

Updated Imaging-Guided ISR PCI 2021

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Disclosure Statement of Financial Interest

I, Do-Yoon Kang, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

In-Stent Restenosis

- Reduction in lumen diameter after PCI
- Angiographic Restenosis (diameter stenosis $\geq 50\%$)
- Clinical Restenosis (requirement for ischemia-driven repeat revasc.)
- ~10% of PCI in US (NCDR registry)
- ~5% of PCI in Korea (IRIS-DES / DEB registry)

Causes of In-Stent Restenosis

Mechanical Factors

- Stent under-expansion
 - Undersized stent, Recoil, Peri-stent heavy calcification
- Stent fracture
- Gap

Tissue Re-growth

- Neointimal hyperplasia
- Neoatherosclerosis

Intravascular Imaging for ISR provides Information of underlying mechanisms



Edge dissection



Neointimal Hyperplasia



Neoatherosclerosis



Stent crush

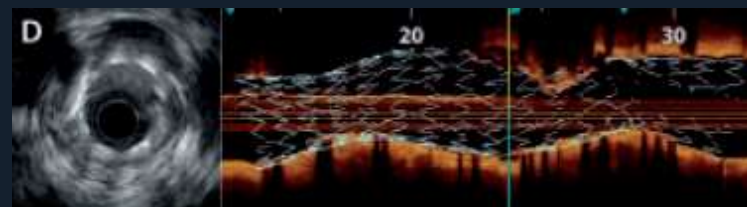
Stent Failure



Late Acquired Malapposition



Evaginations

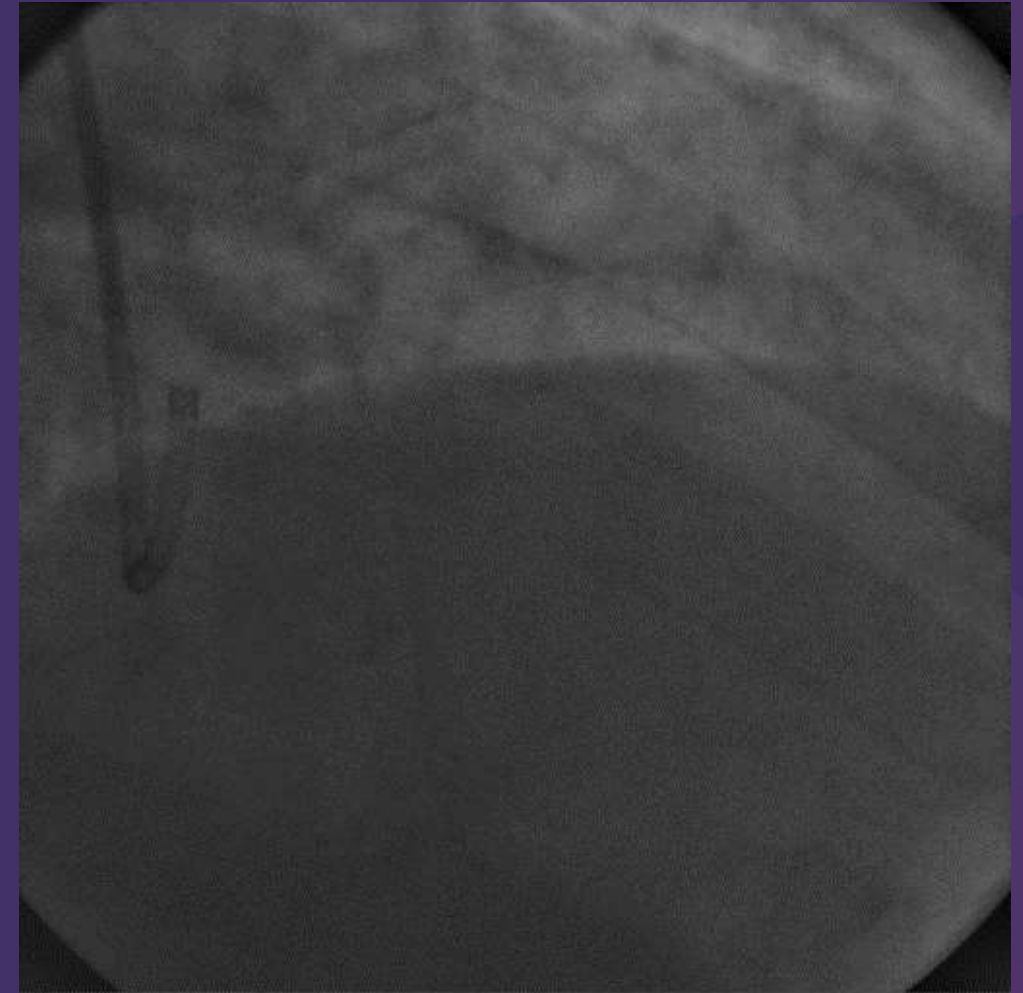
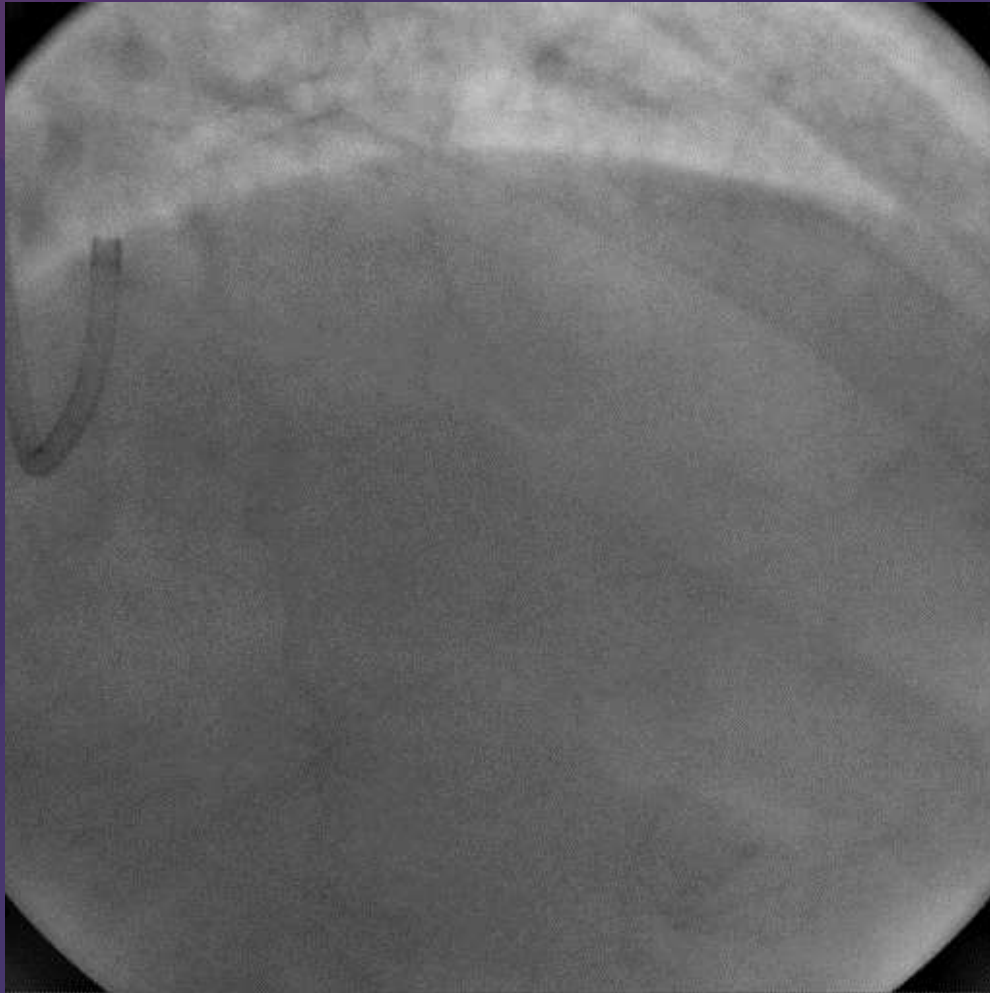


