A new horizon in IVUS-guided PCI of calcified stenoses with AI

Tools and Techniques

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Learning objectives

Join us if you want to:

- To learn about the new AI-assisted IVUS image interpretation
- To share experience on an algorithmic approach, through an IVUS 123 workflow when dealing with heavily calcified lesions
- To tailor treatment through the choice of the most suitable drug eluting device according to the given anatomical setting

Session format

What's in the box:

- A recorded case by the team in St. George's Hospital, London, UK
- 2 focused lectures on key topics
- An outstanding faculty

Team


Emanuele Barbato


Nieves Gonzalo


Dejan Milasinovic


Roberto Diletti


Kalaivani Mahadevan


Robert Byrne


James Spratt


Ganeev Malhotra

Innovation in IVUS-guided PCI

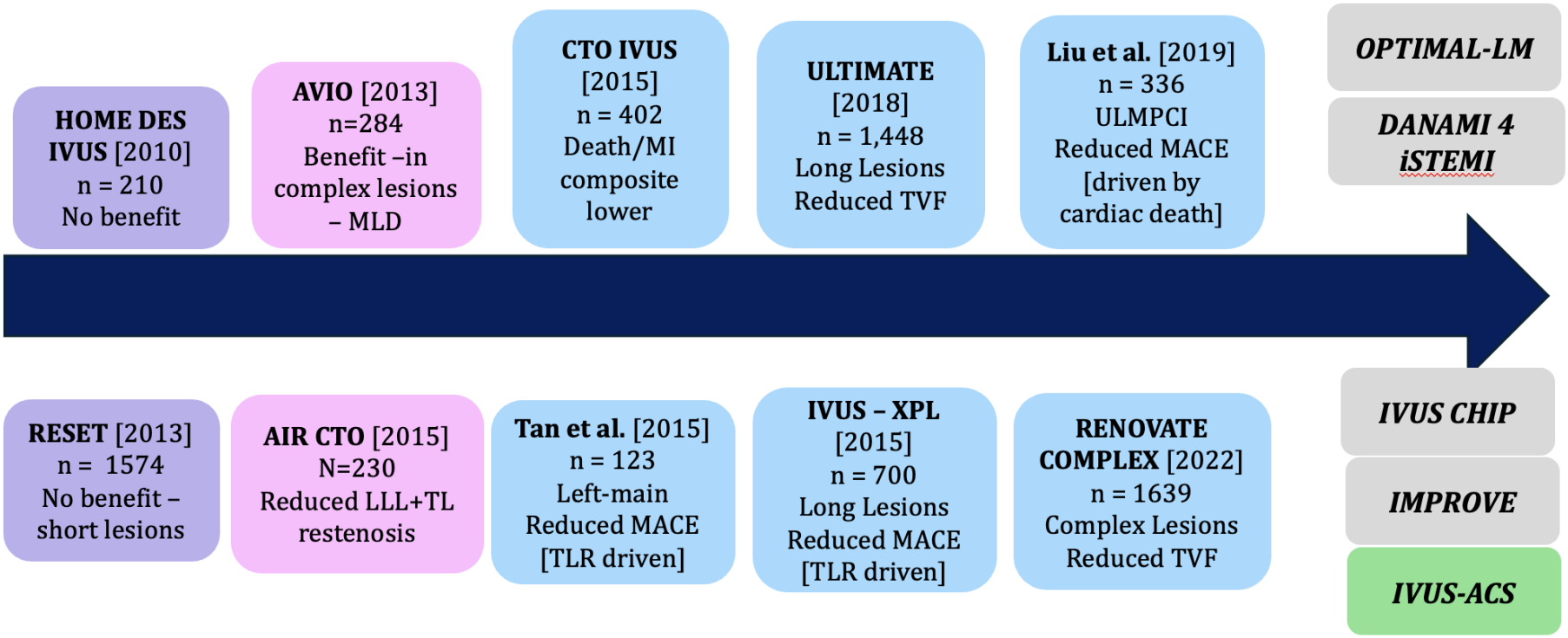
Streamlining the procedure for optimal outcomes

Sponsored by Boston Scientific

Objectives

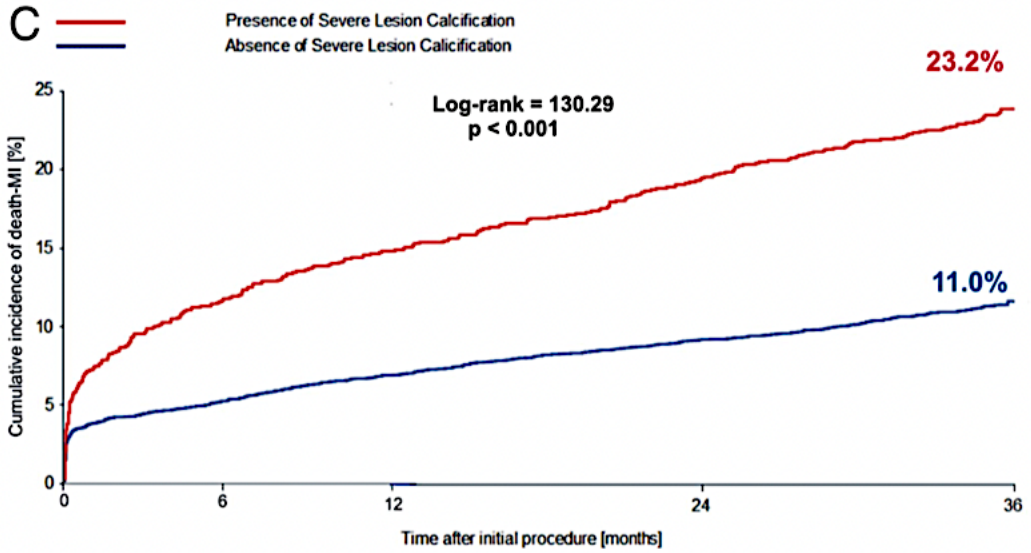
- Why utilize IVUS in complex/calcified lesions
- What are the reported barriers to use
- How can systematic workflows and AI help to optimize PCI

IVUS vs CAG – A Timeline Summary of RCT Data



IVUS in calcific coronary disease

7 pooled studies, n=6296 [20% severe CAC] - CAC confers poorer post-PCI prognosis [TLF, MI + death]



	All studied patients (n=6296)	Patients with severely calcified lesions (n=1291)	Patients without severe calcifications (n=5005)
Death (%)	359 (5.7)	139 (10.8)	220 (4.4)
MI (%)	551 (8.8)	183 (14.2)	368 (7.4)
Any revascularisation* (%)	866 (17.3)	241 (20.5)	625 (16.3)
Combined end-points			
Death—MI (%)	840 (13.3)	295 (22.9)	545 (10.9)
Death—MI-any (%) revascularisation*	1213 (24.2)	373 (31.7)	860 (22.4)
Stent thrombosis†			
Definite (%)	129 (2.1)	38 (3.0)	91 (1.8)
Probable (%)	43 (0.8)	16 (1.3)	27 (0.7)
Possible (%)	97 (1.9)	35 (3.0)	62 (1.6)

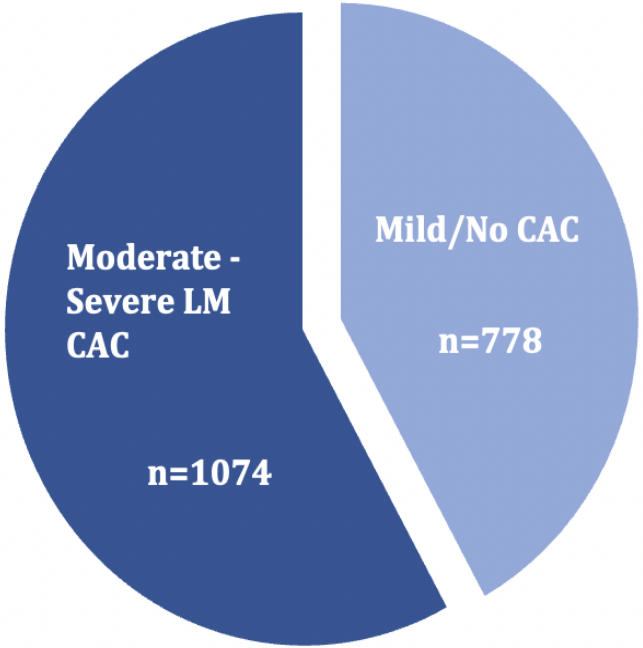
Bourantas CV, *et al. Heart* 2014;**100**:1158–1164.

Impact of Coronary Calcium in Patients Undergoing LMCA Revasc

EXCEL Calcium Substudy Insights - Outcomes in uLM-PCI n= 1852

Mod/Sev Cohort:

Increased:
Age
Hypertension
Hyperlipidaemia
Diabetes
CKD

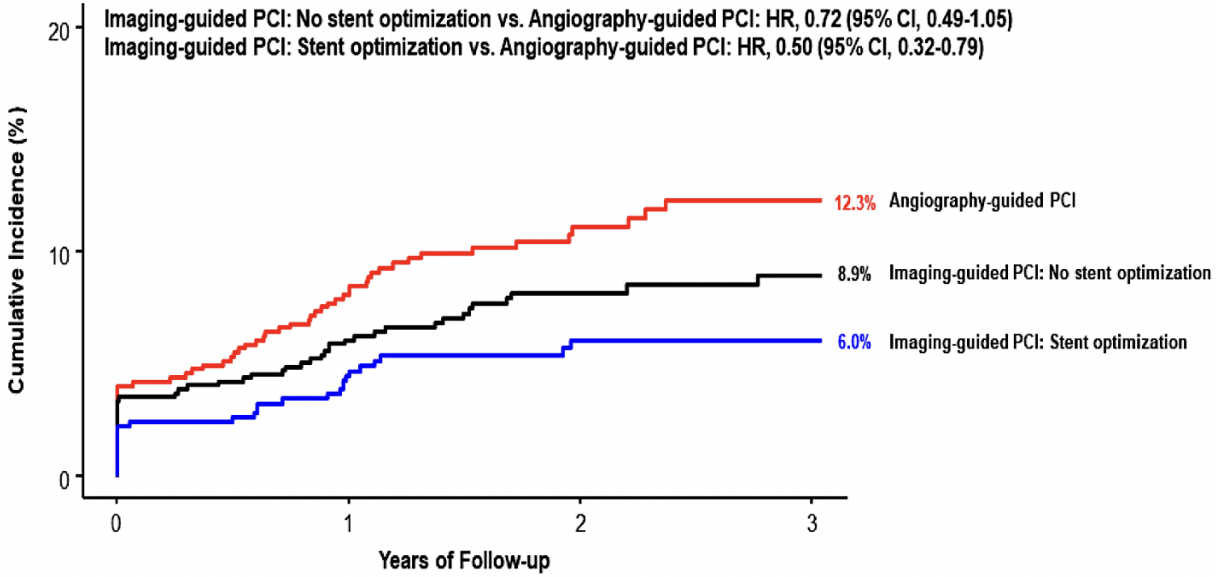


3- Year Mortality:

