29th TCTAP2024

CT-guided PCI is coming to your cath-lab in the near future

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Cardiovascular Center Aalst, Belgium

CVRF

Potential conflicts of interest

Within the past 12+ months, Carlos Collet has had a financial interest/arrangement or affiliation with the organization(s) listed here.

Institutional Support
- Abbott Vascular
- HeartFlow Inc
- GE Healthcare
- ShockWave Medical
- Boston Scientific
- Insight Lifetech
- Pie Medical
- Medis Medical Imaging

Equity/stock options
- Medyria
- Xenter

Consultancy fee
- Abbott Vascular
- HeartFlow Inc
- GE Healthcare
- Boston Scientific
- Insight Lifetech
- Early Bird
- Pfizer
- Siemens

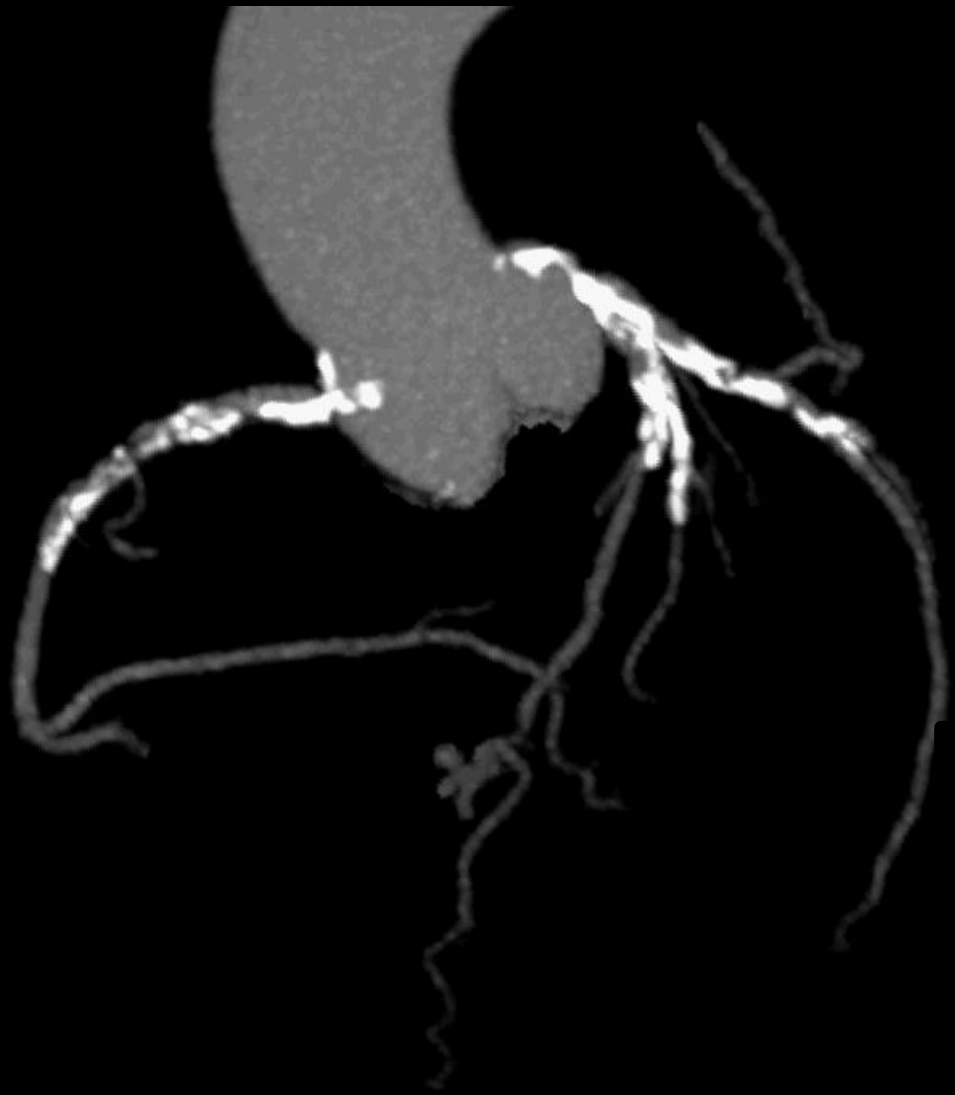
Others

CoreAalst BV

Patents filed: US20220164950A1, US20220175260A1, WO2022136637A1 and WO2021224458A1

One image, two interpretations

I cannot interpret lesion severity (blooming calcium)



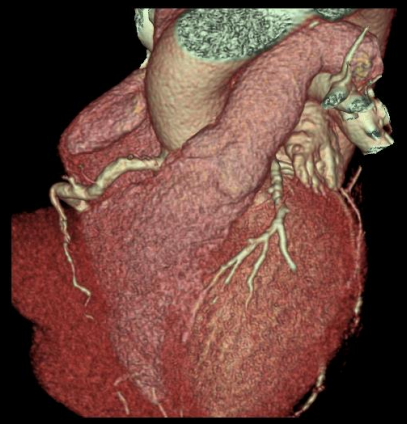
Rota or IVL? (HeartTeam)

Imager

Interventional Cardiologist

All the interventional cardiologists need to know about CT

Volume rendering

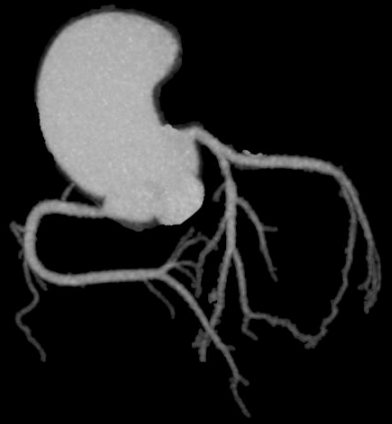


Overview of the heart anatomy

Myocardial bridges

Non-coronary structures

3D MIP

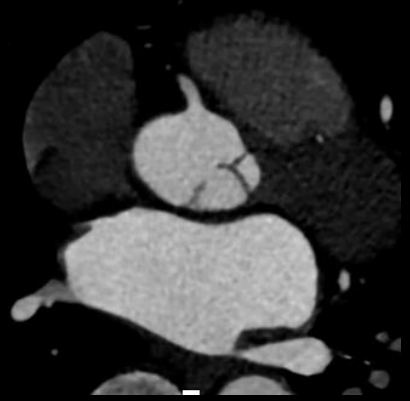


3D of the coronary tree

Distribution and severity of calcium

Location of stenosis

Axial images



Ostium take-off

Dominance

Complete diagnostic evaluation

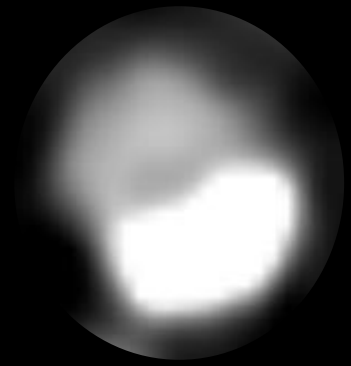
Curved MPR

Stenosis and plaque assessment

Plaque composition

Myocardial bridges

Cross-section



Plaque composition

Plaque burden

Calcium arc

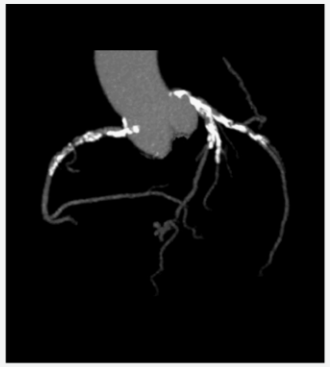
1 Key pre-procedural planning questions

2 What information is needed?

3 How does this help?

1 Key pre-procedural planning questions

- How complex is the case?
- Who is best placed to perform the procedure?



2 What information is needed?

- 3D coronary anatomy
- Global distribution of calcium
- Tortuosity

3 How does this help?

- Anticipate case complexity
- Arterial access

3D MIP

1 Key pre-procedural planning questions

- How complex is the case?
- Who is best placed to perform the procedure?

- What guiding catheter should be used?

2 What information is needed?

- 3D coronary anatomy
- Global distribution of calcium
- Tortuosity

- Position of the ostium

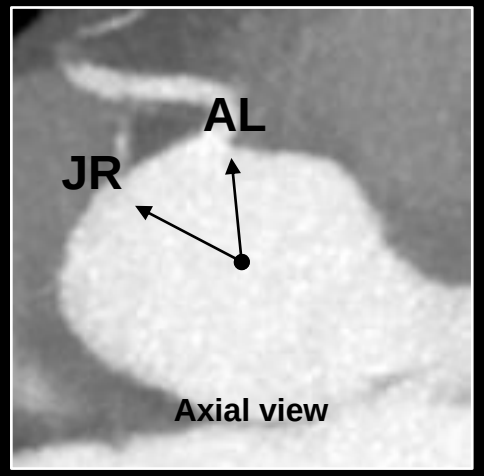
3 How does this help?

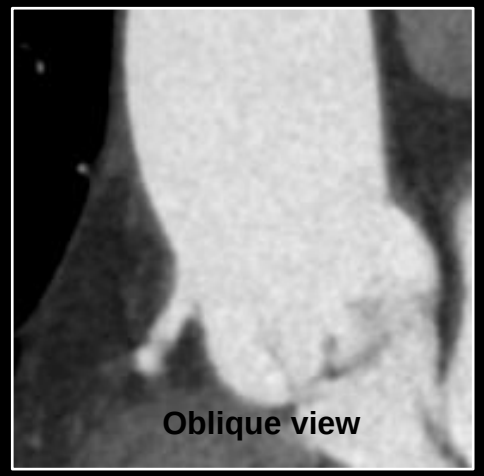
- Anticipate case complexity
- Arterial access

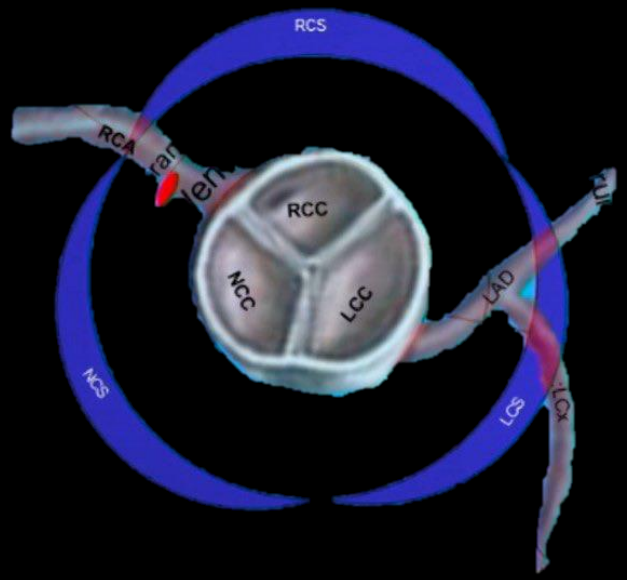
- Catheter selection
- Expected guiding support

