CUORE
E NON SOLO
INTERVENTIONAL
CARDIOLOGY
14/15.04.23
GENOVA

CORONARY IMAGING & PHYSIOLOGY
INNOVATION IN TRANSCATHETER
INTERVENTIONS

Uso dell'imaging (OCT/IVUS) nel trattamento percutaneo delle lesioni calcifiche

Giuseppe Andò

The New England
Journal of Medicine

Volume 301 JULY 12, 1979 Number 2

NONOPERATIVE DILATATION OF CORONARY-ARTERY STENOSIS

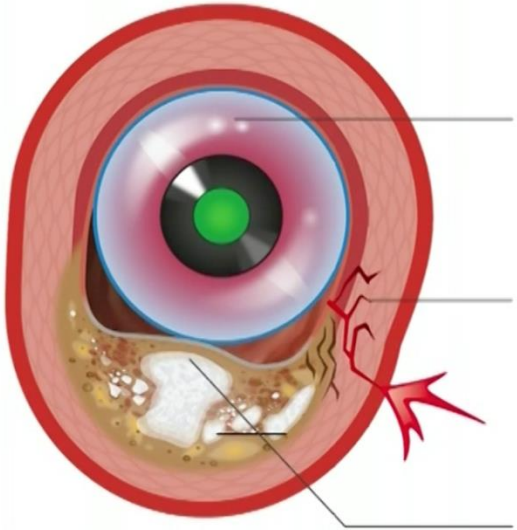
Percutaneous Transluminal Coronary Angioplasty

ANDREAS R. GRÜNTZIG, M.D., ÅKE SENNING, M.D., AND WALTER E. SIEGENTHALER, M.D.

At present, the technic is limited by anatomic factors, such as vessel tortuosity, sharply angled arteries, cul-de-sac-like lesions and fibrotic or calcified stenoses. Most of our 18 failures can be attributed to

Complications Due to Calcified Coronary Lesions

- **Angiography underestimates coronary calcification**
- **Respond poorly to balloon angioplasty**
- **Difficult to completely dilate**
- **Prone to dissection during PTCA or predilatation**



Cross-sectional view

High pressure balloons preferentially expand away from calcium, having limited effect on eccentric calcification. [1]

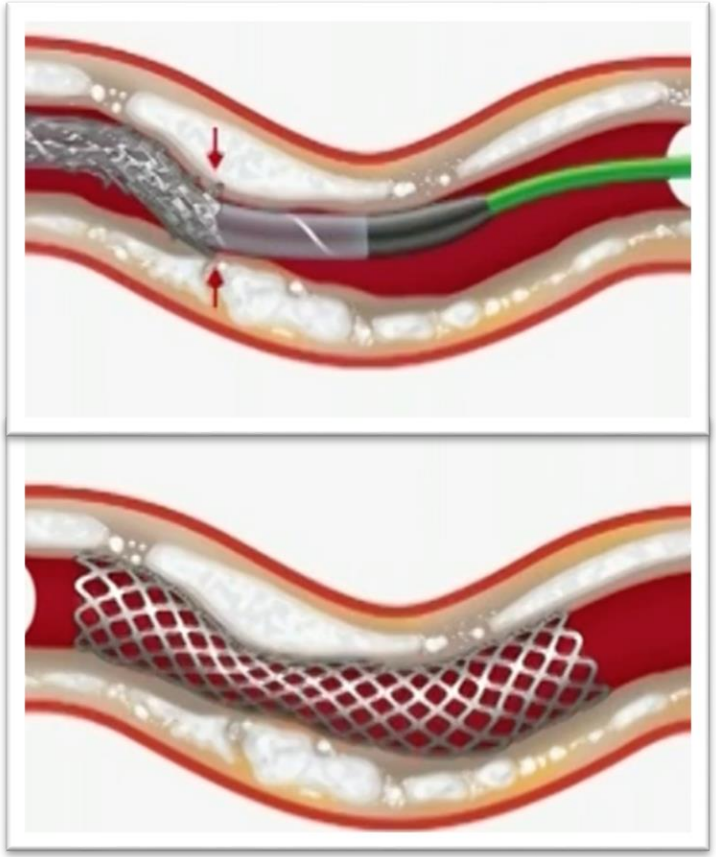
High pressure inflations are predisposed to major dissection and perforation - often at the interface between calcium and healthy tissue.[1]

Balloons are typically unable to modify deep or very thick calcium.[1]

1. *Mintz et al., Circulation 1995;91:1959*
2. *Fitzgerald et al., Circulation 1992;86:64*
3. *Cavusoglu et al., Cath Cardiovasc Intervent 2004;62:485*
4. *Gilutz et al., Catheter Cardiovasc Intervent 2000;50:212*
5. *Moussa et al., Circulation 1997;96:128*
6. *Mosseri et al., Cardiovasc Revasc Med 2006;6:147*
7. *Nakano et al., Eur Heart J 2013;34:3304*
8. *Buckley CJ., Vascular Disease Management 2011;8:87*

Complications Due to Calcified Coronary Lesions

- **Angiography underestimates coronary calcification**
- **Respond poorly to balloon angioplasty**
- **Difficult to completely dilate**
- **Prone to dissection during PTCA or predilatation**
- **Preclude stent delivery to the desired location**
- **May prevent adequate stent expansion ➔ ST / ISR**
- **May result in stent malapposition**
- **Uneven drug distribution associated with restenosis**



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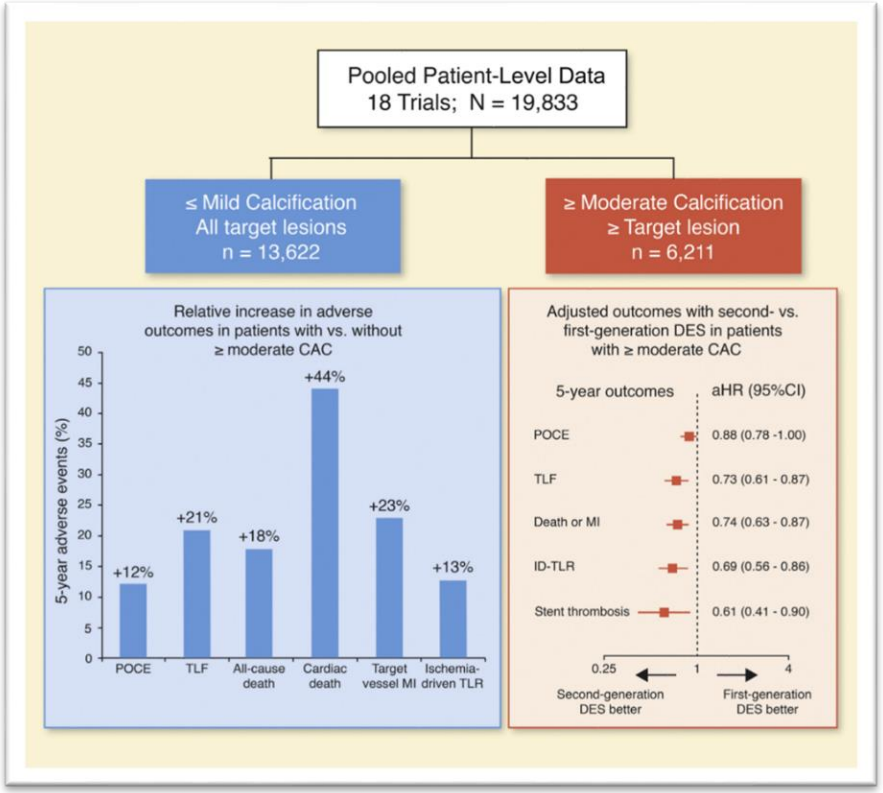
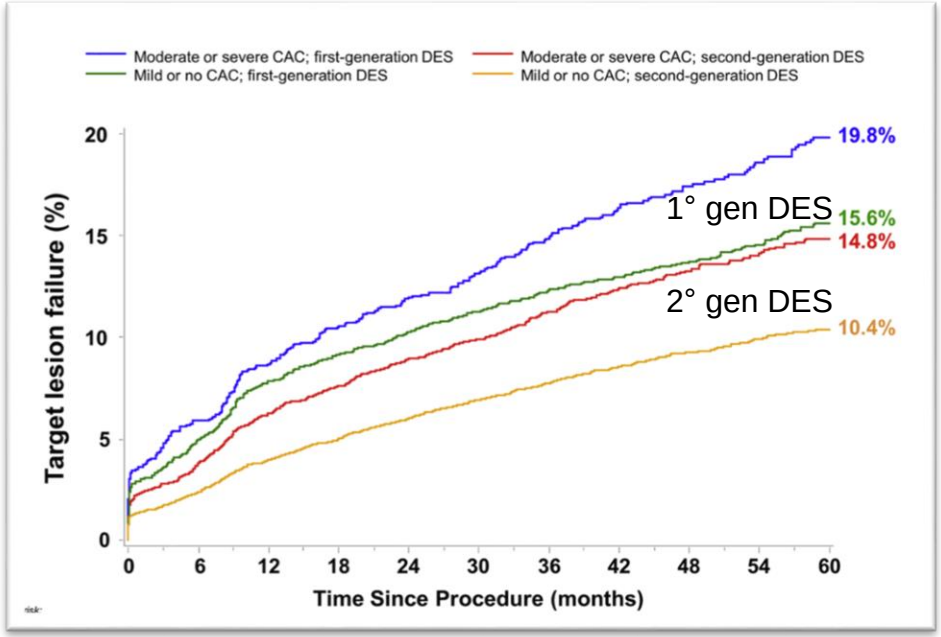
Coronary Calcification and Long-Term Outcomes According to Drug-Eluting Stent Generation





Guedenay P, Stone GW et al. J Am Coll Cardiol Intv 2020

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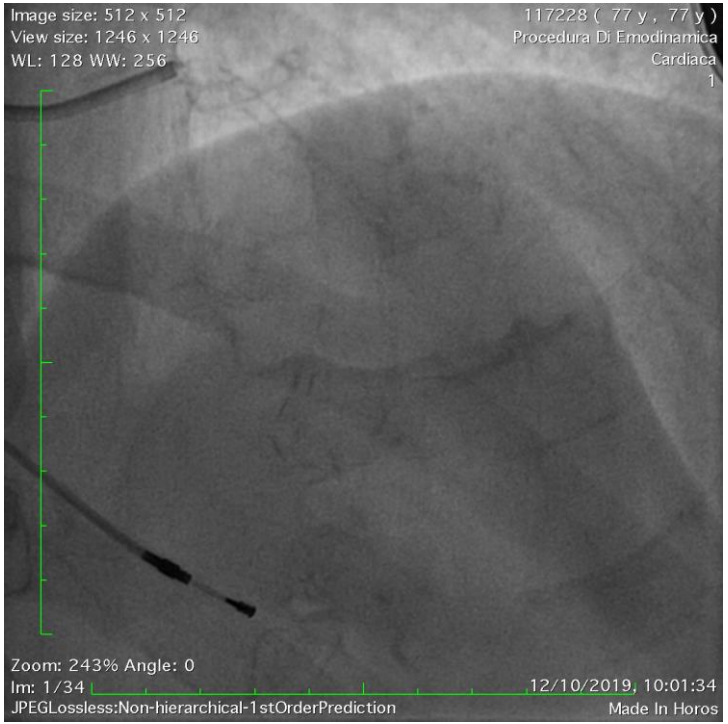
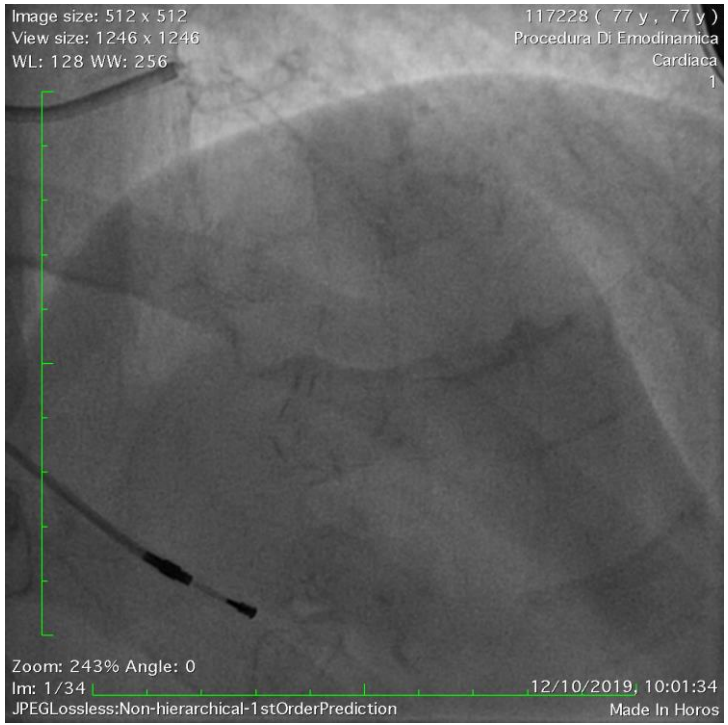
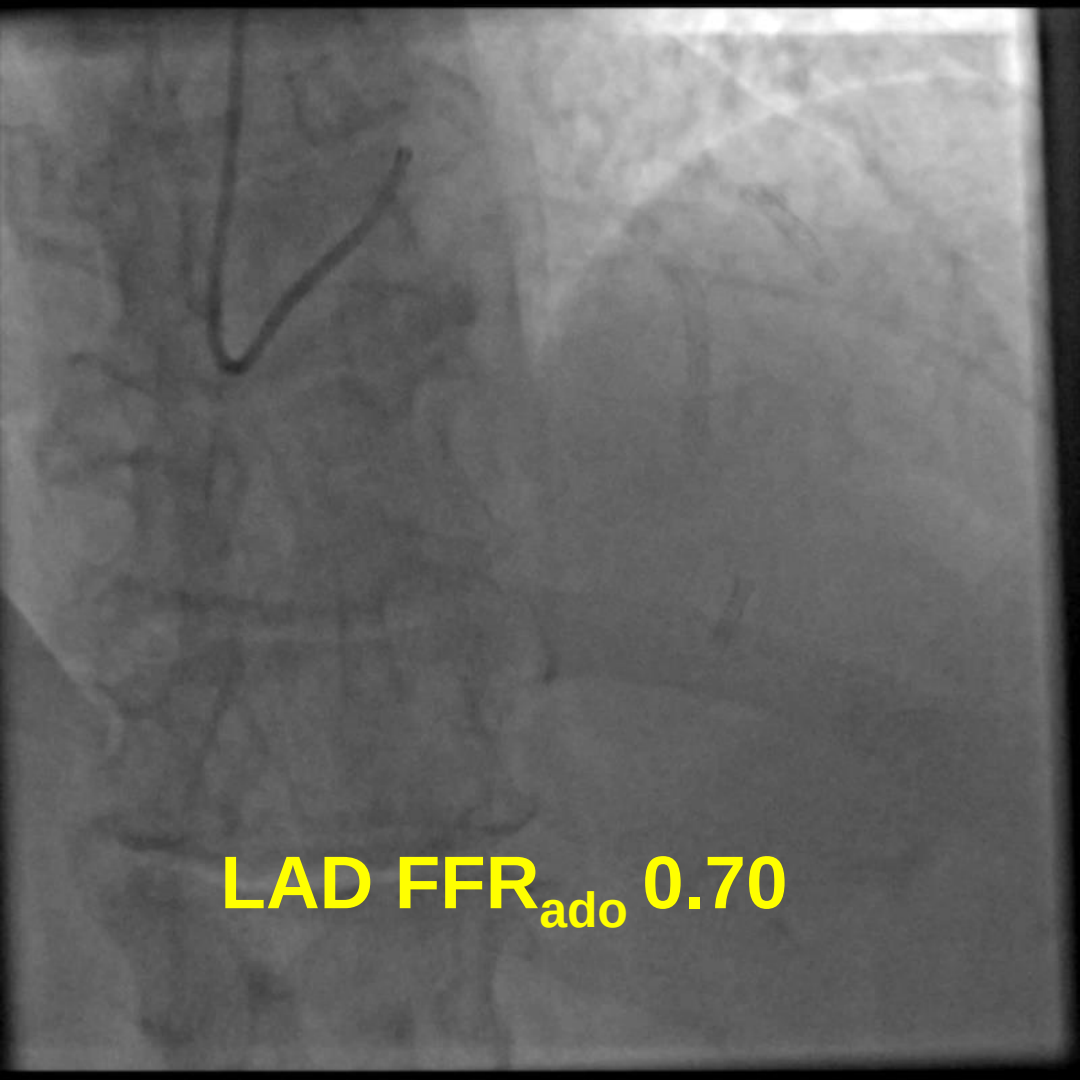
Angiography





Severe coronary calcification is defined angiographically when, before contrast injection, **both sides of the arterial wall** can be identified during cardiac motion.