No/Mild CAC = 4.8%
M/S CAC = 8.6%

HR = 1.85

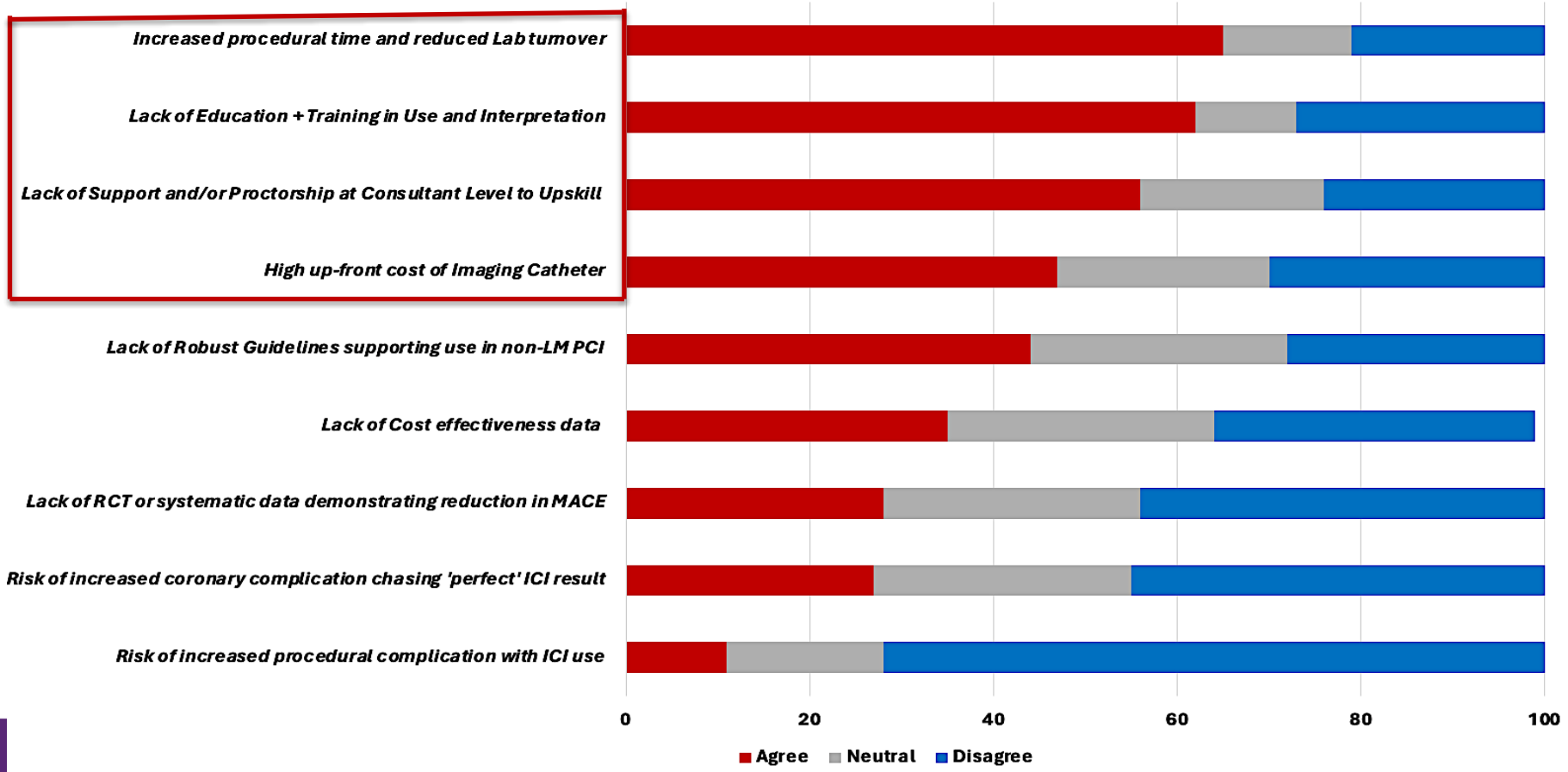
Renovate – Complex PCI: ICI vs CAG in complex CAD



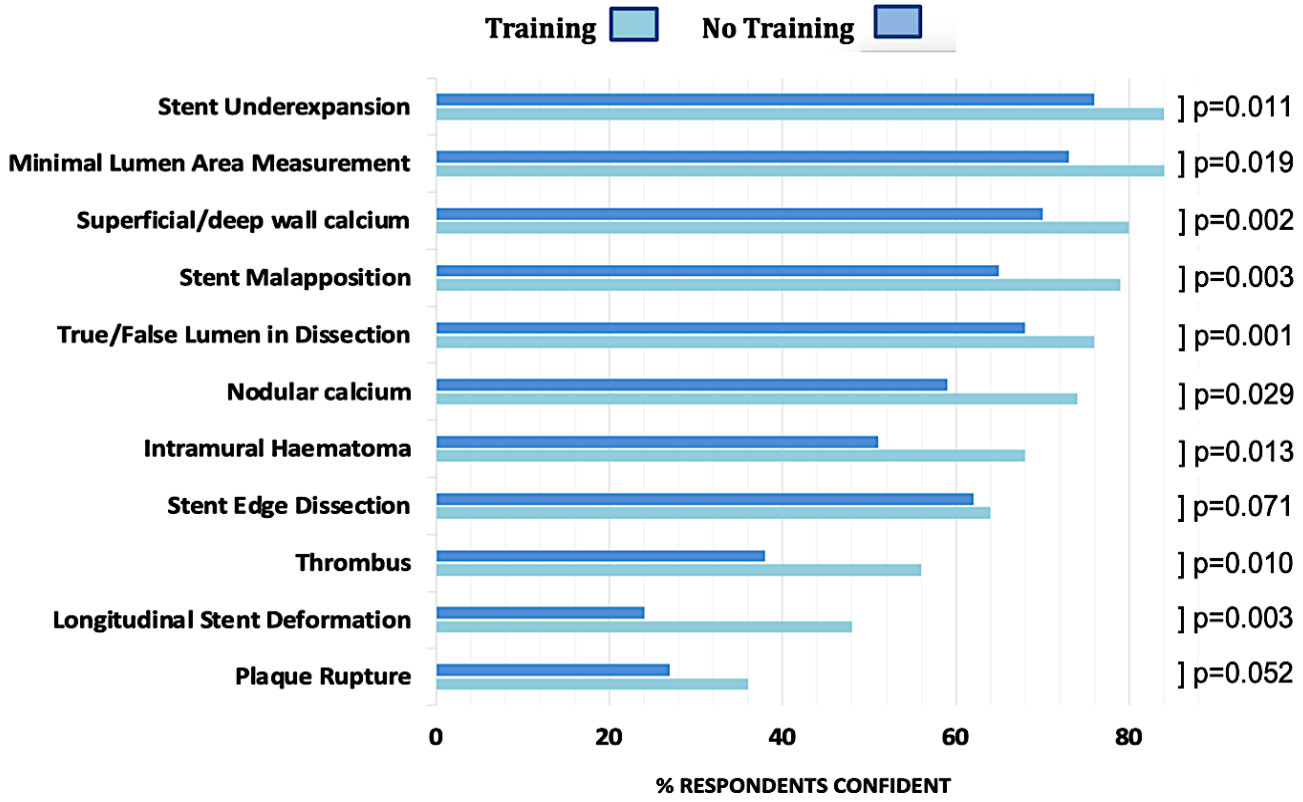
1639 patients, 2:1 Randomisation
[ICI v CAG]
Primary Endpoint – TVF [CV death/TVMI/TVR]

1) True bifurcation lesion
2) Chronic total occlusion
3) Unprotected LM disease
4) Long lesions (≥38 mm stent length)
5) Multi-vessel PCI
6) Multiple stents needed (≥3)
7) In-stent restenosis as target lesion
8) Severely calcified lesion
9) Ostial coronary lesion

Barriers to Use of Intracoronary Imaging

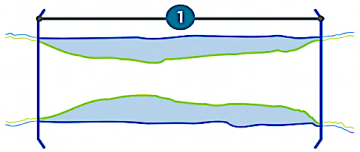


Physician Challenges around IVUS Image Interpretation

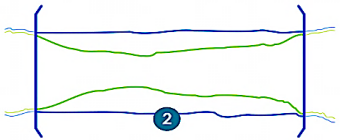


The Role of Systematic Algorithms – Improving Use of Imaging

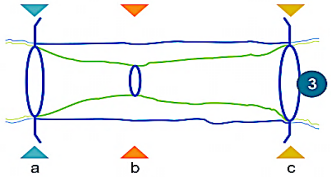
1 | Establish lesion length and define landing zones