Axials for catheter selection

Right coronary artery

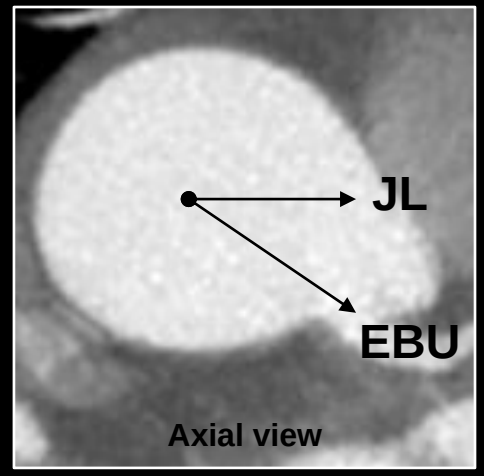


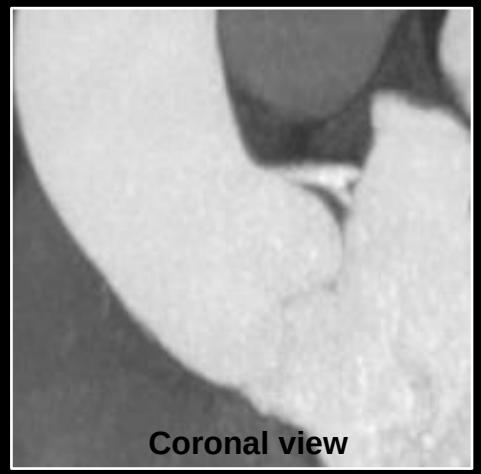




Normal ostia position

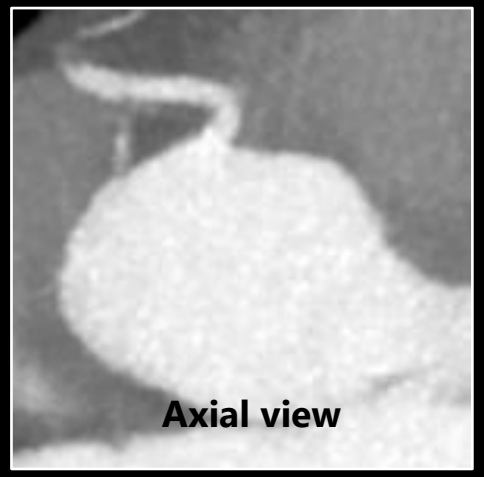
Left coronary artery

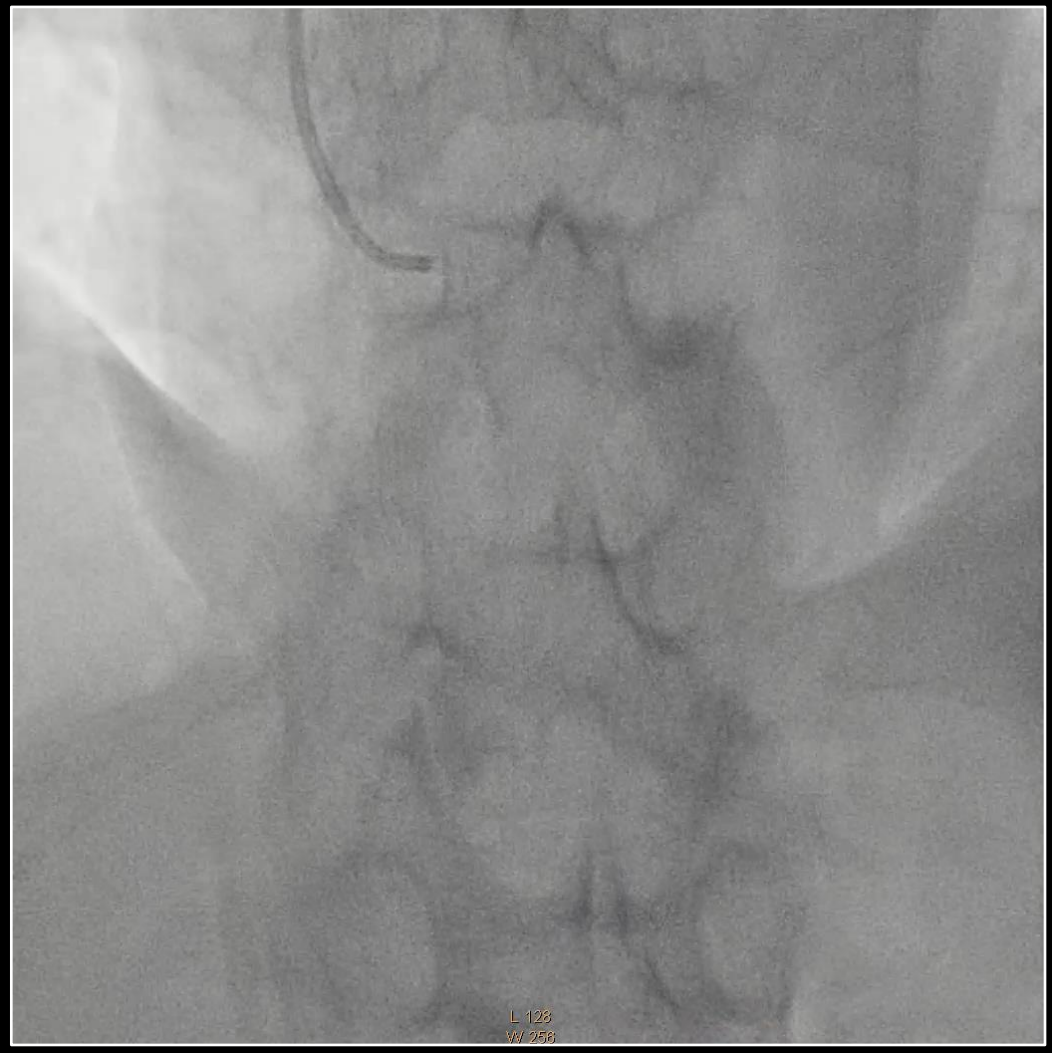




Coronary ostia position

Right coronary artery



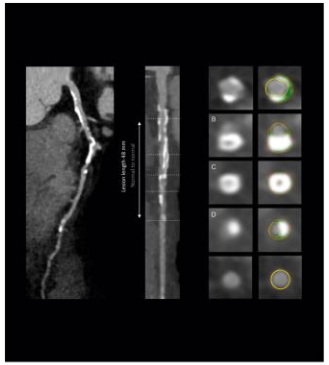


1 Key pre-procedural planning questions

- How complex is the case?
- Who is best placed to perform the procedure?

- What guiding catheter should be used?

- What type of lesion is present?
- What tools do I need to effectively prepare the lesion?



2 What information is needed?

- 3D coronary anatomy
- Global distribution of calcium
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- Position of the ostium

- Lesion location
- Plaque compostion
- Lesion length
- Calcium burden

3 How does this help?

- Anticipate case complexity
- Arterial access

- Catheter selection
- Expected guiding support

- Lesion preparation (probability of stent under-expansion)
- Stent length

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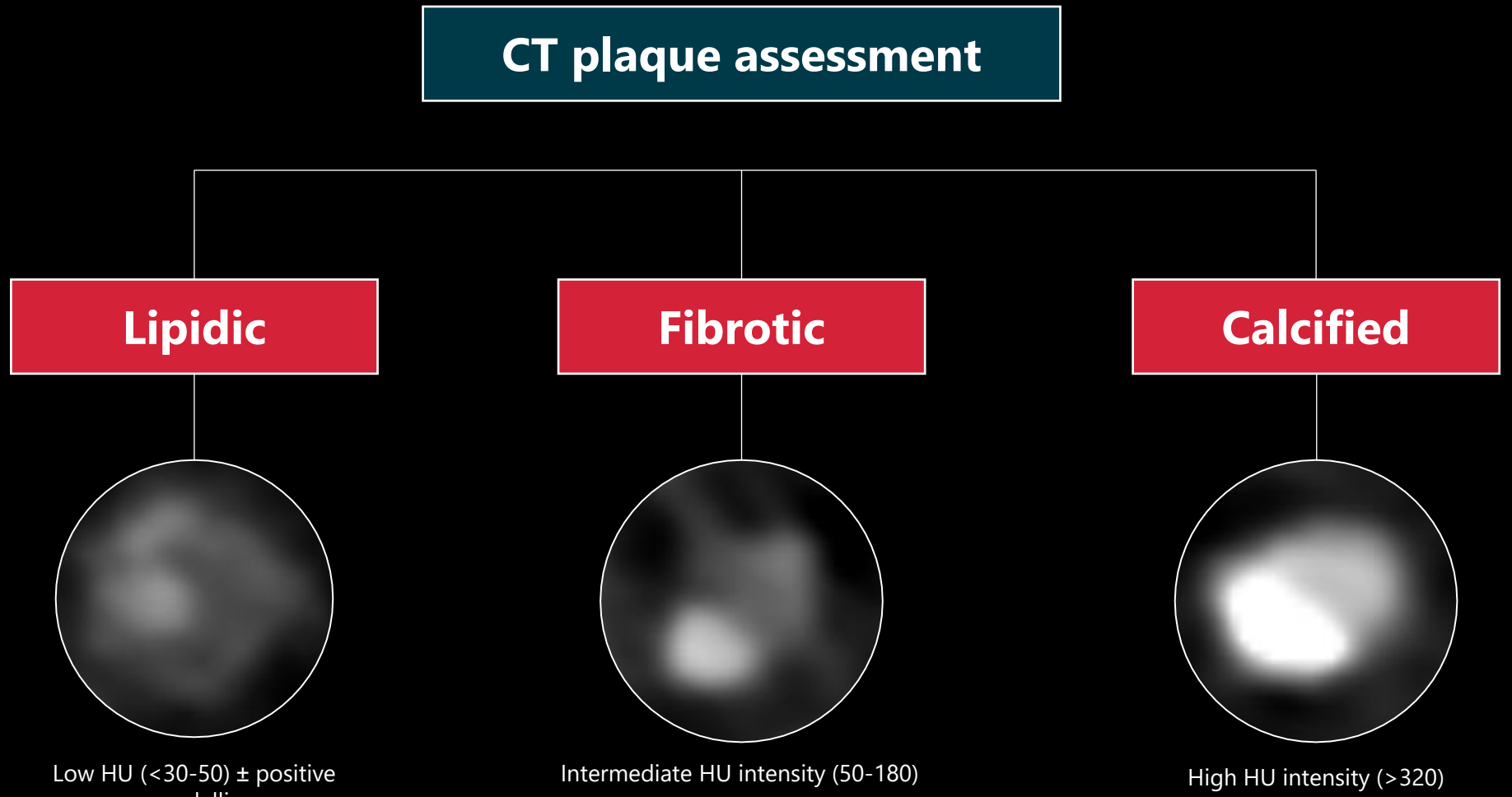
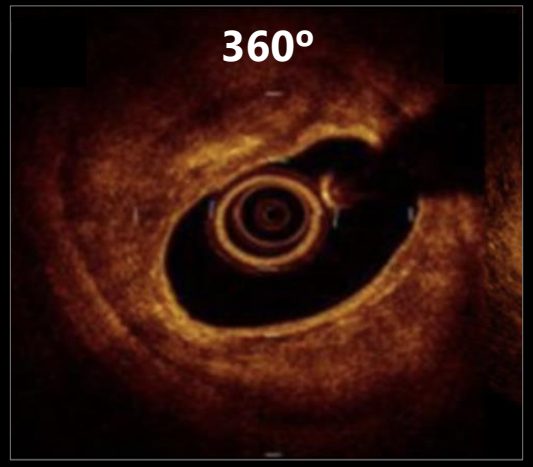
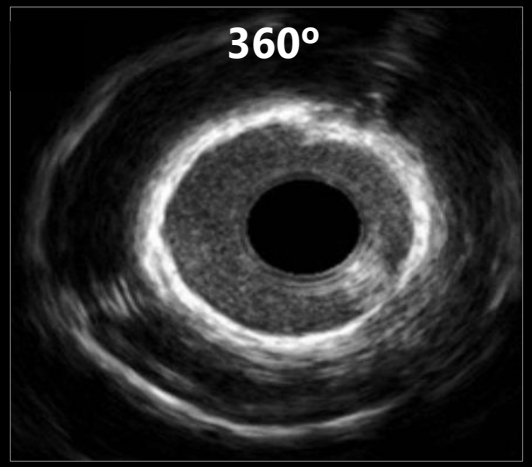
Cross-sections