Underexpansion

Case Information

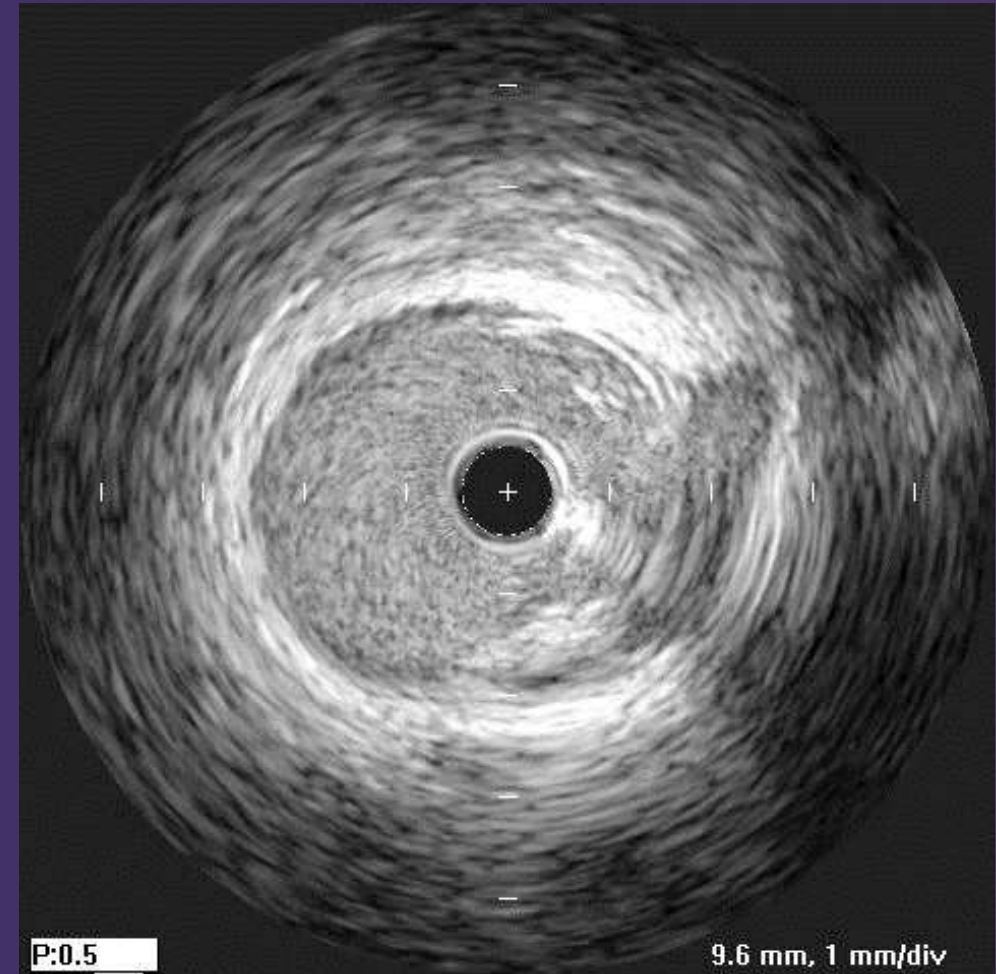
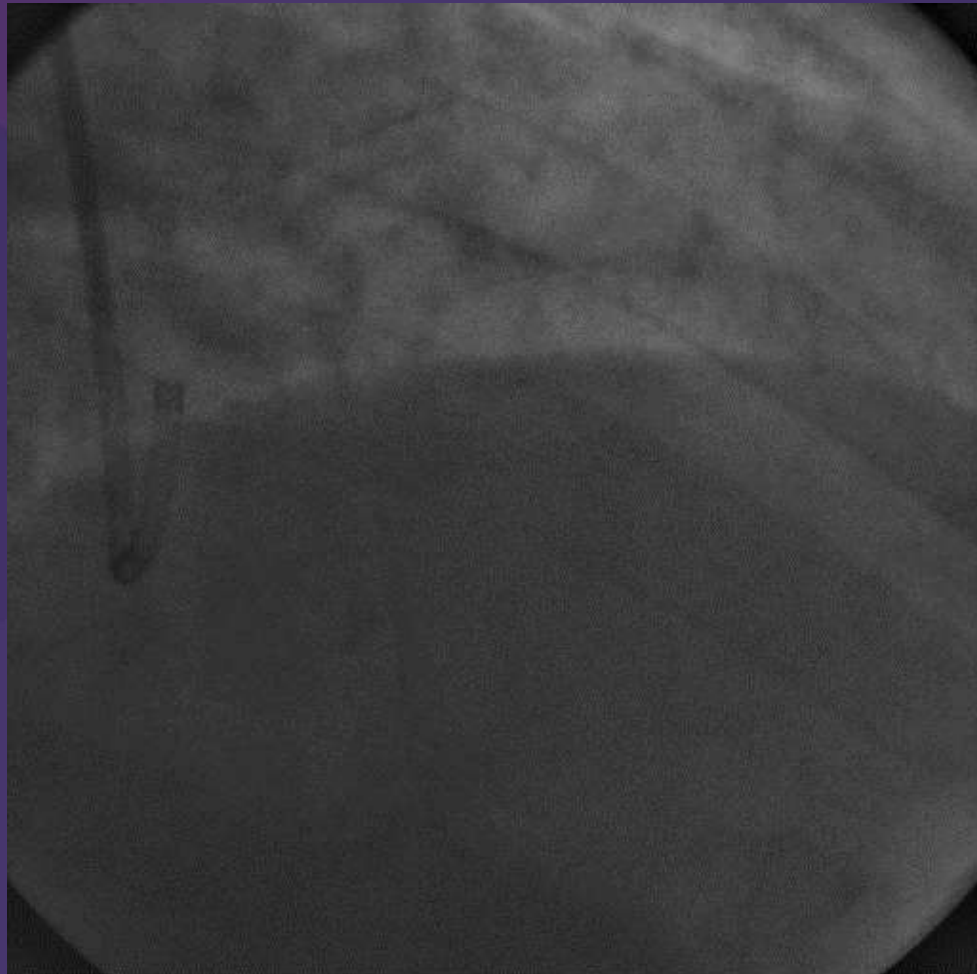
- M/75
- Admitted for aggravated angina for 1 month
- DM, HT on medication
- 3.0 x 24 mm DES implantation at proximal LAD - 13 years ago