2 | Assess plaque morphology



3 | Measure the vessel size



IVUS 1 2 3 ESSENTIALS

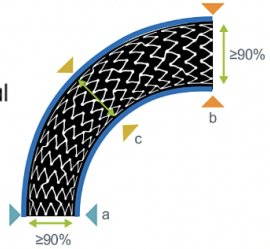
Streamlining of Education and Training

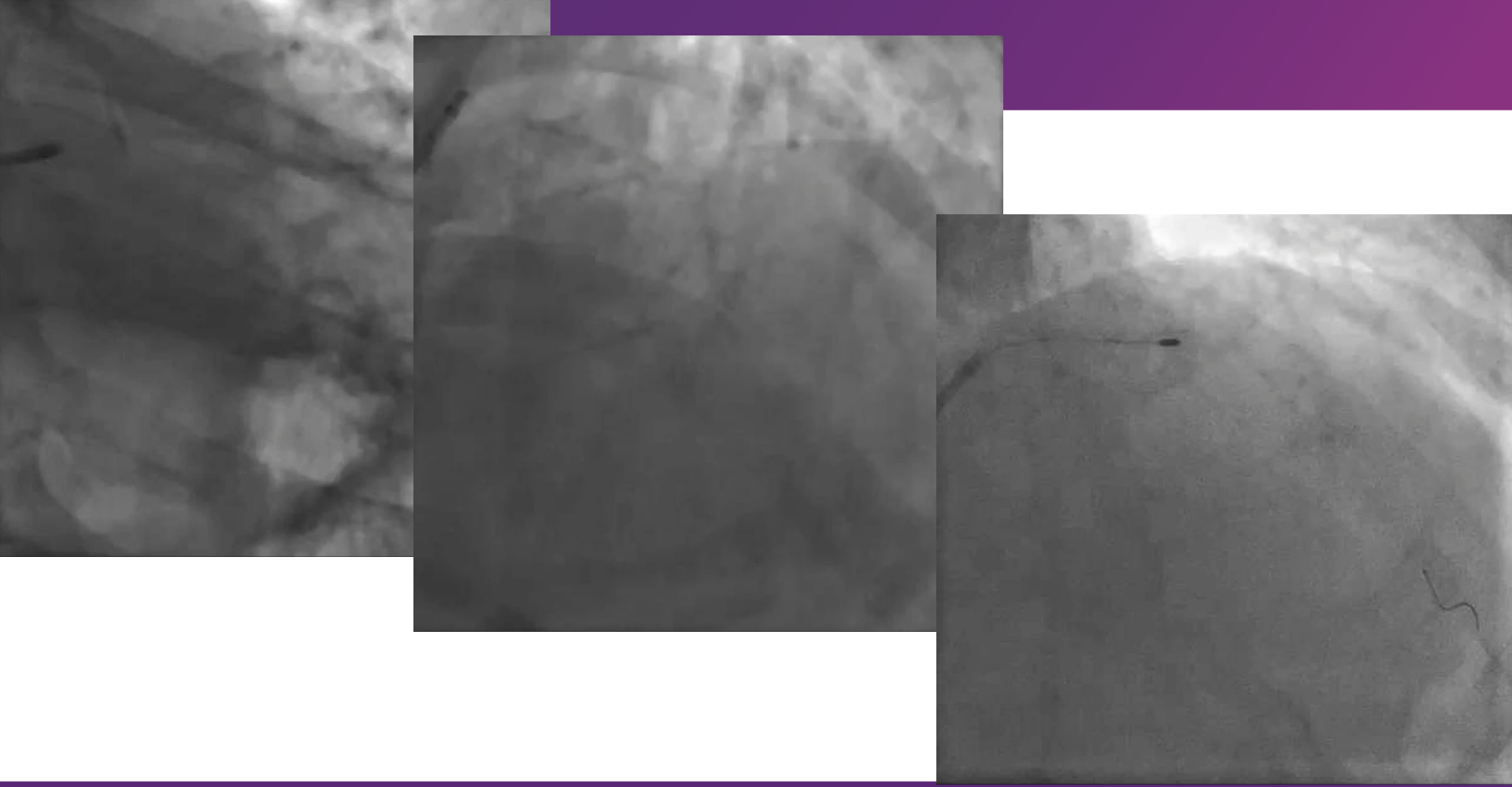
= Competency + Consistency

1 | Check for geographic miss (a) and edge dissection (b)

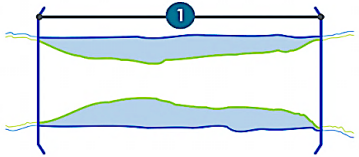
2 | Check for malapposition

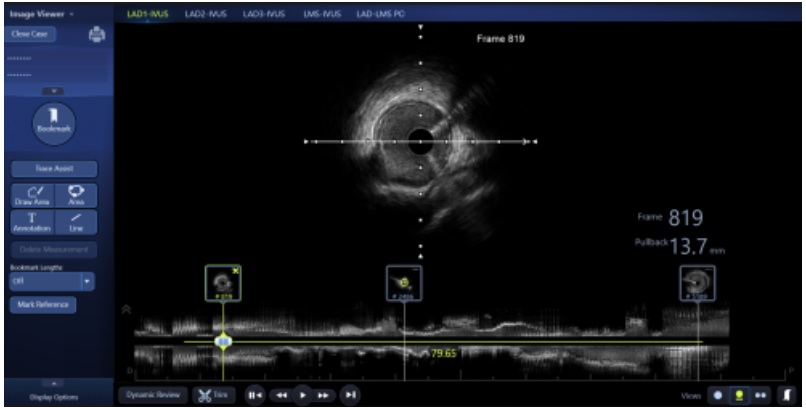
3 | Check for optimal stent expansion





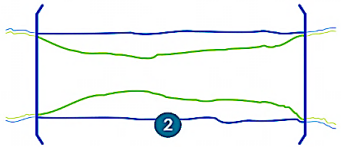
1 Establish lesion length and define landing zones