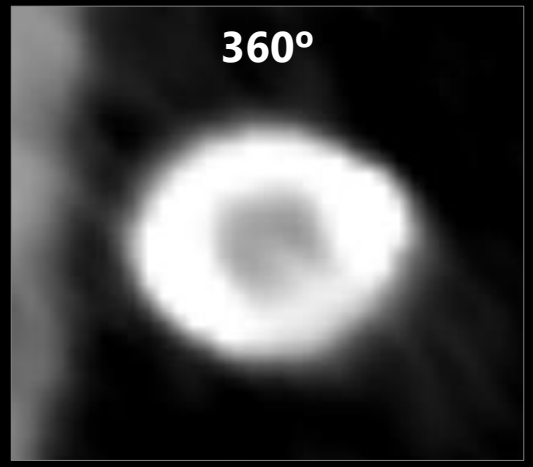


Calcific plaque quantification: calcium arc

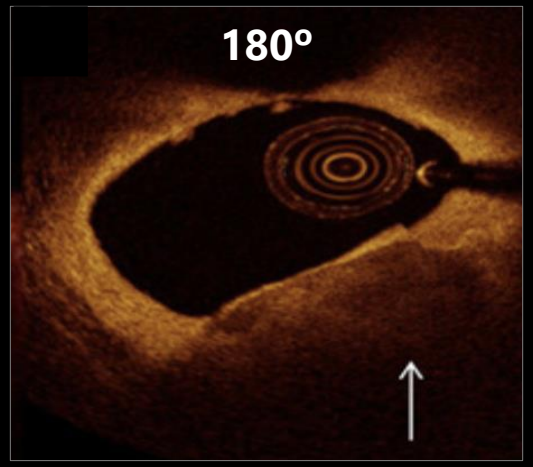
Circumferential

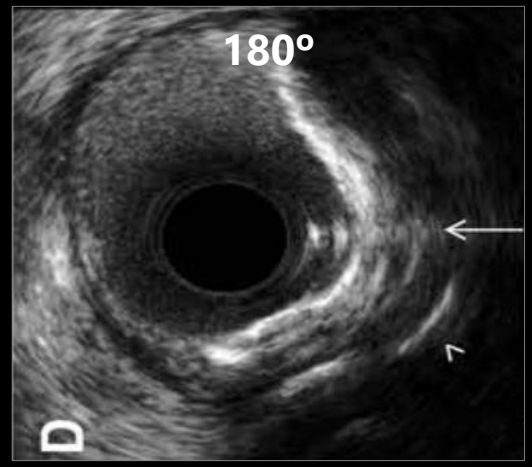


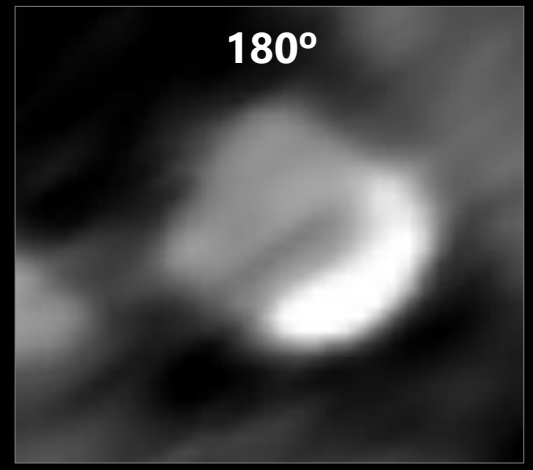




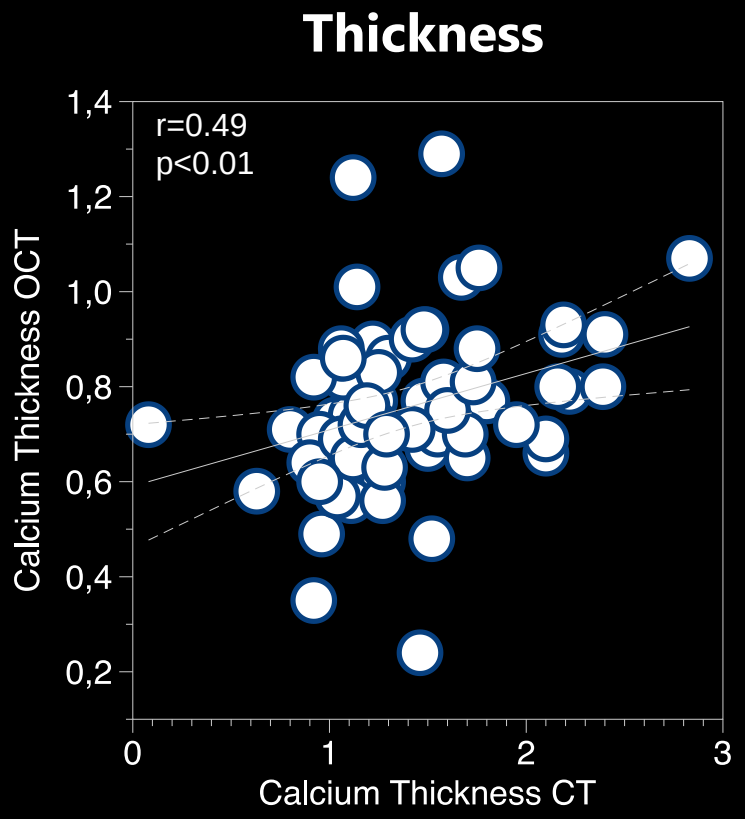
Not circumferential

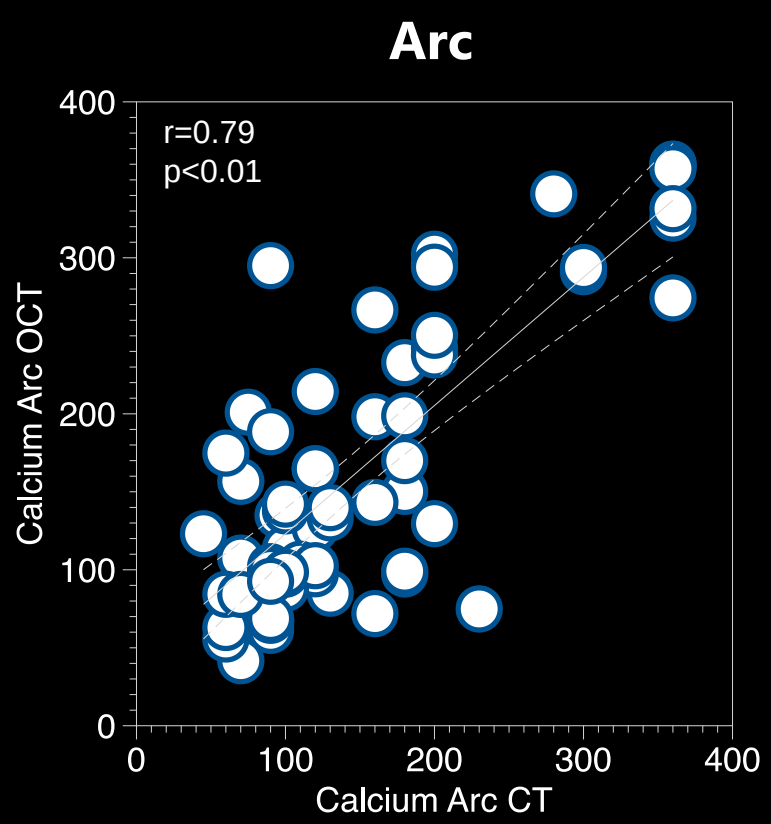


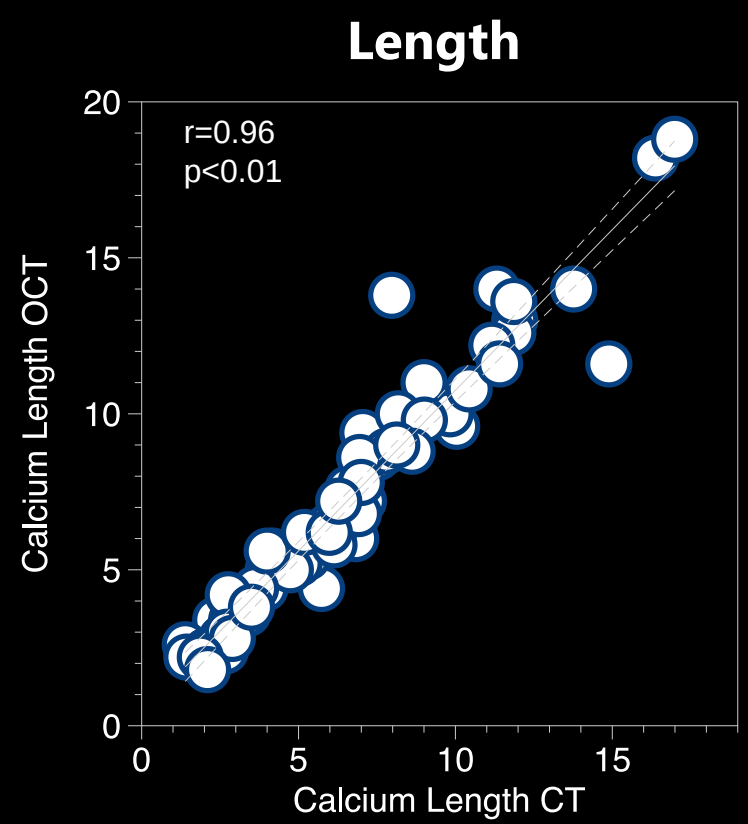




Calcium: CTA versus OCT

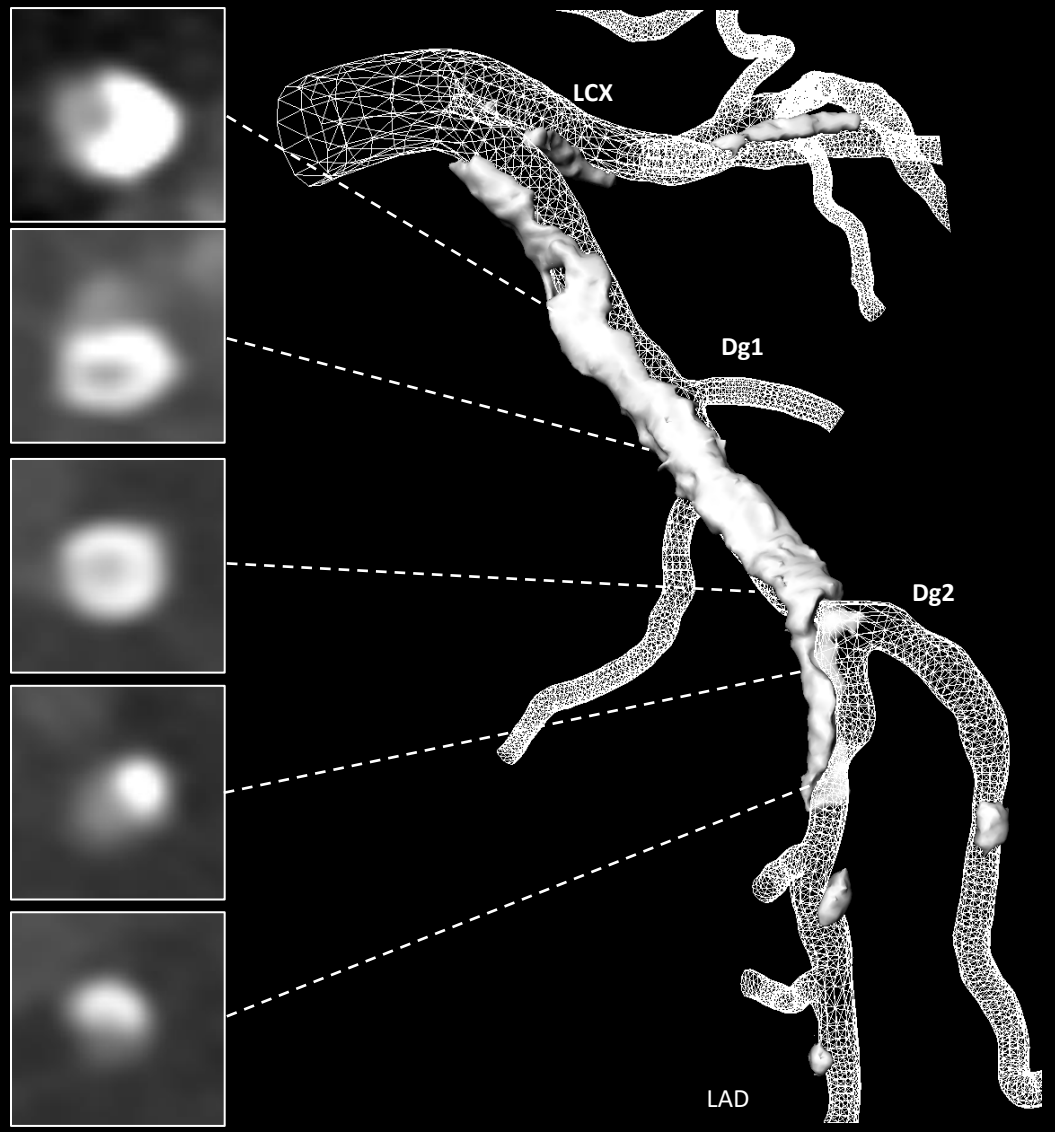


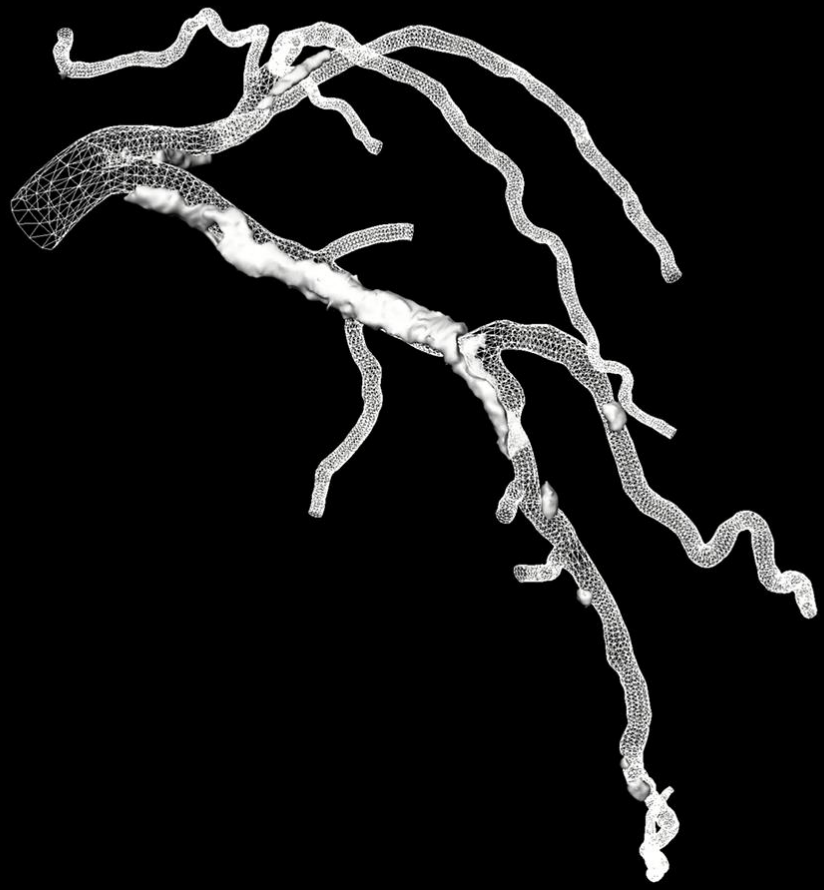


