372



at risk 384 377 364 355 289

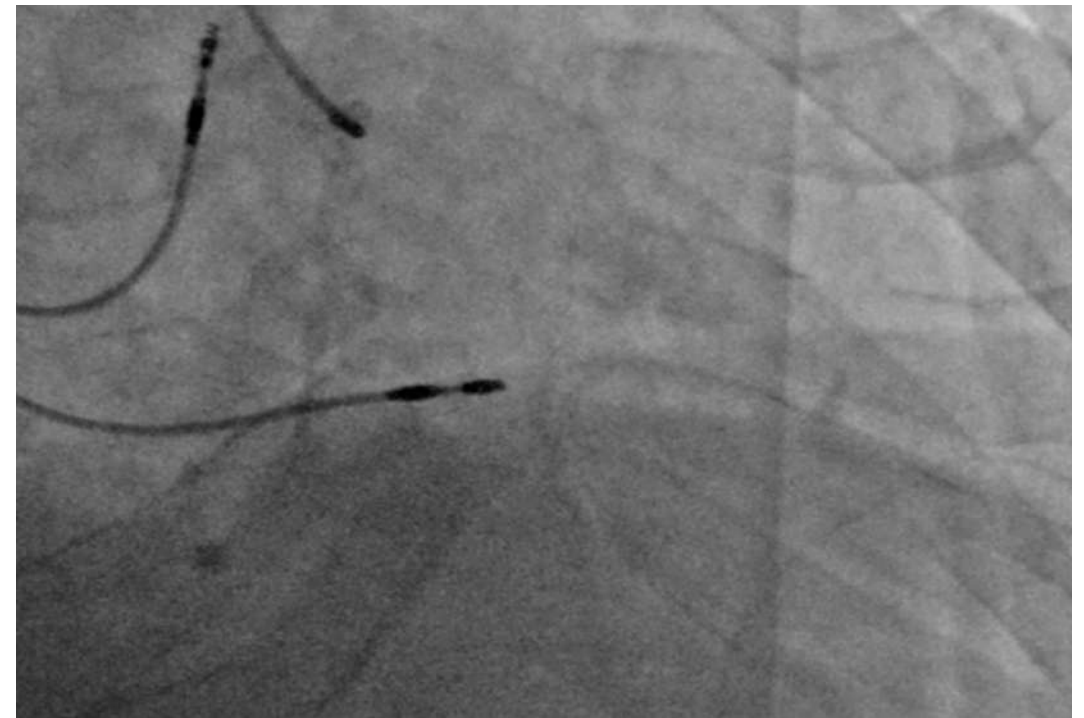
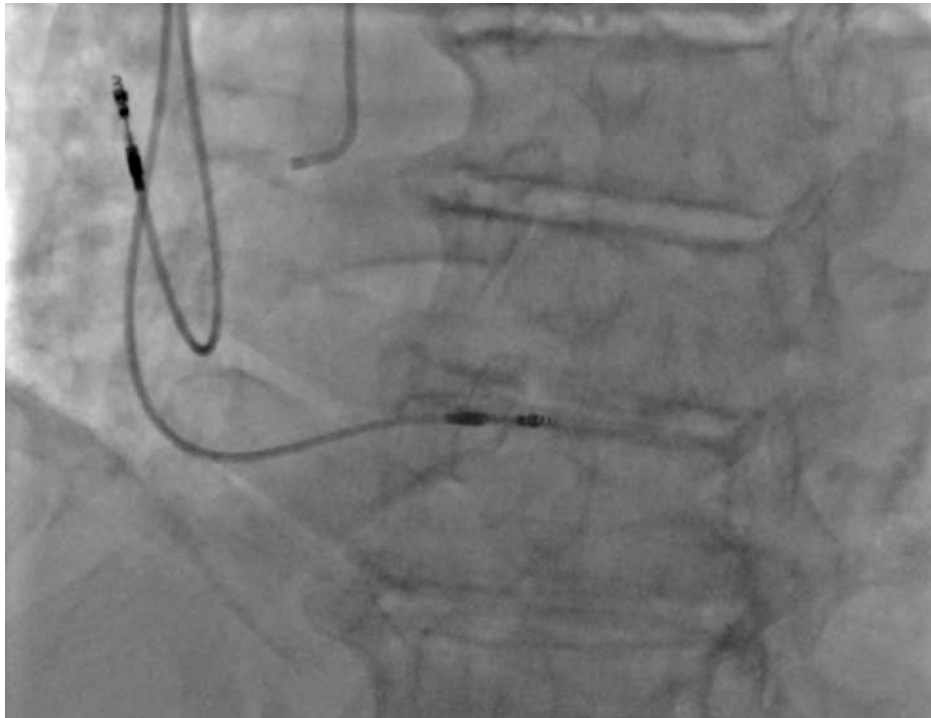


at risk 384 354 344 339 336

ID-TLR	1.3%	4.3%
Stent thrombosis (definite or probable)*	0.8%	1.1%

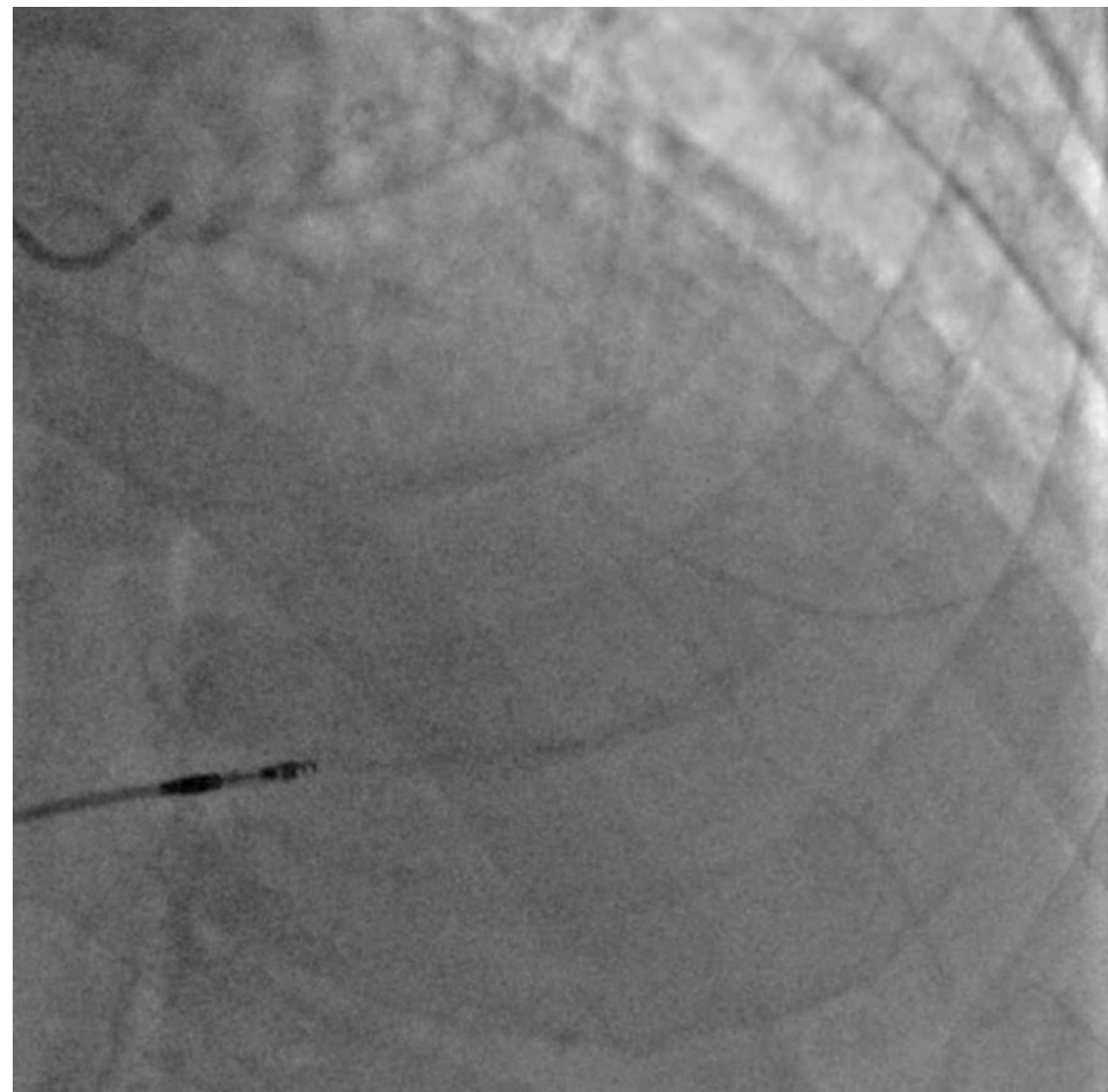
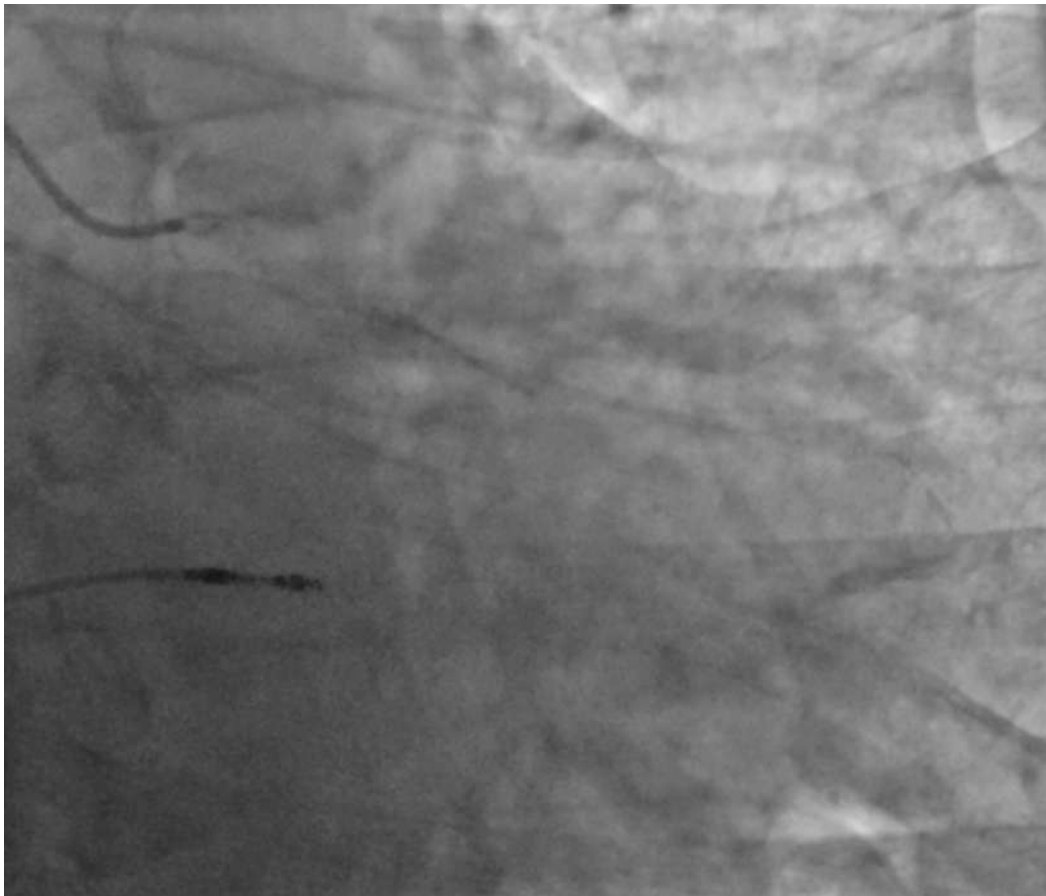
Monsieur B, 87 ans