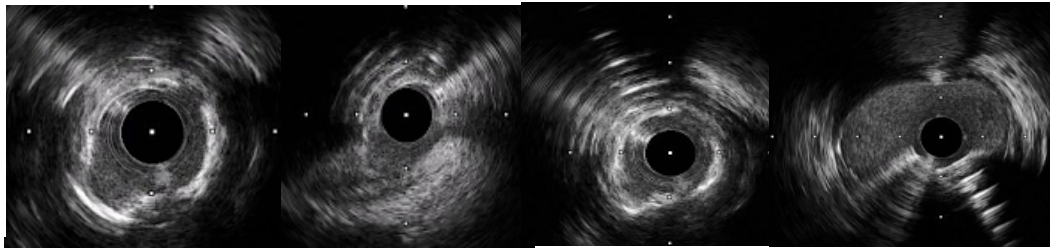




<50% plaque burden

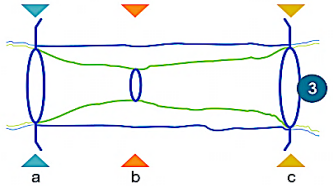
2 Assess plaque morphology

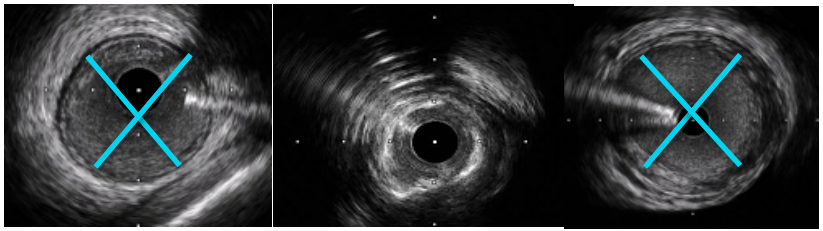




Lesion modification

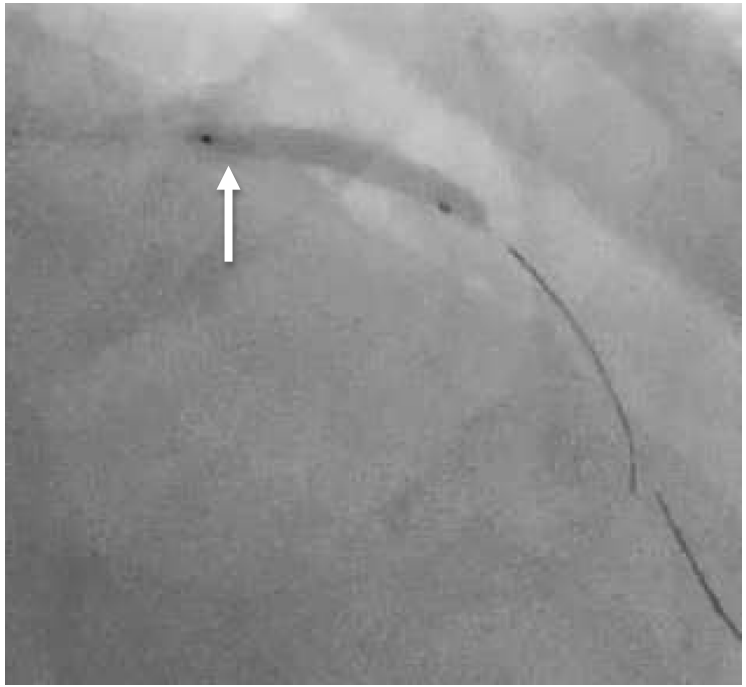
3 Measure the vessel size



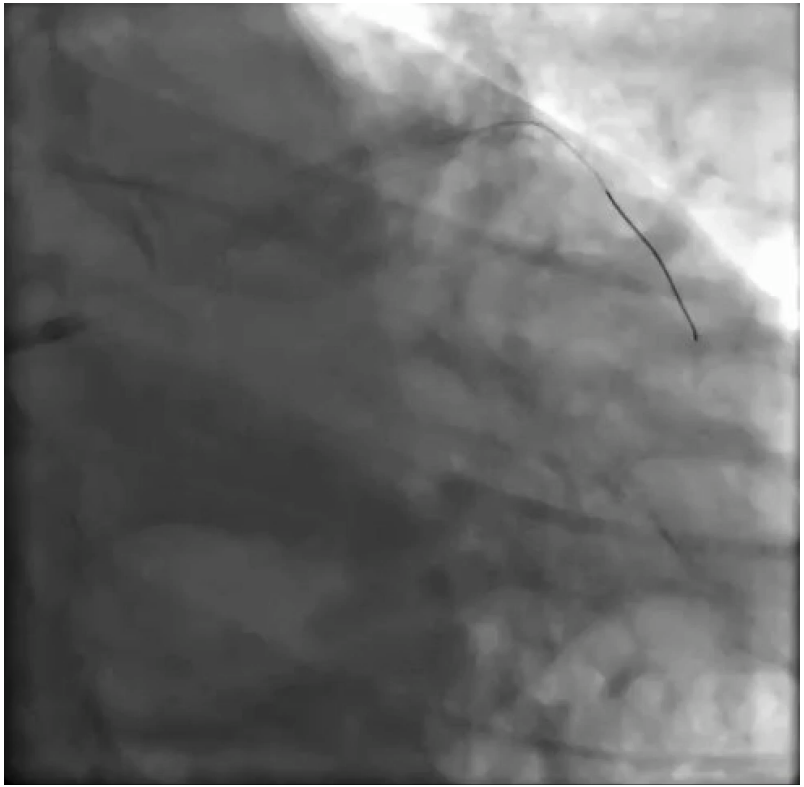


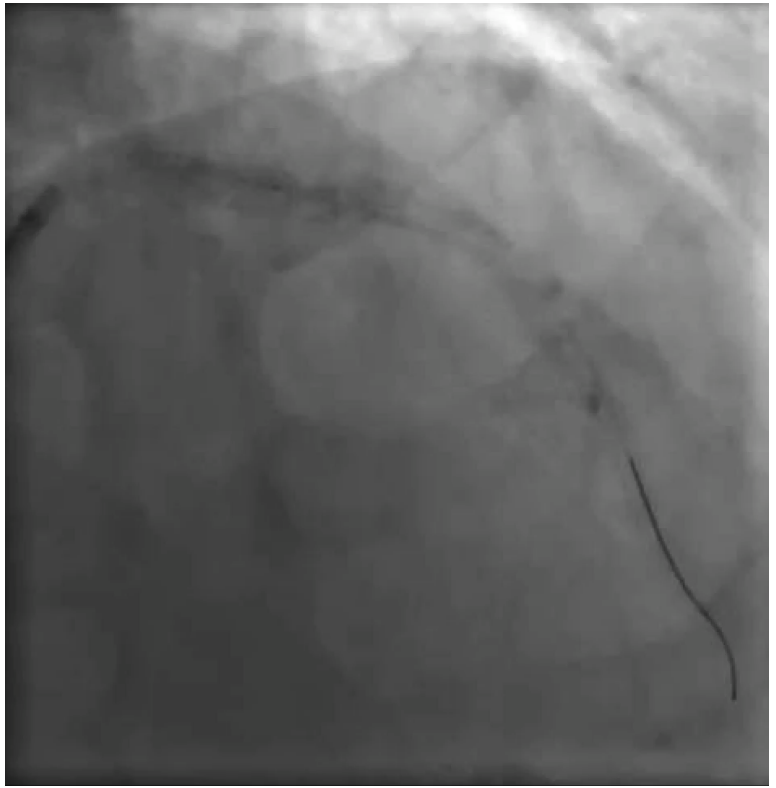
Stent sizing

Focal Waisting with NCB – 3.5 Wolverine Prox LAD + LM



Final Angiographic Result



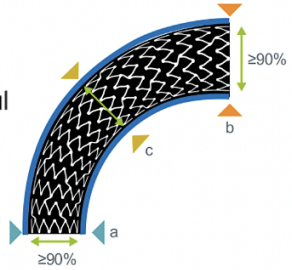


Final Angiographic Result

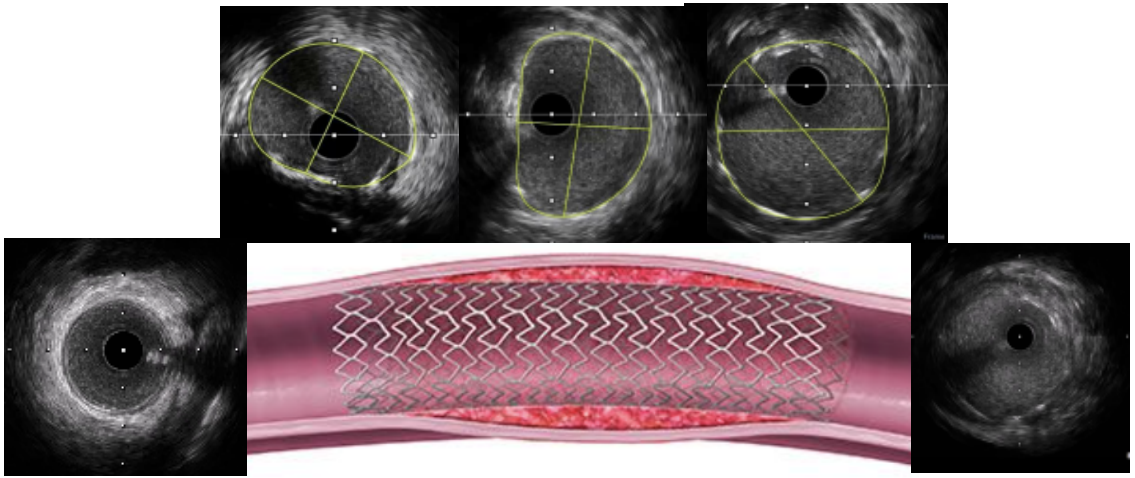
1 | Check for geographic miss (a) and edge dissection (b)

2 | Check for malapposition

3 | Check for optimal stent expansion



Good apposition, good MSA's, area of eccentric expansion around nodular calcium



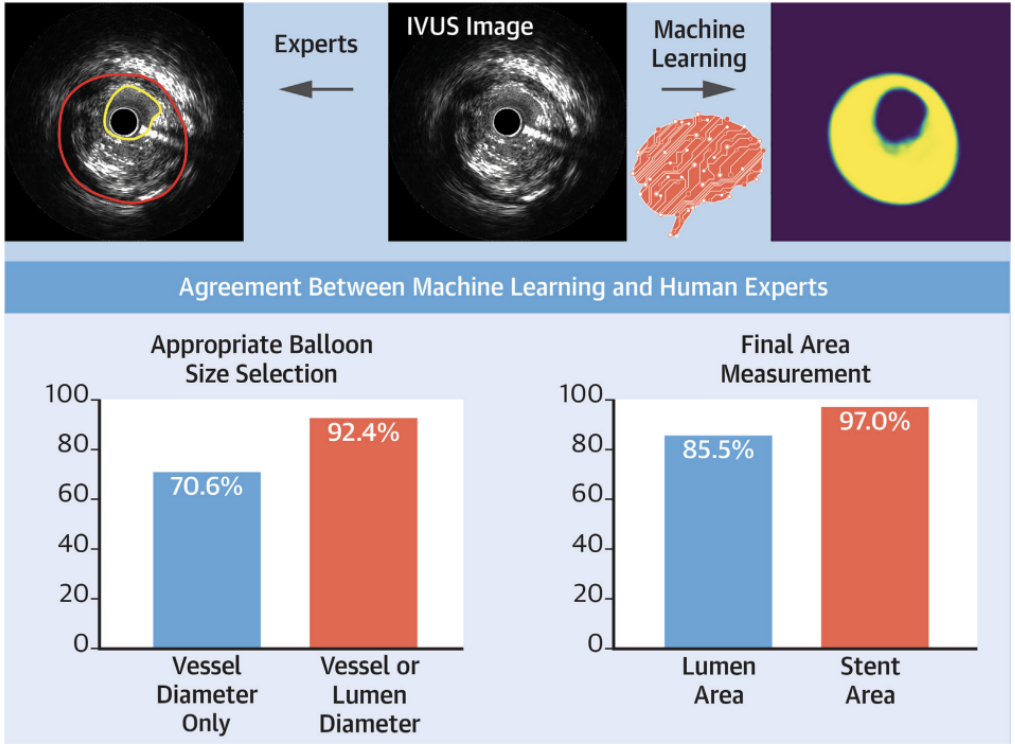
Role of AI – Improving How We Interpret and Act on Imaging

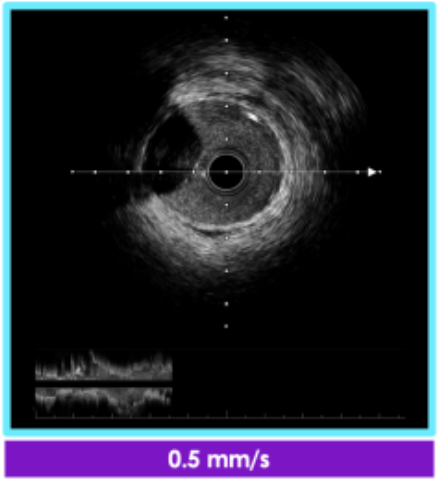
Accuracy of IVUS-Based Machine Learning Segmentation Assessment of Coronary Artery Dimensions and Balloon Sizing

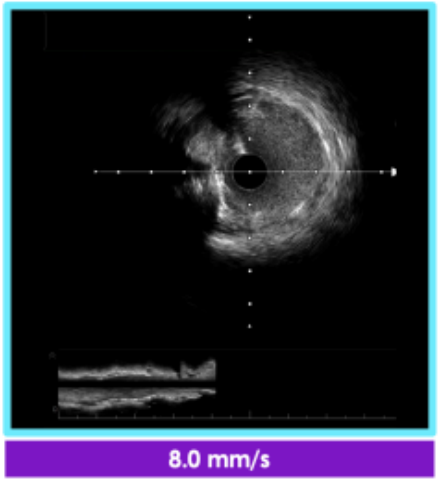
Mitsuaki Matsumura, BS,[a,b] Gary S. Mintz, MD,[a] Tomotaka Dohi, MD, PhD,[b] Wenguang Li, PhD,[c] Alexander Shang, BSE,[c] Khady Fall, MD, MPH,[d] Takao Sato, MD,[a,d] Yoichiro Sugizaki, MD,[a,d] Yiannis S. Chatzizisis, MD,[e] Jeffery W. Moses, MD,[a,d] Ajay J. Kirtane, MD, SM,[a,d] Hajime Sakamoto, PhD,[f] Hiroyuki Daida, MD, PhD,[f] Tohru Minamino, MD, PhD,[b] Akiko Maehara, MD[a,d]

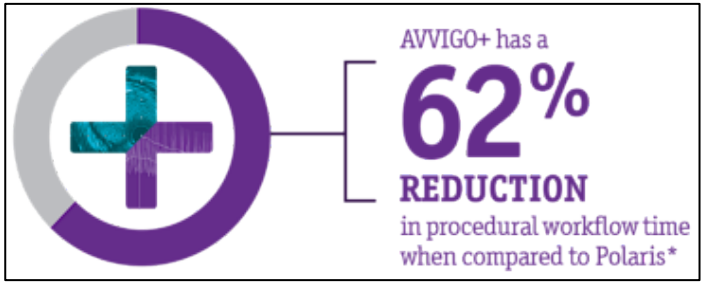
Supporting physicians in image interpretation

= procedural optimization and safety









On-going innovation and improvement
= reduction in procedural duration

= Efficiency

Workflows and AI – can help to break barriers by facilitating consistency in education, training, and Cath Lab efficiency and allowing optimization of procedural + patient outcomes.