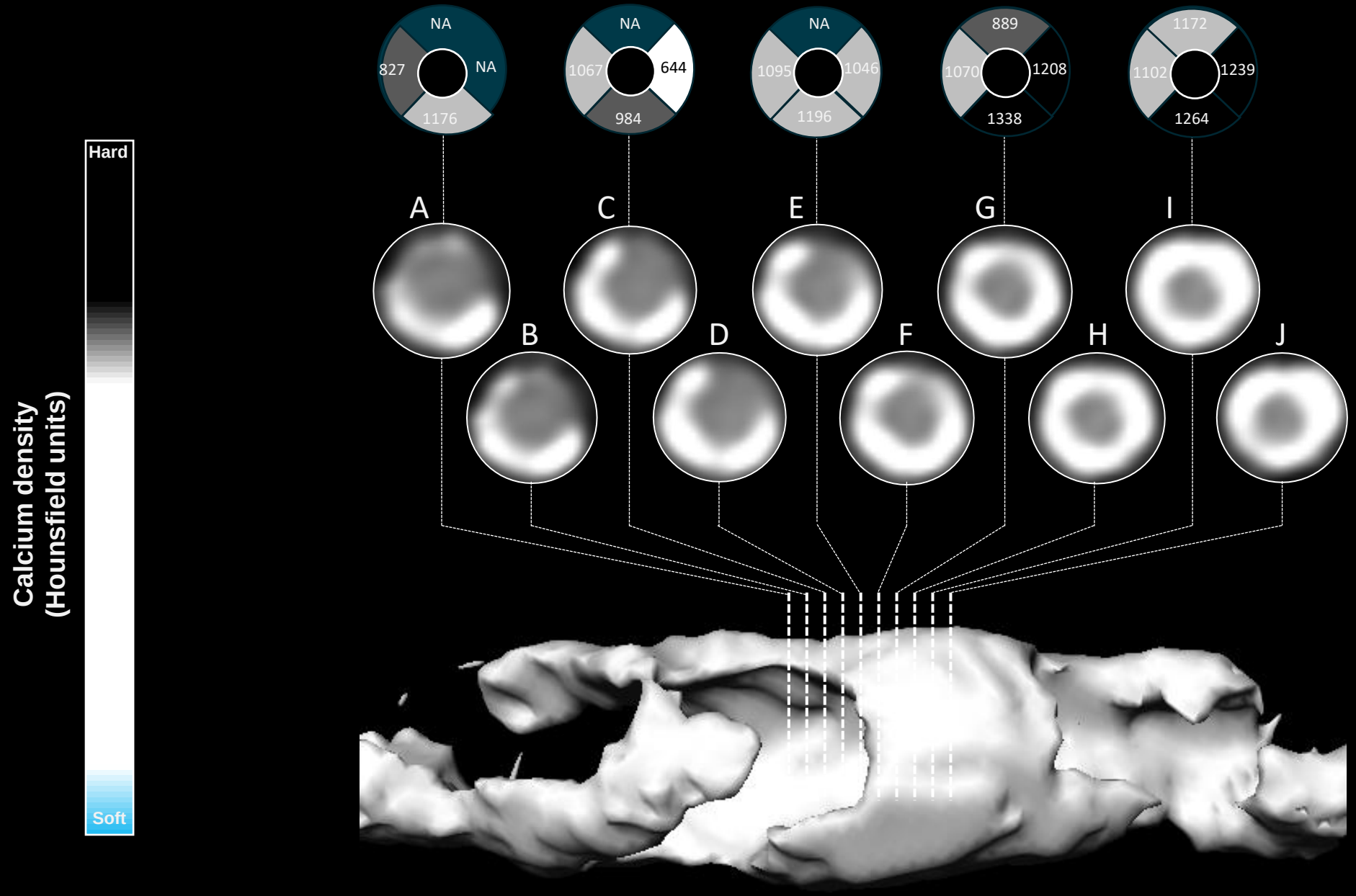


Monizzi G, Collet et al. Int J Cardiovasc Imaging. 2020 Dec;36(12):2393-2402.

3D Calcium assessment by CTA







3D Calcium Plaque

1 Key pre-procedural planning questions

- How complex is the case?
- Who is best placed to perform the procedure?

- What guiding catheter should be used?

- What type of lesion is present?
- What tools do I need to effectively prepare the lesion?

- What are the risks at hand?
- How big is the risk?
- How do I minimise risk and is this worth investing in?