CAG & PCI at LAD – 13 Years ago



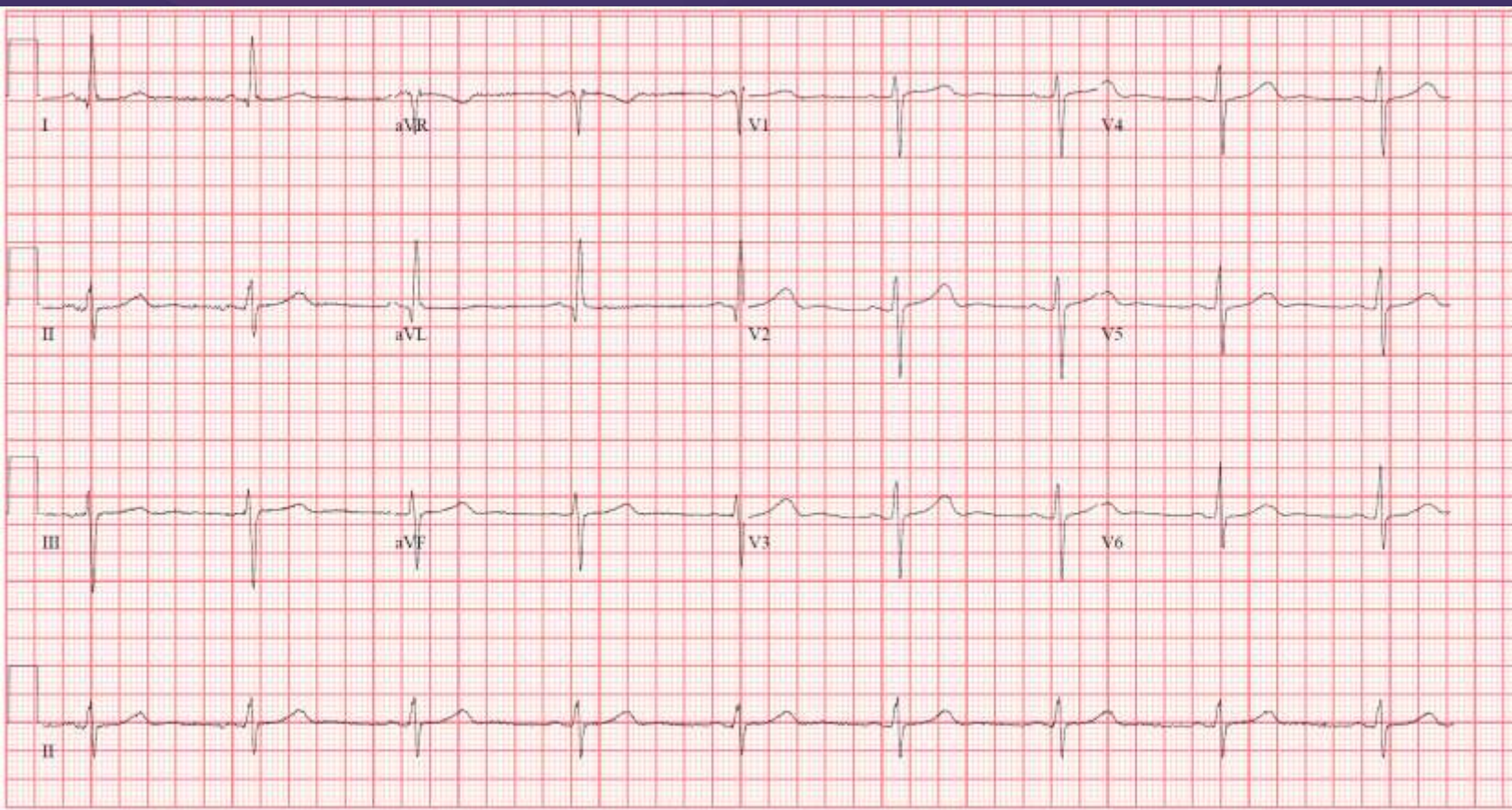
3.0 x 24 mm DES upto 18 atm (3.3 mm)