Angiography

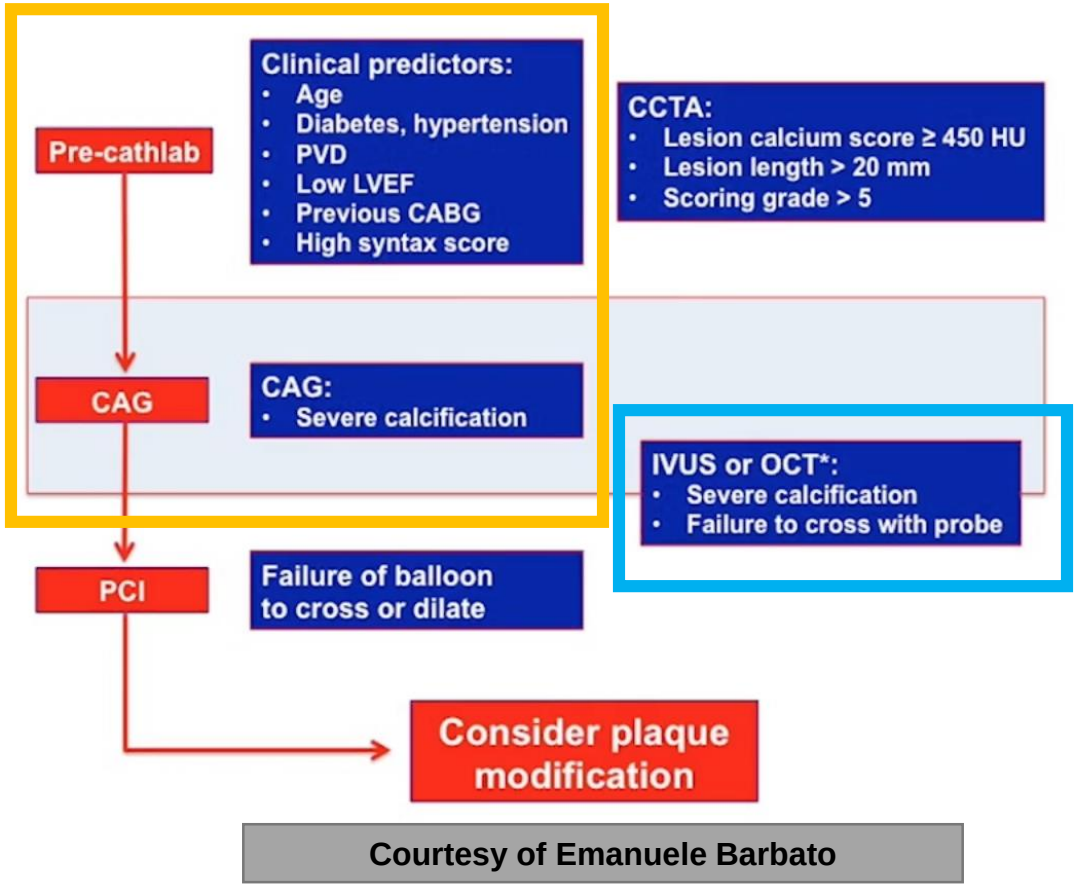
- 78-year-old female
- History of PCI of LAD and OM
- NSTEMI and Parox AF
- Diabetes on insulin
- Hypertension
- Dyslipidemia
- Obesity
- eGFR 36 mL/min/1.73m^2

Vascular Calcification in Chronic Kidney Disease

Risk Factor	Intimal/Atherosclerotic Calcification	Medial/Mönkeberg's Calcification
Dyslipidemia	Yes	No
Advanced age	Yes	Yes
Elevated blood pressure	Yes	Reciprocal (medial lesions worsen blood pressure)
Male	Yes	No
Smoking	Yes	No
Inflammation	Yes (local)	Yes (systemic mediators)
Diabetes/glucose intolerance	Yes	Yes
Kidney disease		
Reduced GFR	No	Yes
Calcium		
Hypercalcemia	No	Yes
Positive balance	No	Yes
Hyperphosphatemia	Yes	Yes
PTH abnormalities	No	No
Vitamin D administration	No	Yes
Duration of treatment with dialysis	No	Yes

Goodman WG et al. American Journal of Kidney Diseases, 2004

Early predictors of plaque modification



Courtesy of Emanuele Barbato

Valutazione e trattamento interventistico delle lesioni coronariche severamente calcifiche

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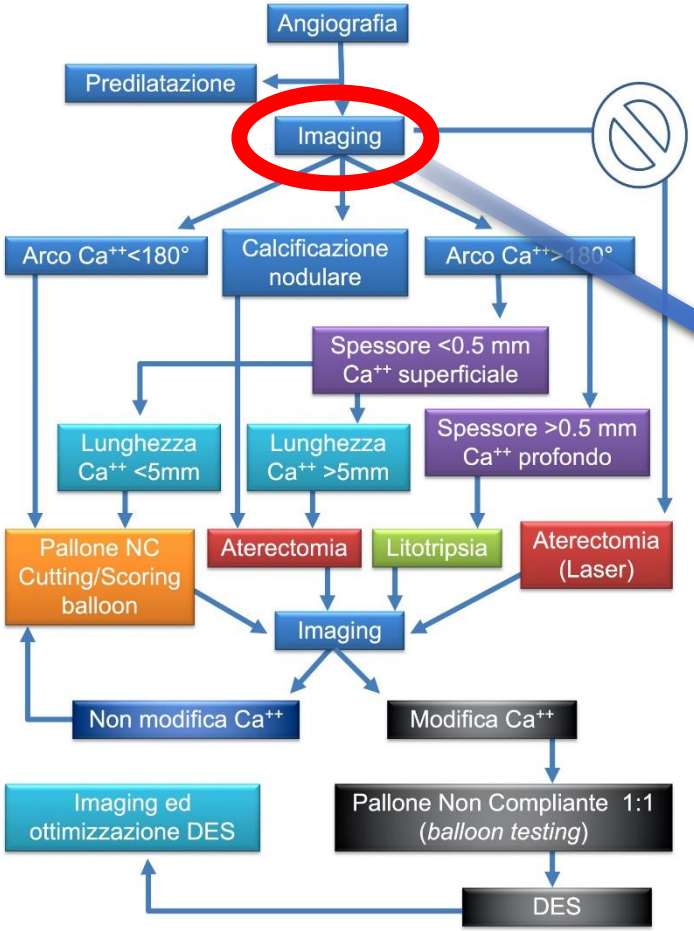

Basal Imaging

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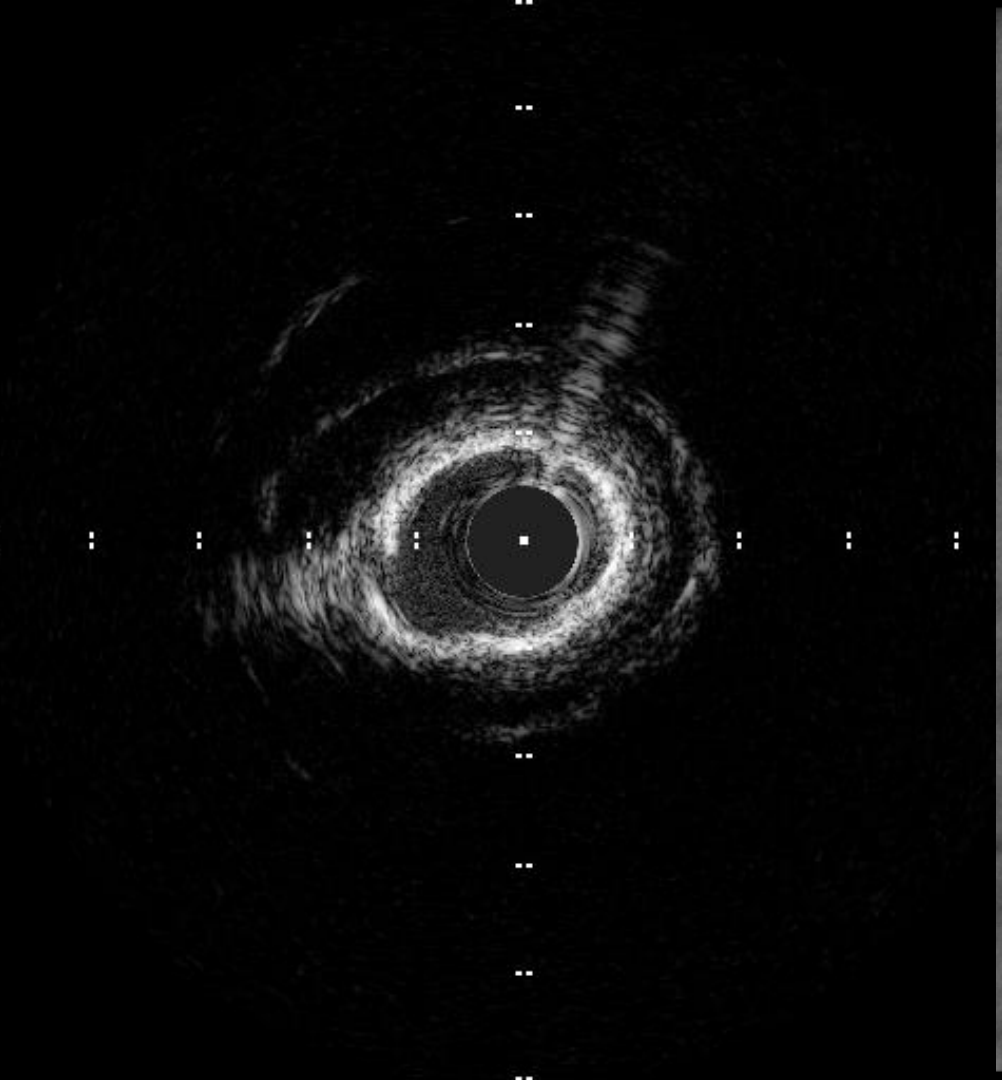

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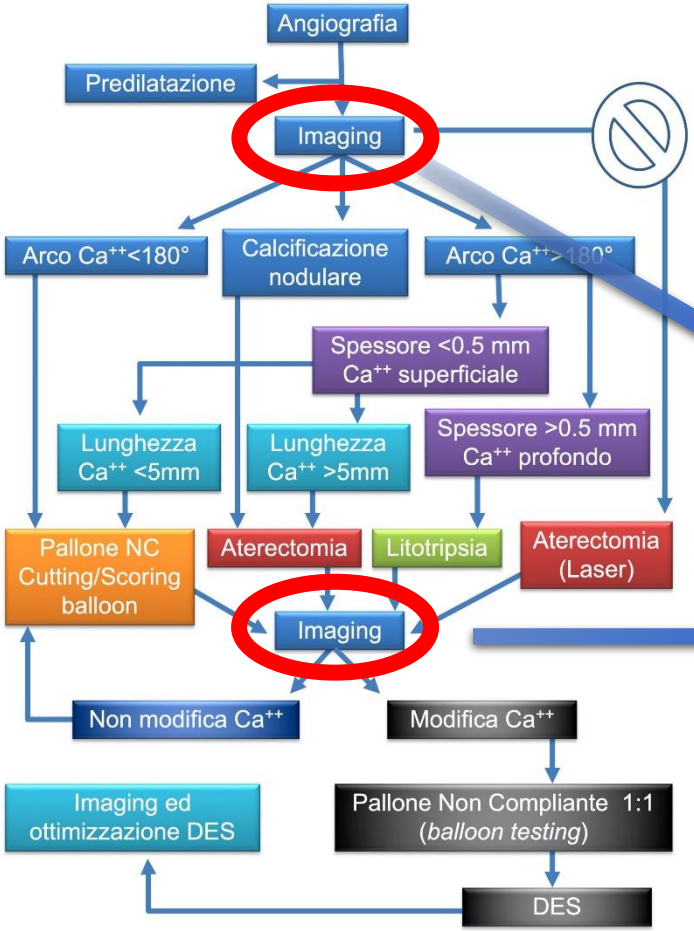

Basal Imaging

Imaging after plaque modification

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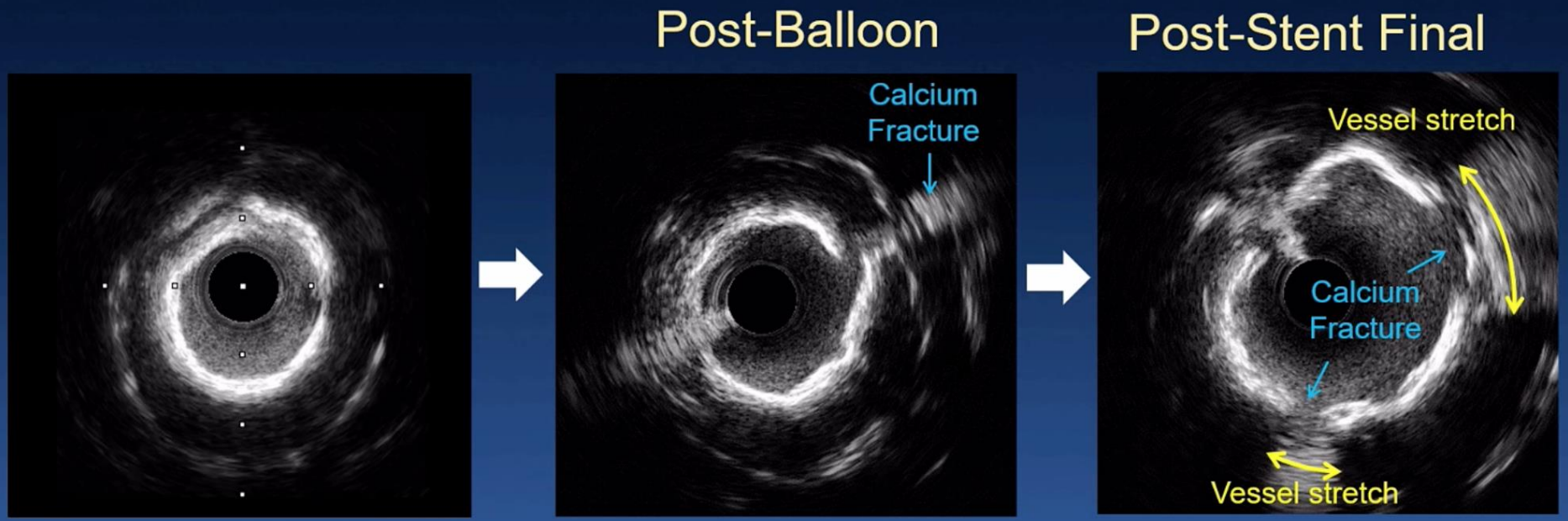
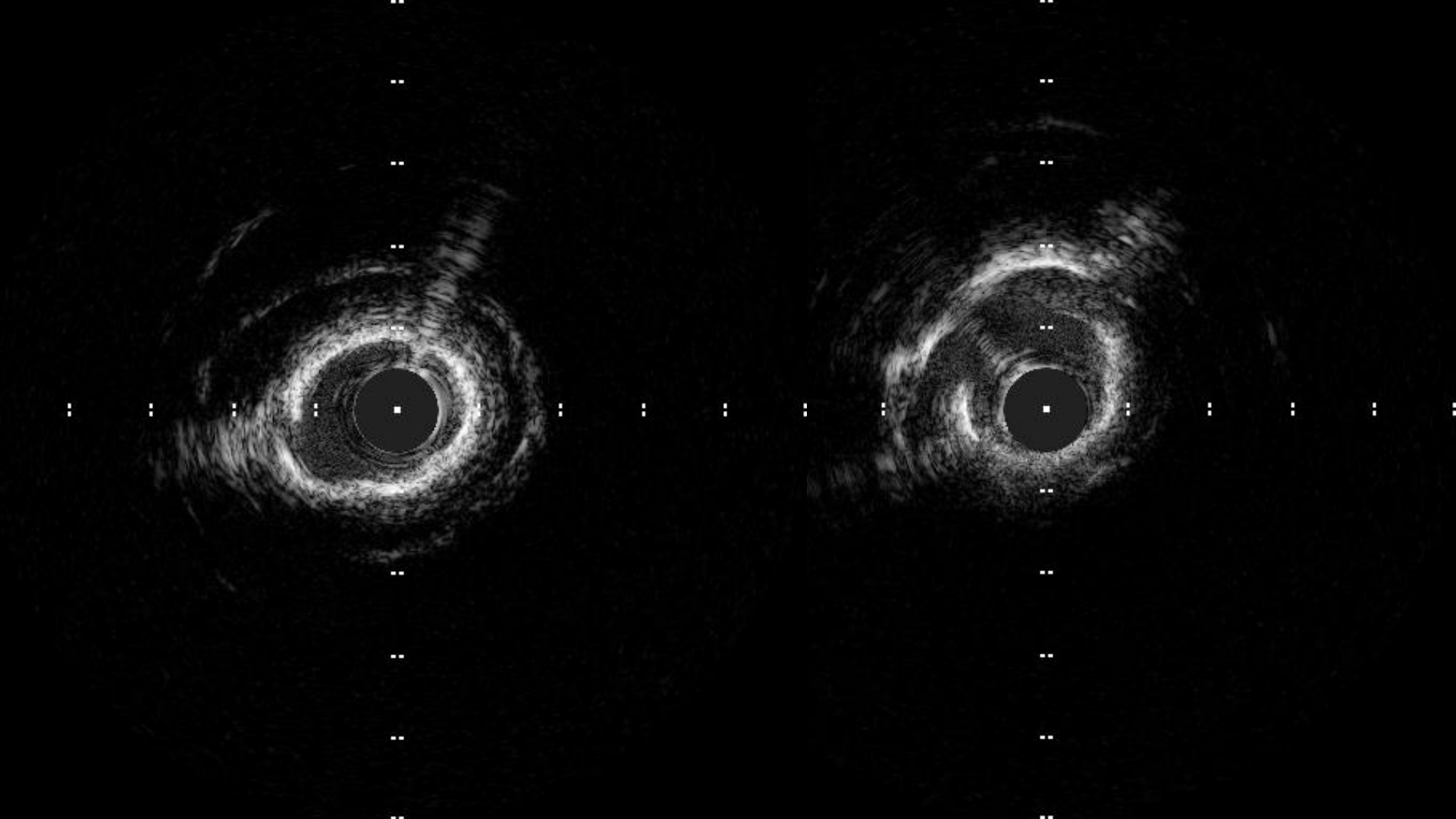
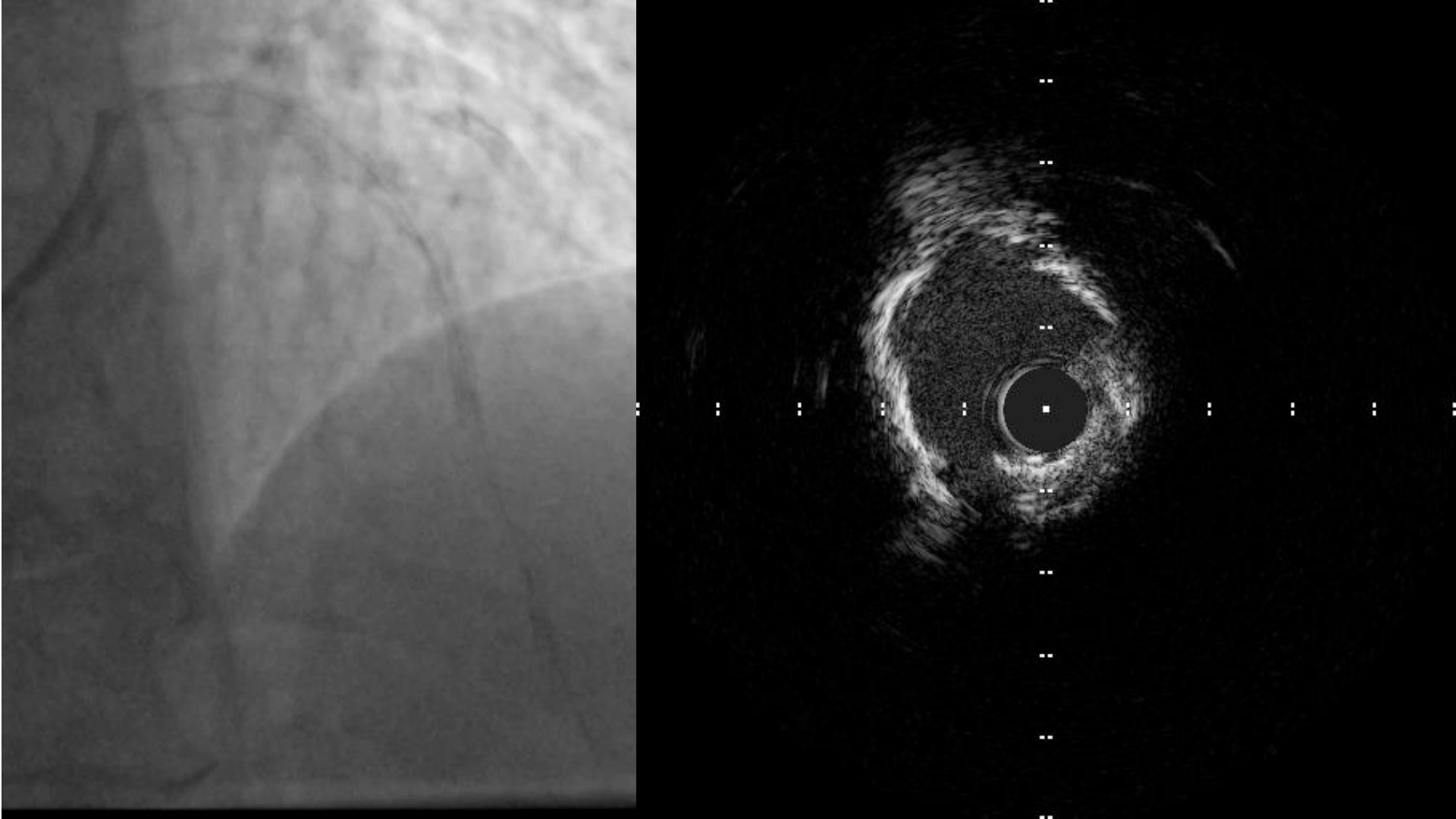
Detection of Calcium Fracture