LIAB (Pt 1) from St. George's Hospital - London

James Spratt & Ganeev Malhotra

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LIAB (Pt 2) from St. George's Hospital - London

James Spratt & Ganeev Malhotra

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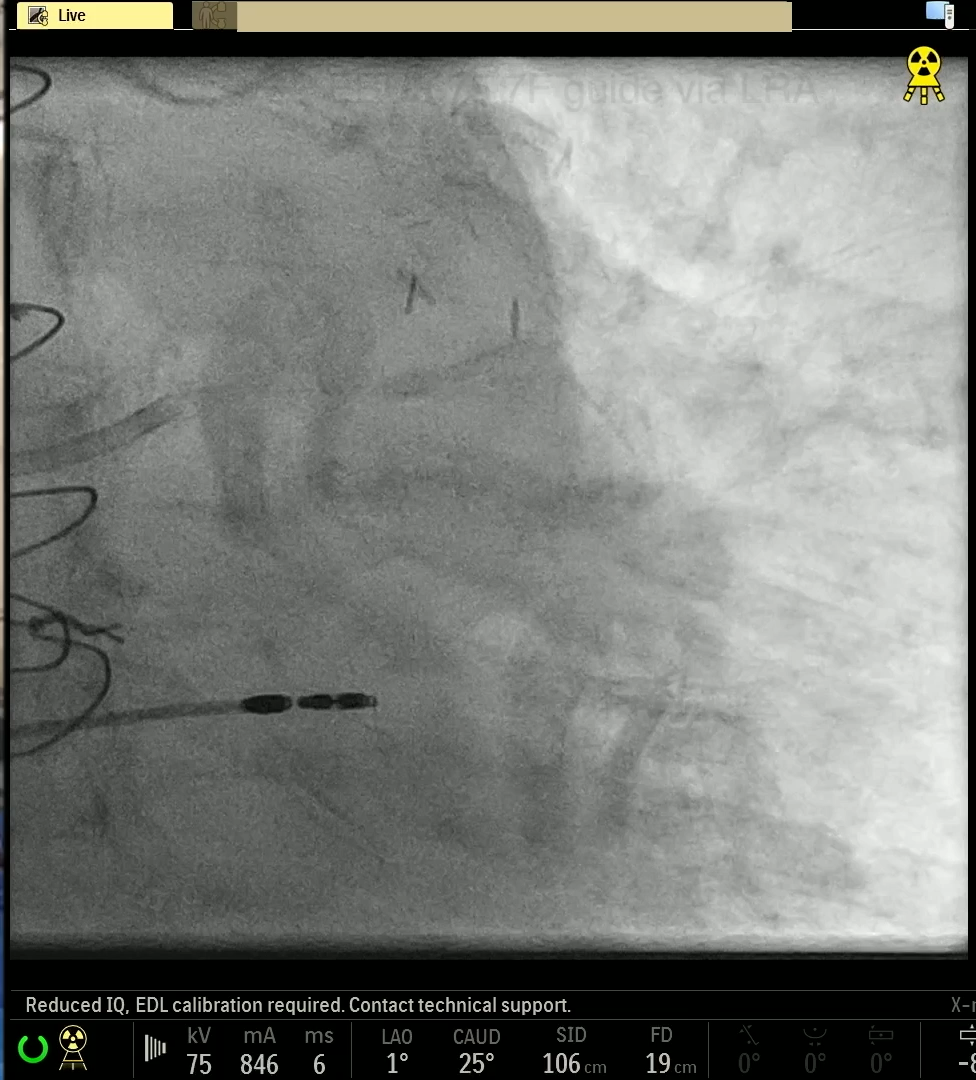
RAMP


Live
Reduced IQ, EDL calibration required. Contact technical support.
kV 75
mA 846
ms 6
LAO 1°
CAUD 25°
SID 106 cm
FD 19 cm
0°
0°
0°

Breaking the calcium ceiling: a roadmap for a systematic approach to calcium treatment

Robert A. Byrne

CVRI Dublin, Mater Private Network and RCSI University

Potential conflicts of interest | Breaking the calcium ceiling

Speaker's name : Robert A. Byrne, MB BCh PhD FESC

☑ I have the following potential conflicts of interest to declare:

I do not accept personal payments from medical device or pharamaceutical industry

My institution(s) of employment receive educational/research grants that do not affect my personal remuneration in any way from:

Abbott, Biosensors International, Boston Scientific, Translumina

Agenda | Breaking the calcium ceiling

1. Introduction
2. Algorithmic approach to calcium modification
3. Review of treatment modalities
4. Current/future evidence
5. Take home message

Byrne R.A. | euroPCR 2024

The Need to Treat Calcium is Growing

Increasing Risk Factors

- Age
- Diabetes
- Renal failure
- Hypertension
- Smoker

New Technologies

- High-Risk PCI
- Pre-TAVR revascularization

Calcium treatment needs will continue to grow over the next 10 years

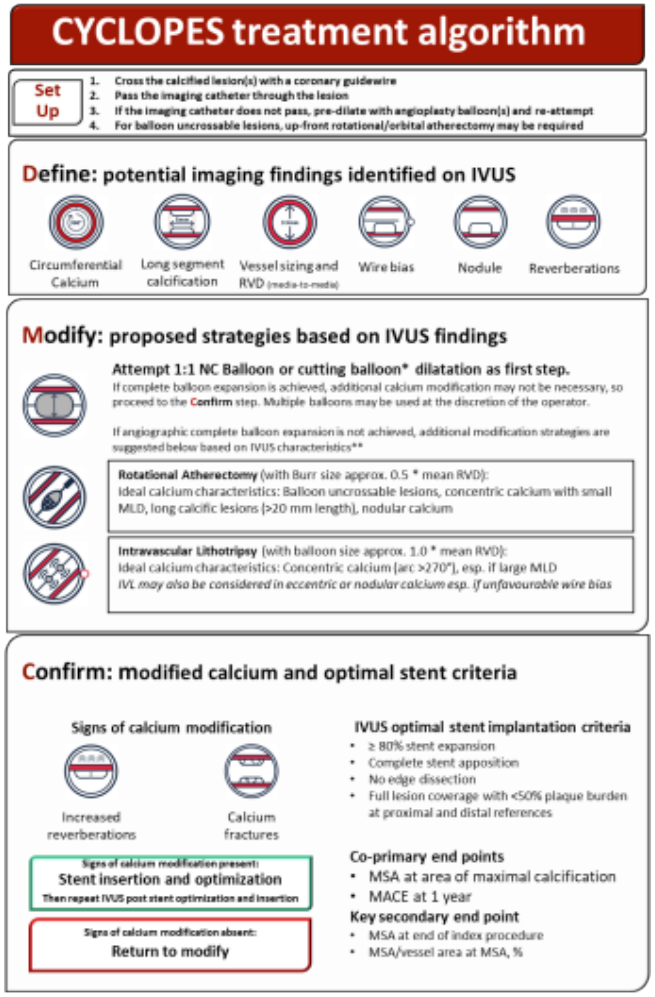
Implementation of a Standardized Algorithm for CoronarY CaLcificatiOn with PlaquE Modification using UltraSound Guidance to Improve Procedural and Clinical Outcomes (CYCLOPES)

CYCLOPES STUDY

1. DEFINE

2. MODIFY

3. CONFIRM



CYCLOPES STUDY

CVRI DUBLIN

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

Mater Private Network

1. DEFINE

CYCLOPES treatment algorithm

Set Up

1. Cross the calcified lesion(s) with a coronary guidewire
2. Pass the imaging catheter through the lesion
3. If the imaging catheter does not pass, pre-dilate with angioplasty balloon(s) and re-attempt
4. For balloon uncrossable lesions, up-front rotational/orbital atherectomy may be required

Define: potential imaging findings identified on IVUS

Circumferential Calcium | Long segment calcification | Vessel sizing and RVD* | Wire bias | Nodule | Reverberations

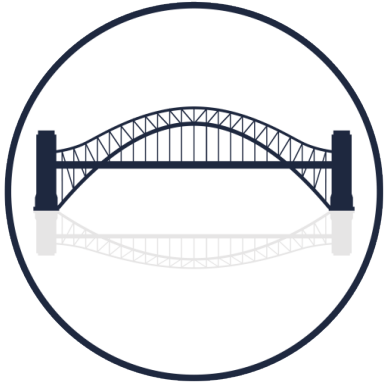
Benefits of IVI in Calcified CAD

IVI improves safety:

By reducing risk in eccentric or nodular calcium

IVI maximises efficacy:

By identifying the need and success of plaque modification

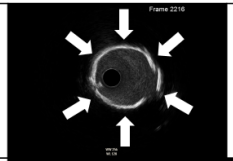
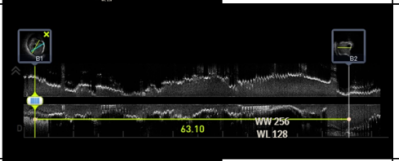
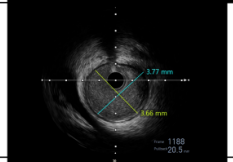
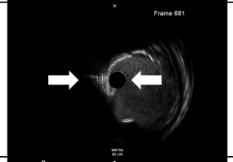
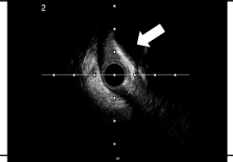
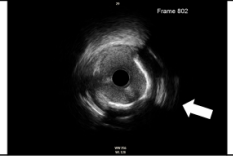


IVI optimises durability:

By maximising MSA safely

1. DEFINE

CYCLOPES treatment algorithm

Circumferential calcium		**Circumferential calcium:** bright calcium echoes with acoustic shadowing in a circumferential pattern
Long segment calcification		**Length of calcium:** the length of calcific disease at the target lesion, measured in the longitudinal view
Vessel sizing and RVD (media-to-media)		**Vessel sizing:** RVD measured at proximal and distal stent landing zones, measuring the mean lumen diameter (media-to-media)
Wire bias		**Wire bias:** the wire is shown to be aligned immediately adjacent to the calcified plaque or nodule
Nodule		**Calcific nodule:** a convex area of calcium protruding into the arterial lumen
Reverberations		**Reverberations:** arched, hyperechoic signals seen behind calcified plaque with IVUS imaging

CYCLOPES STUDY

CVRI DUBLIN

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

Mater Private Network

2. MODIFY

Modify: proposed strategies based on IVUS findings

Attempt 1:1 NC Balloon or cutting balloon† dilatation as first step.

If complete balloon expansion is achieved, additional calcium modification may not be necessary, so proceed to the **Confirm** step. Multiple balloons may be used at the discretion of the operator.