SCA NSTEMI – Akinésie inférieure – Troponine à 4186 ng/ml
ECG : FA - électroentrainé non contributif
HTA – Dyslipidémie



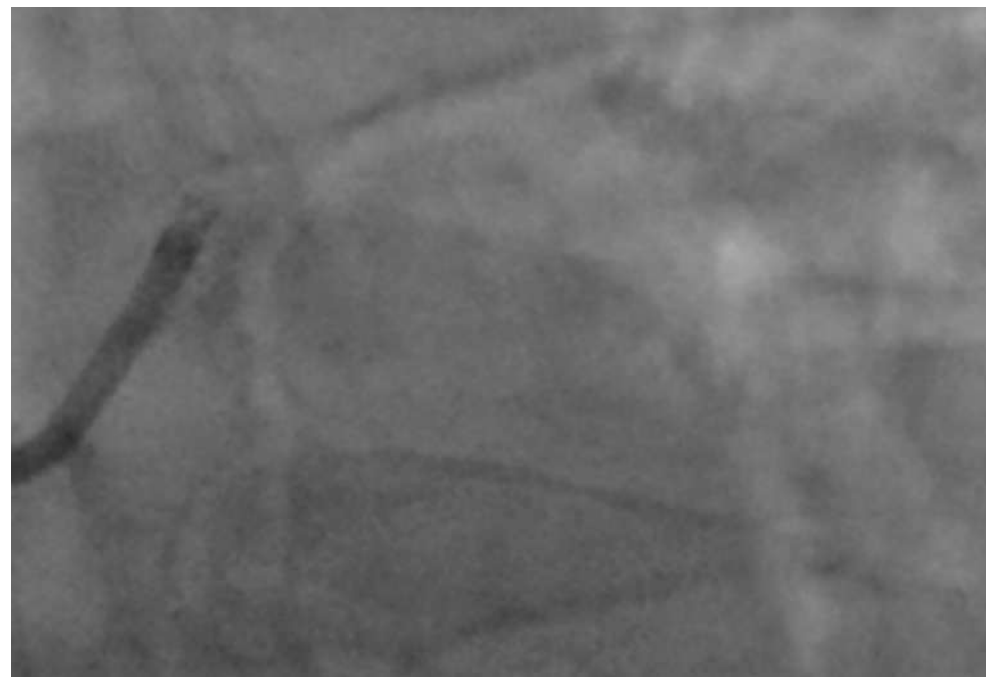
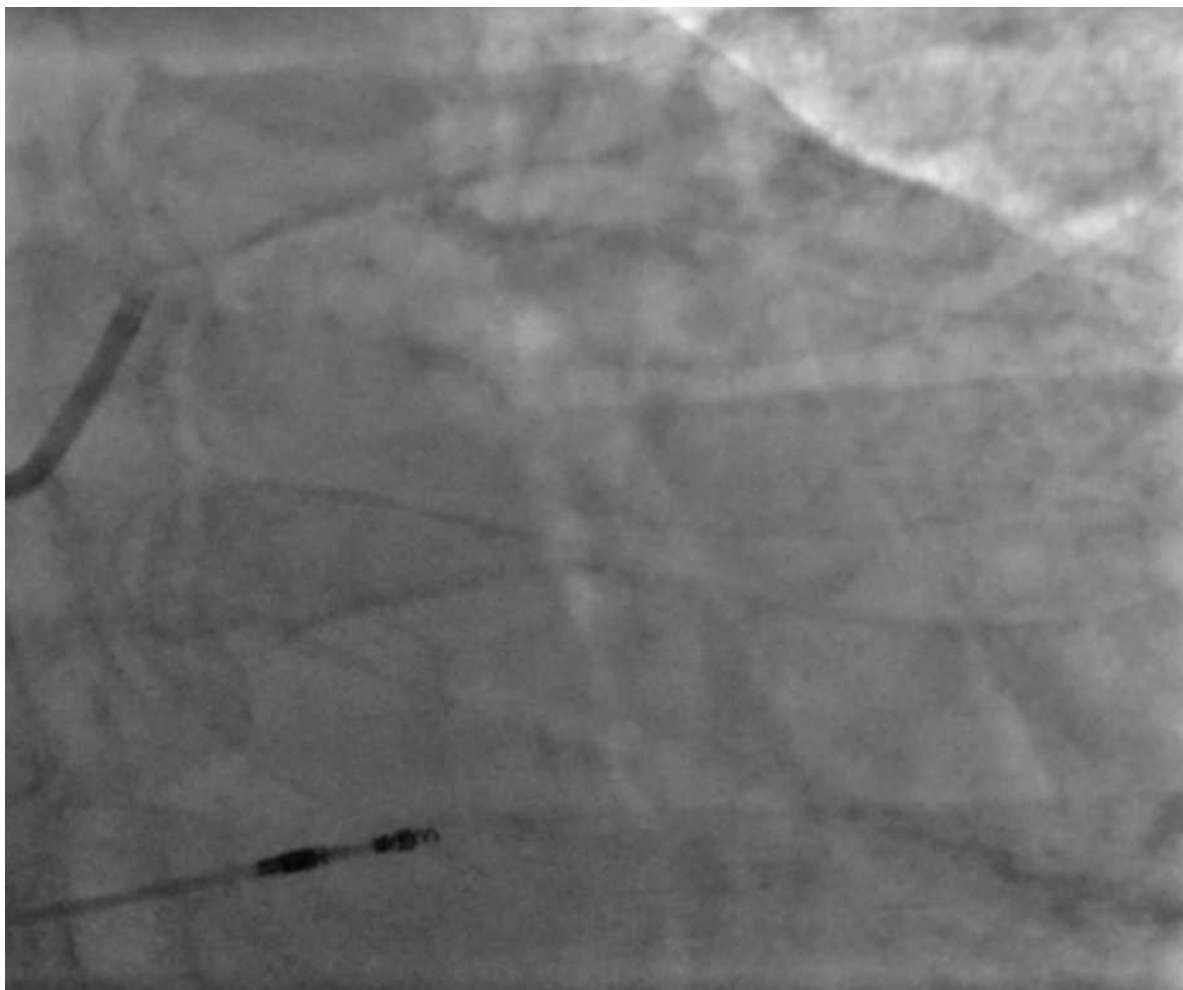
Occlusion / Sténose critique CD2