Cardiovascular Research Foundation

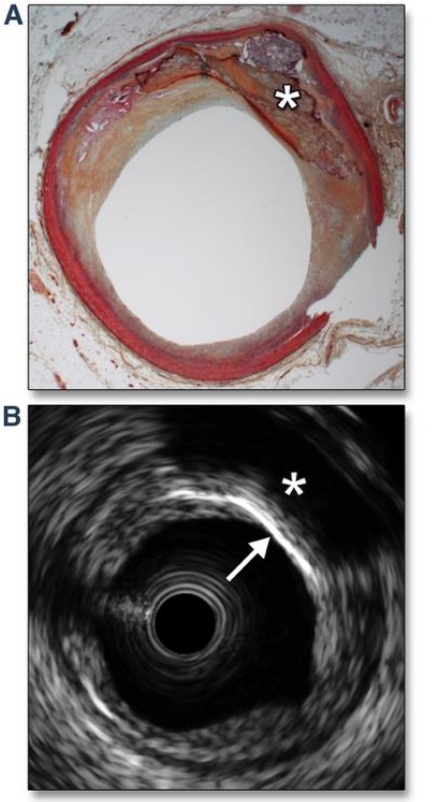
G. Mintz, iPCI 2023





Intravascular Imaging of Coronary Calcification

IVUS



Gary S. Mintz. JACC Imaging 2015

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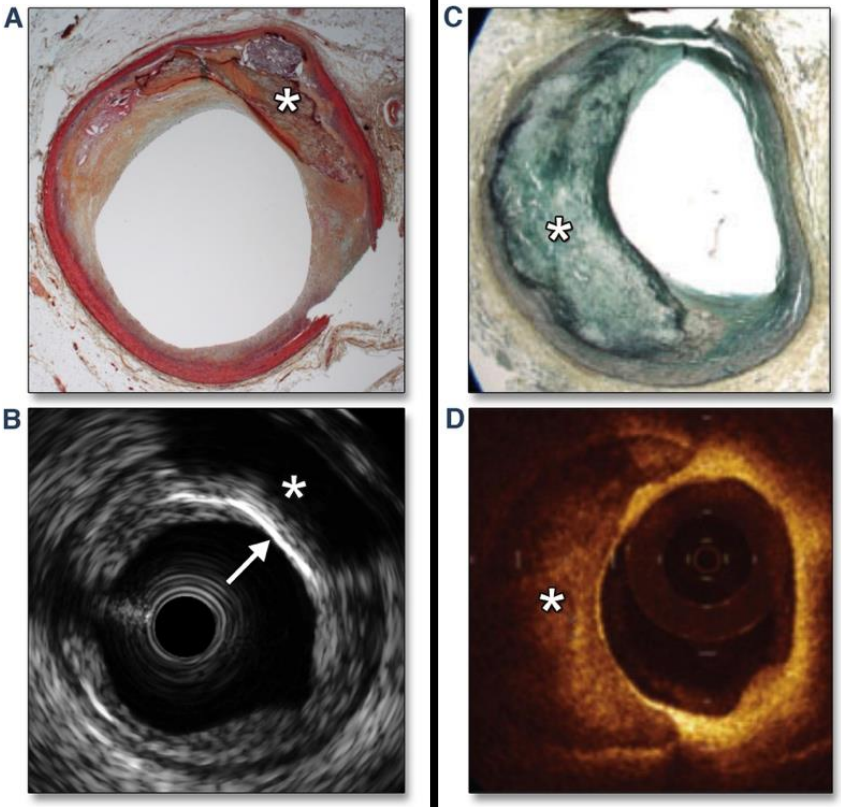
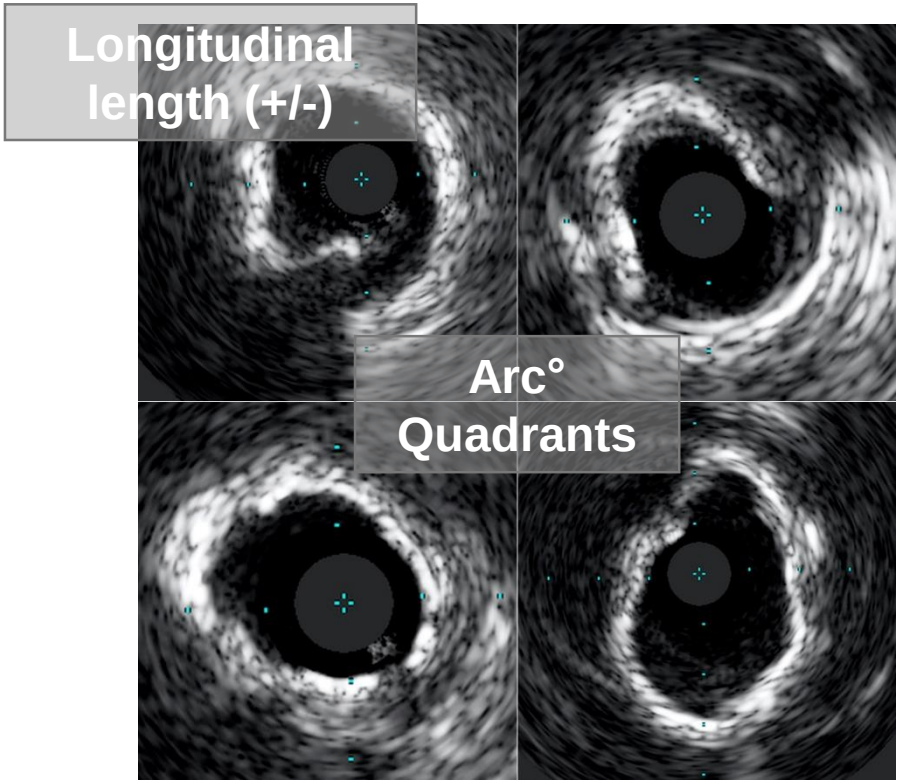


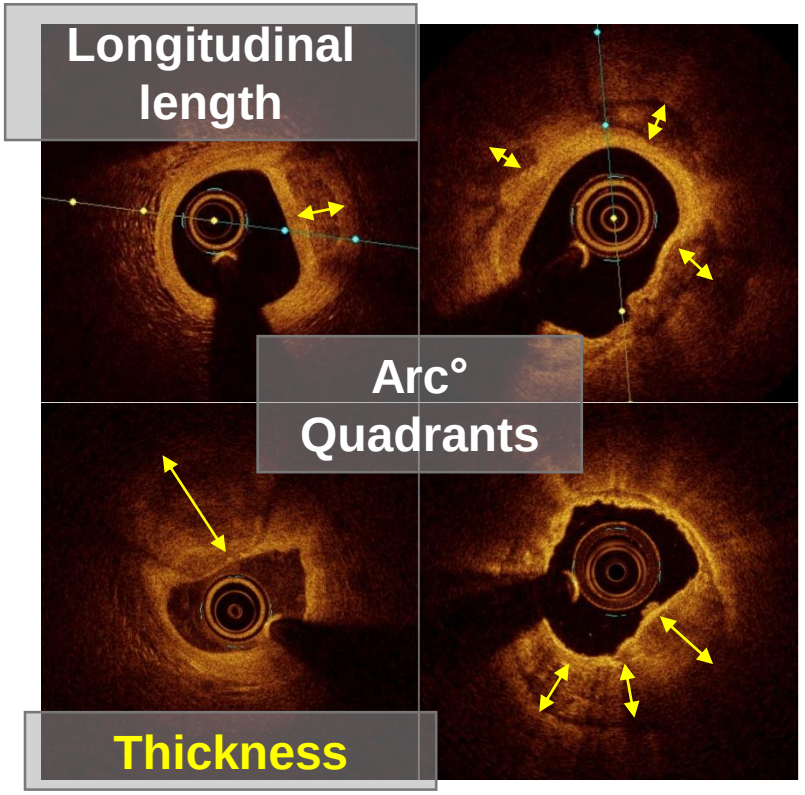
OCT

Gary S. Mintz. JACC Imaging 2015

IVUS
(resolution 150–200 µM)



OCT
(higher resolution10–20 µM)



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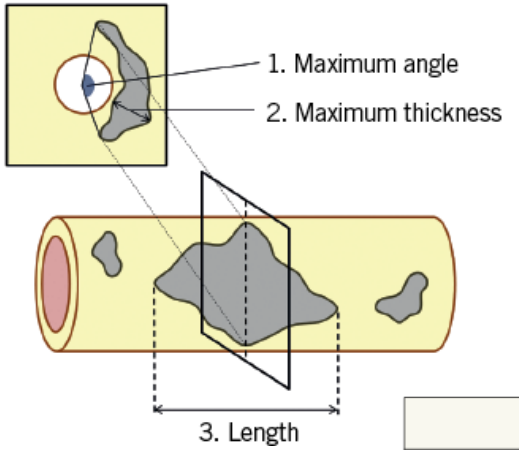
A new OCT-based calcium scoring system to predict stent underexpansion



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**

To identify lesions that would benefit from **plaque modification** prior to stent implantation.

Lesions with

1. **calcium deposit with maximum angle >180°**
2. **maximum thickness >0.5 mm**
3. **length >5 mm**

may be at risk of stent underexpansion.

Fujino, Mahehara et al. – Eurointervention 2018

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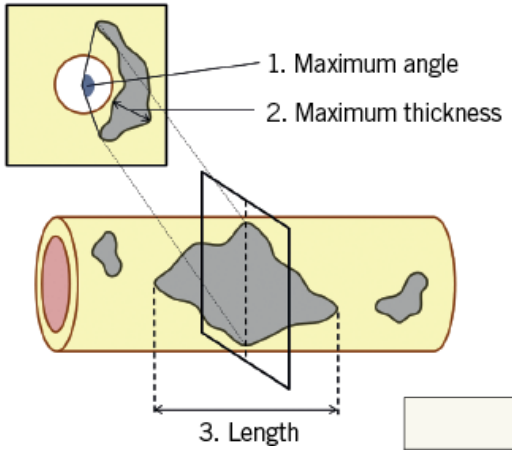

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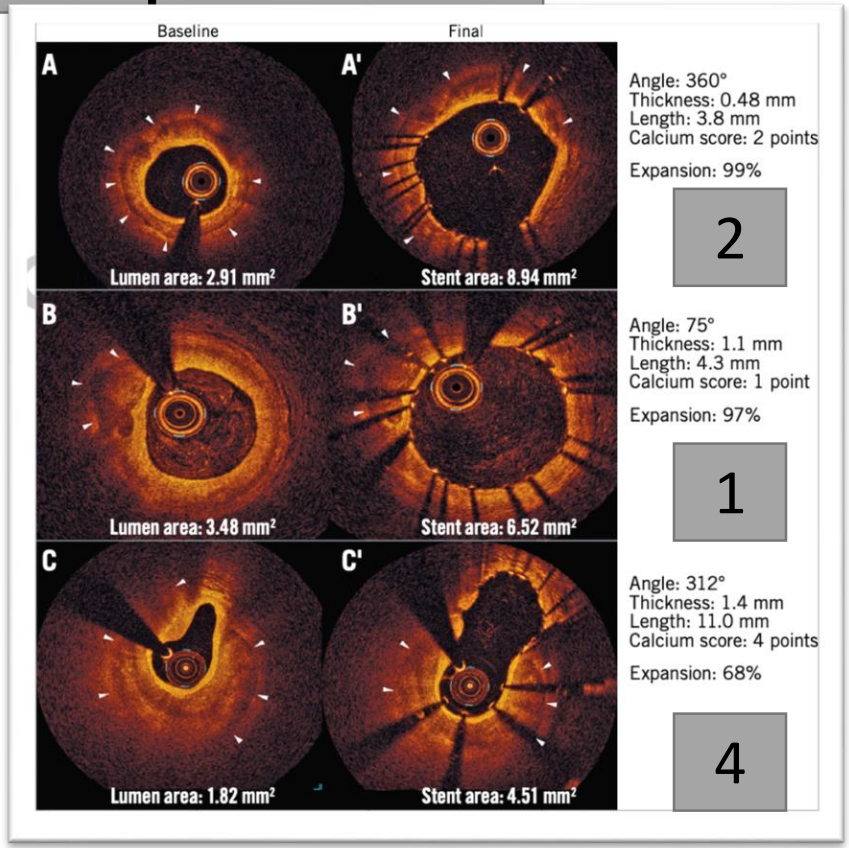