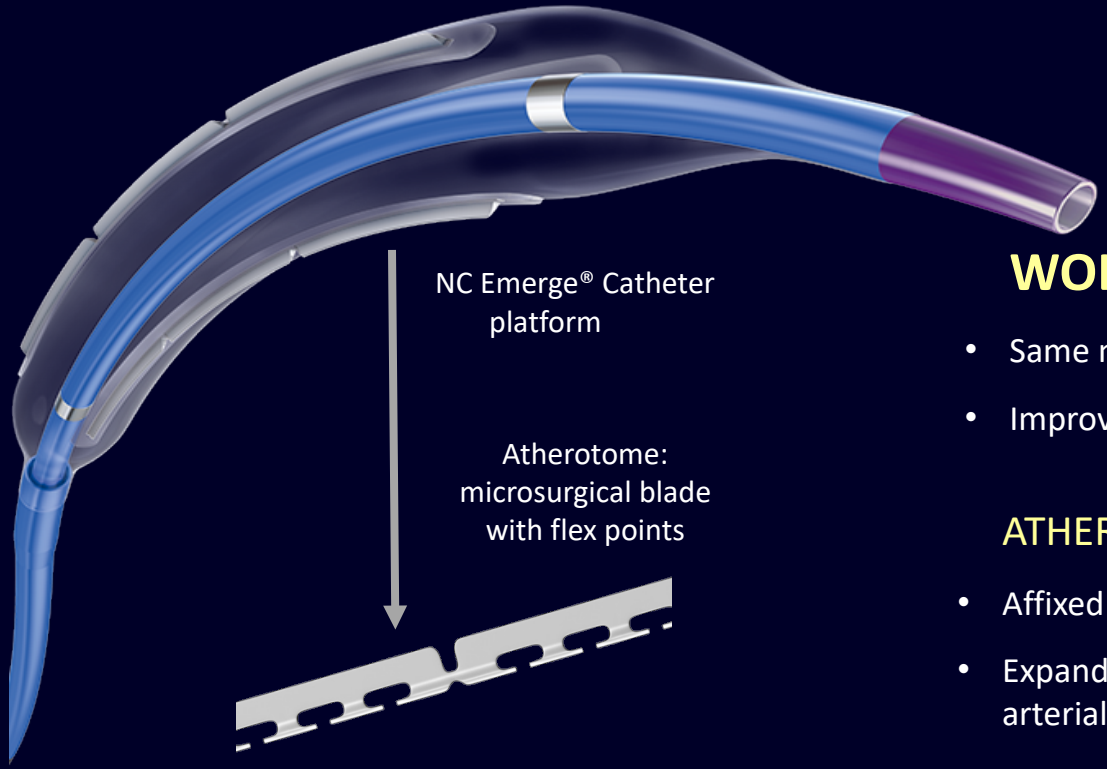
If angiographic complete balloon expansion is not achieved, additional modification strategies are suggested below based on IVUS characteristics‡

Rotational Atherectomy (with Burr size approx. 0.5 x mean RVD):
Ideal calcium characteristics: Balloon uncrossable lesions, concentric or eccentric lesions with small MLD, long calcific lesions (>20 mm length), nodular calcium

Intravascular Lithotripsy (with balloon size approx. 1.0 x mean RVD):
Ideal calcium characteristics: Concentric calcium (arc >270°), esp. if large MLD
IVL may also be considered in eccentric or nodular calcium esp. if unfavourable wire bias

Wolverine™ Cutting Balloon™ Device

Conventional Angioplasty + Microsurgical Technology



WOLVERINE vs. FLEXTOME

- Same mechanism of action
- Improved deliverability and reduced profile

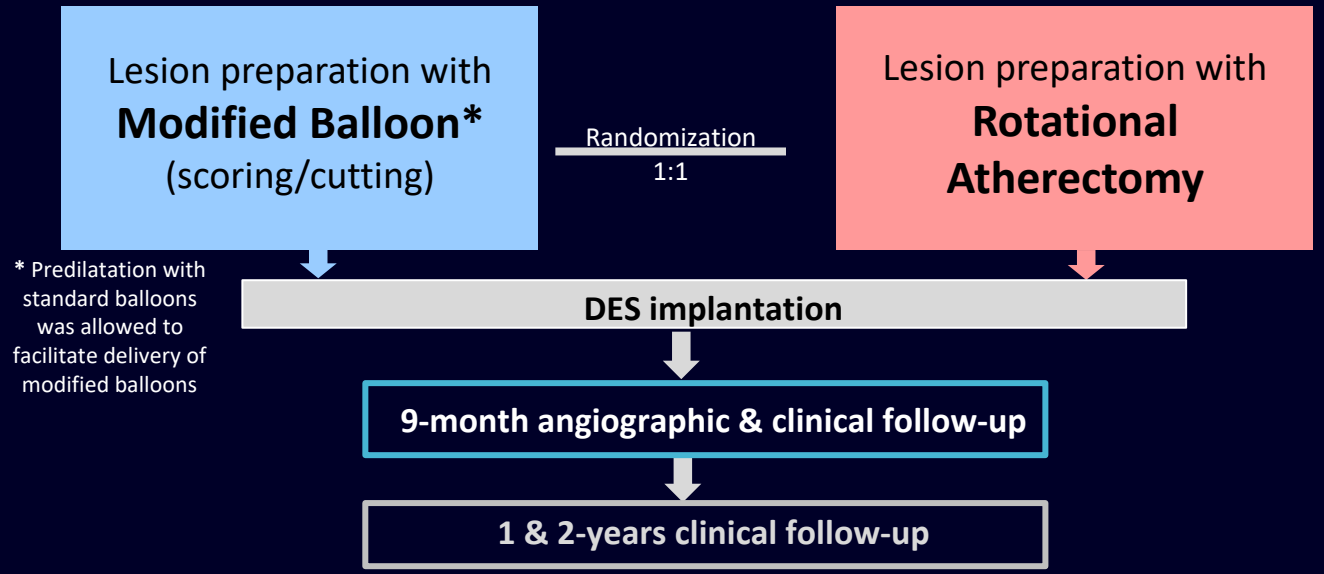
ATHEROTOMES

- Affixed to a nylon non-compliant balloon
- Expand radially as balloon is inflated to score arterial plaque

PREPARE-CALC Trial

Prospective, 1:1 randomized, German study (2 sites)

PCI in 200 patients with severely calcified lesions

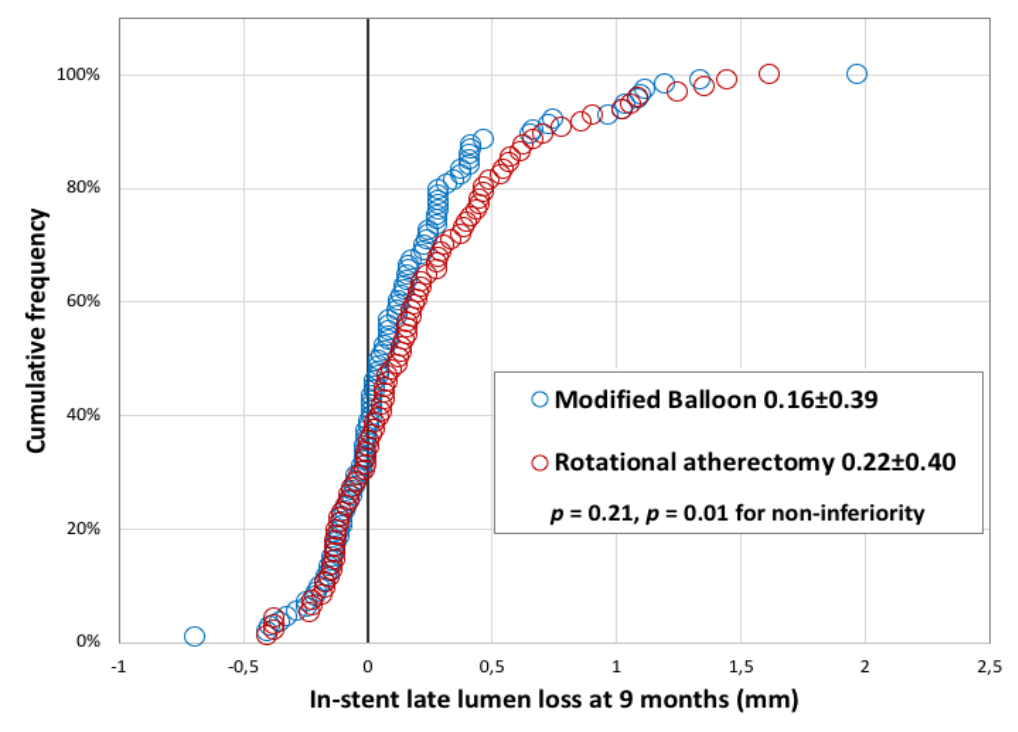


Primary End point:

- **Strategy success** (Superiority): Successful stent delivery and expansion with < 20% in-stent residual stenosis and TIMI 3 flow without crossover or stent failure
- **In-stent late-lumen-loss at 9 months** (Non-inferiority)

PREPARE-CALC Trial

Primary End Point – In-stent Late Lumen Loss at 9 months



Primary end point for non-inferiority was met with no statistically significant difference for clinical outcomes at 9 months

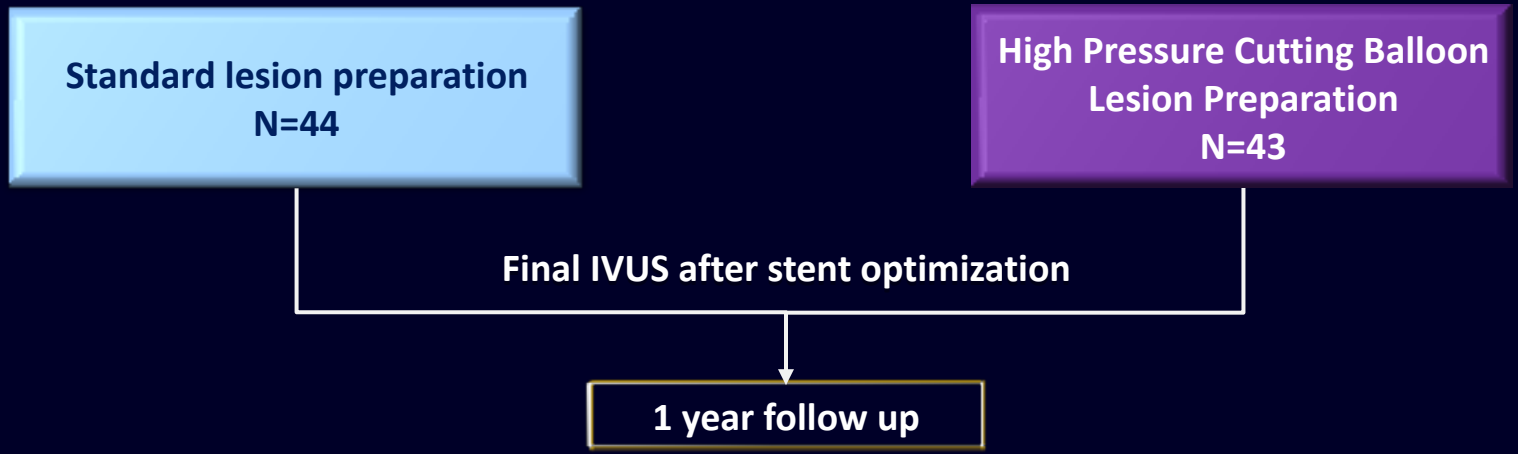
Cutting Balloon to Optimize Predilatation for Stenting (COPS)