2 What information is needed?

- 3D coronary anatomy
- Global distribution of calcium
- Tortuosity

- Position of the ostium

- Lesion location
- Plaque compostion
- Lesion length
- Calcium burden

- Myocardial mass at risk
- Side branch at risk

3 How does this help?

- Anticipate case complexity
- Arterial access

- Catheter selection
- Expected guiding support

- Lesion preparation (probability of stent under-expansion)
- Stent length

- SB wire protection or stenting

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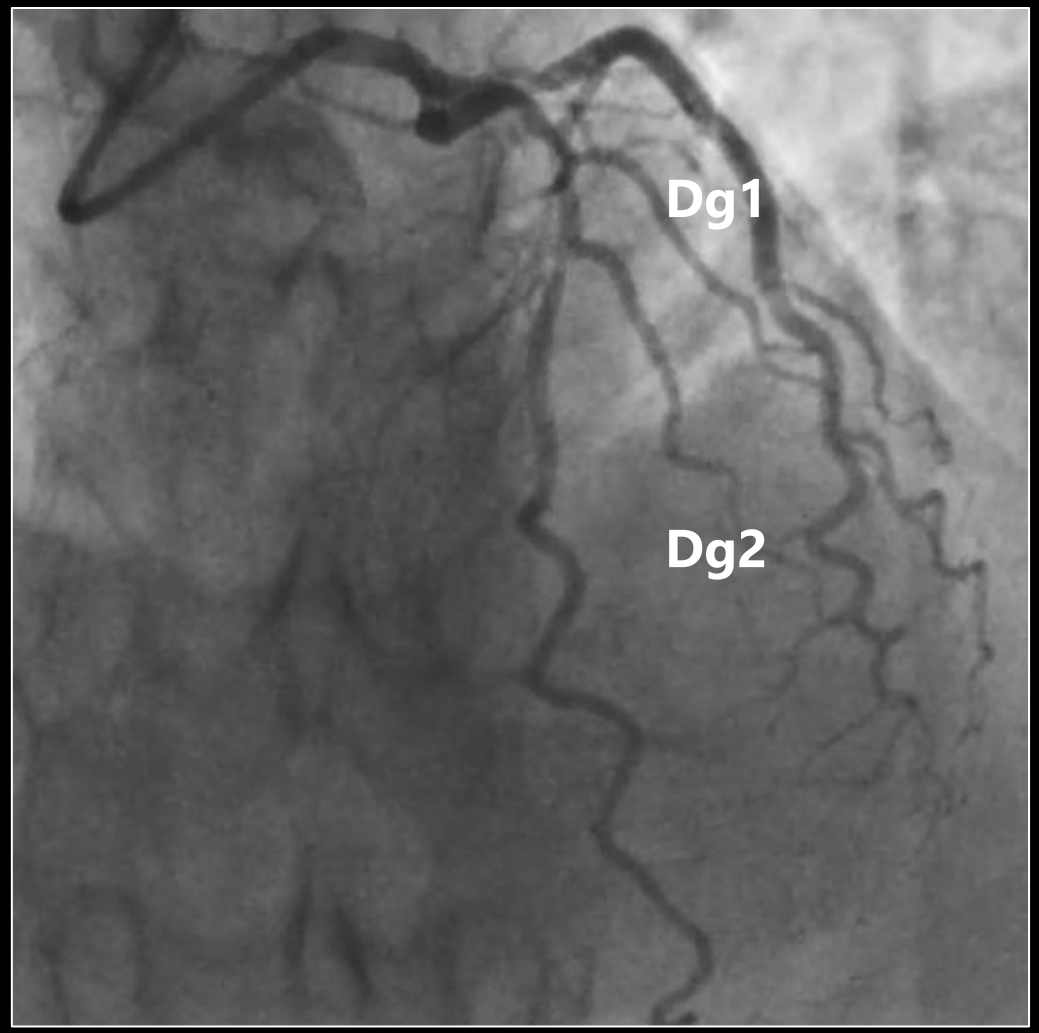
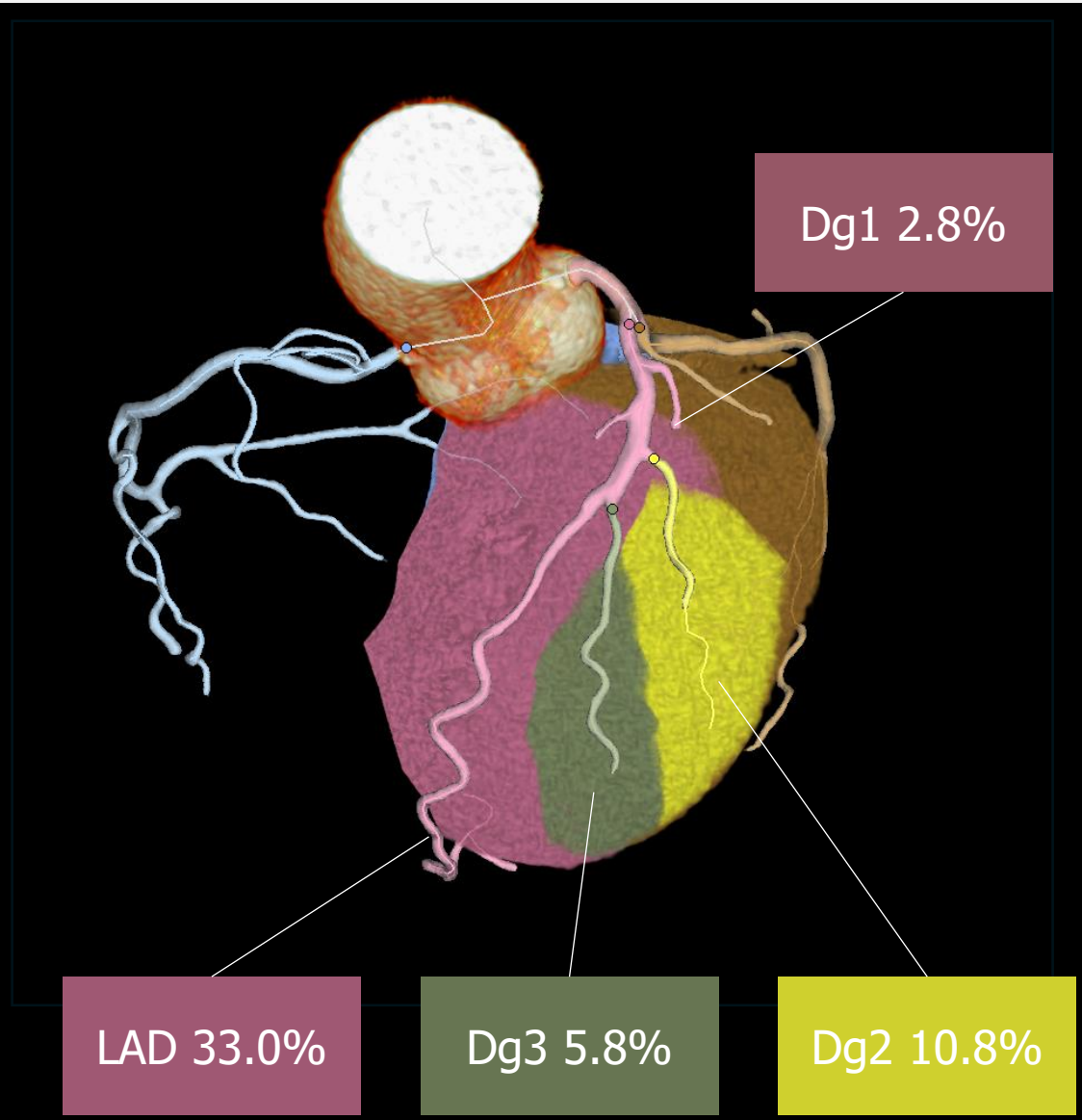
LAD PCI: which diagonal to protect?





1 Key pre-procedural planning questions

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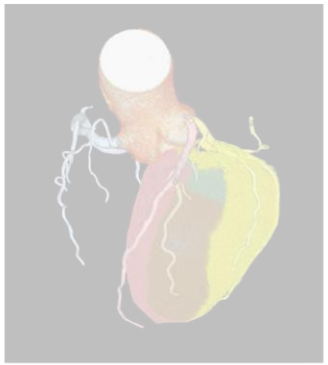
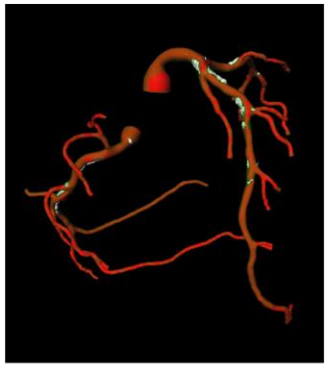
- How do I minimise risk and is this worth investing in?

- How do I best visualise the vessel?





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- Best achievable projection

3 How does this help?

- Anticipate case complexity
- Arterial access

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- Lesion preparation (probability of stent under-expansion)
- Stent length

- SB wire protection or stenting

- C-arm angulation
- Awareness of sub-optimal projection

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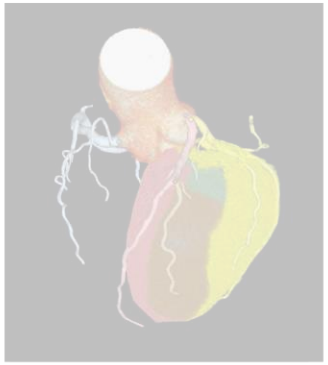
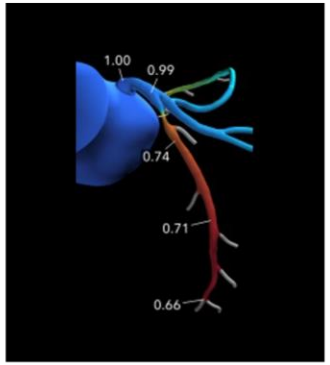
Resource planning	Visualise problem and strategy	Potential outcomes

1 Key pre-procedural planning questions

- How complex is the case? - Who is best placed to perform the procedure?	- What guiding catheter should be used?	- What type of lesion is present? - What tools do I need to effectively prepare the lesion?	- What are the risks at hand? - How big is the risk? - How do I minimise risk and is this worth investing in?	- How do I best visualise the vessel?	- Does this lesion need to be treated? - Should this be treated with a stent?
					

2 What information is needed?

- 3D coronary anatomy - Global distribution of calcium - Tortuosity	- Position of the ostium	- Lesion location - Plaque compostion - Lesion length - Calcium burden	- Myocardial mass at risk - Side branch at risk	- Best achievable projection	- Lesion significance - Pattern (focal vs diffuse) of CAD

3 How does this help?

- Anticipate case complexity - Arterial access	- Catheter selection - Expected guiding support	- Lesion preparation (probability of stent under-expansion) - Stent length	- SB wire protection or stenting	- C-arm angulation - Awareness of sub-optimal projection	- Appropriateness of PCI - Awareness of diffuse disease