Fujino, Mahehara et al. – Eurointervention 2018

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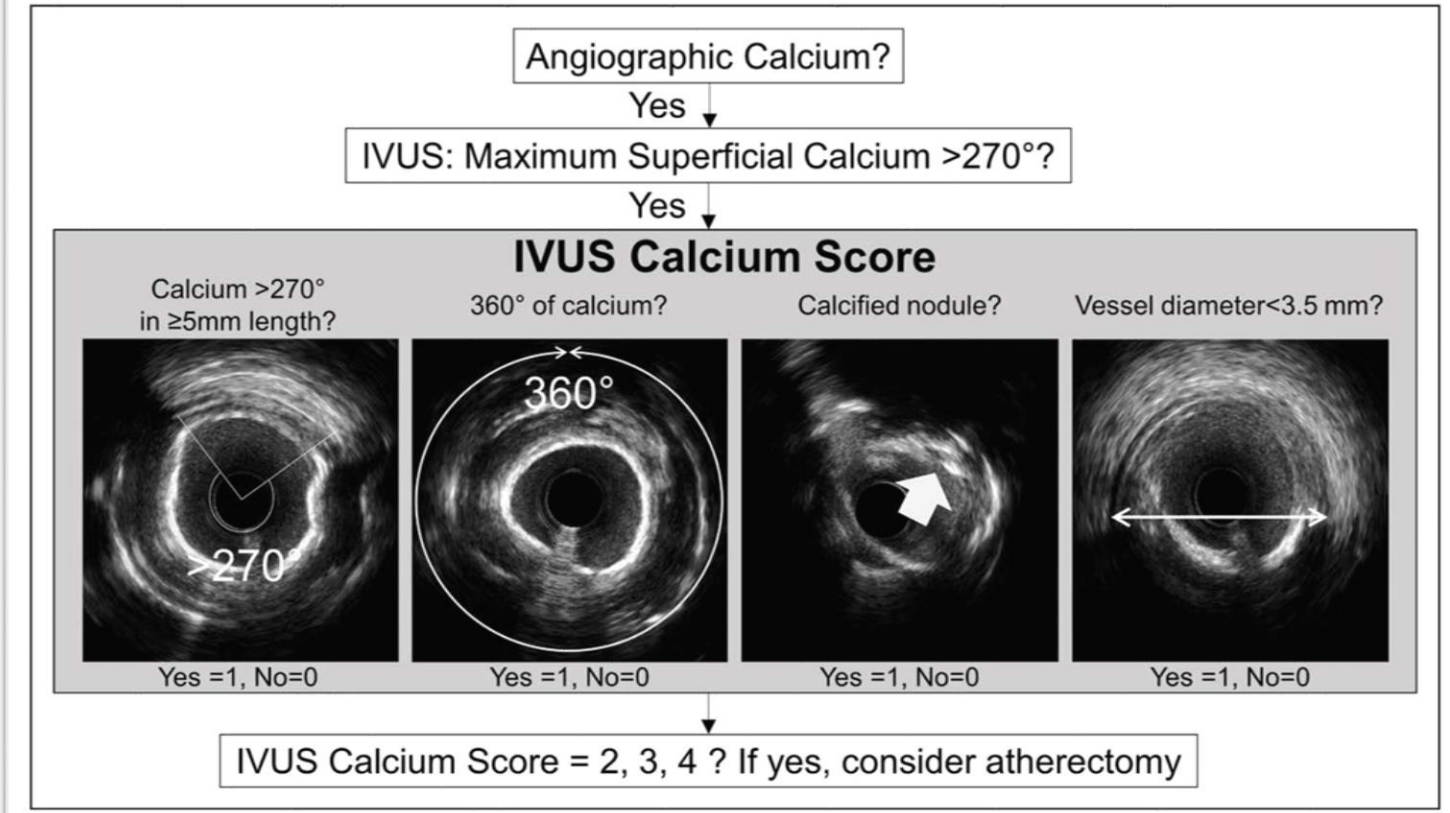
IVUS–Derived Calcium Score to Predict Stent Expansion in Severely Calcified Lesions



Zhang, Mahehara et al. – Circ Intv 2021

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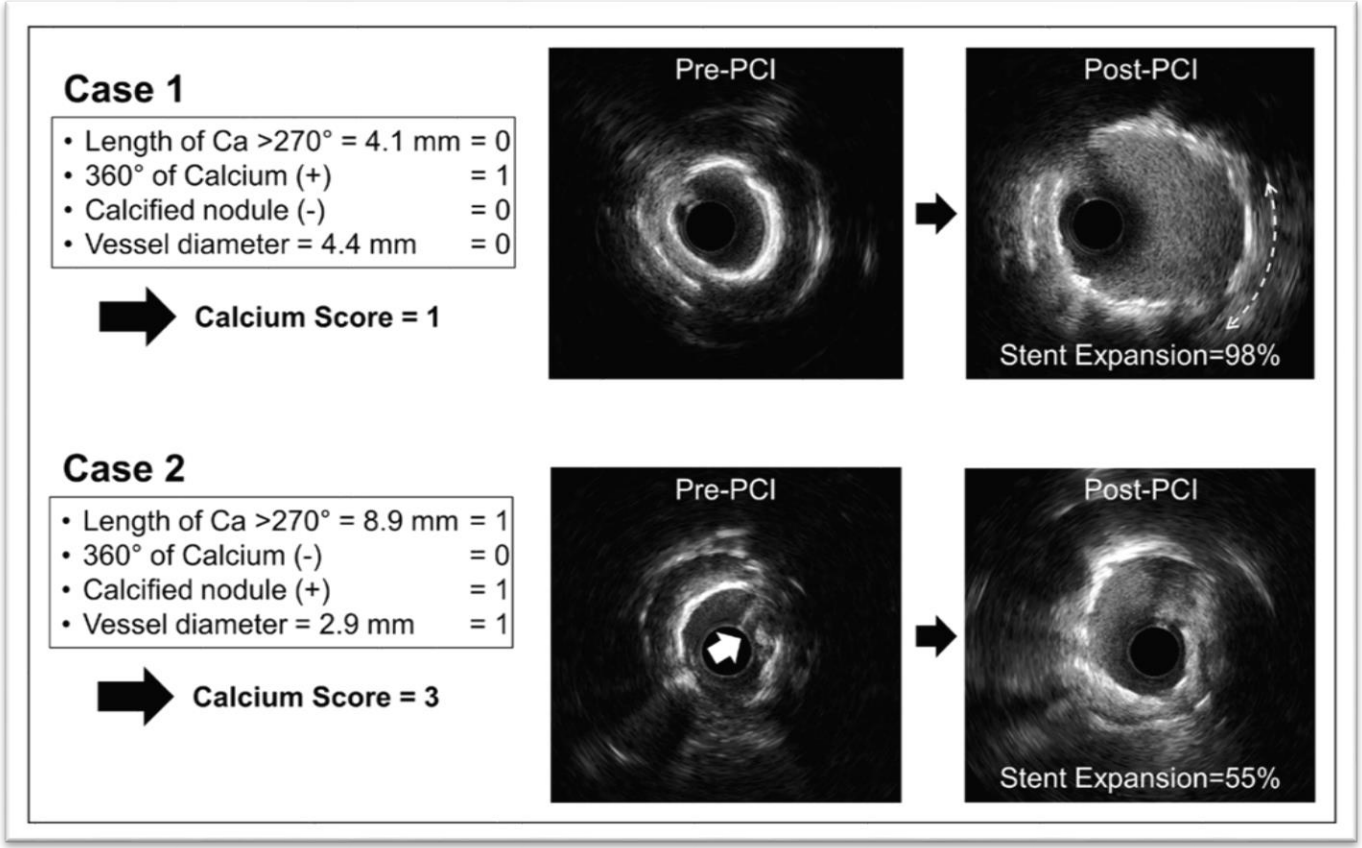

Zhang, Mahehara et al. – Circ Intv 2021

Lesion-Specific Benefits of IVUS Versus OCT

	IVUS	OCT
Left Main	+++	±
Ostial lesions	+++	-
ISR (in-stent restenosis)	+	+++
Calcium	+	+++
CTO (chronic total occlusion)	+++	+
Stent sizing and optimization	+++	+++
Ruptured plaque and thrombus	+	+++
Impaired renal function	+++	-

Shlofmitz et al. Circ Intv 2020

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Shlofmitz et al. Circ Intv 2020

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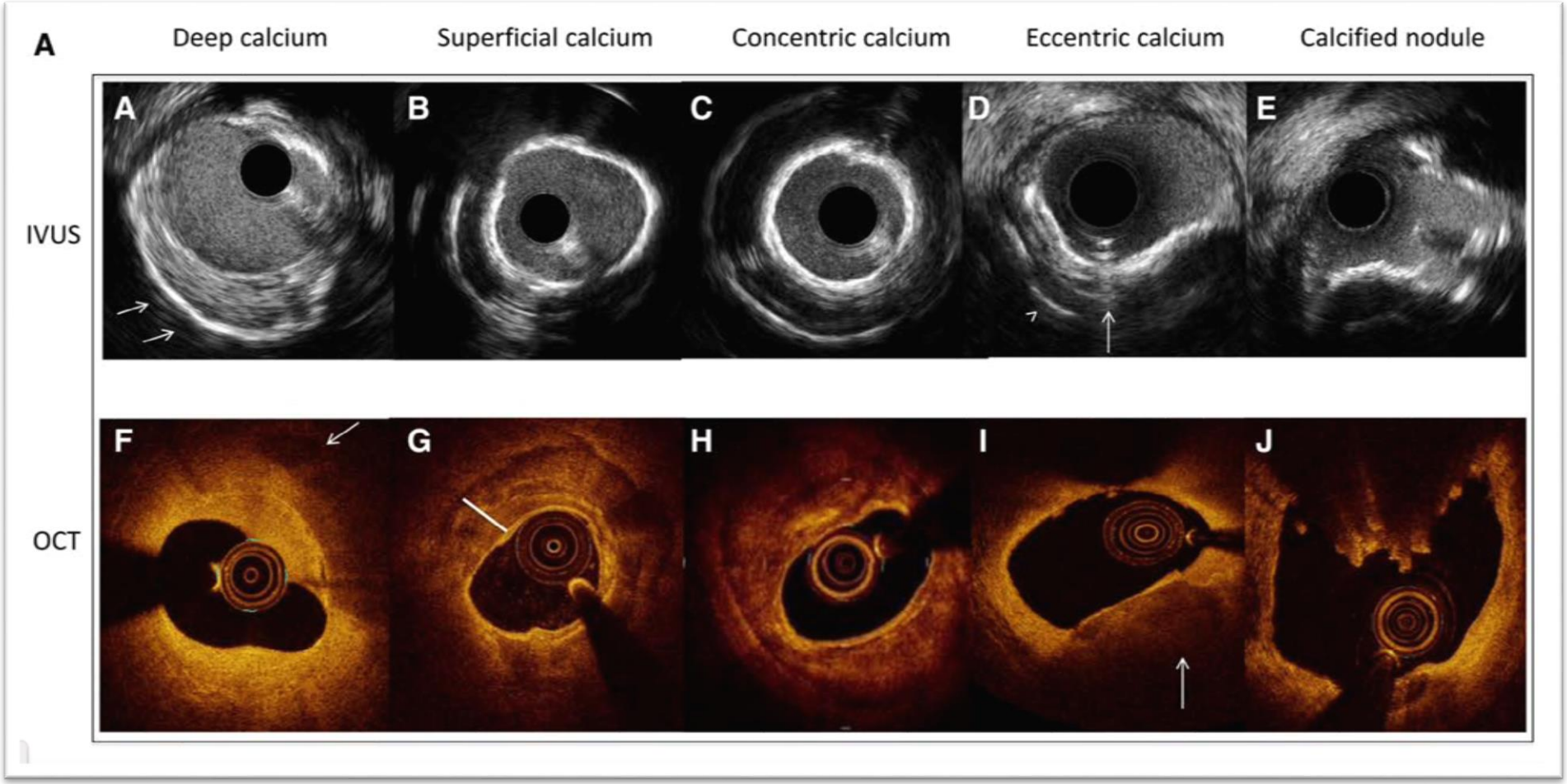

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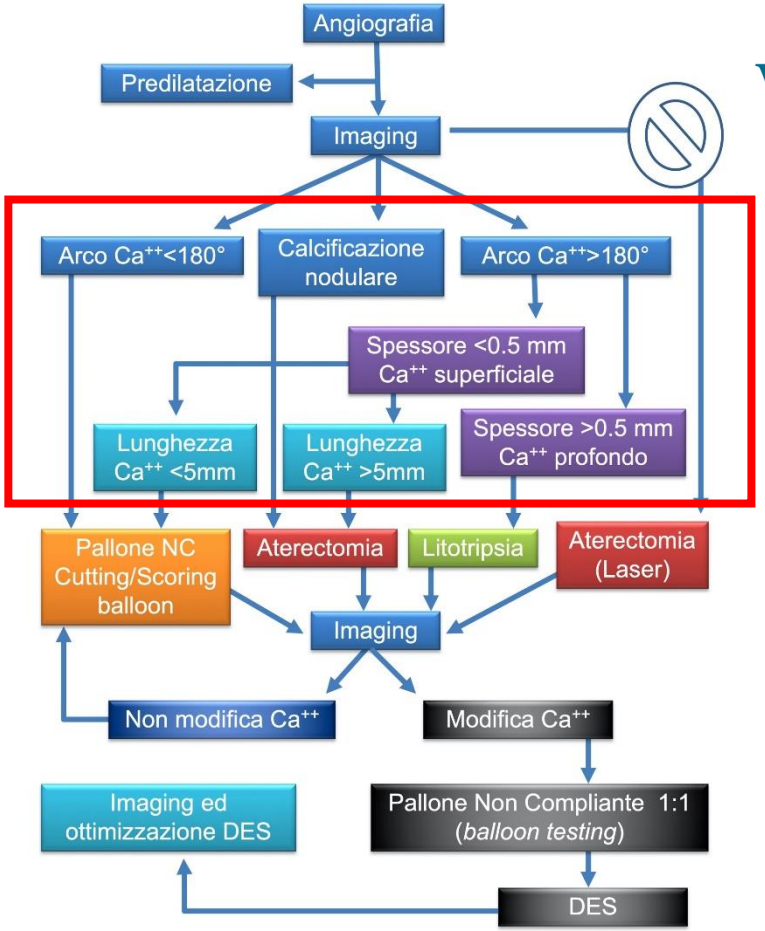

Valutazione e trattamento interventistico delle lesioni coronariche severamente calcifiche

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- **Arco di Ca^{++} >180°**
- **Spessore >0.5 mm**
- **Lunghezza >5 mm**

- **Calcio nodulare**

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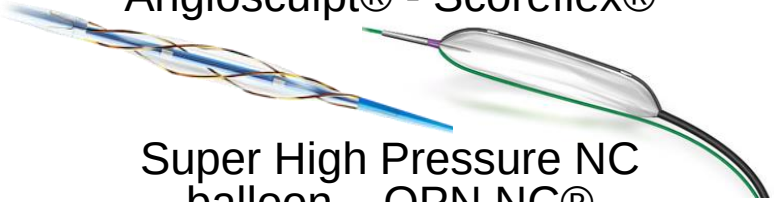
Balloon-based plaque modification

Cutting balloon – Wolverine®

Scoring balloon
Angiosculpt® - Scoreflex®



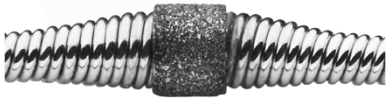
Super High Pressure NC balloon – OPN NC®

Lithotripsy balloon – Shockwave IVL®

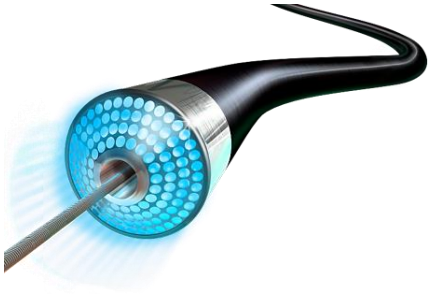
Plaque modification and ablation

Rotational Atherectomy
Rotablator® – RotaPro®

Orbital Atherectomy
DiamondBack 360®



LASER Atherectomy
ECLA



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RPL

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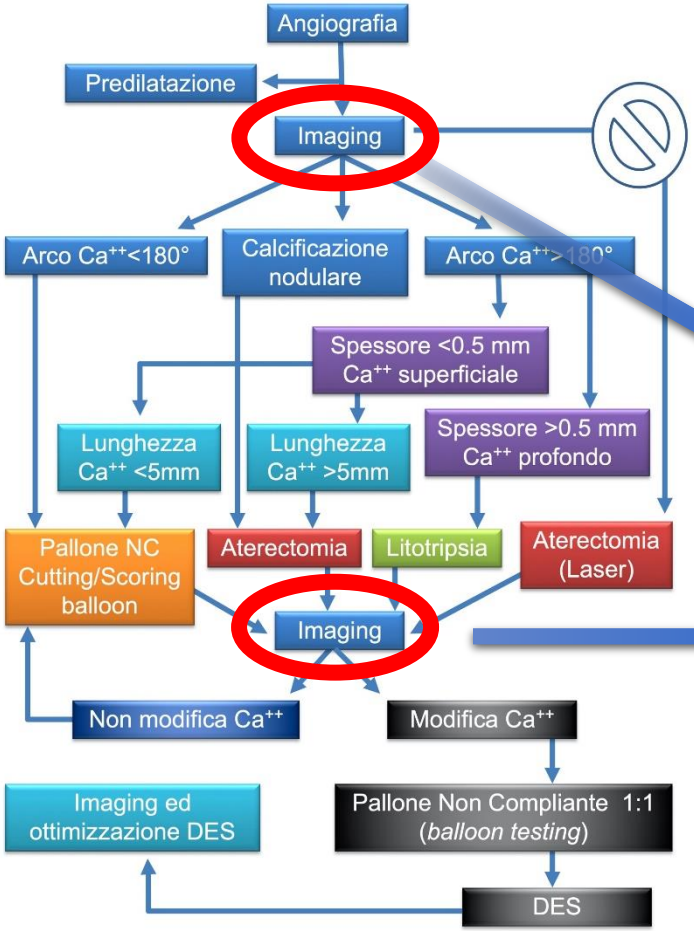