Evaluation of Standard vs. High-Pressure Cutting Balloon lesion Prep Strategy

Prospective, randomized control trial studying 100 patients with target lesions containing:

- Severely calcified plaque Arc >100°
- or concentric fibrotic plaque extending for at least > 100°

evaluated by IVUS

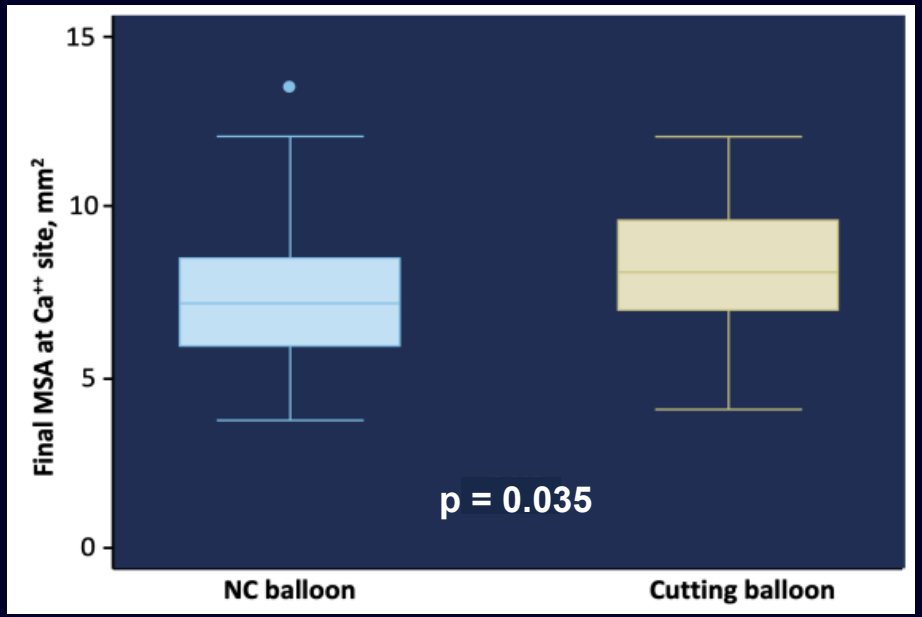


Primary endpoint. Final minimal stent area (MSA) **at calcium site** after DES implantation evaluated with IVUS

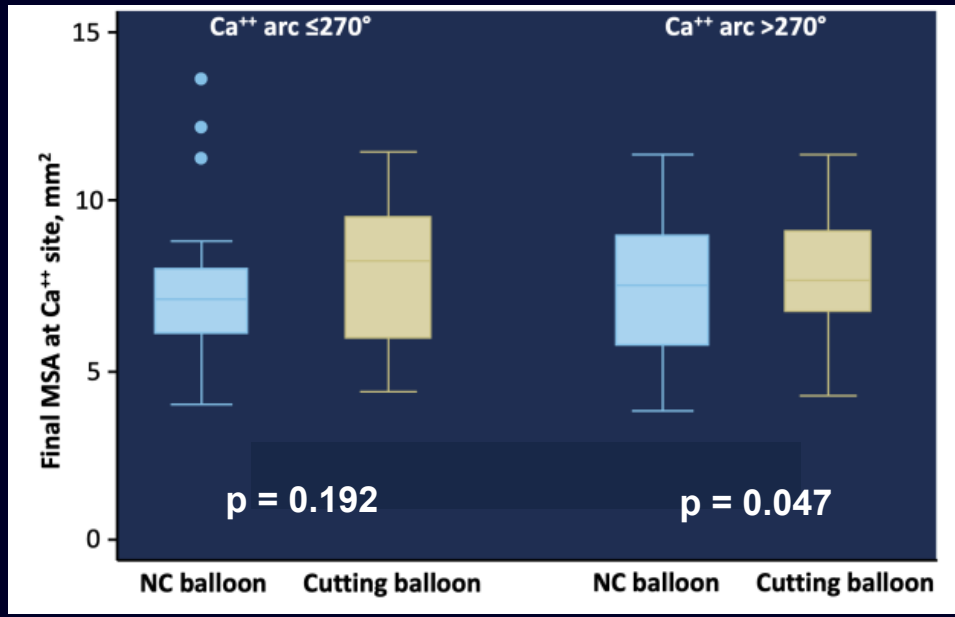
COPS

Results – Primary Endpoint of MSA at calcium site

Final MSA at calcium site (mm^2)



Final MSA at calcium site (mm^2) by arc



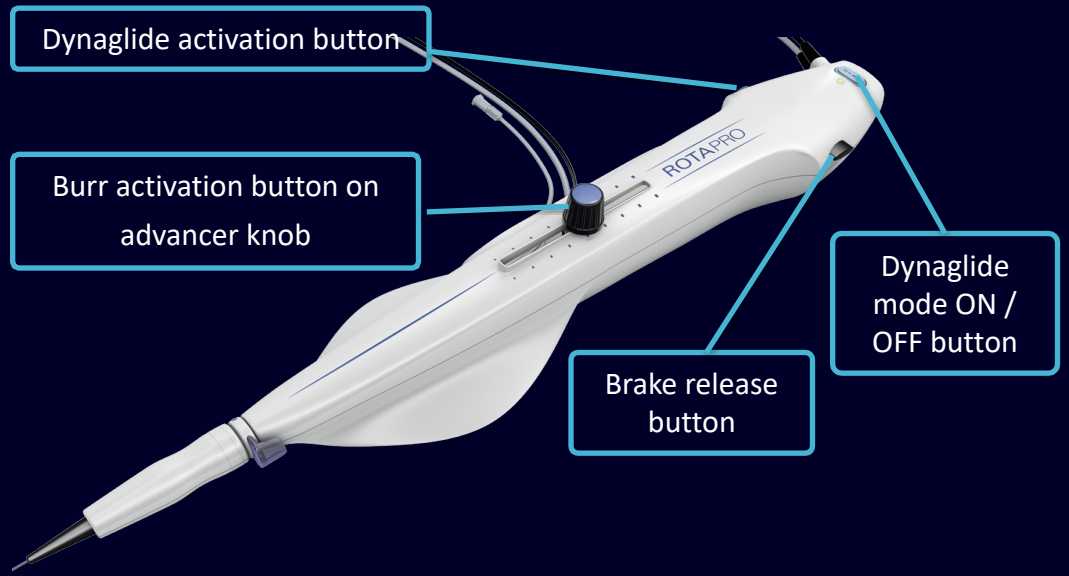
Final MSA (mm^2) at the calcium site is significantly larger with CB vs. NCB *(8.1 vs. 7.3, p=0.035).*
The benefit of lesion preparation with Wolverine is magnified in presence of severe calcifications (Ca arc >270°)

Mangieri, Antonio, et. al. "Cutting Balloon to Optimize Predilatation for Stent Implantation: The COPS Randomized Trial." Presented at TCT2022

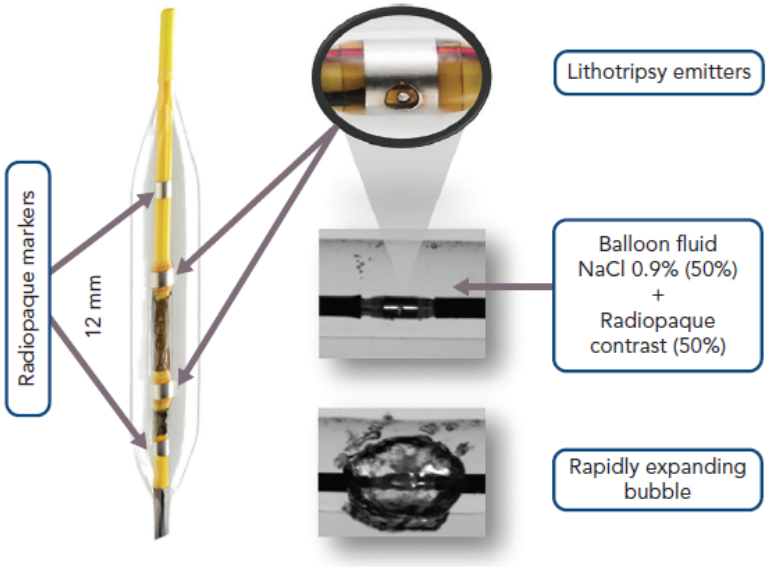
ROTAPRO™ Rotational Atherectomy System

Design Goals:

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



Intravascular Lithotripsy



3. CONFIRM

Confirm: modified calcium and optimal stent criteria

Signs of calcium modification

Increased reverberations

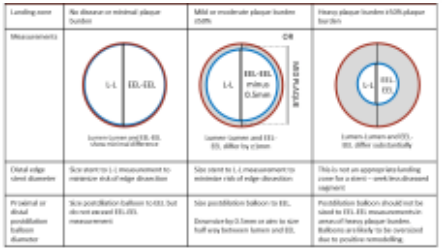
Calcium fractures

Signs of calcium modification present:
Stent insertion and optimization
Then repeat IVUS post stent optimization and insertion

Signs of calcium modification absent:
Return to modify

IVUS optimal stent implantation criteria

- ≥ 80% stent expansion
- Complete stent apposition
- No edge dissection
- Full lesion coverage with <50% plaque burden at proximal and distal references