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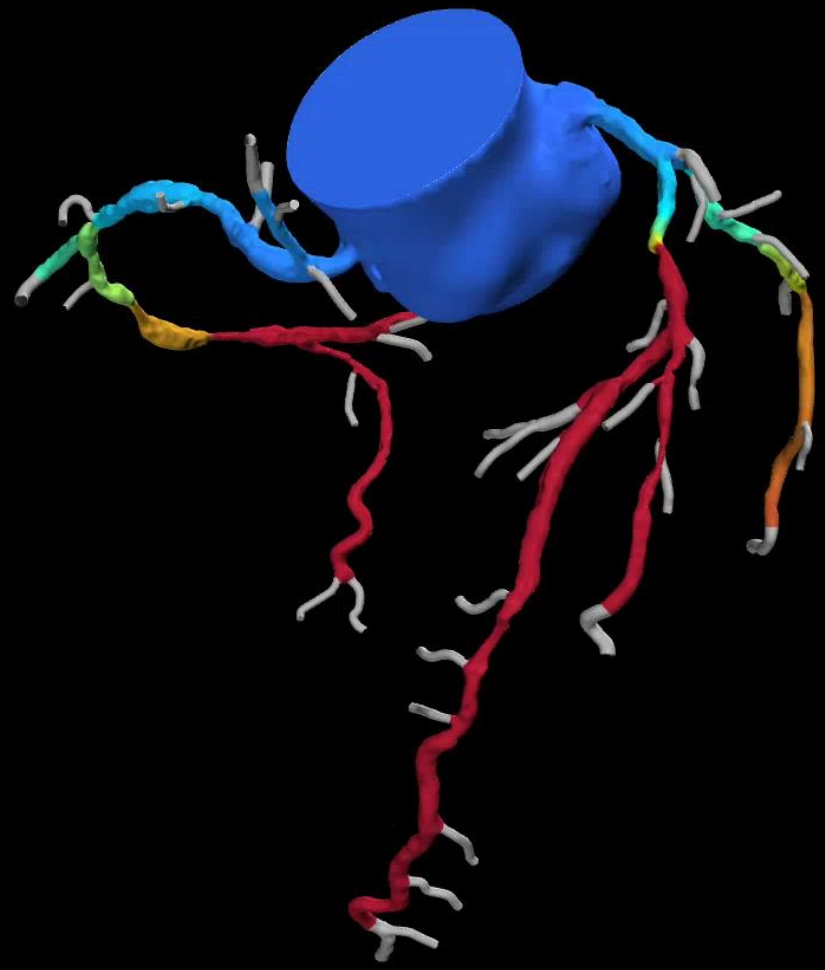
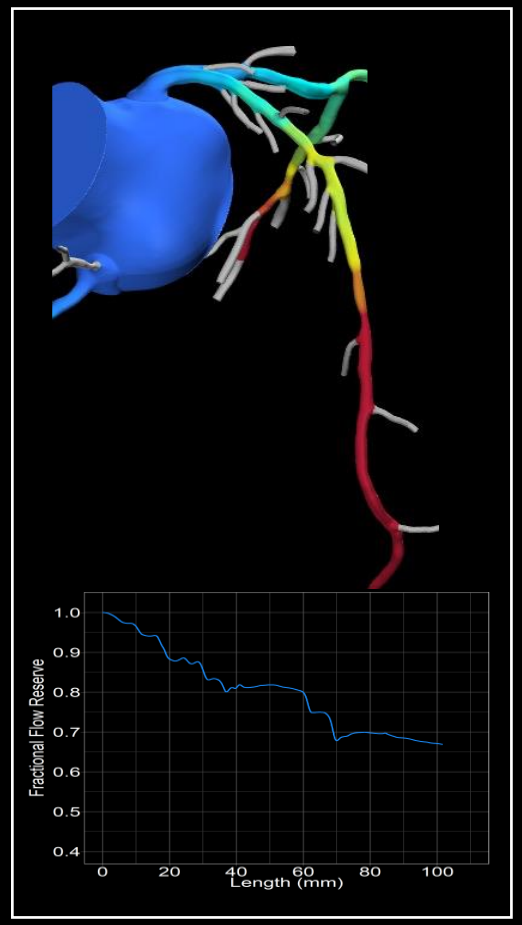
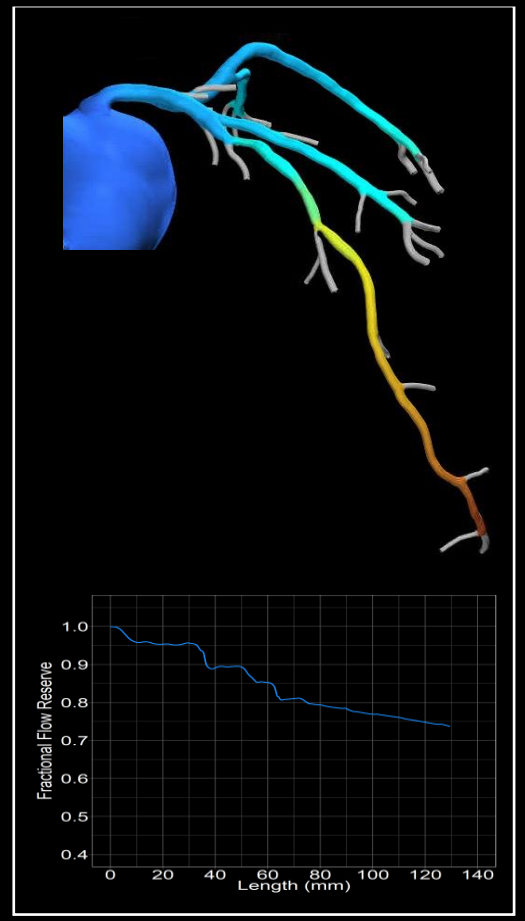
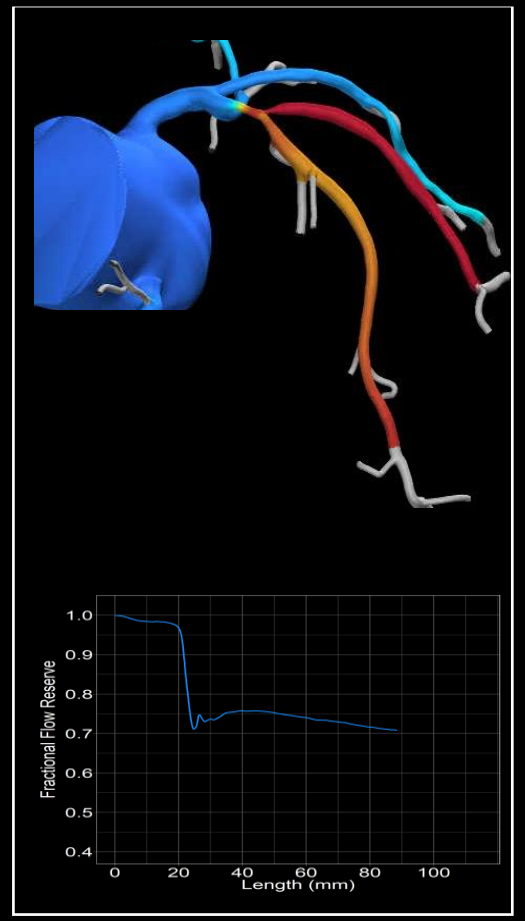
Physiology derived from CT

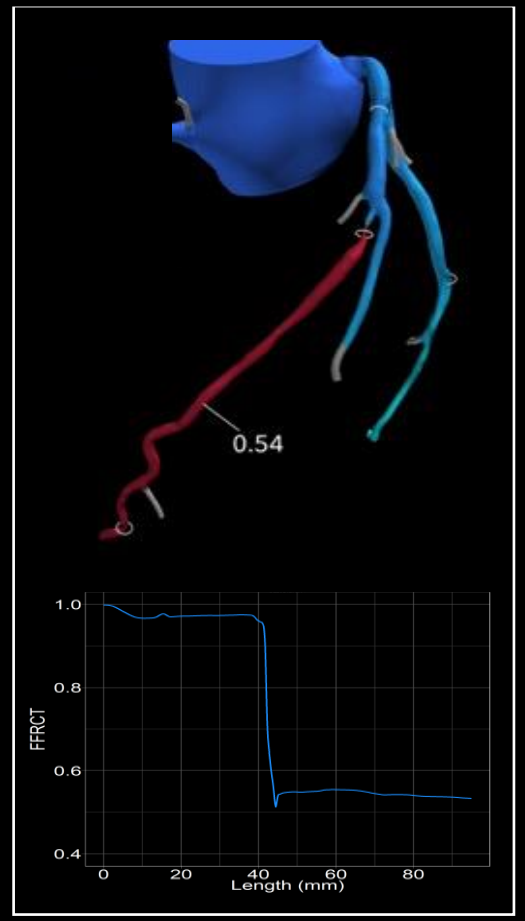


Physiological CAD patterns derived from CT





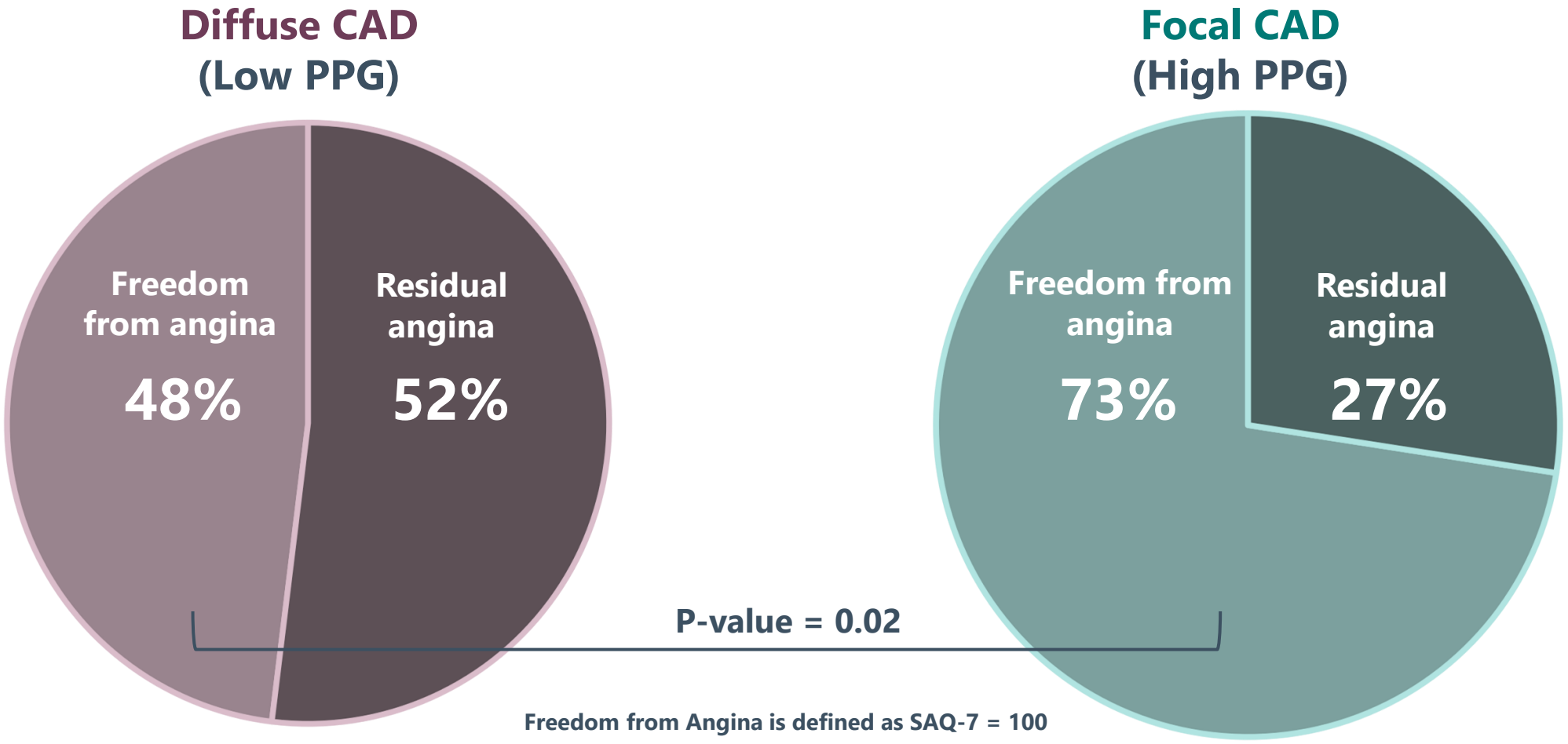




Diffuse CAD — **Focal CAD**

0 ← **PPG** → **1**

PPG and patient-reported outcomes



Freedom from Angina is defined as SAQ-7 = 100

Collet et al JACC Cardiovasc Interv. 2022 Dec 26;15(24):2506-2518.