Monsieur B, 87 ans

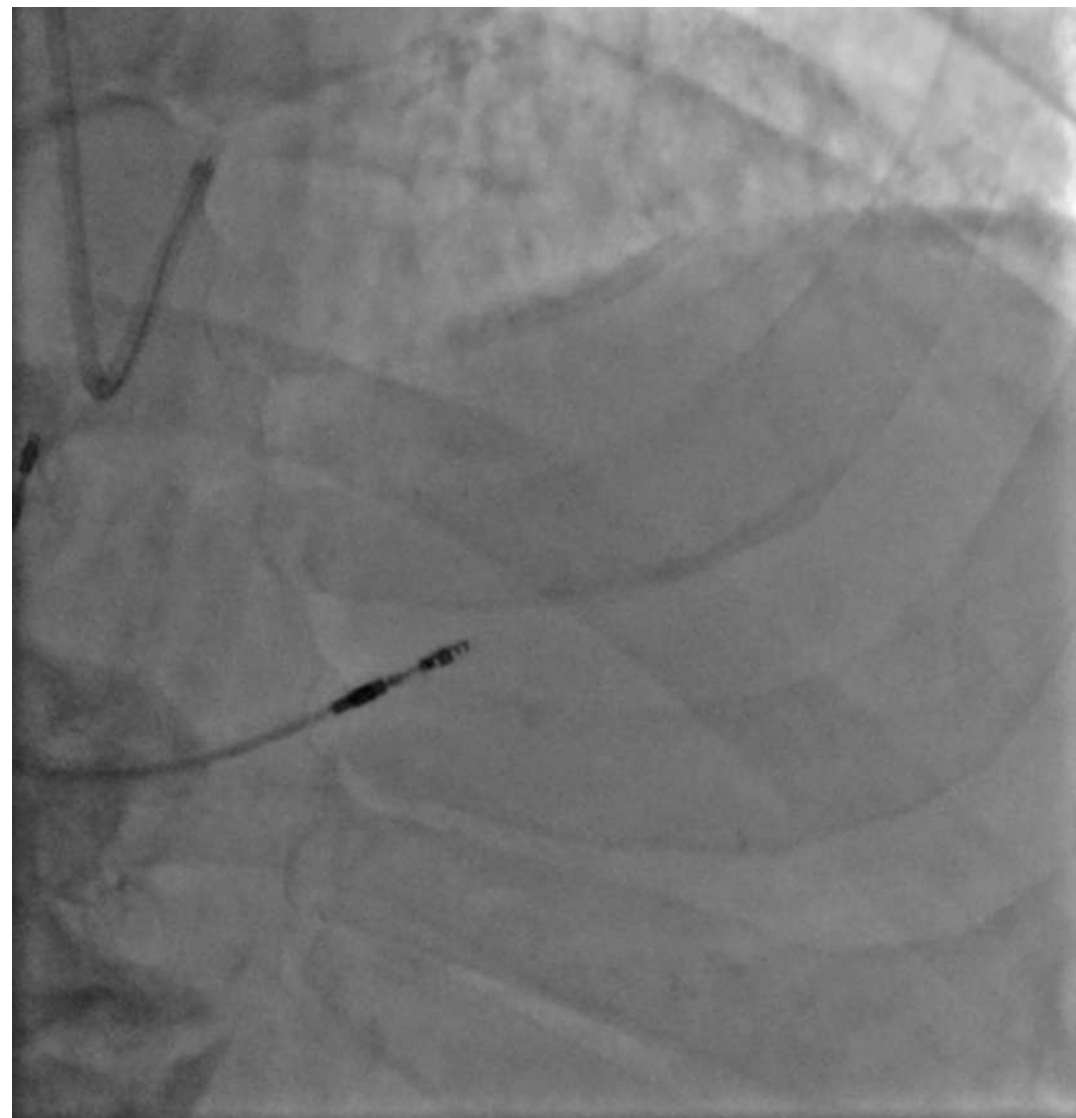
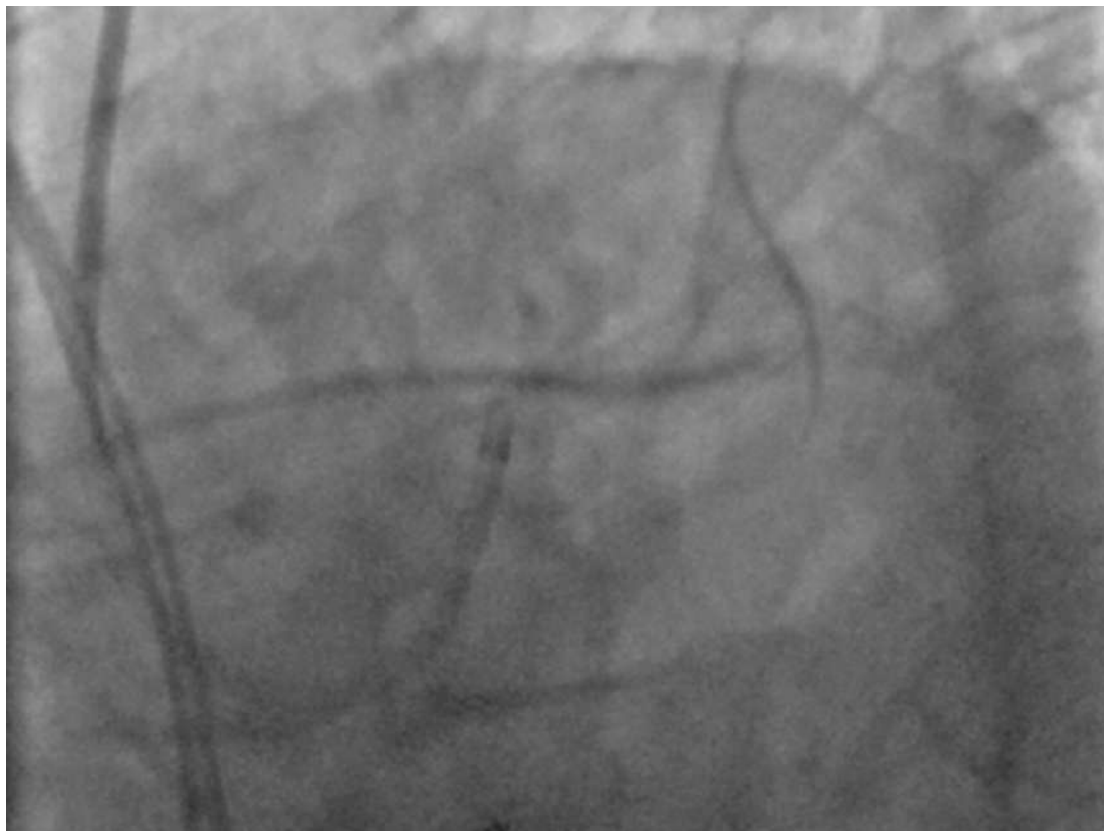