PCI at LAD 13 Years ago – Final Angio & IVUS

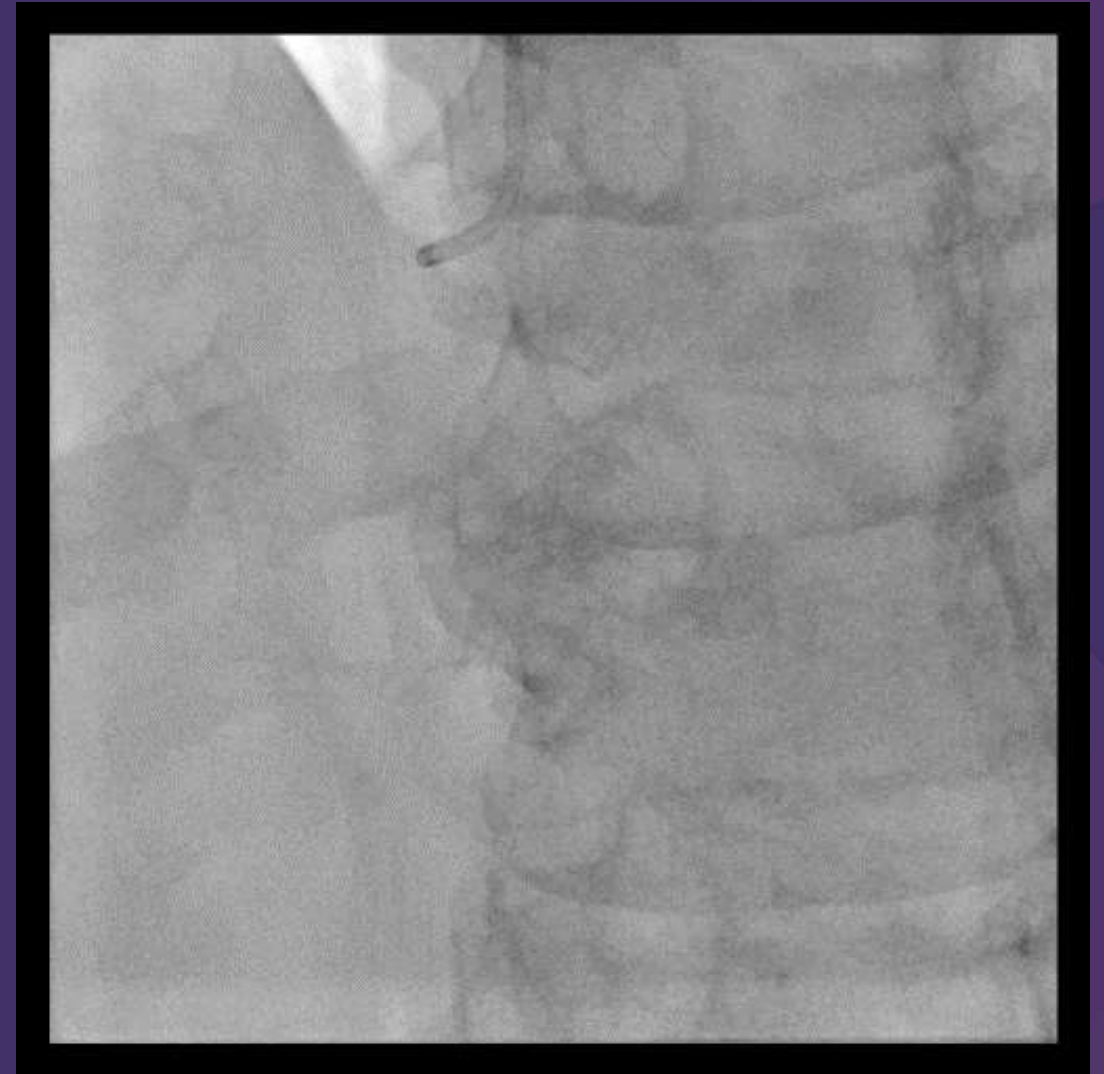
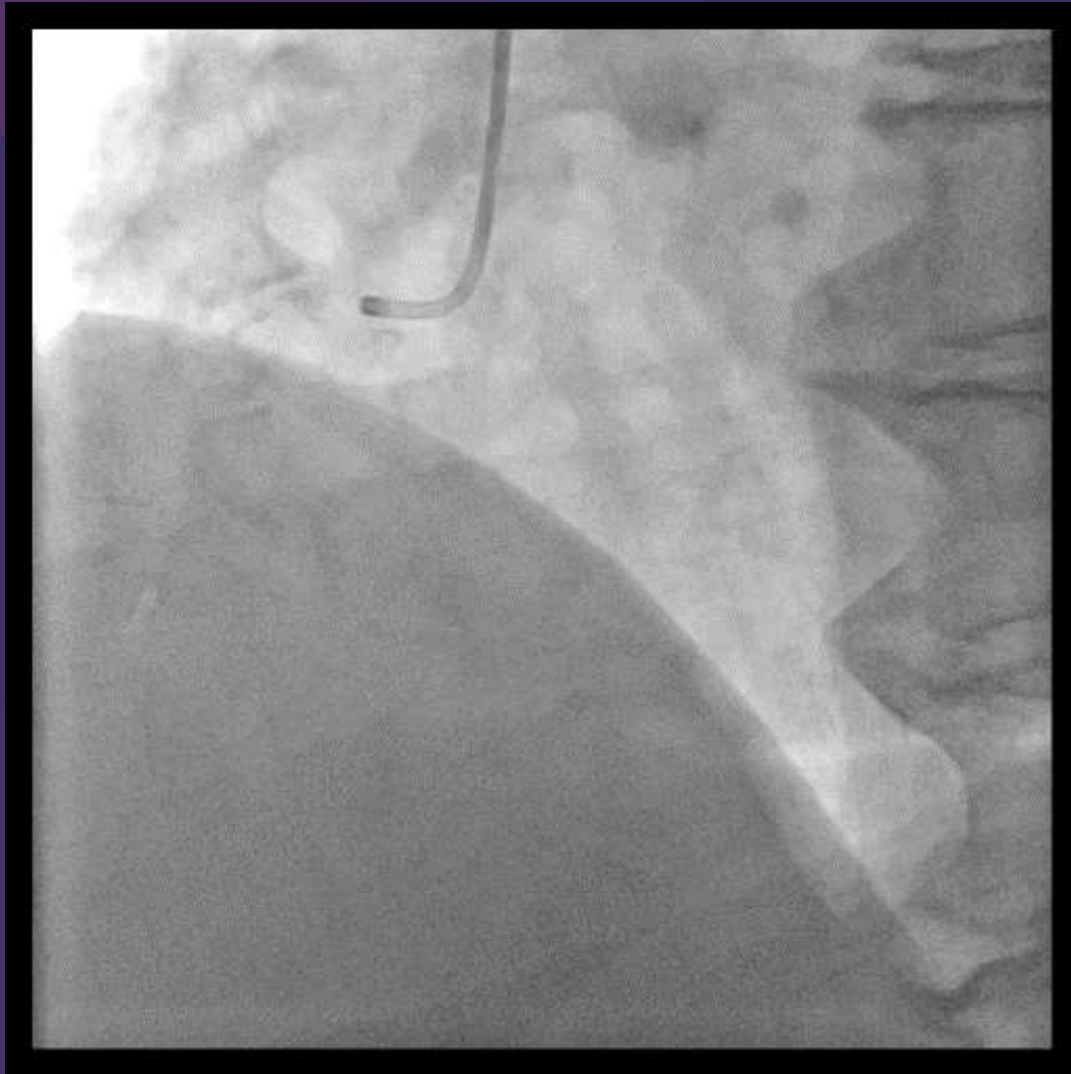