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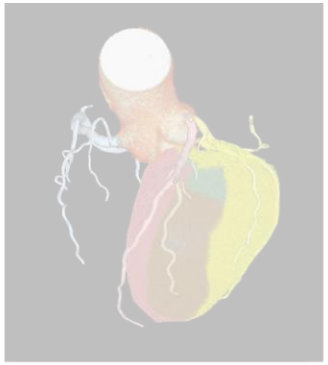
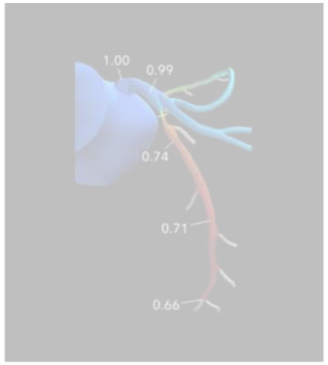
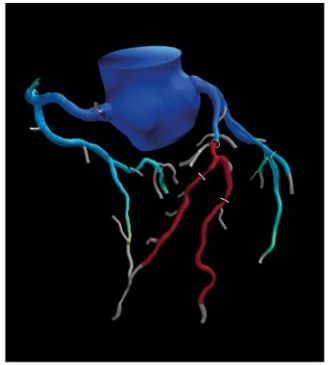
Resource planning	Visualise problem and strategy	Potential outcomes

1 Key pre-procedural planning questions

- How complex is the case? - Who is best placed to perform the procedure?	- What guiding catheter should be used?	- What type of lesion is present? - What tools do I need to effectively prepare the lesion?	- What are the risks at hand? - How big is the risk? - How do I minimise risk and is this worth investing in?	- How do I best visualise the vessel?	- Does this lesion need to be treated? - Should this be treated with a stent?	- What is the best way to stent the lesion?
						

2 What information is needed?

- 3D coronary anatomy - Global distribution of calcium - Tortuosity	- Position of the ostium	- Lesion location - Plaque compostion - Lesion length - Calcium burden	- Myocardial mass at risk - Side branch at risk	- Best achievable projection	- Lesion significance - Pattern (focal vs diffuse) of CAD	- Prediction of post-PCI FFR

3 How does this help?

- Anticipate case complexity - Arterial access	- Catheter selection - Expected guiding support	- Lesion preparation (probability of stent under-expansion) - Stent length	- SB wire protection or stenting	- C-arm angulation - Awareness of sub-optimal projection	- Appropriateness of PCI - Awareness of diffuse disease	- PCI strategy

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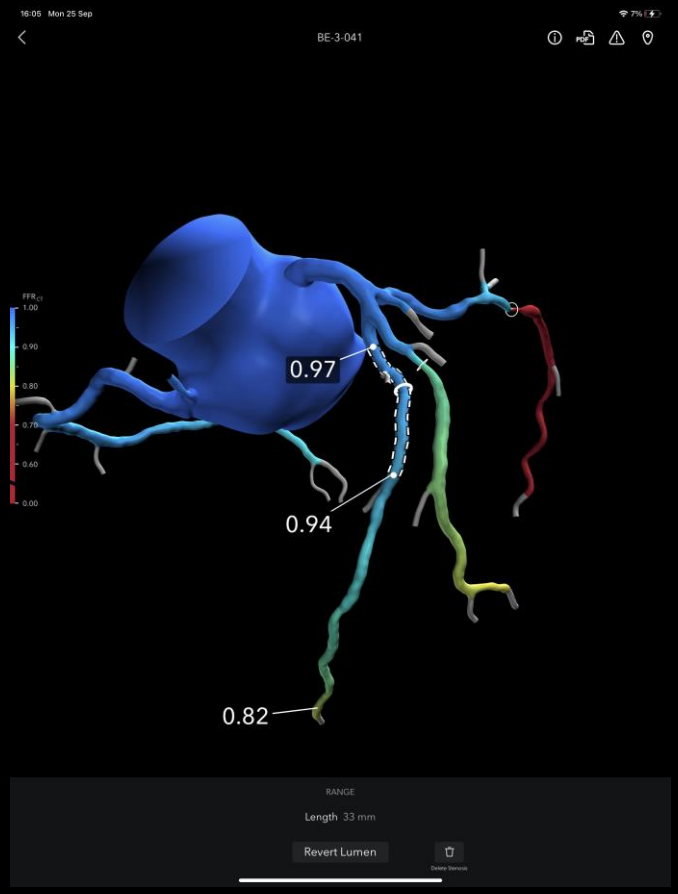
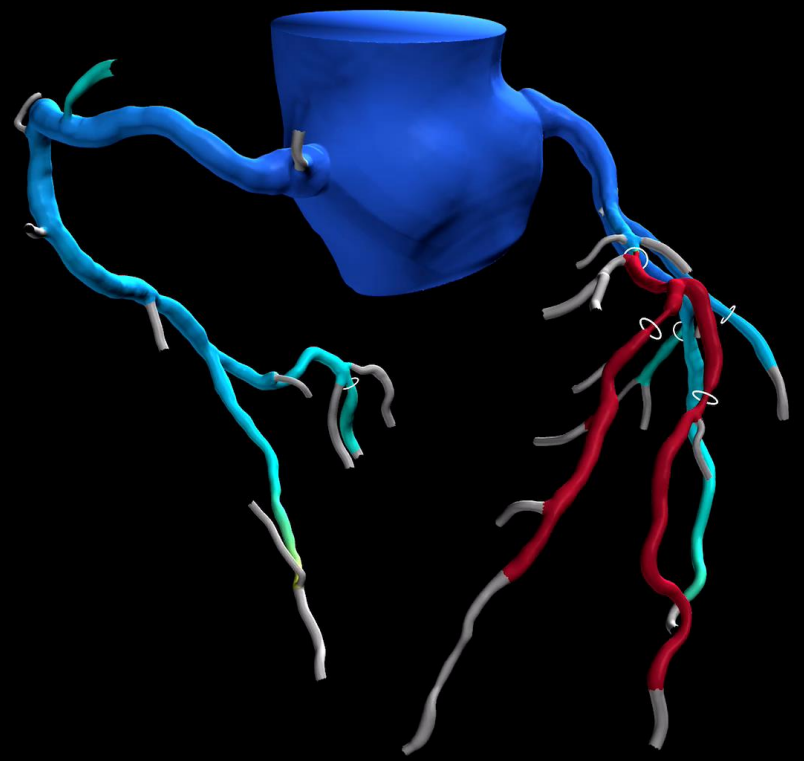
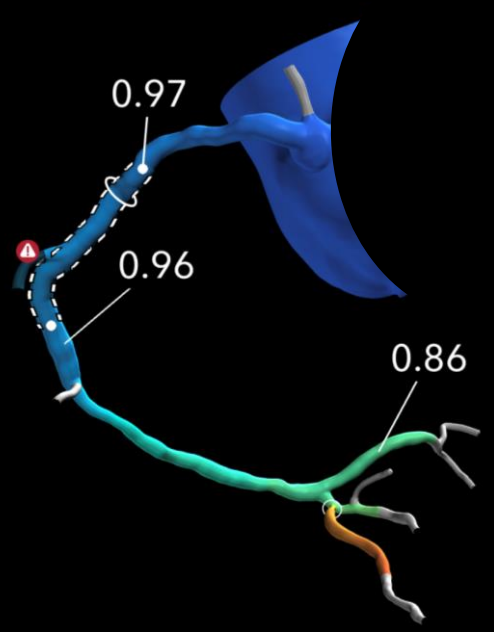
FFR_{CT} Planner