Sténose critique TCG MEDINA 1-1-1

Monsieur B, 87 ans – Angioplastie TCG

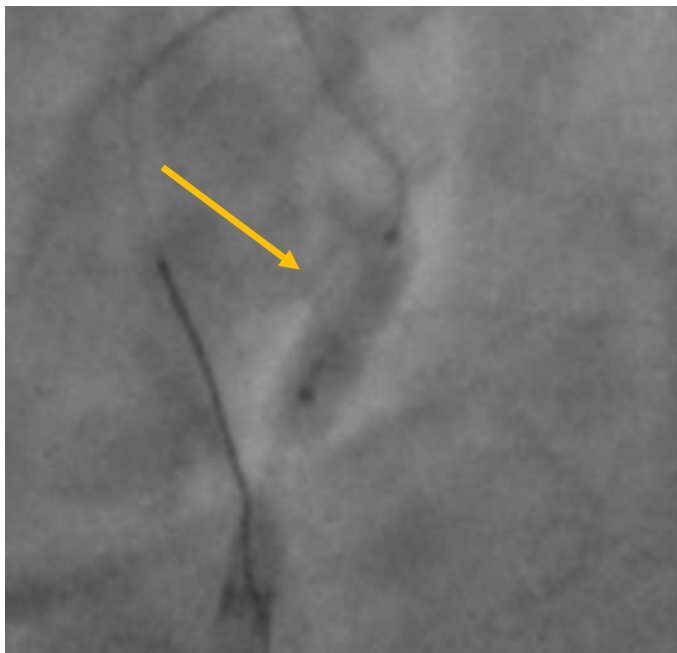
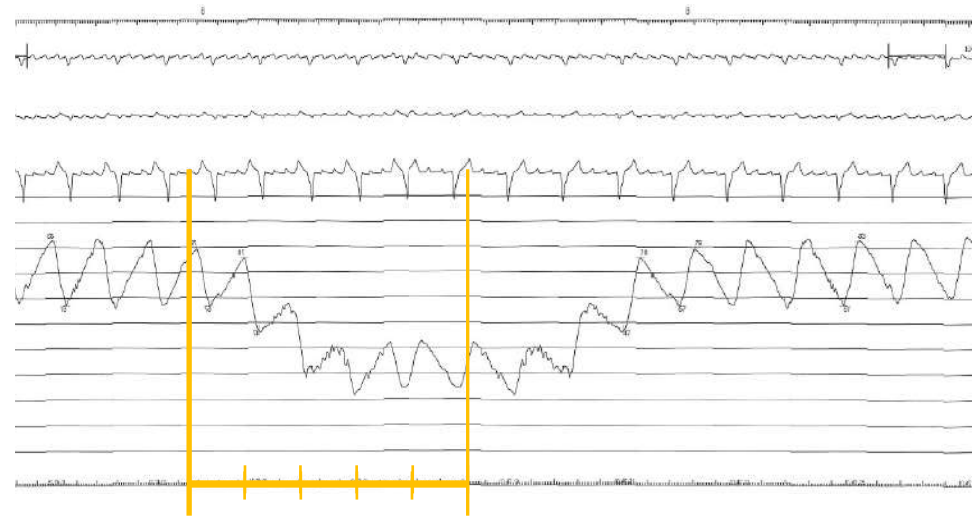