M/75 with Angina

- TTE : Normal LV size and systolic function (EF 60%)



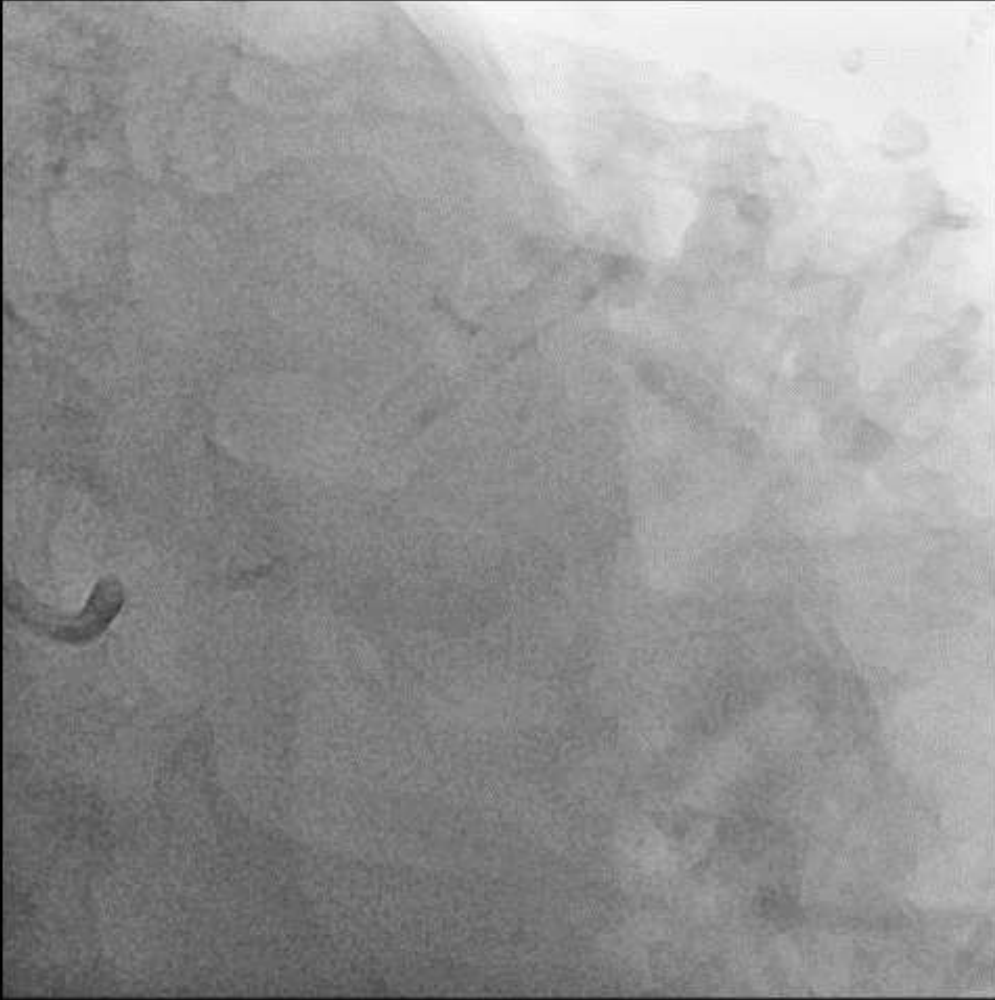
CAG



CAG



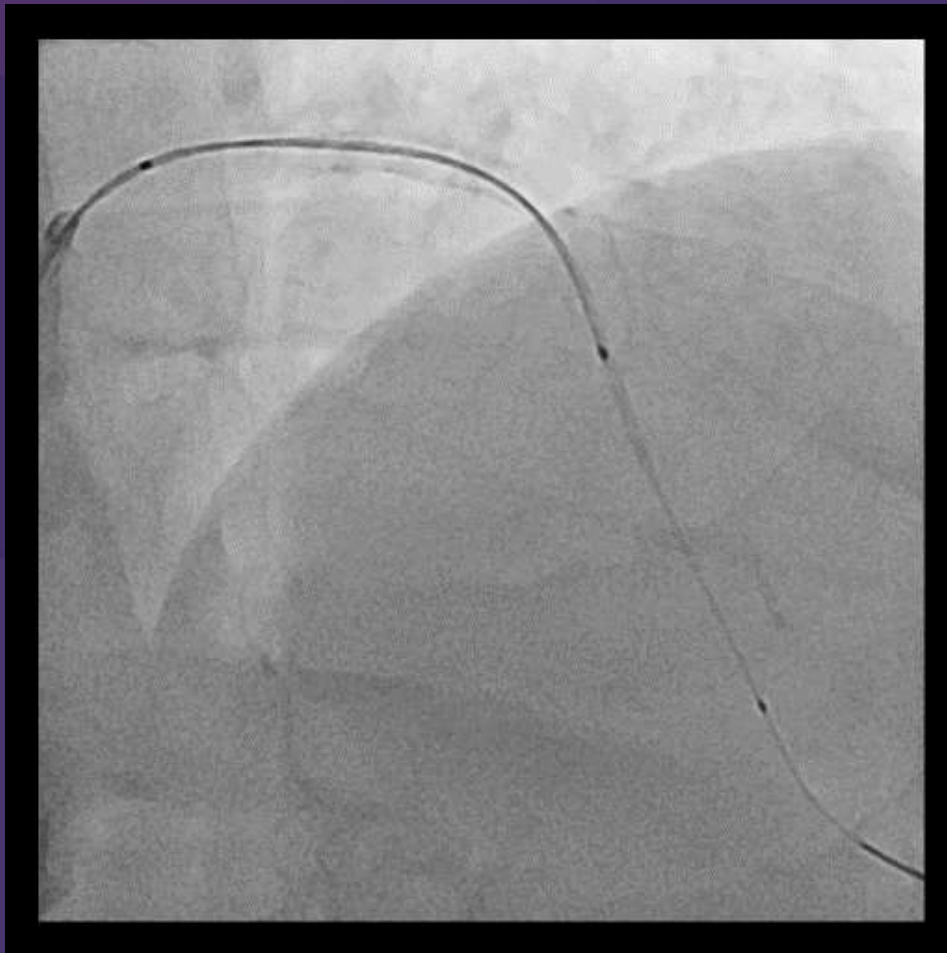
PCI at LAD ISR



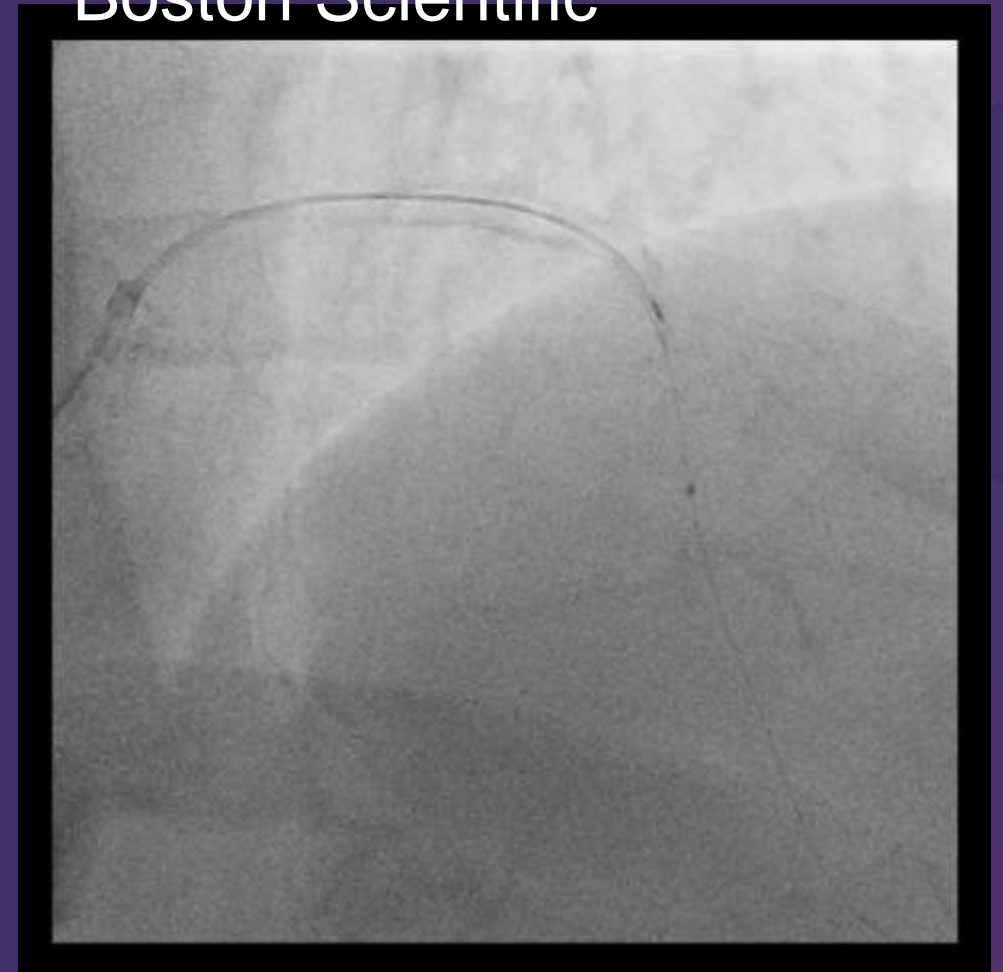