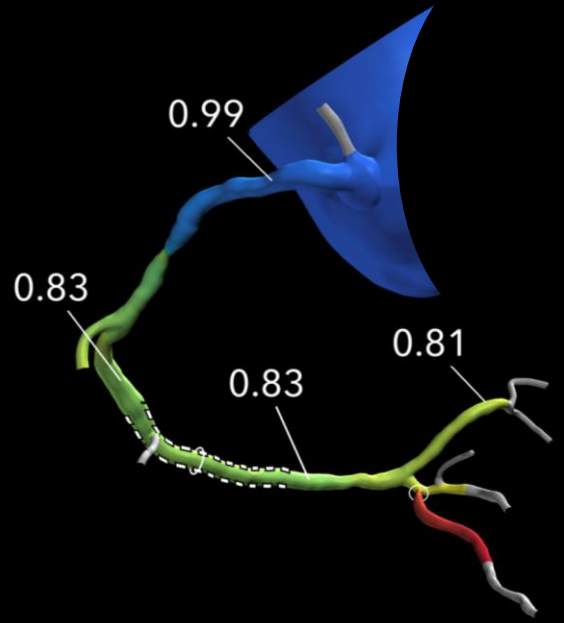
FFR_{CT} Planner in serial lesions

Strategy 1



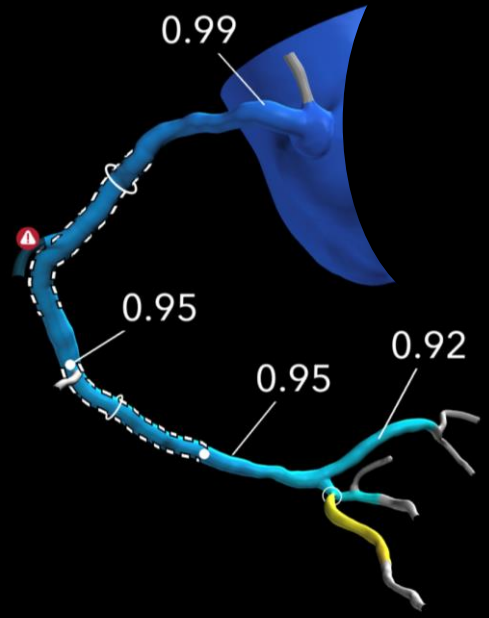
1 DES
Proximal RCA 33mm

Strategy 2



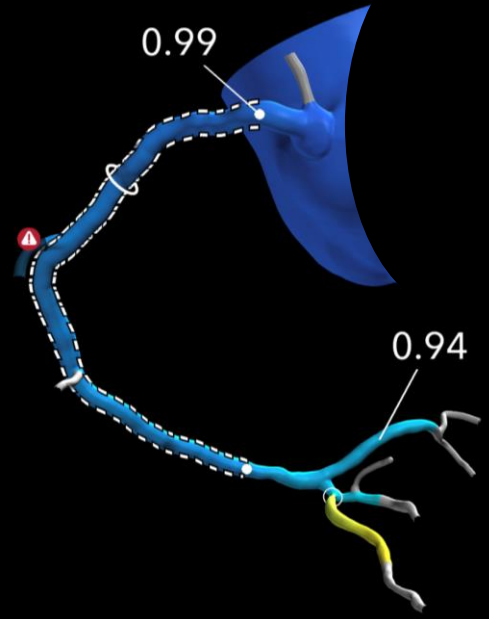
1 DES
Distal RCA 33mm

Strategy 3



2 DES
Poximal RCA 33mm
Distal RCA 33mm

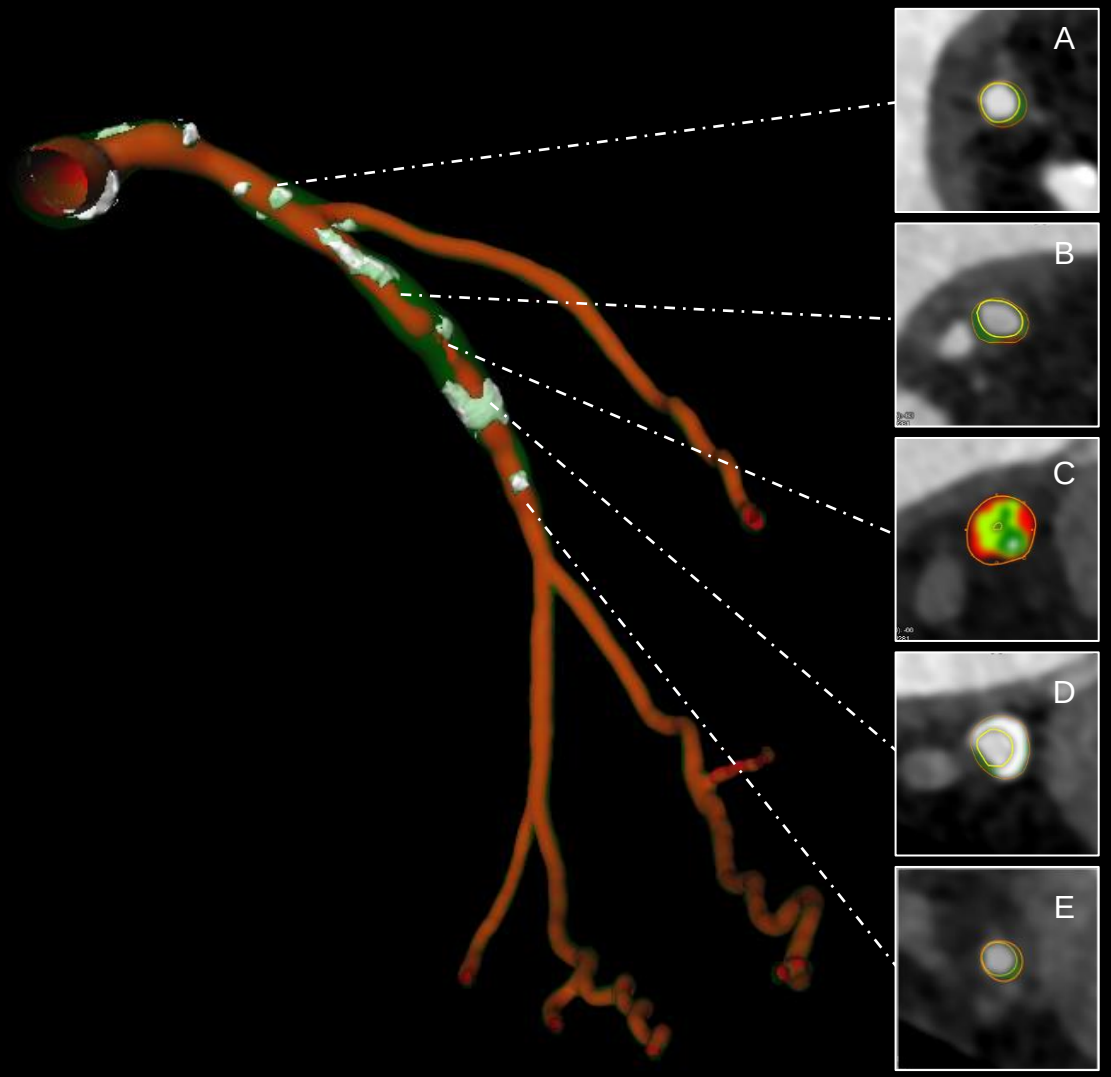
Strategy 4

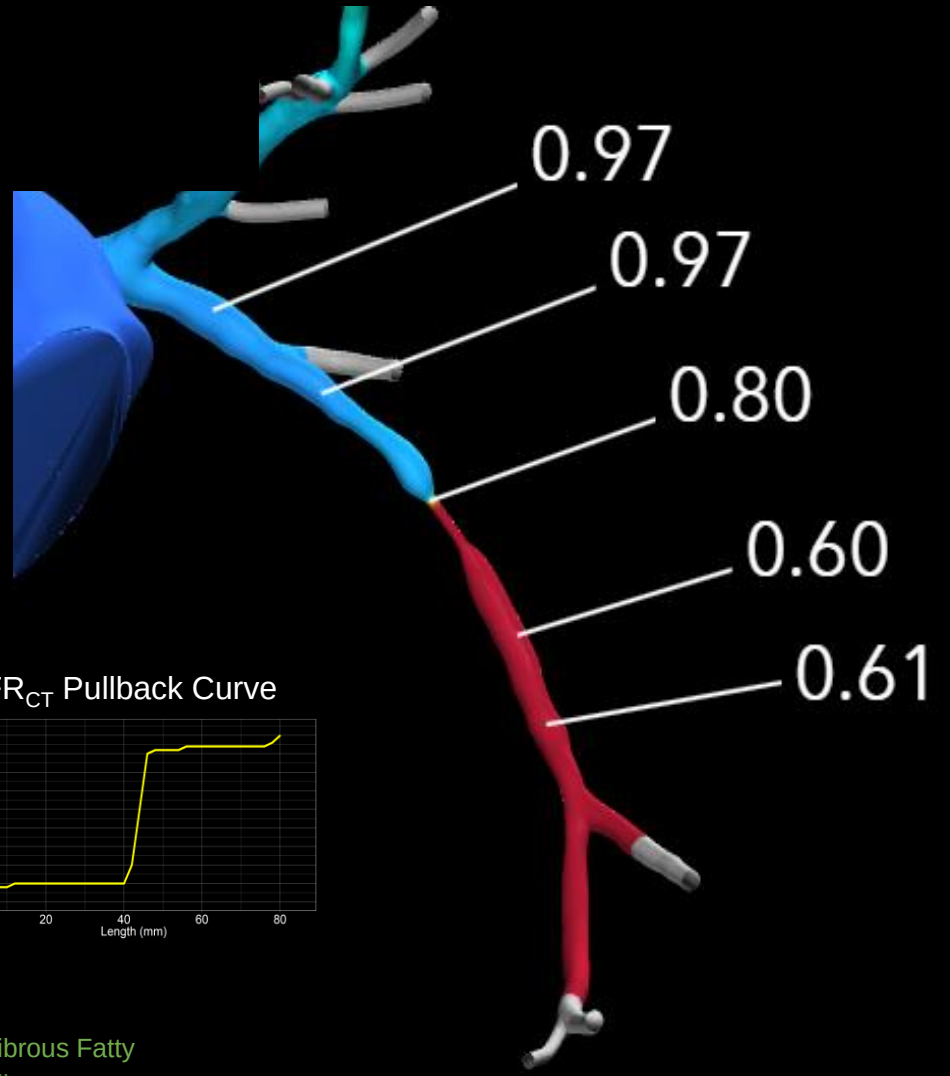


3 DES
Total stent length 105mm

FFR_{CT} Planner in diffuse disease

CT Guided PCI: Planning





FFR_{CT} Pullback Curve

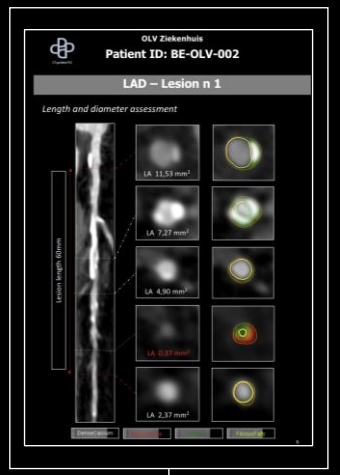
- Fibrous Fatty
- Fibrous
- Necrotic Core
- Calcium

PLAN

CT Based PCI Planning

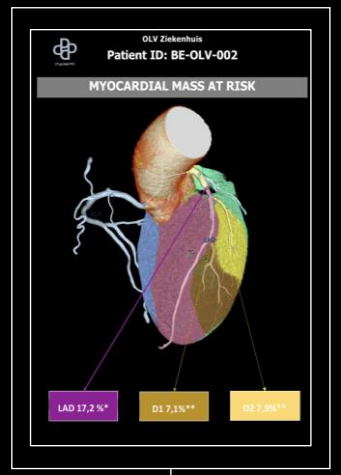
3D coronary anatomy
Global distribution of calcium
Position of the ostium
Tortuosity ~ Calcium ~ Lesion location
Expected level of guiding support

Catheter selection
Anticipate case complexity



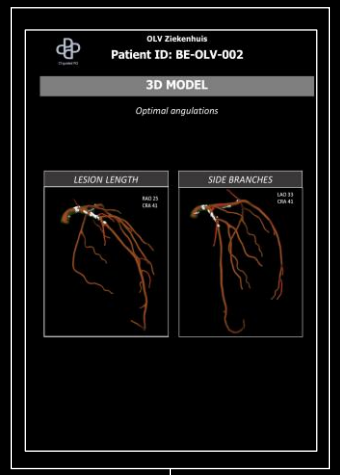
Lesion location
Plaque composition
Lesion length

Lesion preparation
(Probability of stent under-expansion)
Stent length



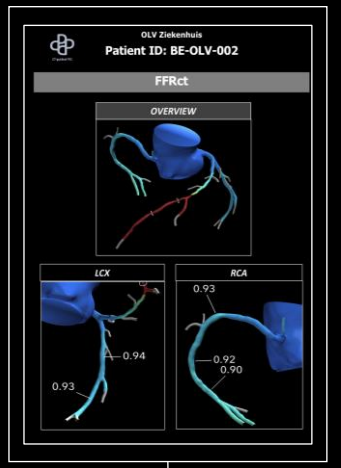
Myocardial mass at risk
Side branch protection

SB wire protection or stenting



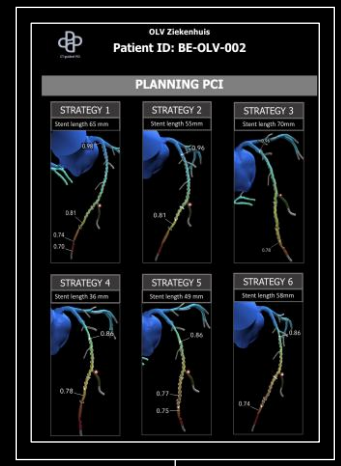
Best achievable projection

C-arm angulation
Awareness of sub-optimal projection



Lesion significance
Pattern of CAD

Appropriateness of PCI
Awareness of diffuse disease



Prediction of post-PCI FFR

PCI strategy

P4 RCT

CT-guided PCI

Patients with stable CAD* (n=1000) with at least one lesion with diameter stenosis >70% and FFR_{CT} ≤0.80

* or stabilized ACS

20 clinical sites in 6 countries (BE, IT, DK, UK, US and HU)

Centralize Core Laboratory Screening for Eligibility

Key Exclusion Criteria: LM stenosis, STEMI, eGRF <30 ml/Kg,previous PCI in target vessel or CABG, insufficient CTA quality.

R

PI: Carlos Collet & Daniele Andreini
Chairman: Bernard De Bruyne
Sponsor: CoreAalst BV
Core Lab: CoreAalst BV
CRO: QbD Consulting

CT-guided PCI strategy
FFR_{CT} Planner + Online CT guidance

X

IVUS-guided PCI strategy
Mandatory pre and post PCI imaging

PCI at operator discretion
Invasive physiology pre and post-PCI recommended

Primary endpoint (non-inferiority)

MACE (cardiac death, target vessel MI and ischemia-driven TVR) between CT- vs. IVUS-guided PCI at 1-year follow-up.

Key secondary endpoint

Radiation dose and contrast volume between CT-and IVUS-guided PCI strategies.
Post-PCI FFR measured immediately after PCI between CT-and IVUS-guided PCI strategies.
SAQ-7 scores between CT and IVUS guided PCI strategies at 12 months.

Hypothesis: *A CT-guided PCI strategy is* ***non-inferior*** *to IVUS guided PCI with respect to* ***MACE***