Monsieur B, 87 ans – Angioplastie TCG

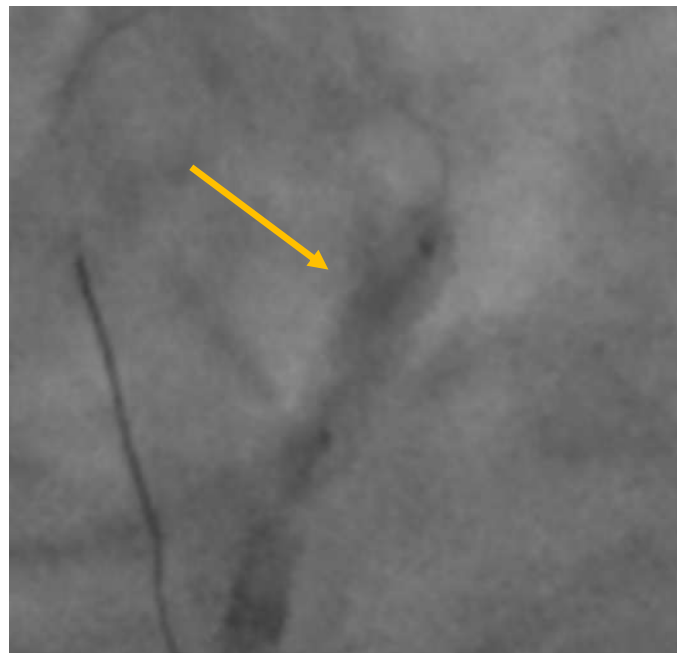


Monsieur B, 87 ans

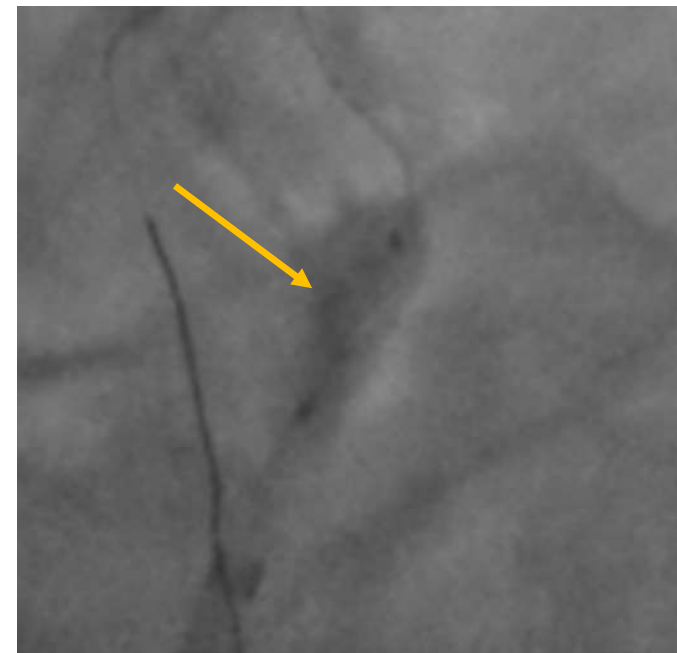
Ballon SW 4x12 mm
5s inflation



20 pulses

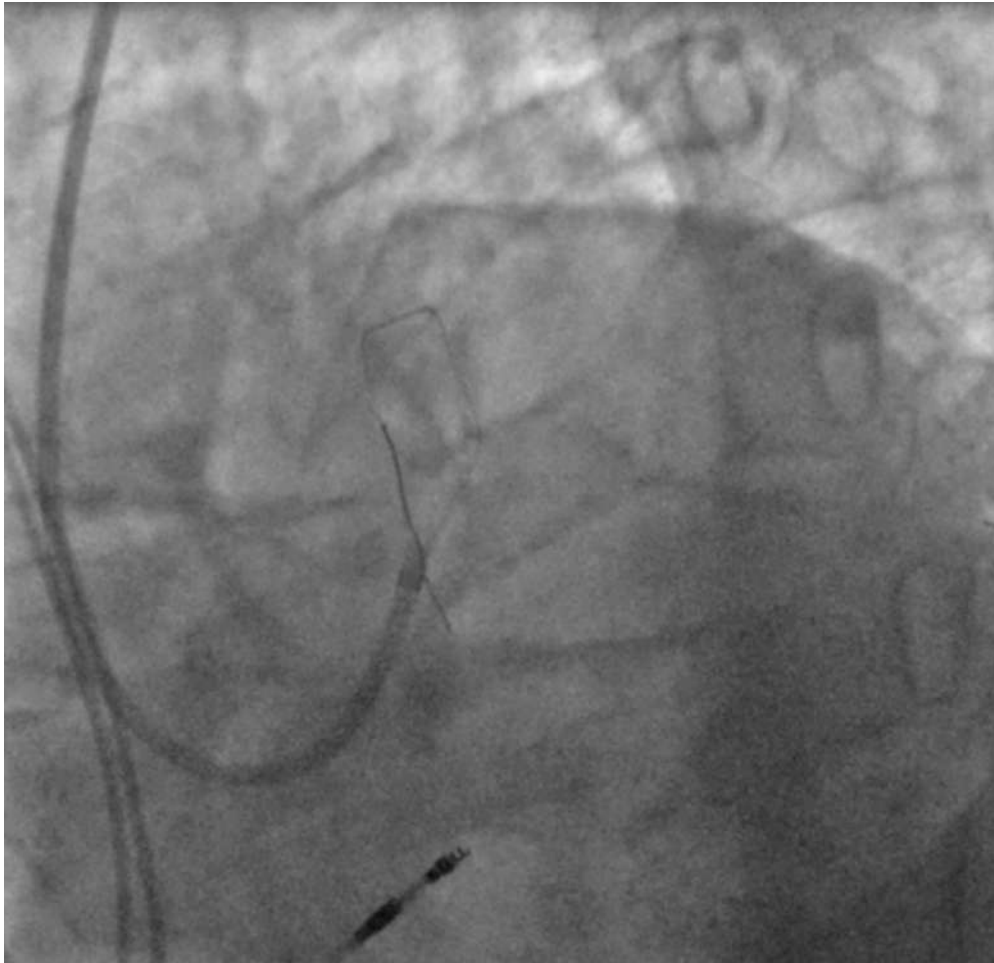