FFR 0.74

Baseline OCT / IVUS

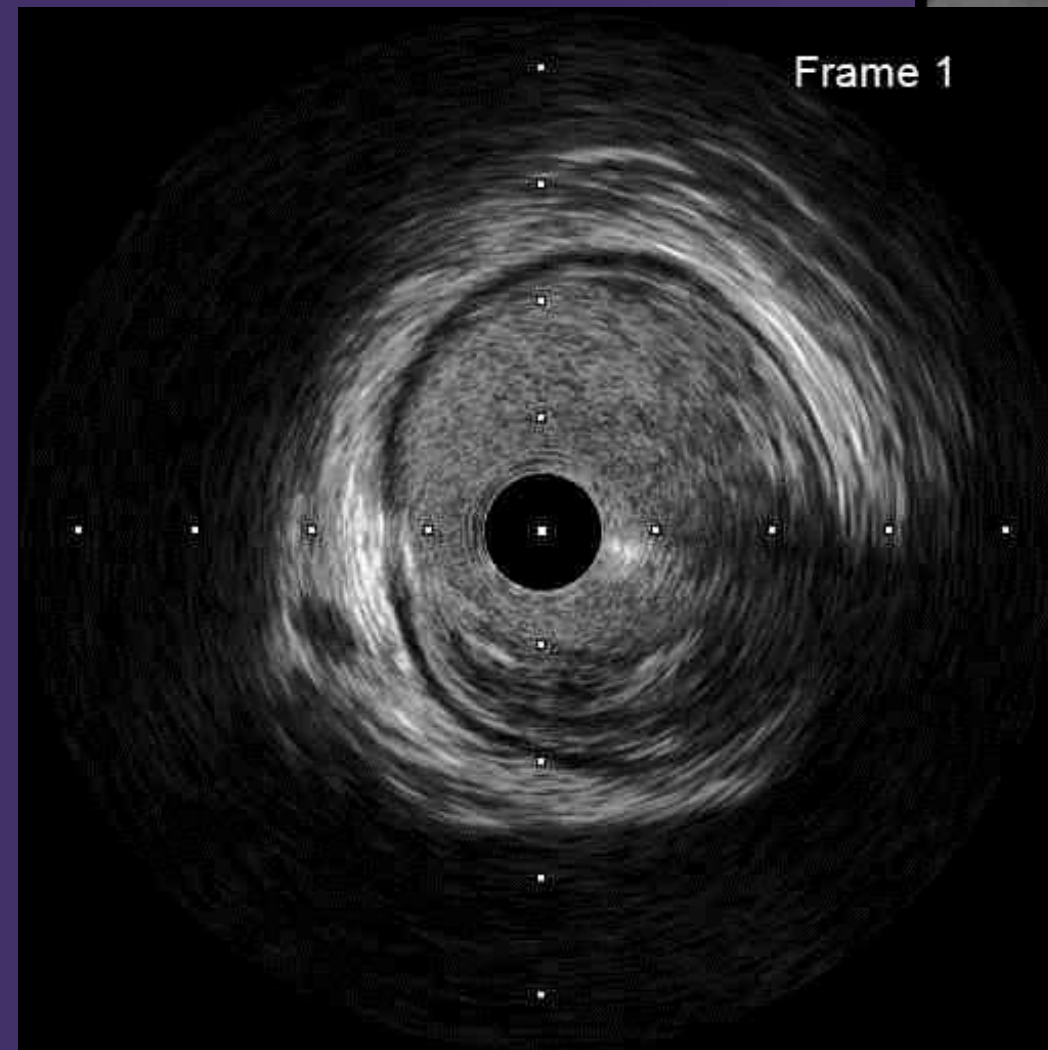
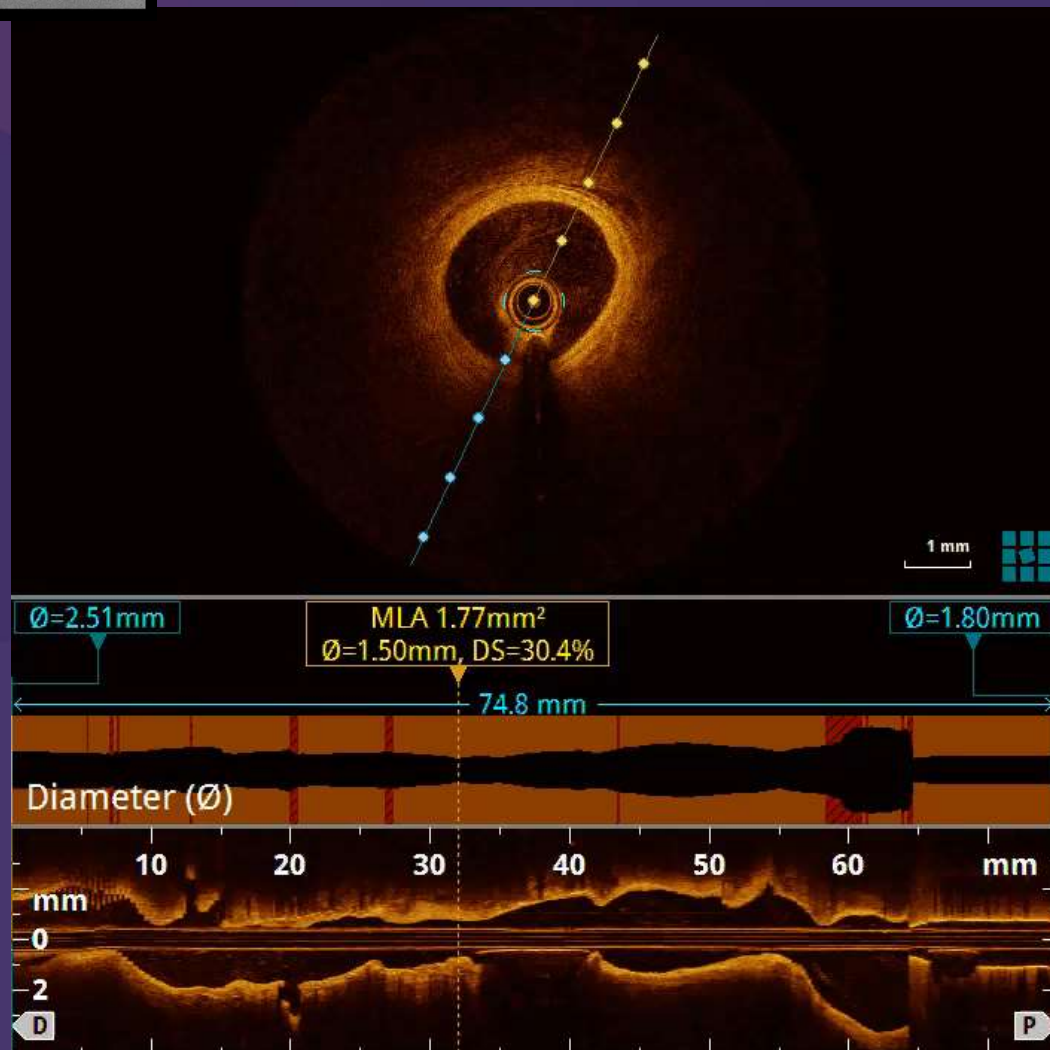
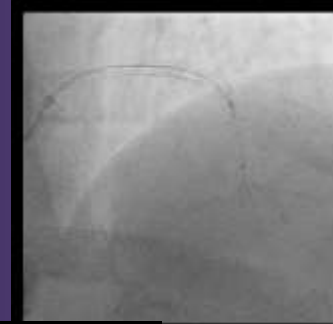
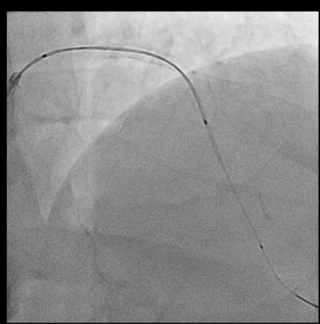
OCT, OPTIS™, Abbott