Basal Imaging

Imaging after plaque modification

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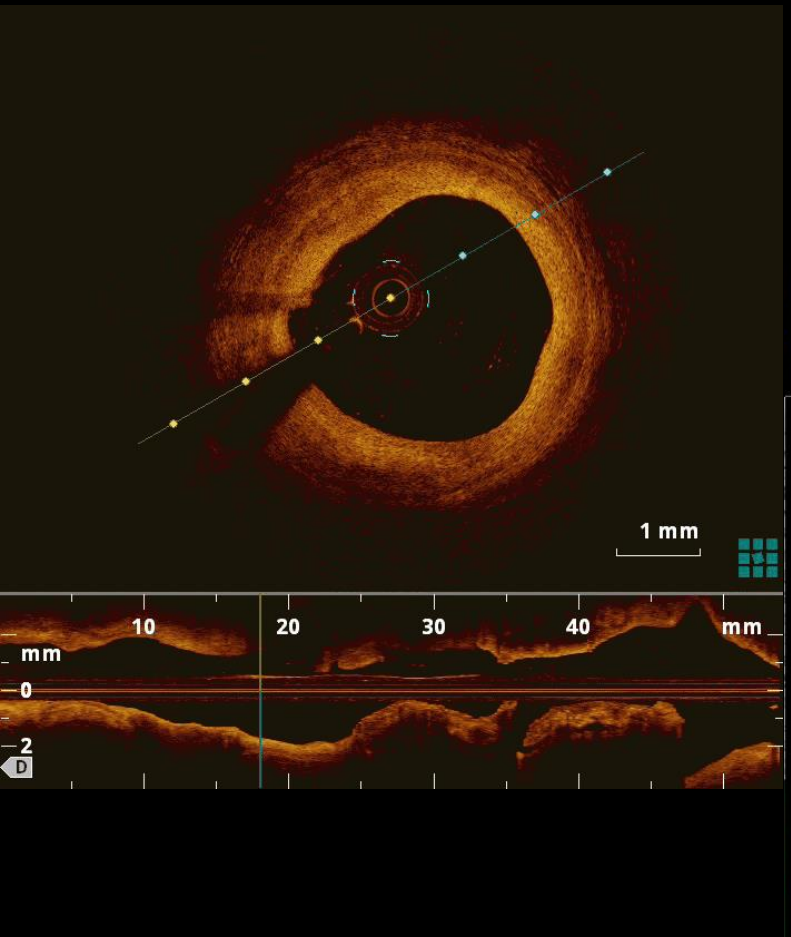
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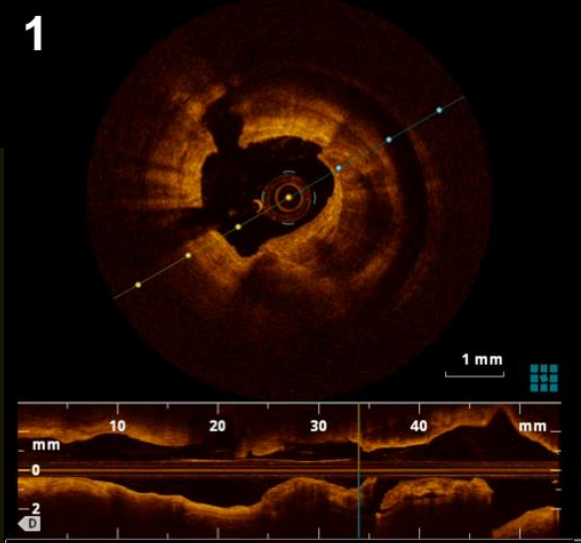
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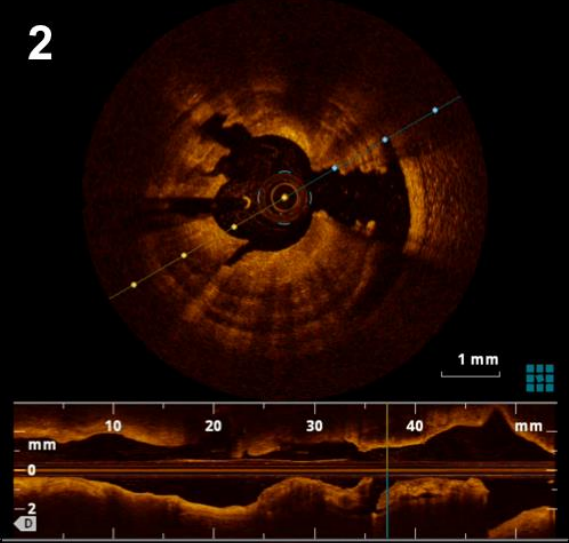
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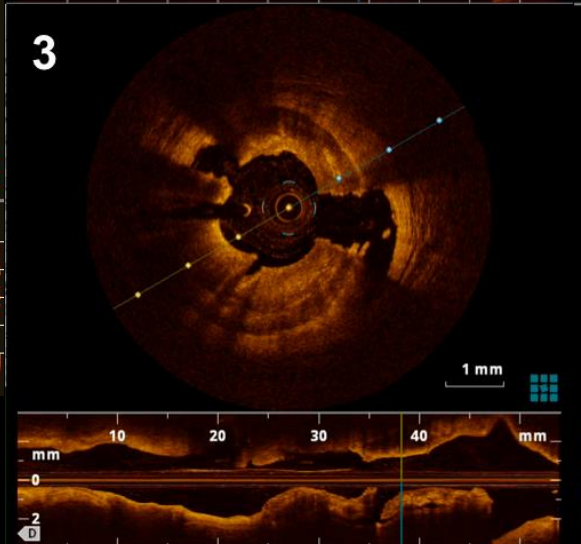
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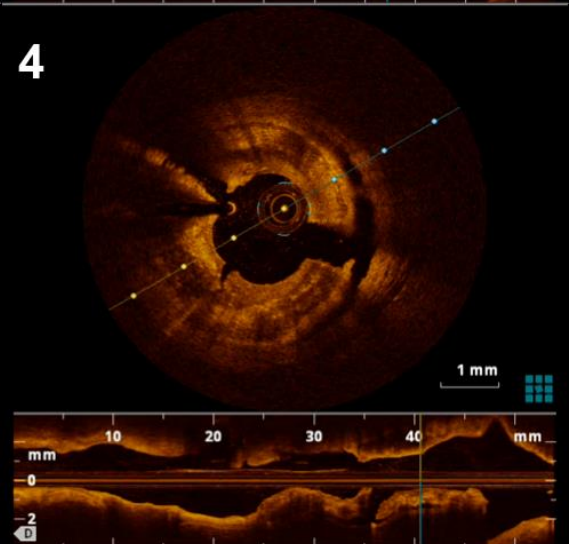
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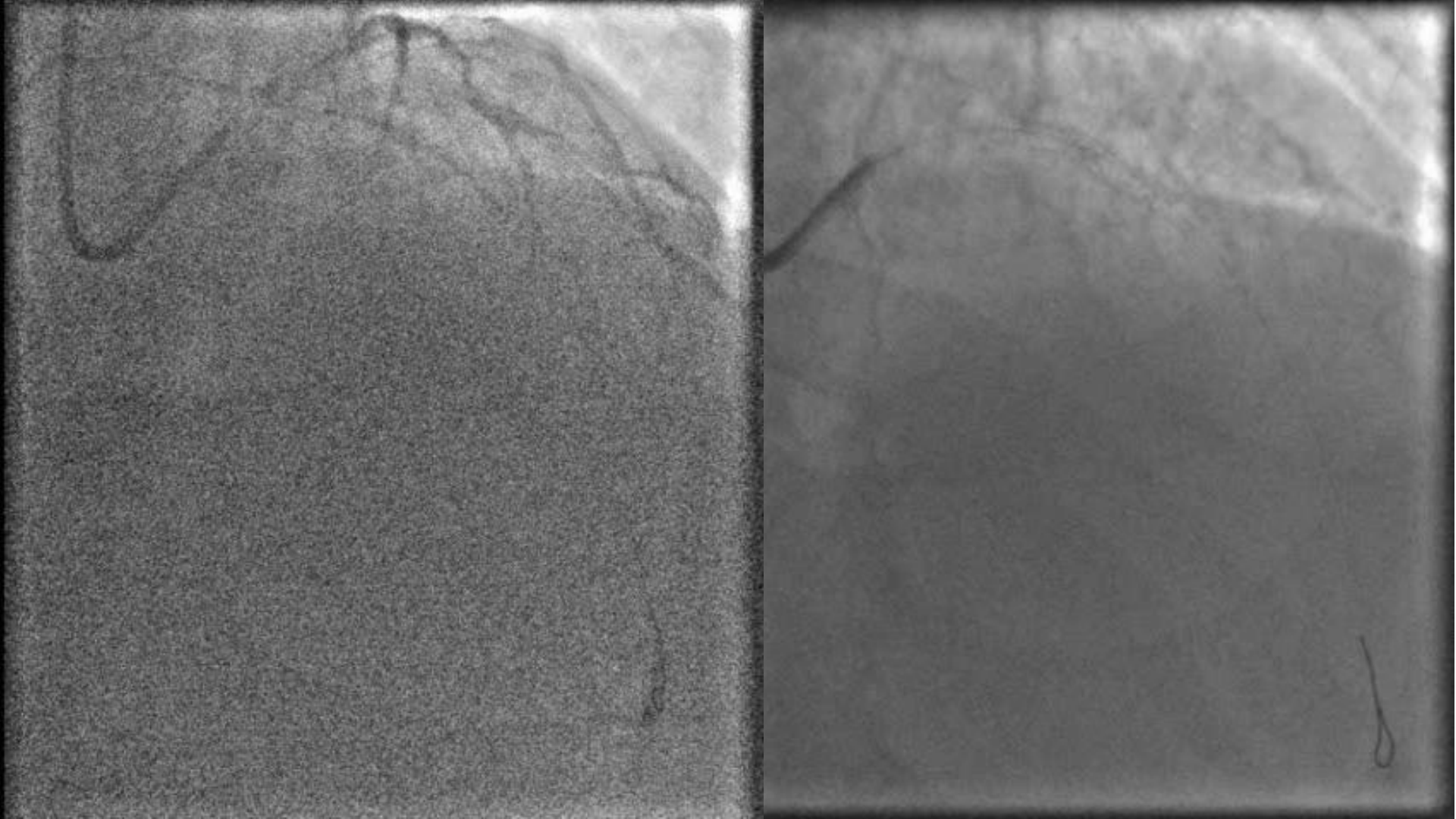

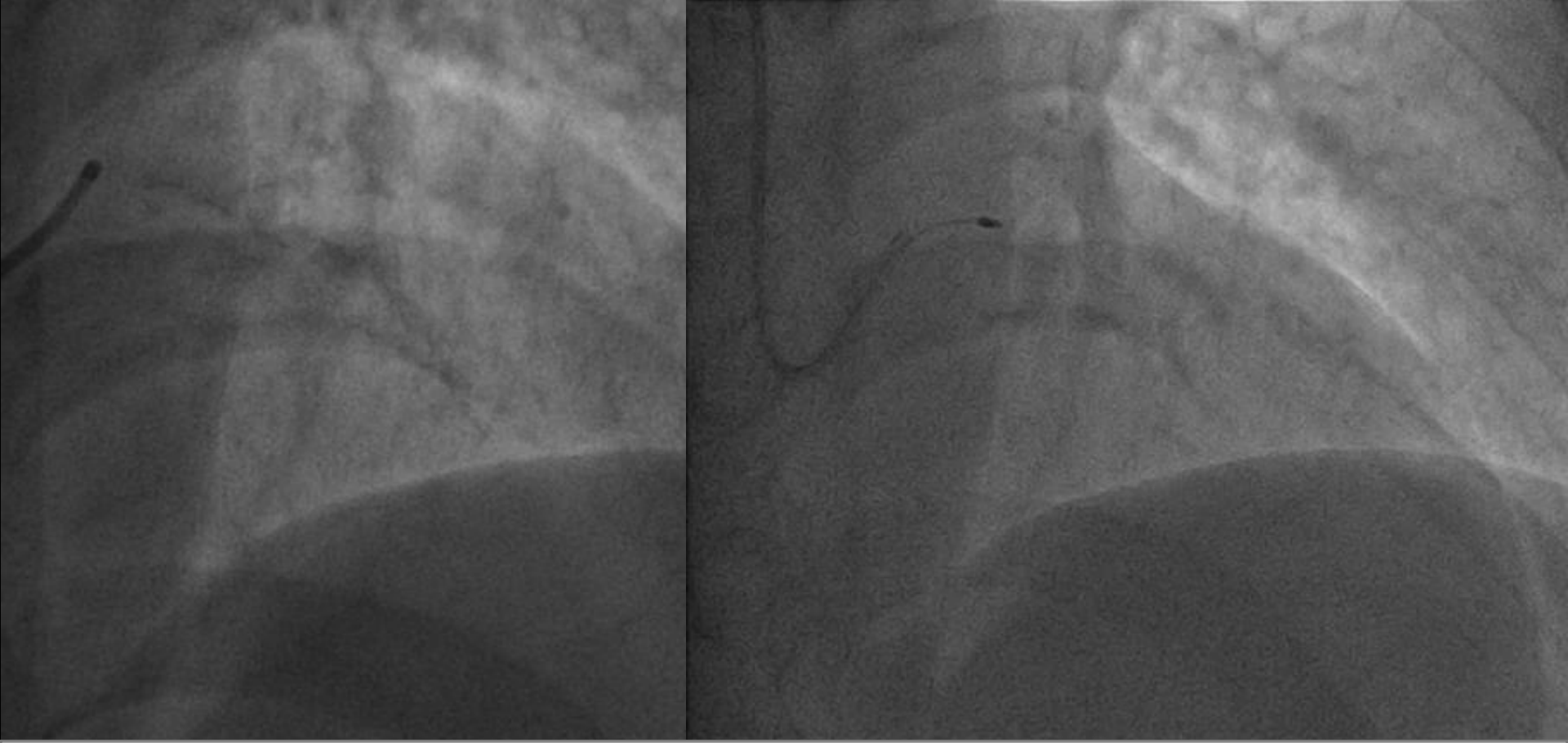

48yo male, HeFH, smoker, NSTEMI, IVUS uncrossable
Primary Rotational Atherectomy (1.5 burr) ➔ 3.5 NC balloon

Valutazione e trattamento interventistico delle lesioni coronariche severamente calcifiche

Giuseppe Andò[1], Giampiero Vizzari[1], Giampaolo Niccoli[2], Paolo Calabrò[3],
Marco Zimarino[4], Carmen Spaccarotella[5], Salvatore De Rosa[5], Raffaele Piccolo[6], Felice Gragnano[3],
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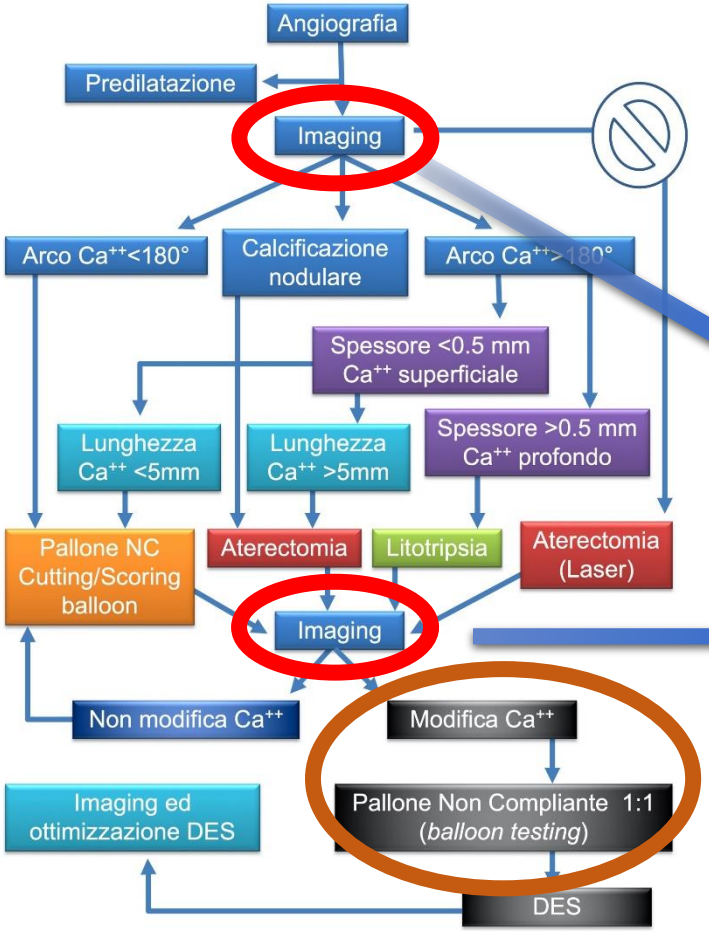
a nome del Gruppo di Studio "Cardiologia Interventistica" della Società Italiana di Cardiologia