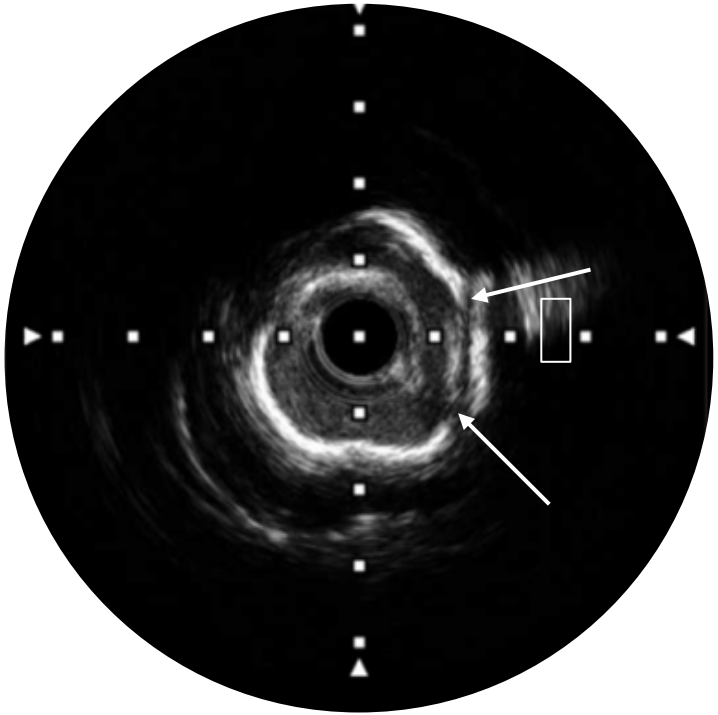
CYCLOPES STUDY

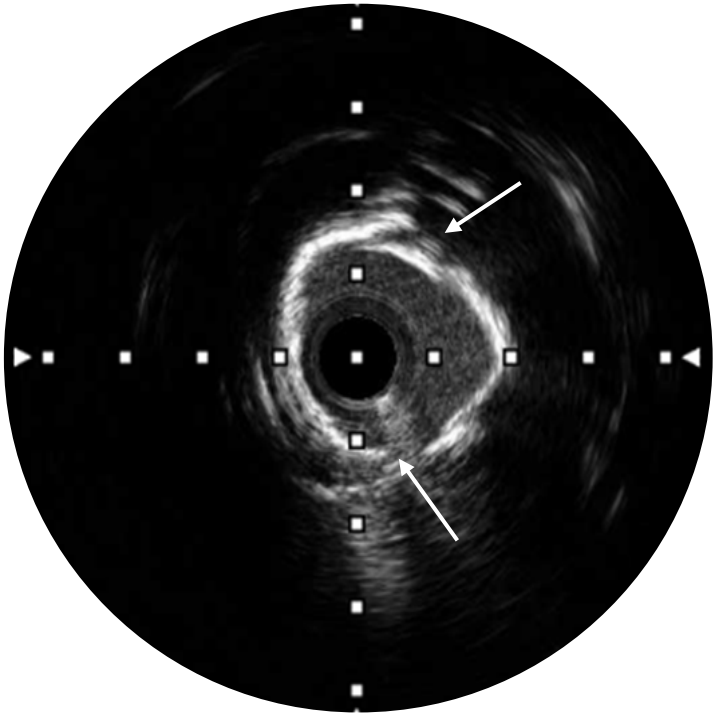
CVRI DUBLIN

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

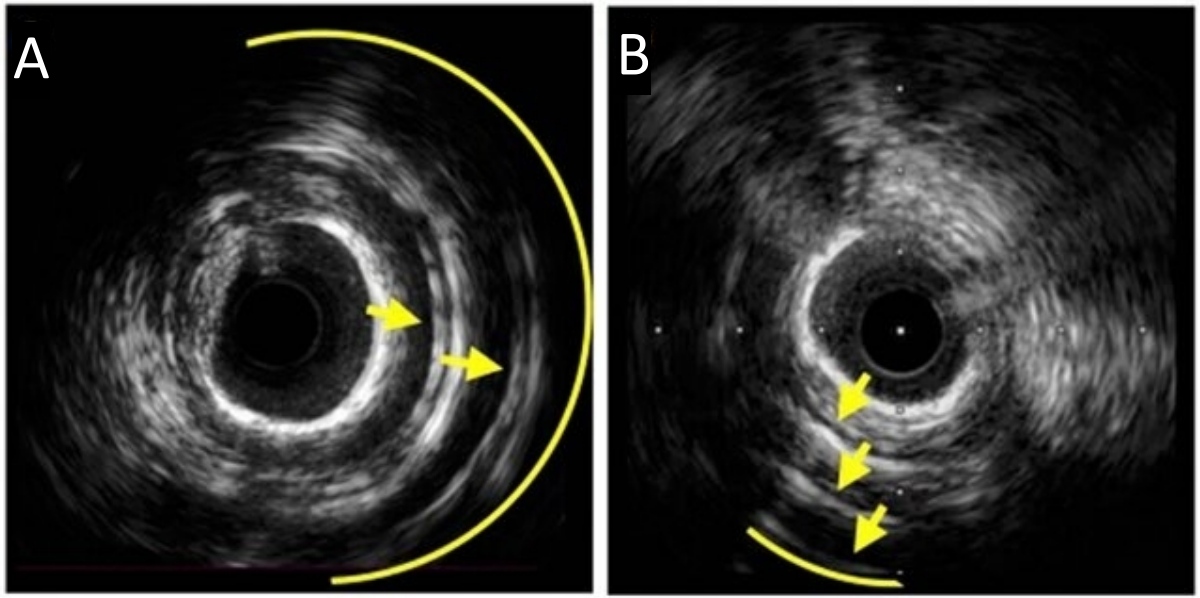
Mater Private Network

Calcium Fractures: IVUS





Reverberations: IVUS



A. A cross-sectional IVUS image showed two lines of reverberations (yellow arrows) with the distribution of nearly two quadrants (yellow arc).

B. There were three arctic lines of reverberations (yellow arrows) with the distribution of less than one quadrant (yellow arc).

Implementation of a Standardized Algorithm for CoronarY CaLcificatiOn with PlaquE Modification using UltraSound Guidance to Improve Procedural and Clinical Outcomes (CYCLOPES)

CYCLOPES Study

↓

500 patients with severe calcification who are planned for percutaneous intervention requiring calcium modification at 25 sites in EU/UK/CH

Aim of the study is to validate a streamlined intravascular imaging-based calcium modification algorithm for the treatment of severely calcified coronary lesions

↓

Minimum stent area (MSA) at the end of the index procedure

Clinical Endpoint: Major adverse cardiac events (MACE) at 1 year

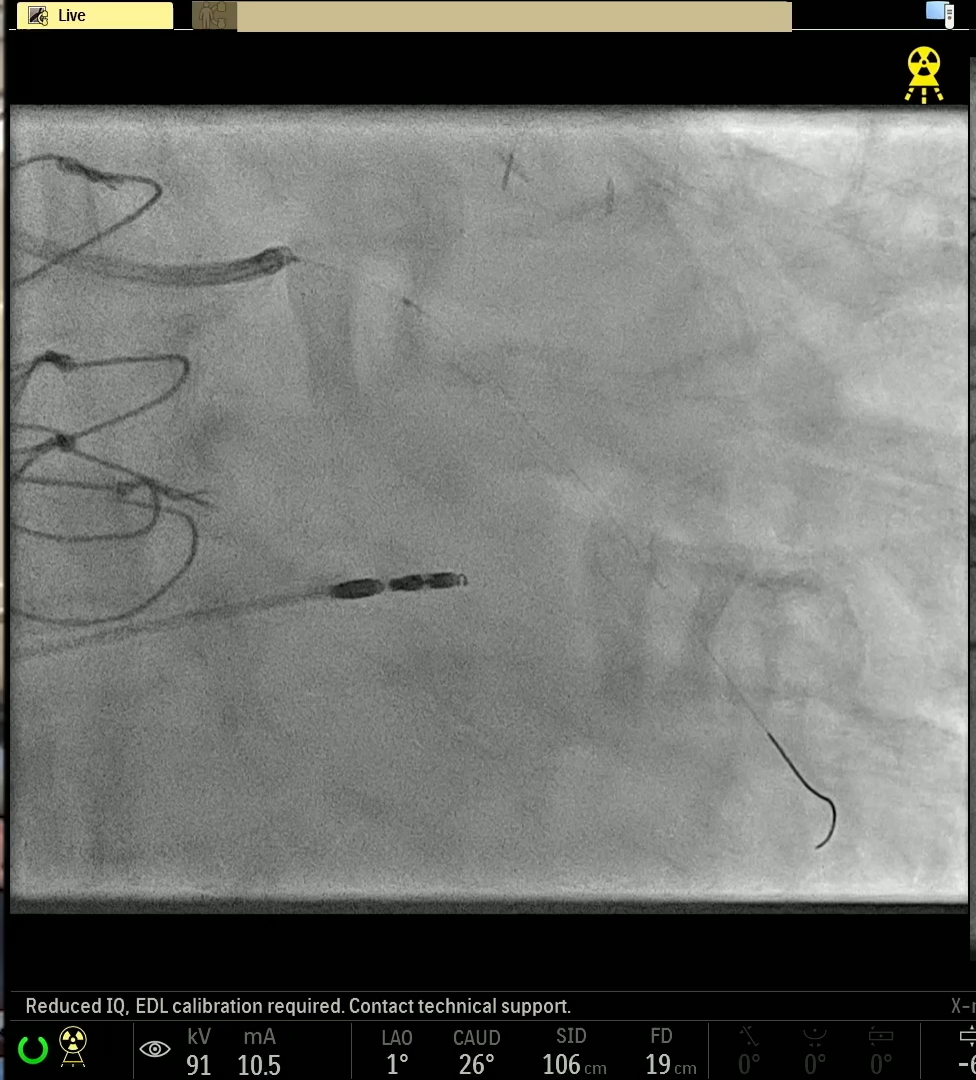
all-cause death, non-fatal myocardial infarction, and unplanned ischemia-driven revascularization

LIAB (Pt 3) from St. George's Hospital - London

James Spratt & Ganeev Malhotra

Sponsored by Boston Scientific


RAMP


Live
Reduced IQ, EDL calibration required. Contact technical support.
kV 91
mA 10.5
LAO 1°
CAUD 26°
SID 106 cm
FD 19 cm
0°
0°
0°

LIAB (Pt 4) from St. George's Hospital - London

James Spratt & Ganeev Malhotra

Sponsored by Boston Scientific

Key learnings

- IVUS-guidance of complex PCI has never been so user-friendly thanks to improved AI-algorithms
- Optimal PCI result in heavily calcified stenoses is warranted when combining experience with superior knowledge of the available tools and techniques
- Tailoring drug-eluting devices in calcified lesion might help simplifying the procedure without compromising on the clinical outcomes

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