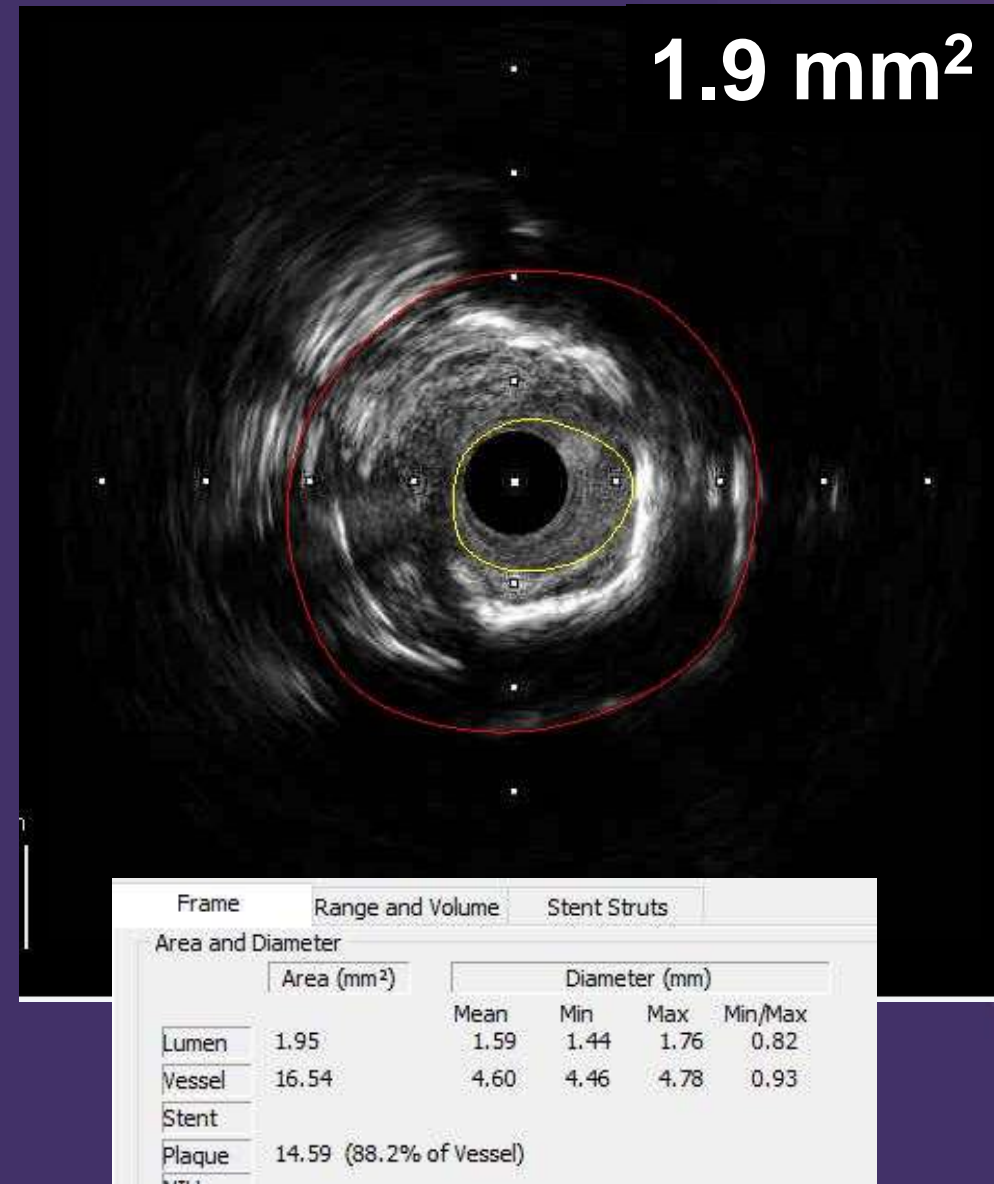
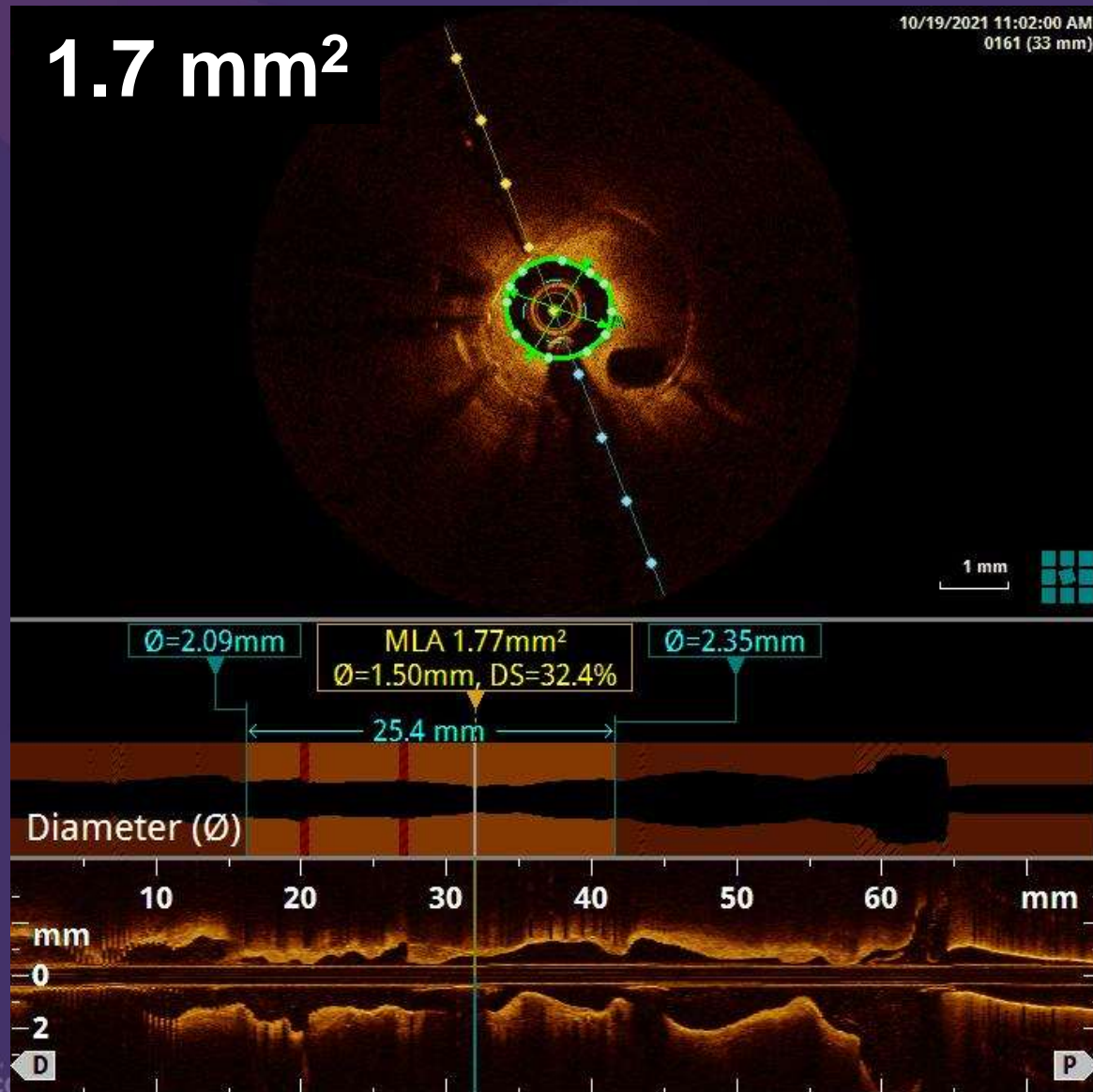
HD-IVUS, OPTICROSS™, Boston Scientific