Basal Imaging

Imaging after plaque modification

«Balloon testing»
Lesion «Palpation» or «Probing»
1:1 NC in 2 orthogonal views

Andò G et al. – G Ital Cardiol 2021

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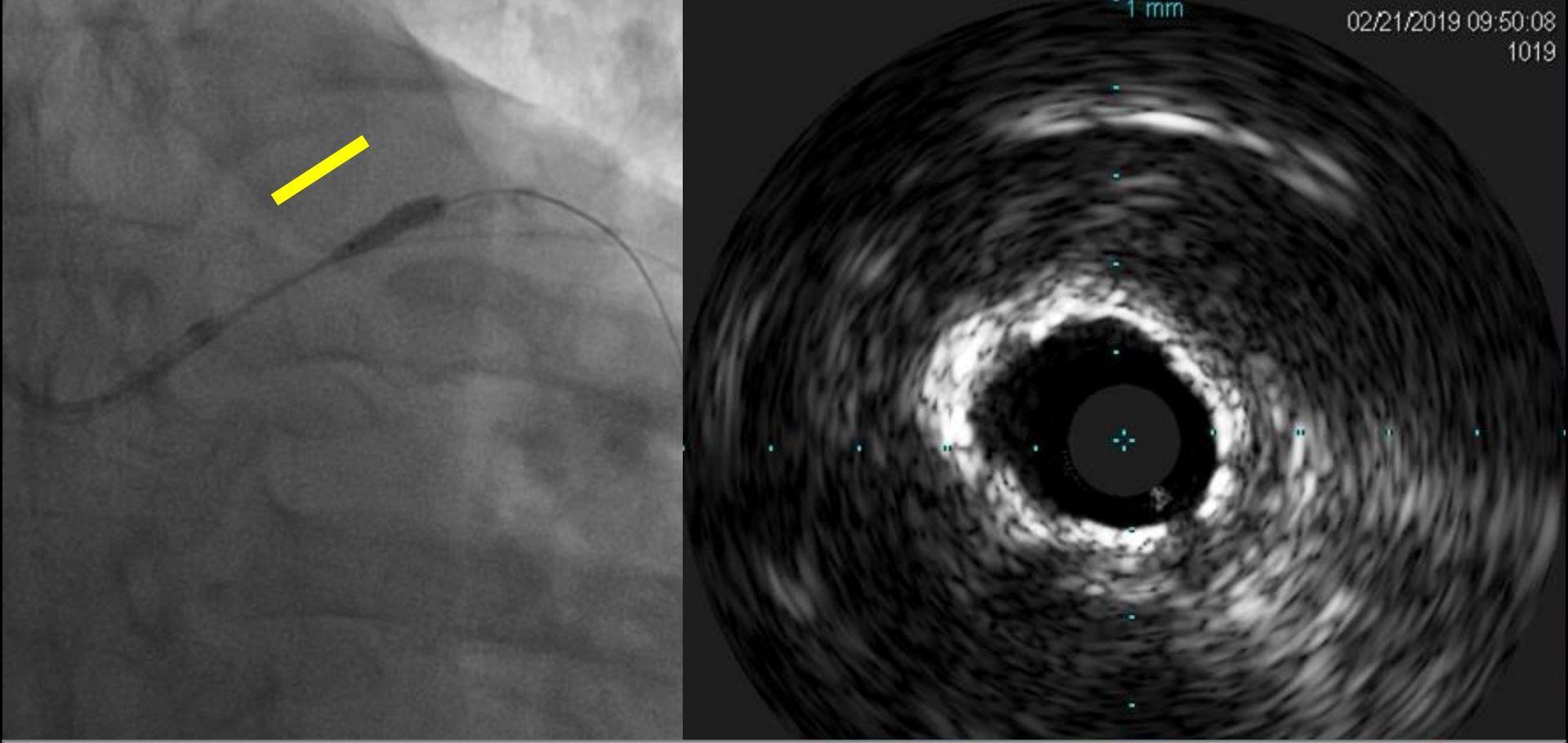
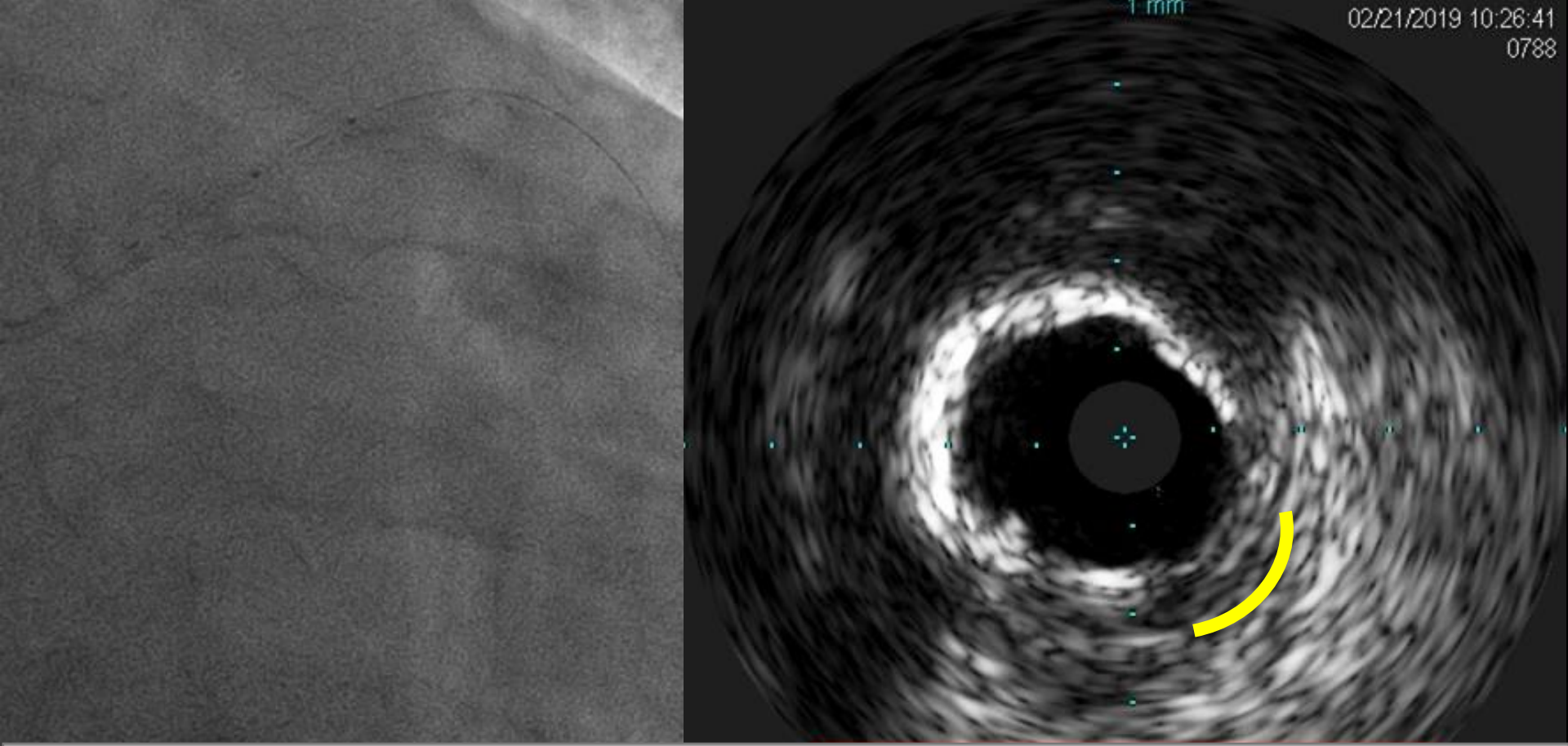
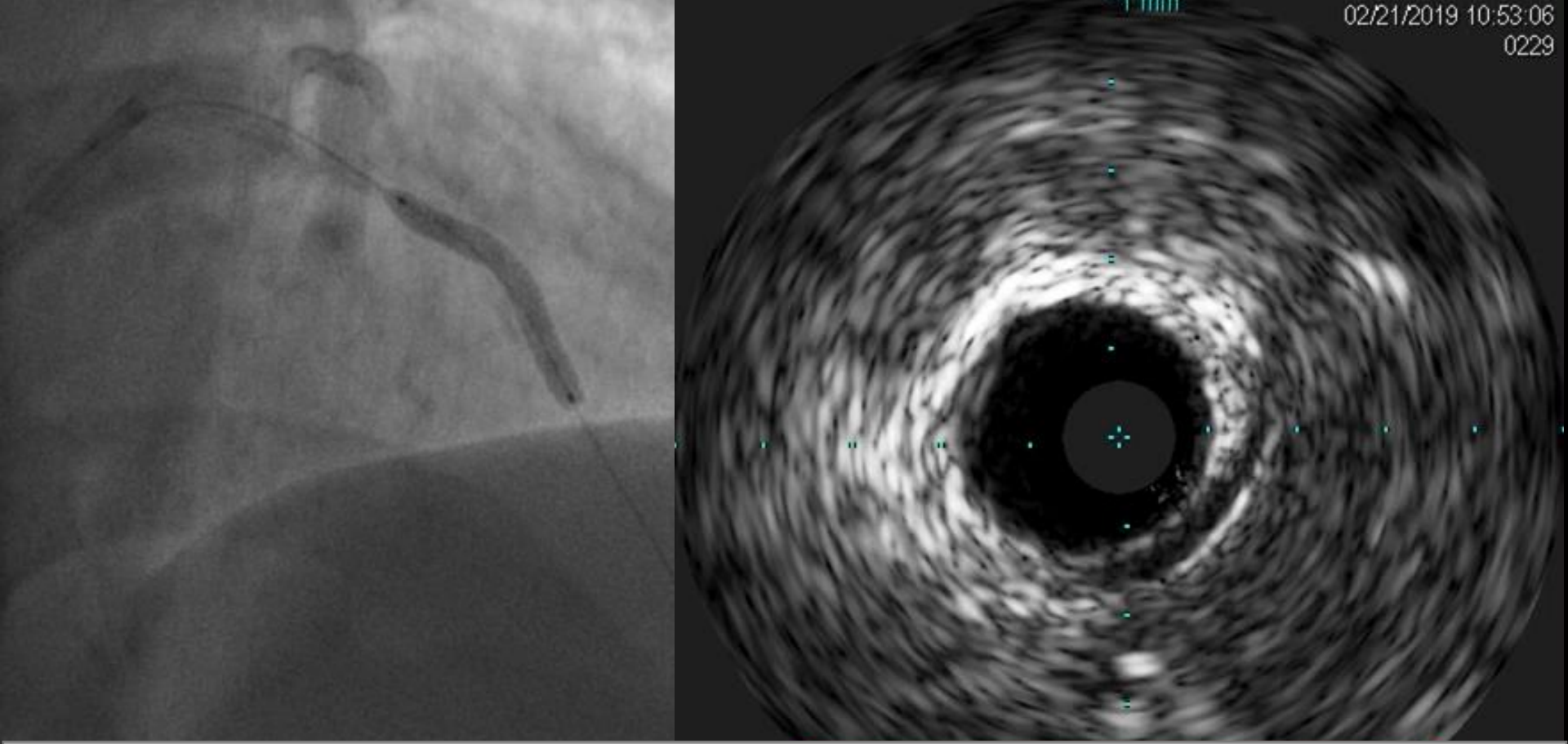


IVUS after NC balloon dilatation demonstrates a persistent concentric calcific ring in the pLAD, precluding proper balloon dilatation



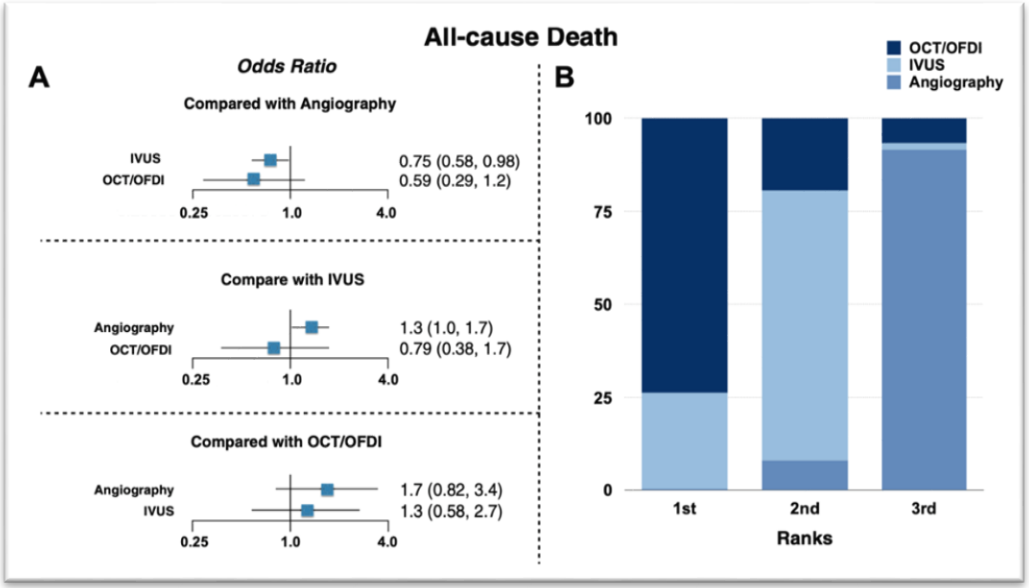
IVL with 3,5 mm balloon (80 pulses) disrupts calcium
-please note the fracture in the ring in the right lower quadrant-



Final result after DES implantation

Intravascular Imaging- Versus Angiography-Guided PCI

A Systematic Review and Bayesian Network Meta-Analysis of 31 Studies and 17,882 Patients



	Angiography	IVUS	OCT/OFDI
MACE			
Angiography	–	0.79 (0.67-0.91)	0.68 (0.49-0.97)
IVUS	1.30 (1.10-1.50)	–	0.87 (0.61-1.30)
OCT/OFDI	1.50 (1.00-2.00)	1.10 (0.78-1.60)	–
Cardiovascular death			
Angiography	–	0.47 (0.32-0.66)	0.31 (0.13-0.66)
IVUS	2.10 (1.50-3.10)	–	0.66 (0.27-1.50)
OCT/OFDI	3.20 (1.50-7.60)	1.50 (0.66-3.70)	–
Myocardial infarction			
Angiography	–	0.72 (0.52-0.93)	0.79 (0.44-1.40)
IVUS	1.40 (1.10-1.90)	–	1.10 (0.60-2.10)
OCT/OFDI	1.30 (0.72-2.30)	0.90 (0.47-1.70)	–
Target lesion revascularization			
Angiography	–	0.74 (0.58-0.90)	0.66 (0.35-1.20)
IVUS	1.40 (1.10-1.70)	–	0.88 (0.47-1.60)
OCT/OFDI	1.50 (0.83-2.90)	1.10 (0.61-2.10)	–
Stent thrombosis			
Angiography	–	0.42 (0.20-0.72)	0.39 (0.10-1.20)
IVUS	2.40 (1.40-5.10)	–	0.93 (0.24-3.40)
OCT/OFDI	2.60 (0.80-10.0)	1.10 (0.29-4.20)	–

Buccheri S et al. – JACC Intv 2017

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Intravascular Imaging-Guided Versus Angiography-Guided Complex PCI

The RENOVATE-COMPLEX-PCI Trial

Joo-Yong Hahn, MD, PhD

Director of Interventional Cardiology

Professor, Samsung Medical Center, Korea

@mySMC

On behalf of RENOVATE-COMPLEX-PCI Investigators

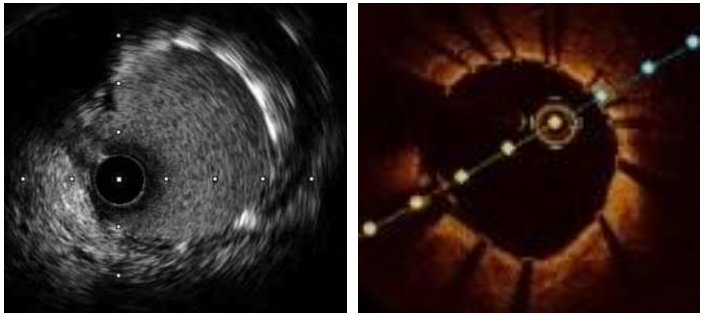
ACC.23 TOGETHER WITH WCC

AMERICAN COLLEGE of CARDIOLOGY

WORLD HEART FEDERATION

Background

- Patients with complex coronary artery lesions undergoing PCI have worse clinical outcomes than patients without complex coronary artery lesions.
- Intravascular imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) are used to select the appropriate stent size, to determine the stent landing zone, and to determine if the stent is underexpanded, or there is a stent edge dissection.



- **Previous trials** (CTO-IVUS, AVIO, HOME-DES-IVUS, IVUS-XPL, ULTIMATE) have reported lower rates of major adverse clinical events following IVUS-guided PCI compared with angiography-guided PCI **but have not been considered definitive due to limited sample size, short follow-up duration, or inclusion of highly selected coronary lesion subsets.**

Randomized controlled trial is needed to confirm the prognostic benefit of intravascular imaging-guided PCI than angiography-guided PCI in patients with complex coronary artery lesions.