60 pulses



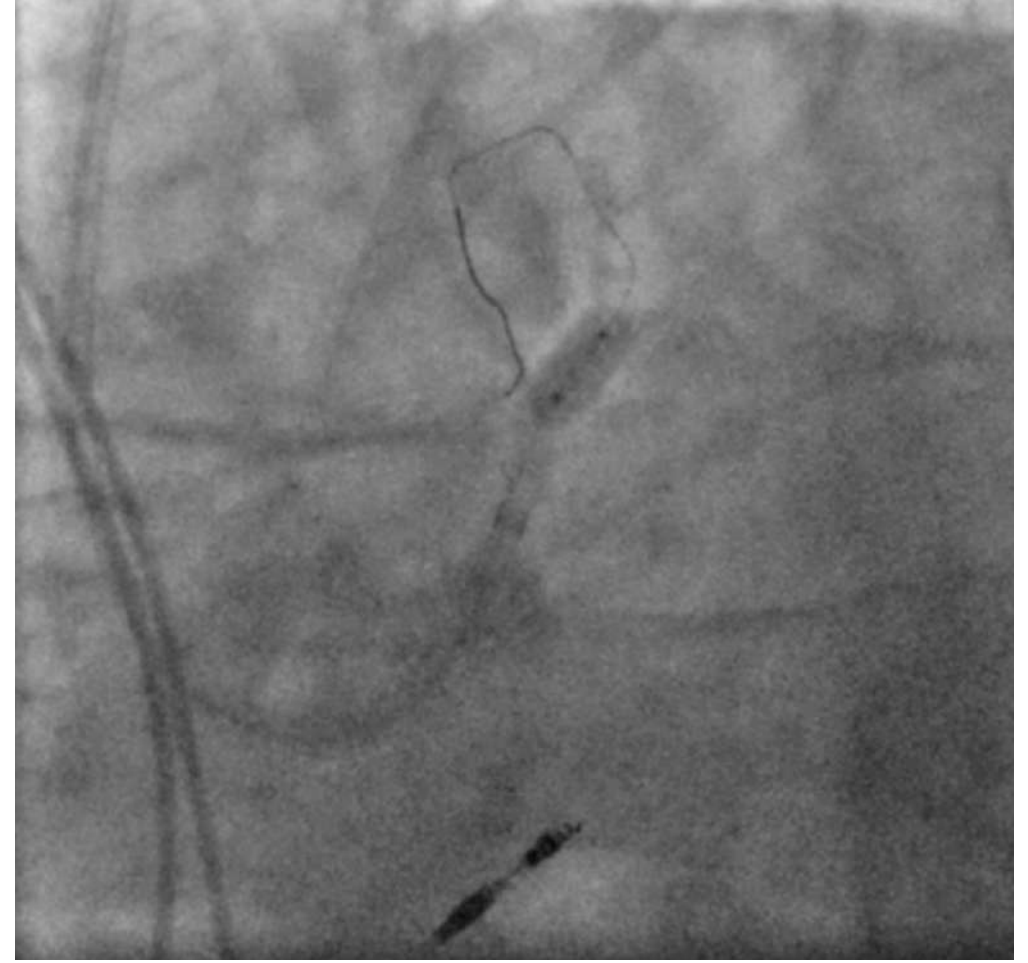
80 pulses

Monsieur B, 87 ans – Angioplastie TCG



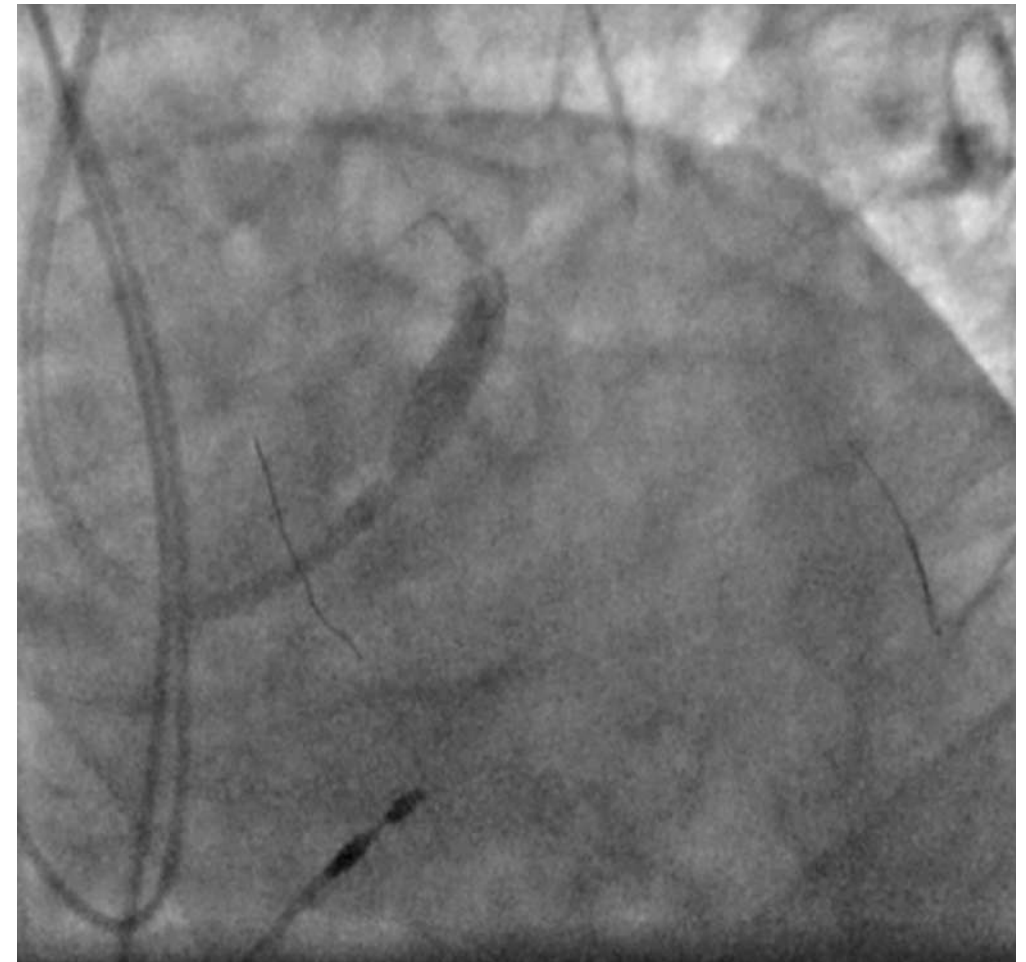
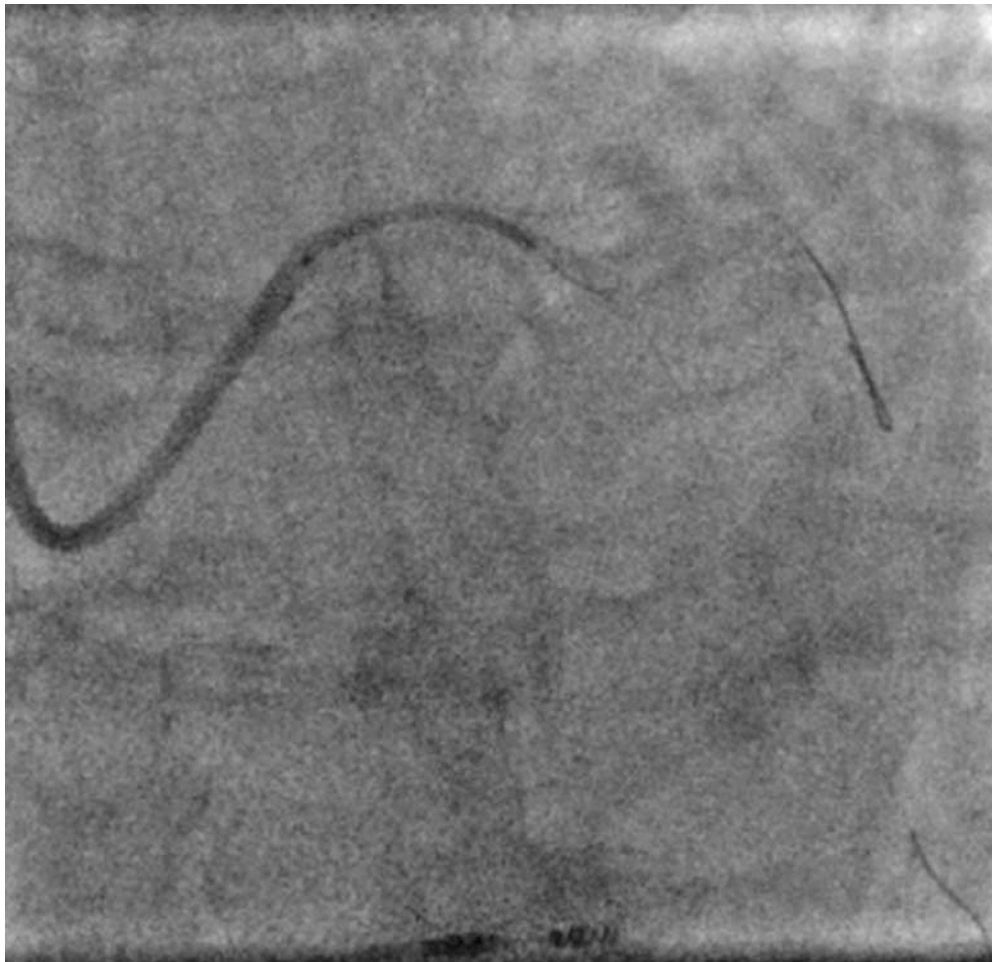
Kissing avec ballon de 3.5 x 20 mm