Lee JM, Choi KH, Song YB ,,,,, Hahn JY, et al. NEJM 2023

Inclusion and Exclusion Criteria

INCLUSION

1. Patients (≥ 19 years) with coronary artery disease requiring PCI
2. Patients with a **complex coronary artery lesion** defined as:
   - True bifurcation lesion (Medina 1,1,1/1,0,1/0,1,1) with side branch ≥2.5mm
   - Chronic total occlusion (≥3 months) as target lesion
   - Unprotected LM disease PCI (LM ostium, body, distal LM bifurcation including non-true bifurcation)
   - Long coronary lesions (implanted stent ≥38 mm in length)
   - Multi-vessel PCI (≥2 vessels treated at one PCI session)
   - Multiple stents needed (≥3 more stent per patient)
   - In-stent restenosis lesion as target lesion
   - **Severely calcified lesion (encircling calcium in angiography)**
   - Ostial coronary lesion (LAD, LCX, RCA)

KEY EXCLUSION

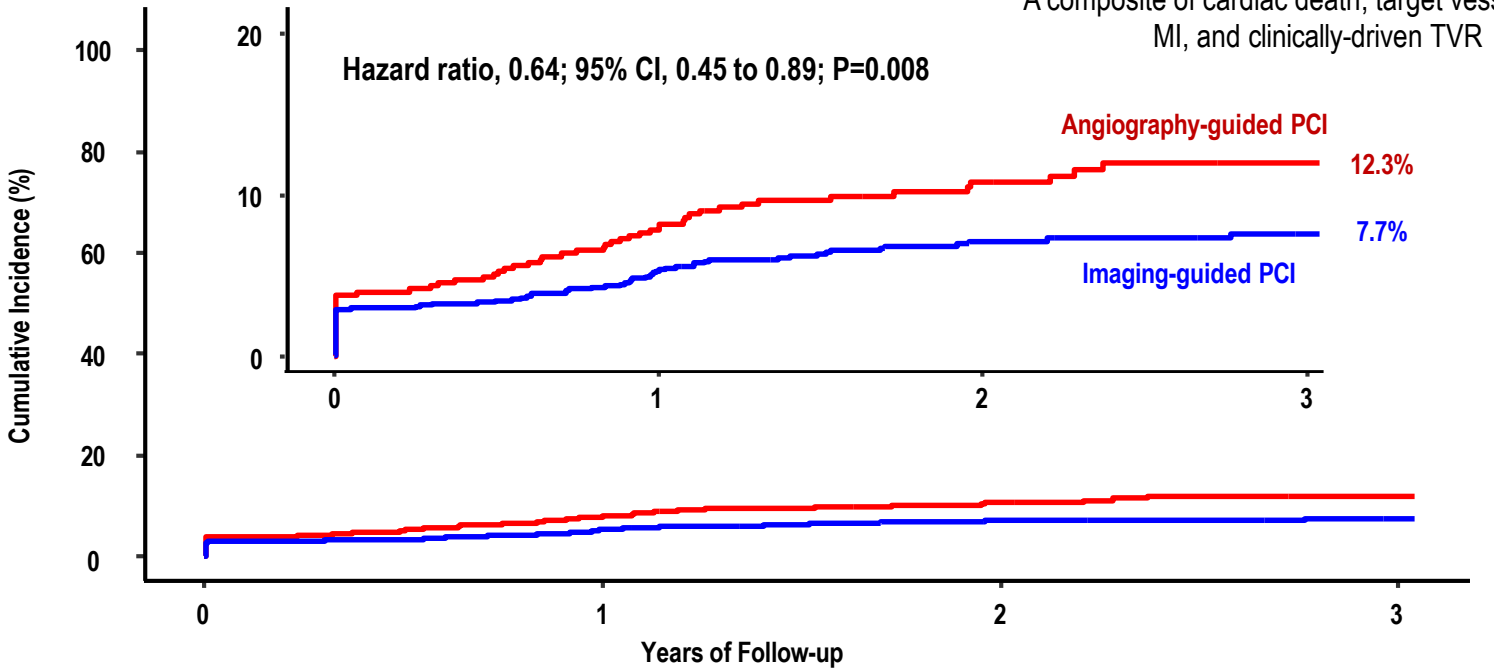
1. Target lesions not amenable to PCI by operators' decision
2. Cardiogenic shock (Killip class IV) at presentation
3. Intolerance to Aspirin, Clopidogrel, Prasugrel, Ticagrelor, Heparin, or Everolimus
4. Known true anaphylaxis to contrast medium (not allergic reaction but anaphylactic shock)
5. Pregnancy or breast feeding
6. Non-cardiac co-morbid conditions are present with life expectancy <1 year or that may result in protocol non-compliance (per site investigator's medical judgment)
7. Unwillingness or inability to comply with the procedures described in this protocol.

Lee JM, Choi KH, Song YB ,,,,, Hahn JY, et al. NEJM 2023

Primary End Point

Target vessel failure

A composite of cardiac death, target vessel-related MI, and clinically-driven TVR



Number at risk				
Angiography-guided PCI	547	496	280	120
Imaging-guided PCI	1092	1023	591	255

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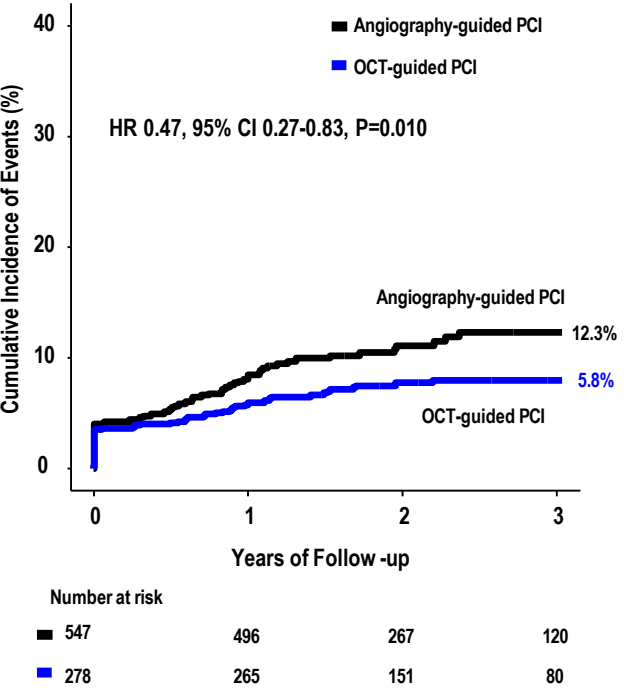
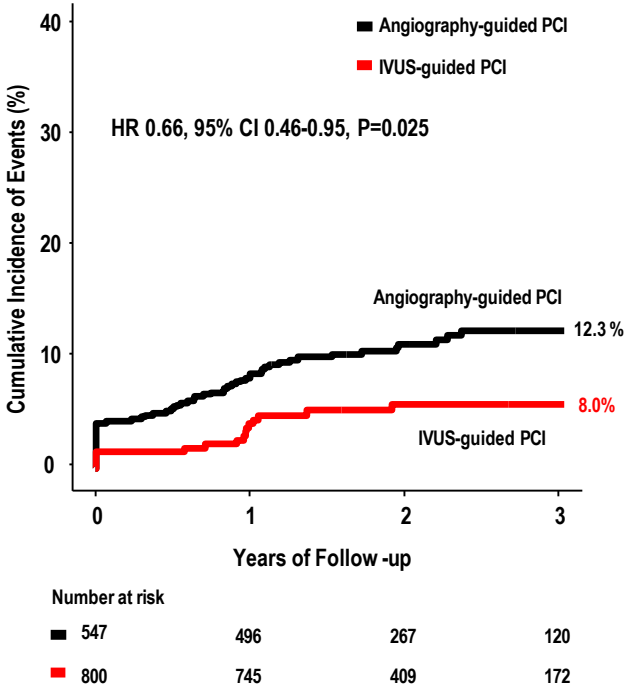
OCT-guided PCI vs. IVUS-guided PCI vs. Angiography-PCI

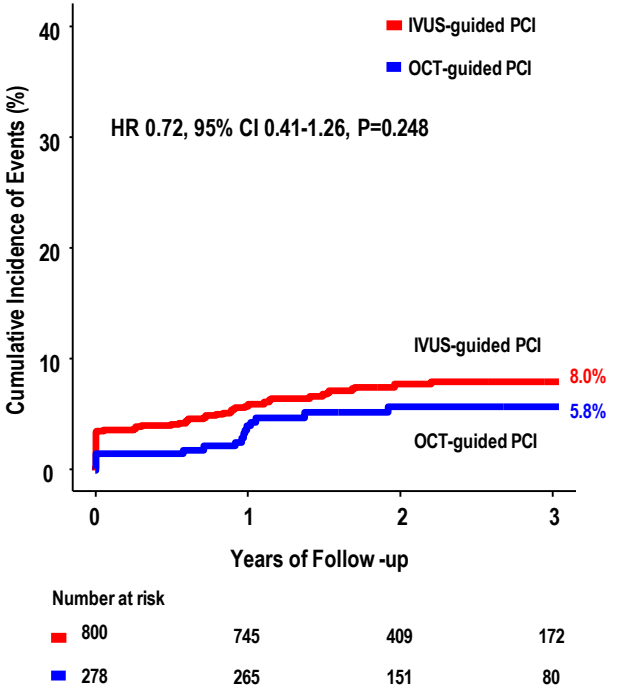
OCT-guided PCI vs. Angiography-guided PCI



IVUS-guided PCI vs. Angiography-guided PCI



OCT-guided PCI vs. IVUS-guided PCI



Lee JM, Choi KH, Song YB ,,,,, Hahn JY, et al. NEJM 2023

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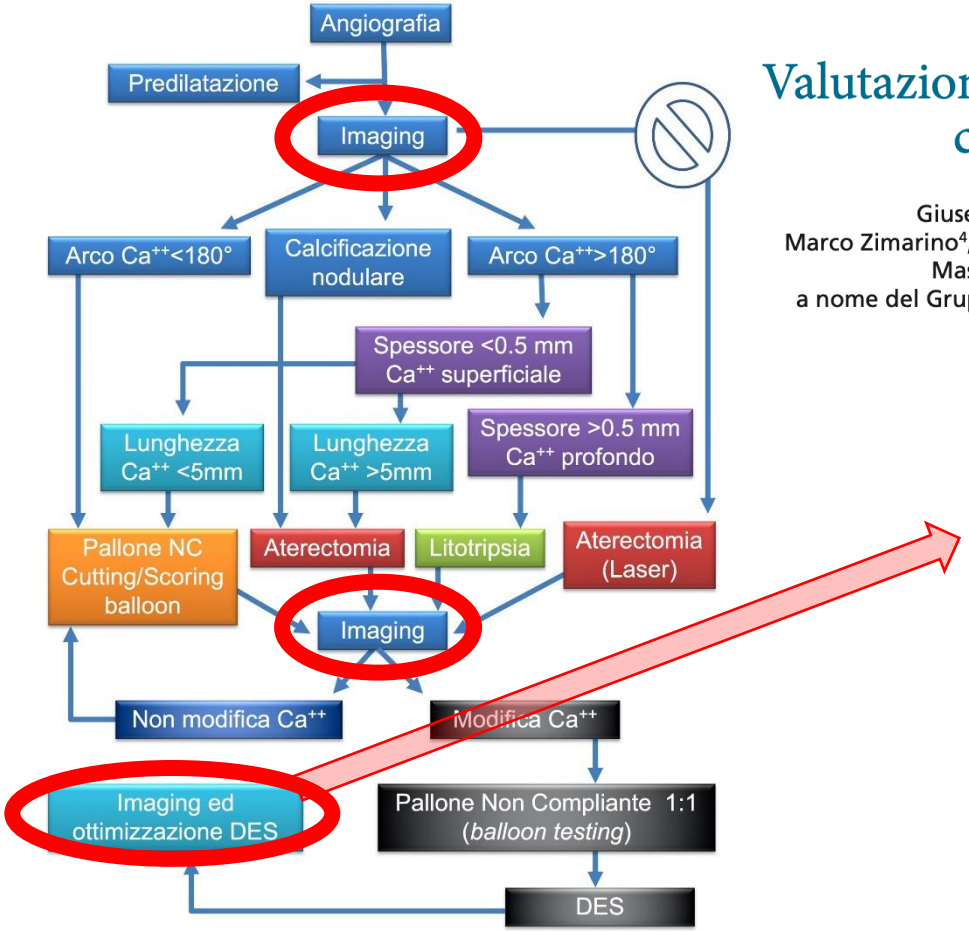

Stent optimization

Andò G et al. – G Ital Cardiol 2021

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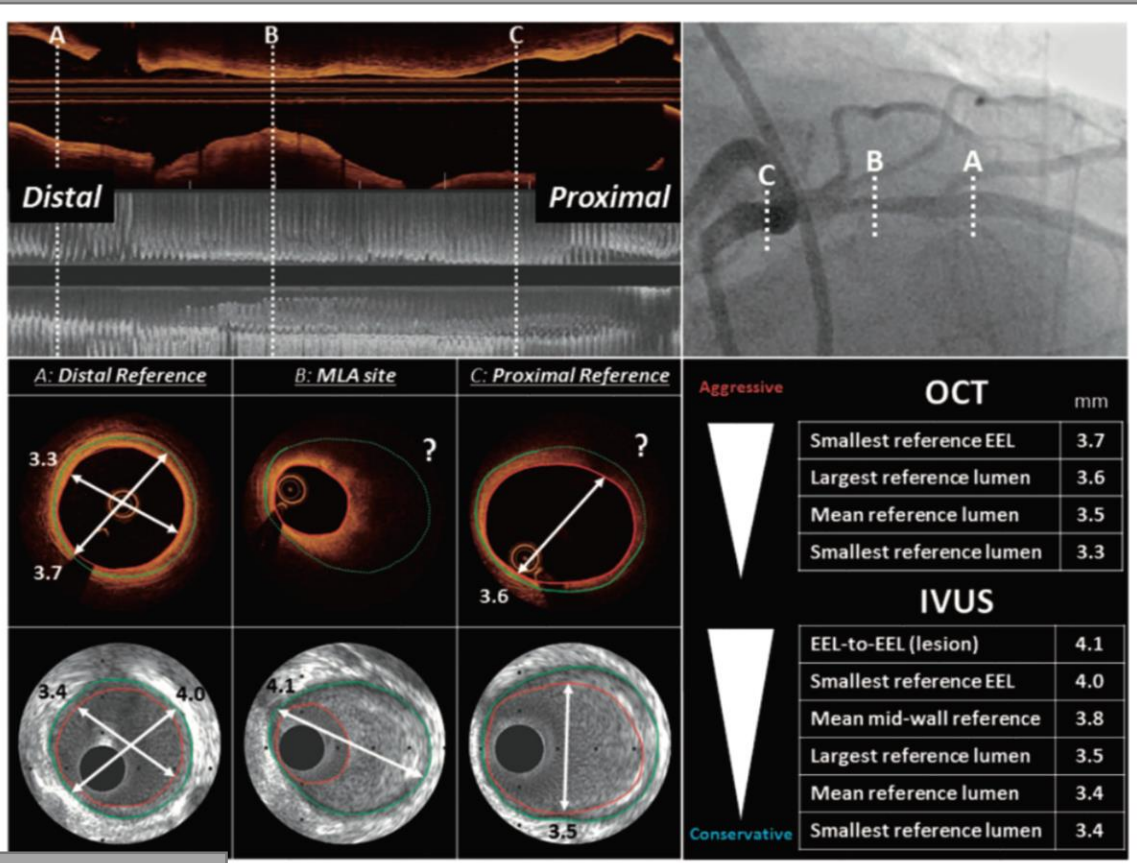
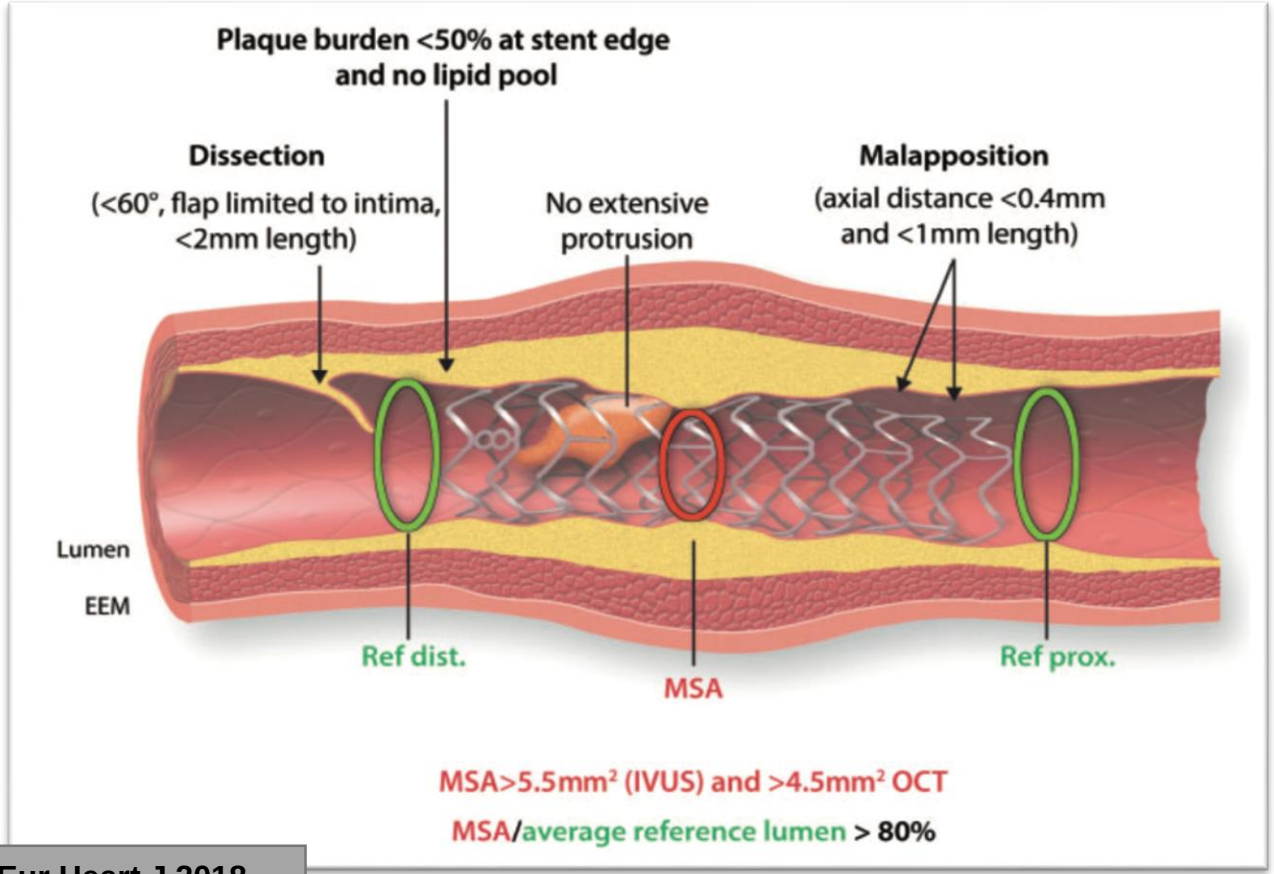
IVUS- and OCT-based stent sizing approaches