Monsieur B, 87 ans – Angioplastie TCG



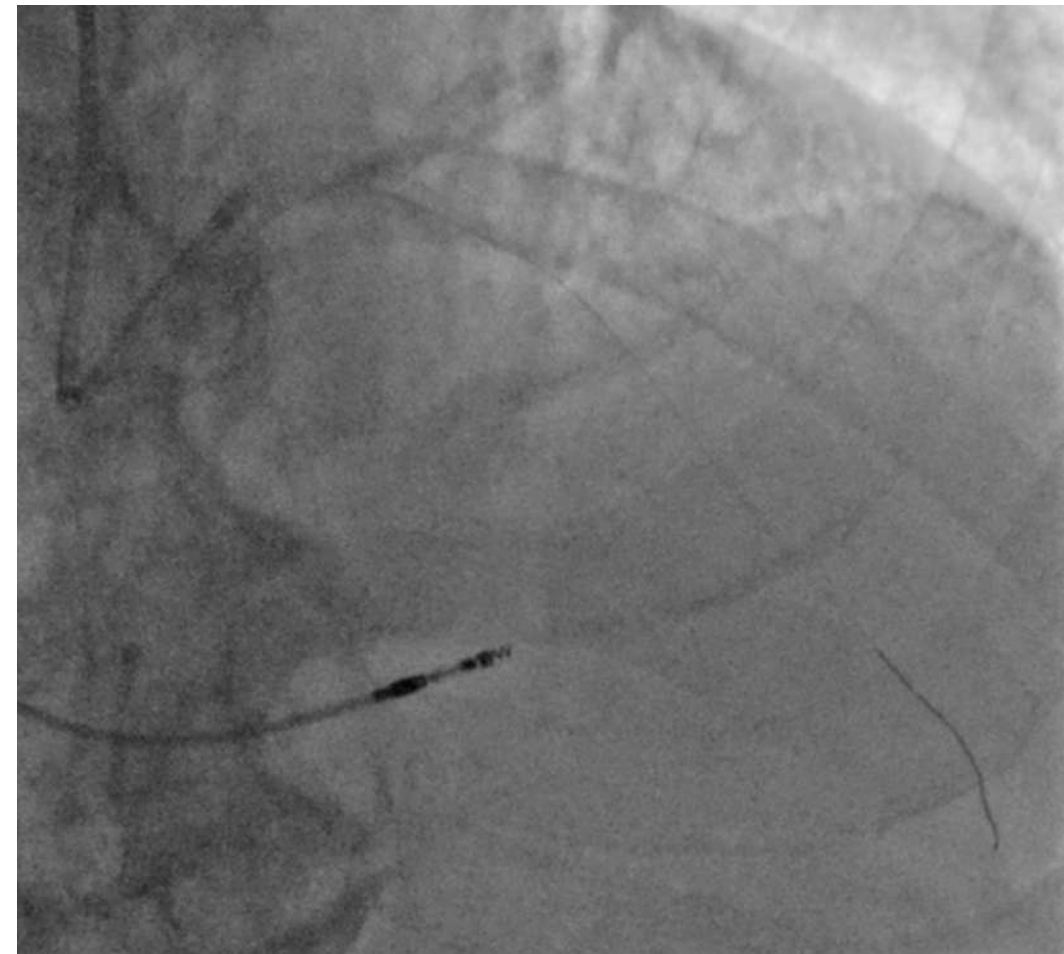
Stent de 3.5 x 24 mm – Crush à 5 mmm

Monsieur B, 87 ans – Angioplastie TCG



Stent IVA de 3.5 x 24 mm – POT à 6 mmm

Monsieur B, 87 ans – Angioplastie TCG



Individual Patient-data Pooled Analysis

Disrupt CAD I-IV: OCT Sub-studies



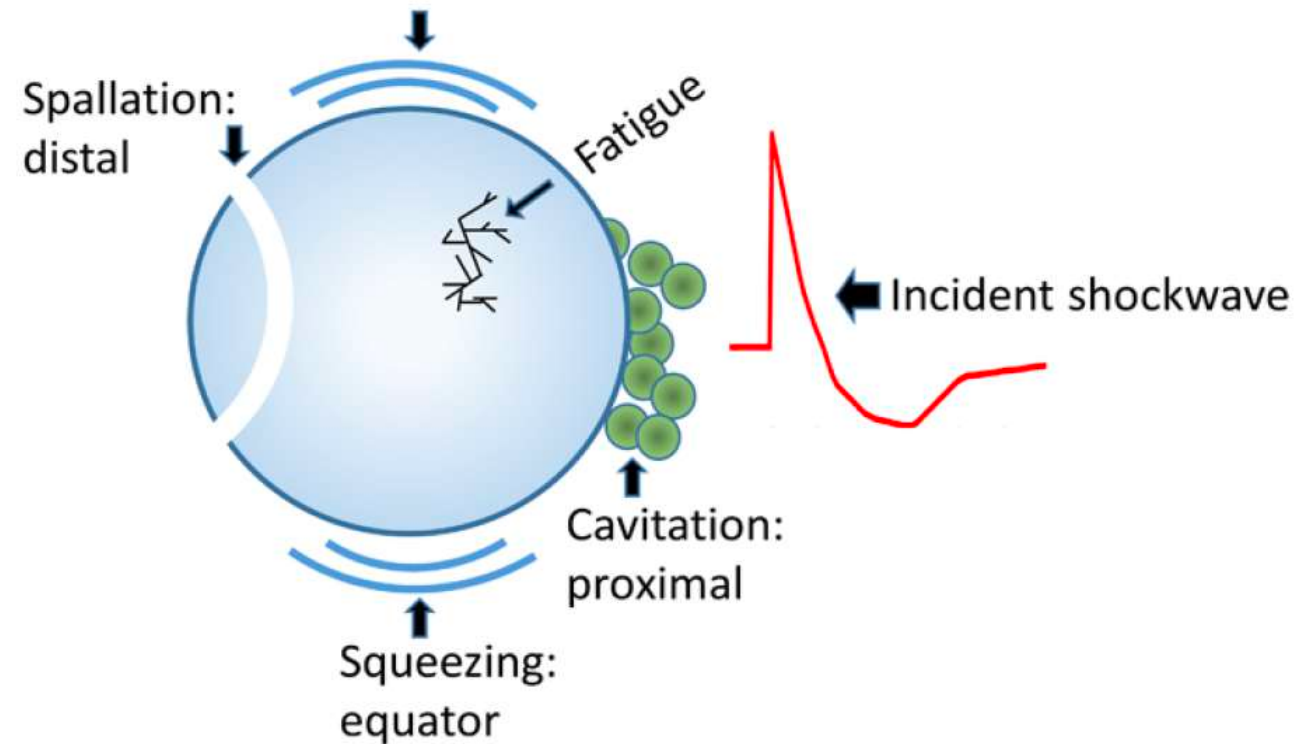
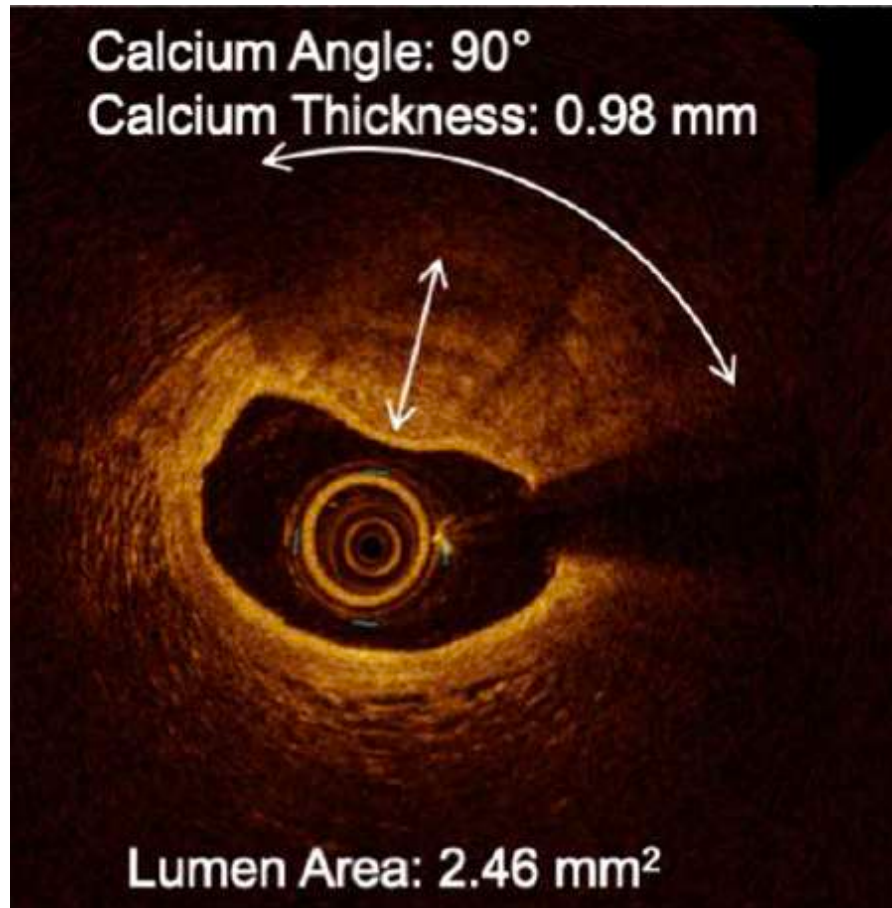
	CAD I	CAD II	CAD III	CAD IV	Pooled
Enrollment	Dec 2015 – Sep 2016	May 2018 – Mar 2019	Jan 2019 – Mar 2020	Nov 2019 – Apr 2020	Dec 2015 – Apr 2020
Study design	Prospective, multi-center, single-arm				
ITT (N)	60	120	384	64	628
OCT Analysis* (N)	28	57	106	71	262
OCT core laboratory	Cardiovascular Research Foundation New York, NY				
Target lesions	Severely calcified*, de novo coronary artery lesions				
Target lesion RVD	2.5mm – 4.0mm				
Target lesion stenosis	≥50% and <100%	≥50% and <100%	≥70% and <100%	≥70% and <100%	
Publications	Circulation 2019	Circ Interv 2019	JACC 2020	Circulation Journal 2021	JACC Interv 2021

OCT Characterization of Eccentric Versus Concentric lesion

Disrupt CAD I-IV: OCT Sub-studies

Core Lab Analysis	≤ 180° N=56	181° - 270° N=56	271° - 359° N=51	360° N=66	P value
Minimum lumen area, mm ²	2.0 ± 1.1	2.1 ± 1.0	2.0 ± 0.8	2.1 ± 0.9	0.85
Area stenosis, %	72.4 ± 10.5	70.1 ± 11.2	72.7 ± 10.3	73.1 ± 12.5	0.24
Max continuous calcium arc*, °	131.1 ± 30.4	225.3 ± 27.3	309.3 ± 23.6	360.0 ± 0.0	<0.0001
Calcium index, ° × mm	1660 ± 803	3069 ± 1074	3794 ± 1423	5522 ± 2291	<0.0001
Max calcium thickness, mm	0.93 ± 0.27	0.92 ± 0.21	1.01 ± 0.27	0.97 ± 0.25	0.21
Min calcium thickness, mm	0.41 ± 0.13	0.35 ± 0.13	0.28 ± 0.14	0.27 ± 0.13	<0.0001

IVL dans les lesions excentriques



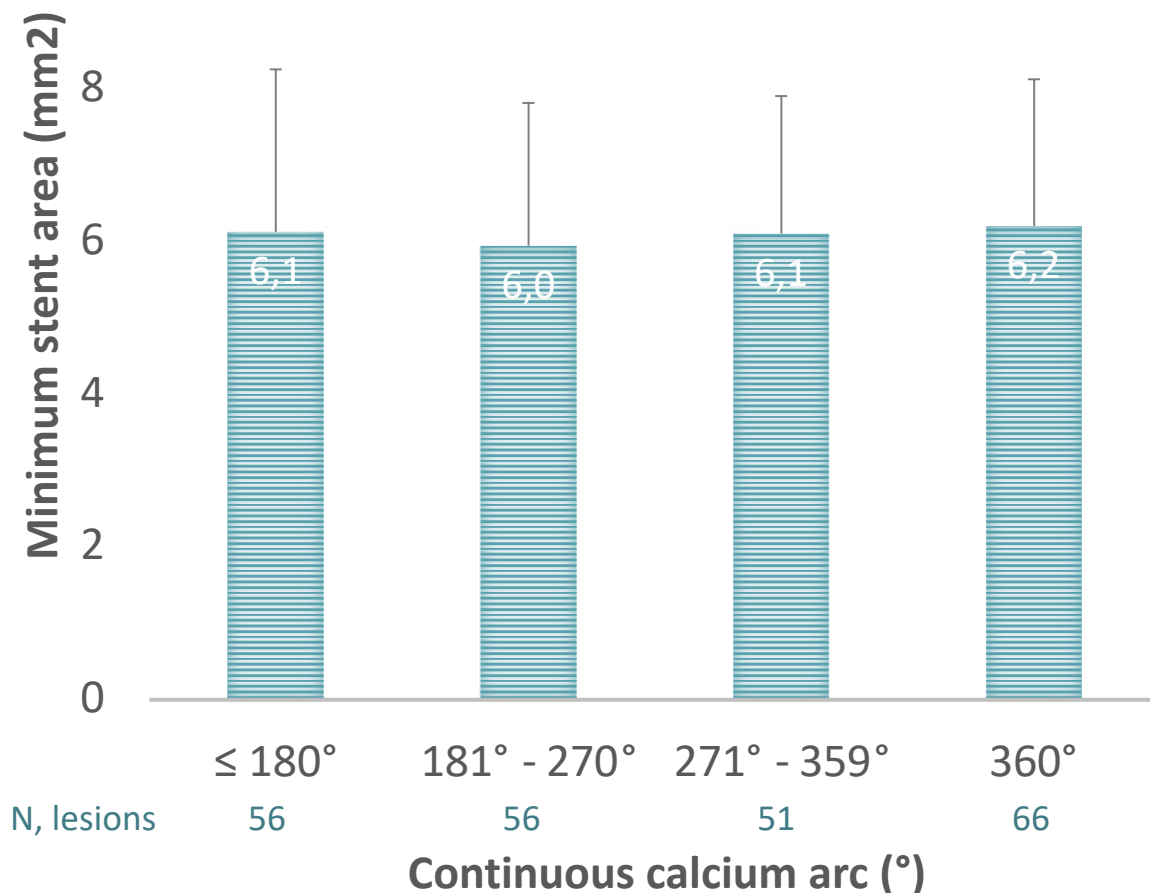
Electrodes further from calcified root
Lost of the spallation