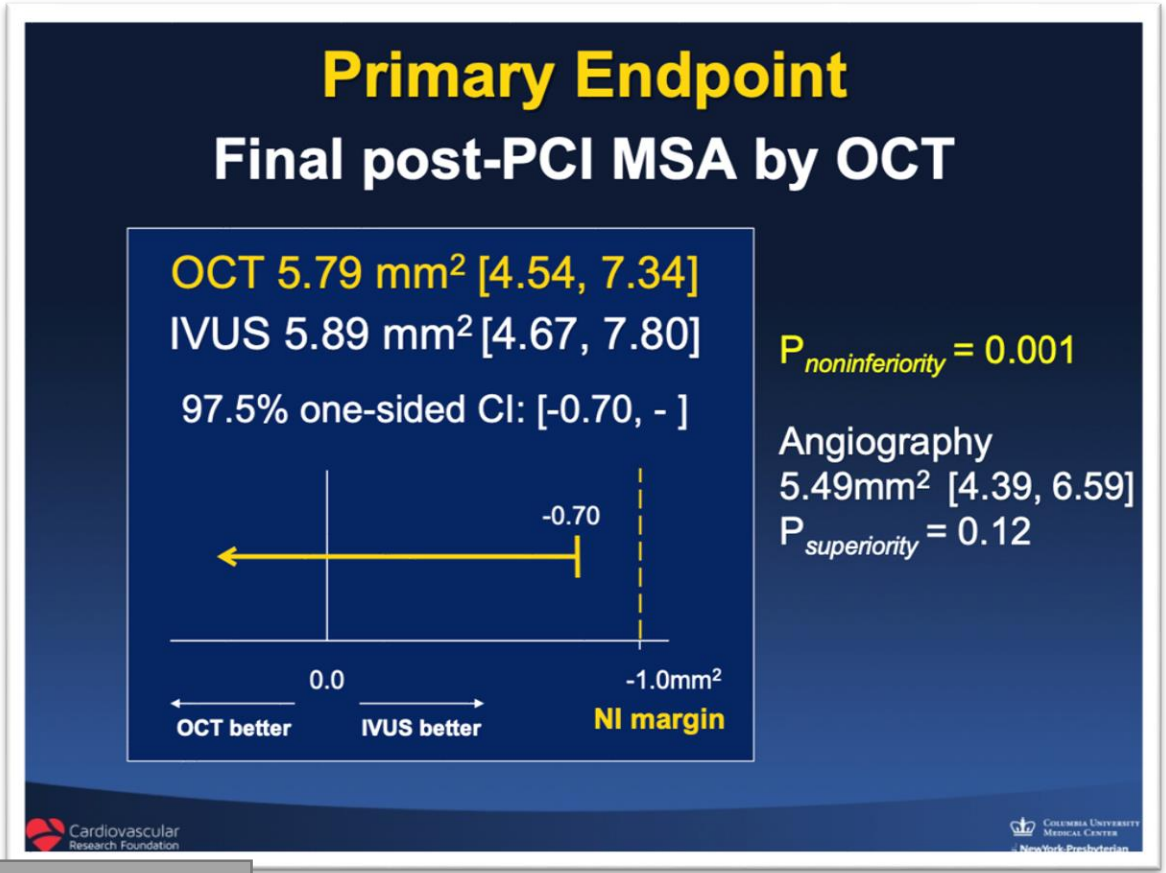
Raber et al. – Eur Heart J 2018

Post-PCI optimization targets



Raber et al. – Eur Heart J 2018

ILUMIEN-III



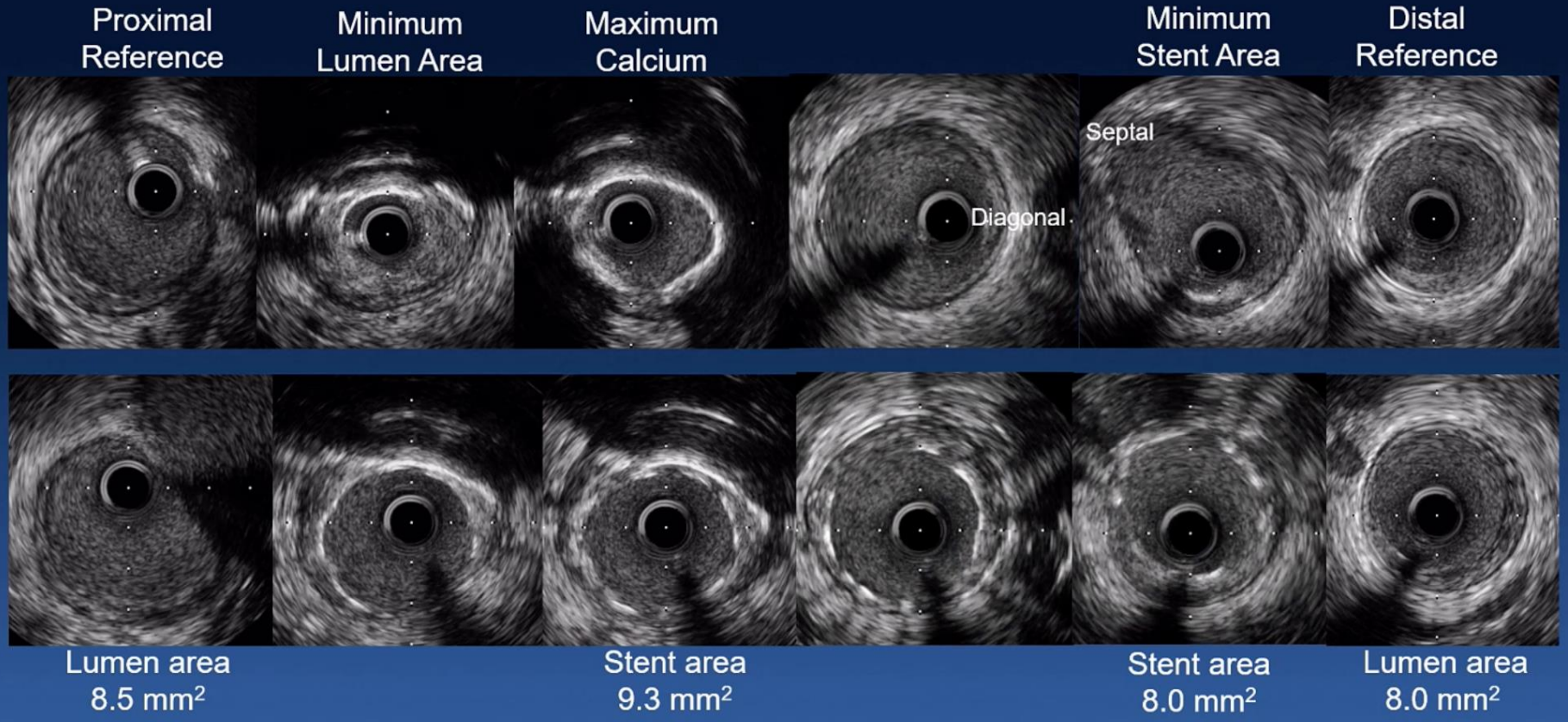
Ali et al. – Lancet 2016

Limitations

- The trial was unblinded and it was not possible to mask the operator to the study arm. However, precisely defined criteria was used for endpoint analysis, core laboratories were done, and clinical events were adjudicated by a independent committee.
- **Intravascular imaging-defined stent optimization was achieved in only 45.4% of patients. One possible explanation may be that we focused our study only on complex coronary artery lesions.**
- Since patients in the angiography-guided PCI group did not undergo intravascular imaging, we can only assess stent optimization in this group by quantitative coronary angiography when examining the relationship between stent optimization and clinical differences between the groups.

Lee JM, Choi KH, Song YB ,,,,, Hahn JY, et al. NEJM 2023

The present



Cardiovascular Research Foundation

G. Mintz, iPCI 2023

MLD MAX: A Workflow for Optimal PCI Guidance

Pre-PCI OCT | Strategize: 83% impact[1]

M — MORPHOLOGY
Search for high calcium[2]

L — LENGTH
Select landing zones based on healthy tissue/ EEL visualization[3]

D — DIAMETER
Measure vessel, stent, balloon diameters[4]

Post-PCI OCT | Optimize: 31% impact[1]

M — MEDIAL DISSECTION
Address significant dissection[5]

A — APPOSITION
Address significant malapposition

X — XPANSION
Address expansion[5,6]

Ali et al. – EuroIntervention 2021

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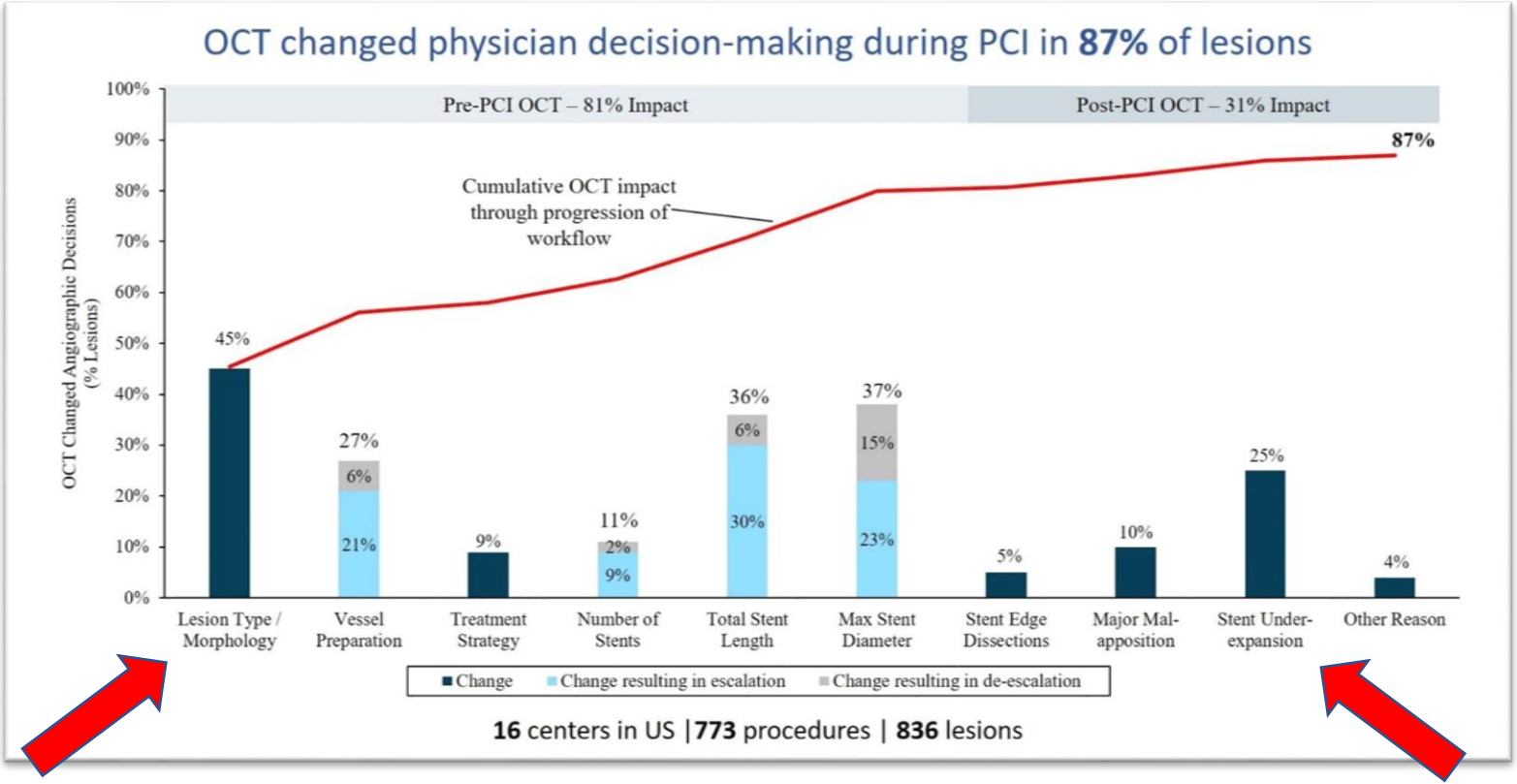
Decision-Making During PCI Guided by OCT
Insights From the LightLab Initiative



Bergmark et al. – Circ Intv 2022

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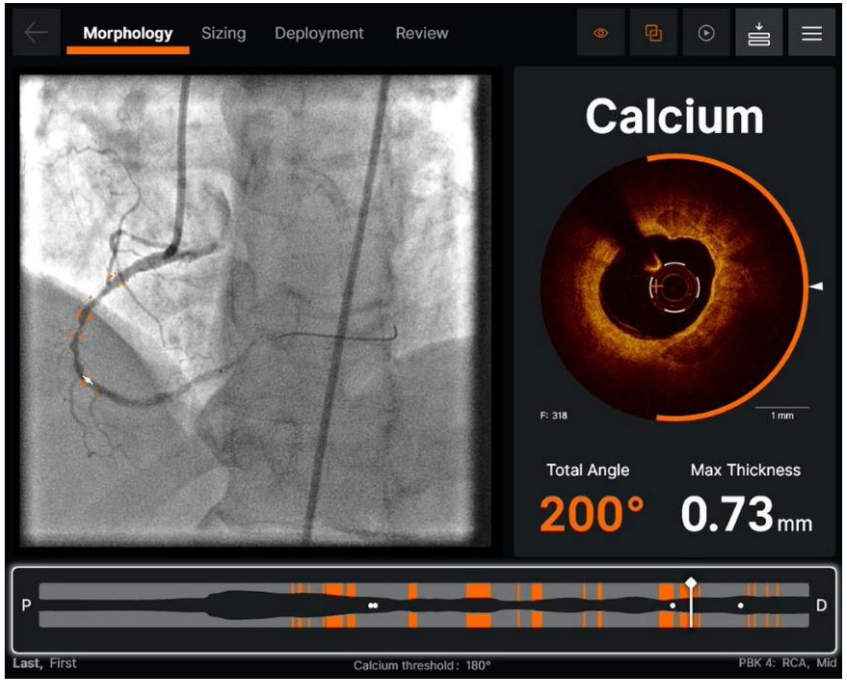
Calcium Autodetection



Calcium autodetection

- Calcium indicated in **orange**
- Orange arc around the cross-sectional view indicates calcium in the current frame
  - Arc is calculated from the lumen center (orange crosshair)
  - Arc is displayed when calcium angle is at or above 60° of circumferential calcium
- Maximum thickness of calcium in the current frame indicated by white triangle
- Total angle of calcium highlighted when value exceeds user-defined calcium threshold (in physician preferences)
- Lumen profile highlights frames with total calcium angle that exceeds user-defined threshold

Co-registration view allows user to visualize calcium on angio still-frame

The future

Trial	NCT number		Imaging	Calcific lesions
IMPROVE	NCT04221815	Impact on revascularization outcomes of IVUS-guided treatment of **complex lesions** and economic impact	IVUS vs. angio	✔
IVUS-CHIP	NCT04854070	Intravascular ultrasound guidance for **complex high-risk indicated** procedures	IVUS vs. angio	✔
OPTIMAL	NCT04111770	Optimization of **left main PCI** with intravascular ultrasound	IVUS vs. angio	
DK CRUSH VIII	NCT03770650	IVUS-guided DK Crush Stenting Technique for Patients With **Complex Bifurcation Lesions**	IVUS vs. angio	✔
ILUMIEN IV	NCT03507777	Optical coherence tomography-guided coronary stent implantation compared to angiography	OCT vs. angio	✔
OCTOBER	NCT03171311	European Trial on Optical Coherence Tomography Optimized **Bifurcation** Event Reduction	OCT vs. angio	✔
OCTIVUS	NCT03394079	Optical Coherence Tomography Versus Intravascular Ultrasound Guided Percutaneous Coronary Intervention	OCT vs. IVUS	✔

Final perspectives

- Calcific lesions remain a major challenge in the current era of PCI, and patients with calcific lesions have high risk of procedural **complications**, procedural **failure** and **poor outcomes**.
- Rigorous **learning curve**, **training** and **continuous education** should be maintained in order to prioritize **safety**, given the **unforgiving** anatomies and clinical scenarios.
- The proper combination of older and newer tools and techniques permits to **tailor** treatment of calcific lesion based on anatomy and **intravascular imaging** and is associated with optimal procedural results, that are key to satisfactory long-term outcomes.
- **Cost-effectiveness** is an issue not to be underestimated.

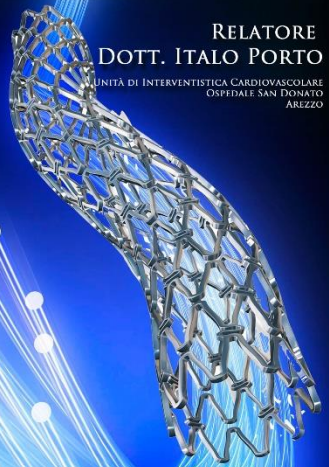
Dottorato di Ricerca
in Applicazioni cliniche
dell'Imaging Cardiovascolare
Coordinatore Prof. Scipione Carerj

Seminario su:

Ecografia intravascolare e tomografia a coerenza ottica

dalla cardiologia interventistica clinica alla ricerca

Relatore
Dott. Italo Porto
Unità di Interventistica Cardiovascolare
Ospedale San Donato
Arezzo



Credits: F. Costa

23/03/2013 ore 9:30 - Aula di Radiologia Pad. E 4°Piano