Consistent Outcomes in Eccentric and Concentric Calcium

Disrupt CAD I-IV: OCT Sub-studies

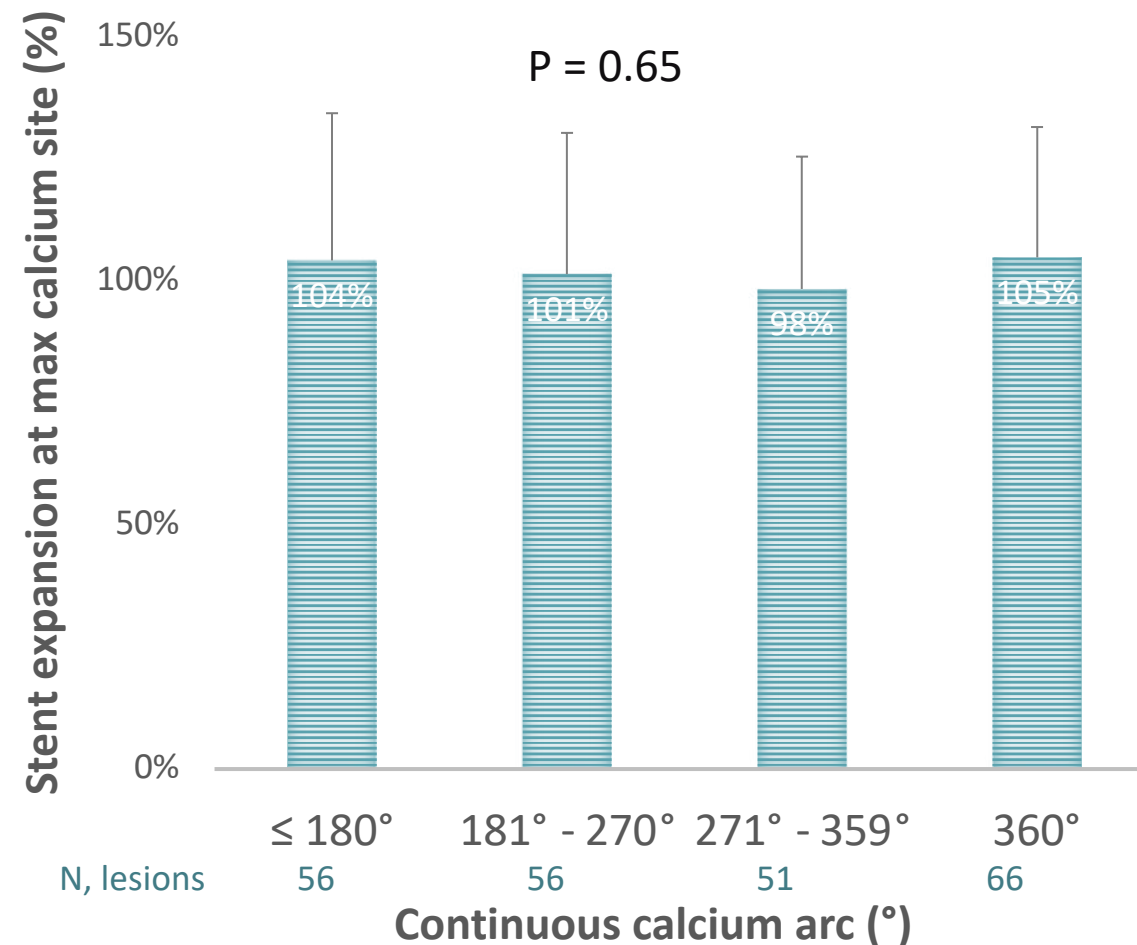
MSA

P = 0.94



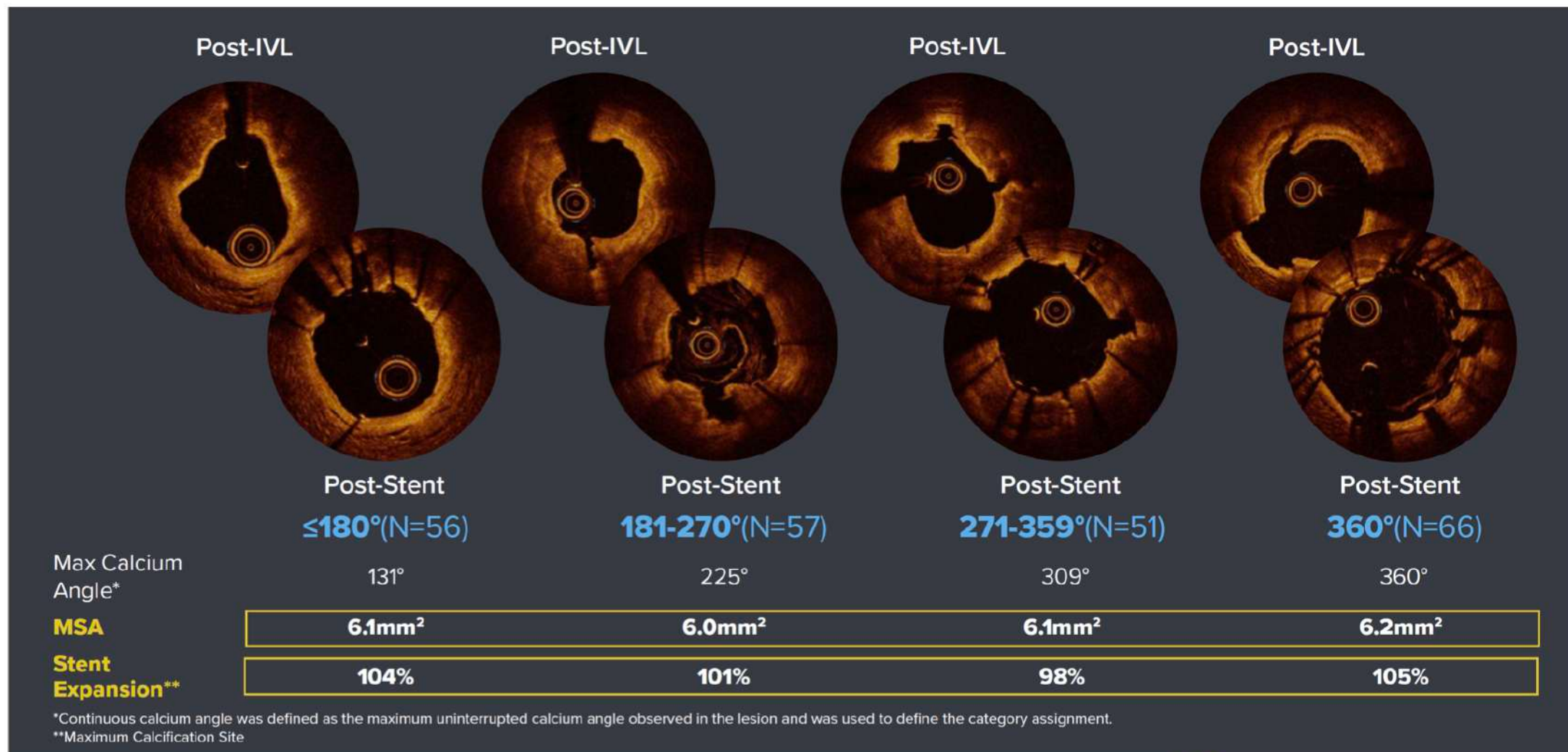
Stent Expansion at Max Calcium Site

P = 0.65



Consistent Outcomes in Eccentric and Concentric Calcium

Disrupt CAD I-IV: OCT Sub-studies





REGISTRE NATIONAL **FRANCE LILI** LithopLastie Intracoronaire

GACI

Le registre France LILI, dont la SFC est le Promoteur, a pour objectif d'évaluer la sécurité et les performances du système de Lithotripsie coronaire C2 Shockwave Medical® (IVL), Inc. dans l'angioplastie coronaire chez des patients « tout venants » en France.

Critère composite Target Vessel Failure (TVF) à 1 an :

- Décès d'origine cardiaque
- Infarctus du myocarde selon la 4eme définition universelle de l'infarctus du myocarde (sauf si l'infarctus est clairement attribuable à un vaisseau non-cible)
- Revascularisation du vaisseau cible (TVR)
- 12 mois d'inclusion à partir du 16/11/2021 + 12 mois de suivi par patient

45 patients / 500 – 12 centres actifs

HOT TOPIC



HAUTE AUTORITÉ DE SANTÉ

ÉVALUER LES TECHNOLOGIES DE SANTÉ

**AVIS SUR LES
DISPOSITIFS
MÉDICAUX**

C2 IVL CATHETER

Cathéter du système de lithotripsie
intravasculaire (ou IVL) coronaire

Inscription

**Adopté par la Commission nationale d'évaluation des dispositifs
médicaux et des technologies de santé le 18 janvier 2022**