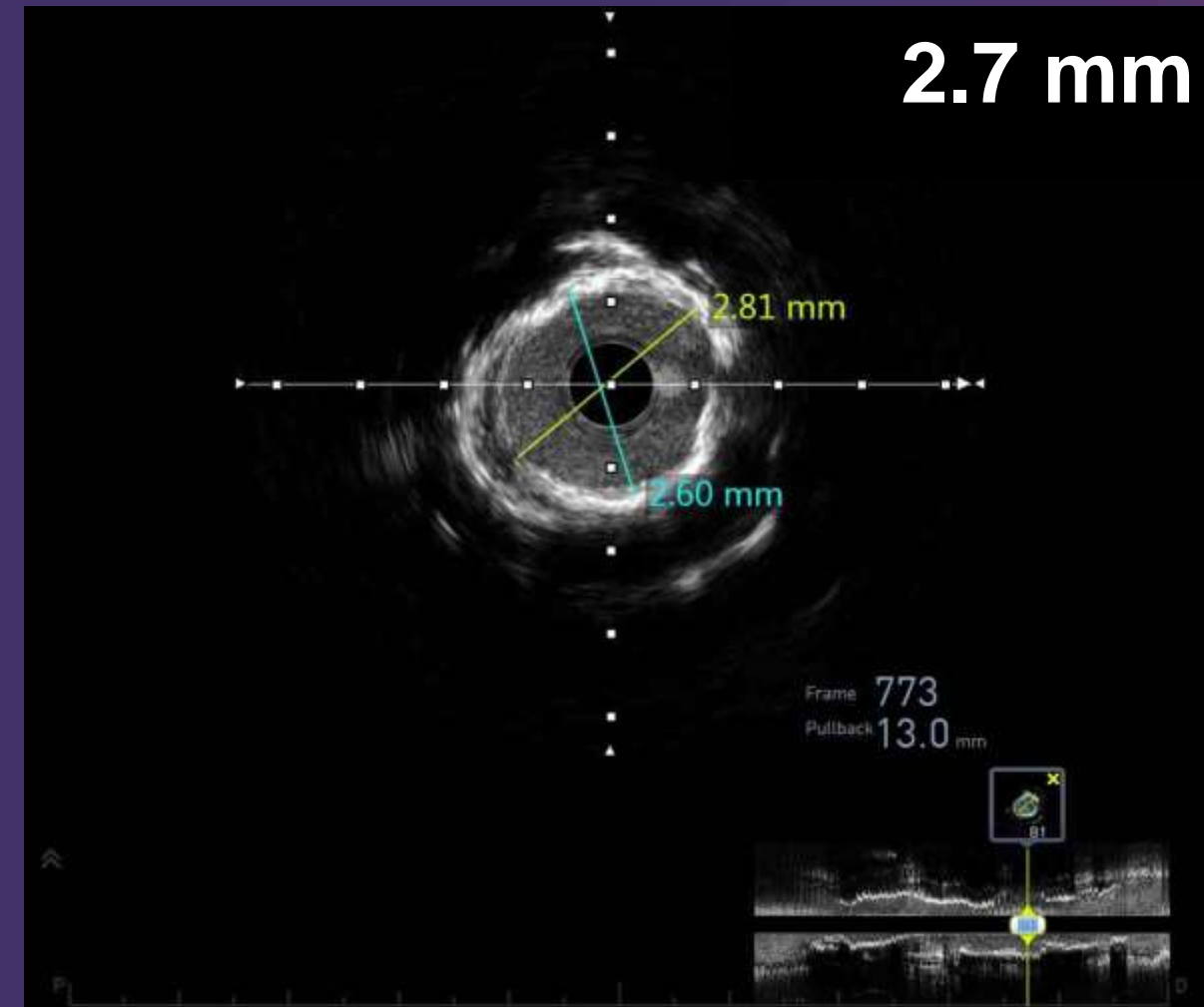
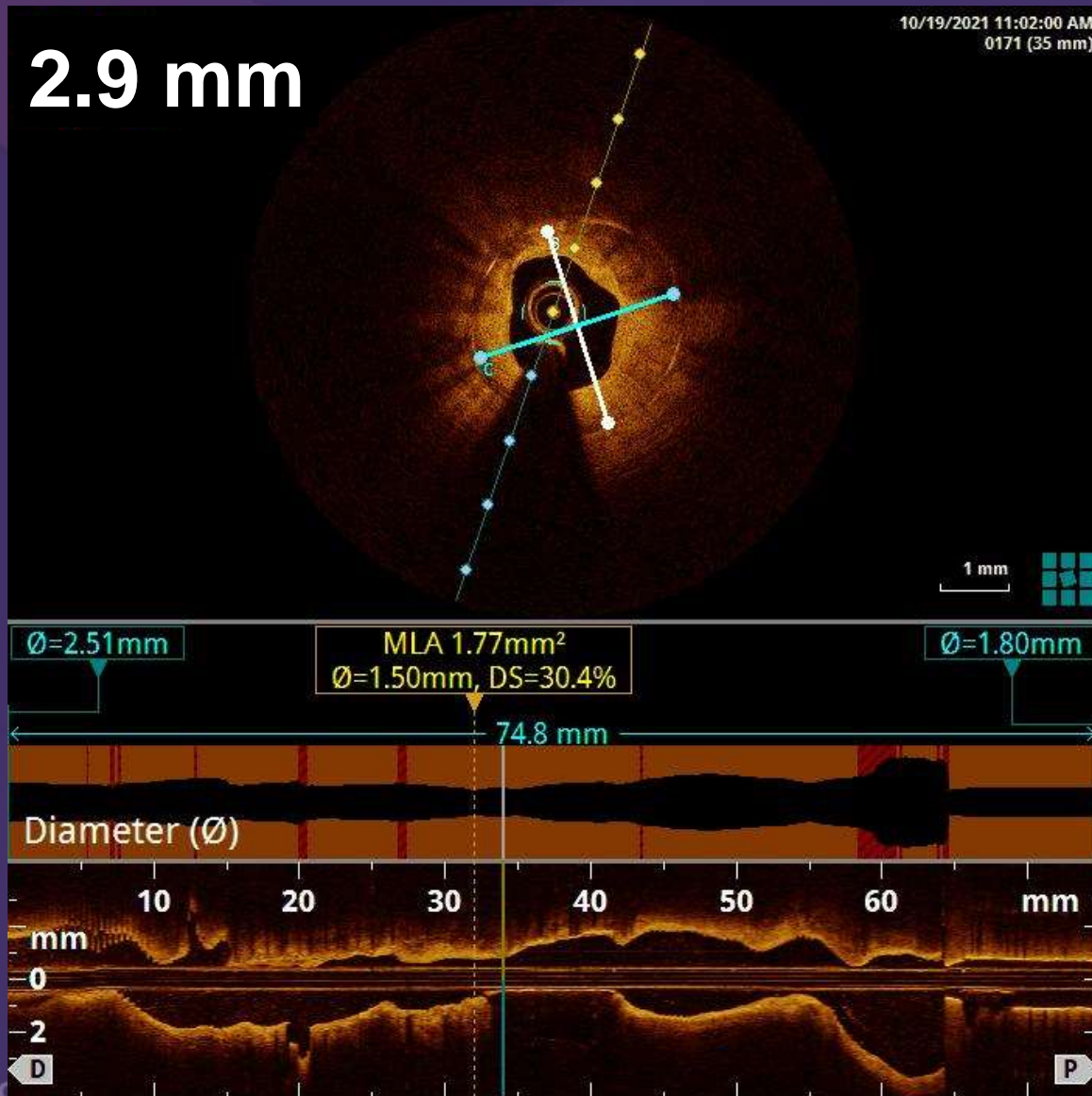
Baseline OCT / IVUS



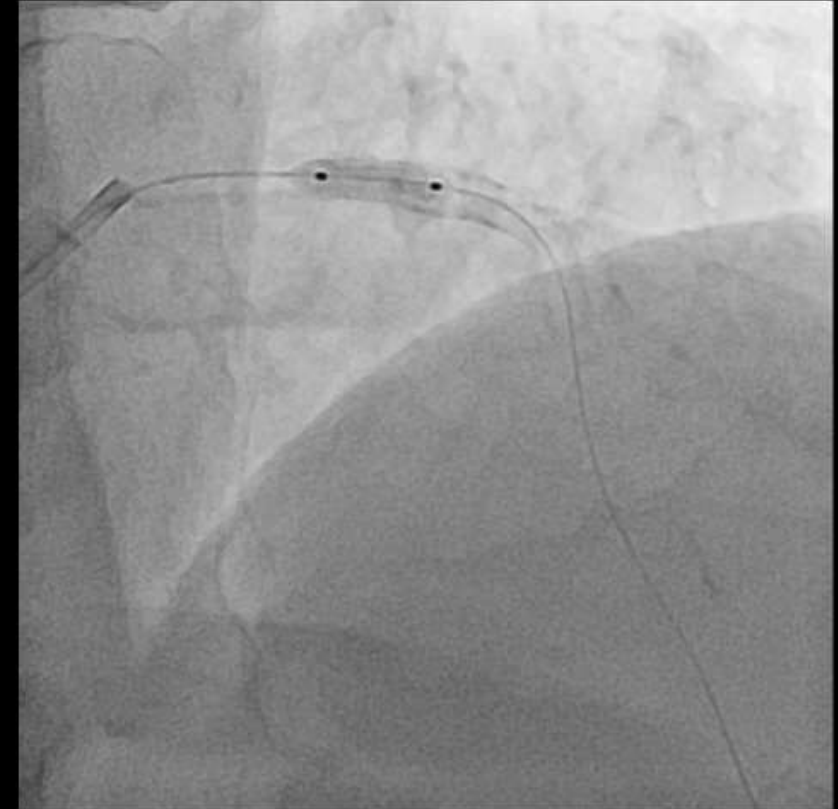
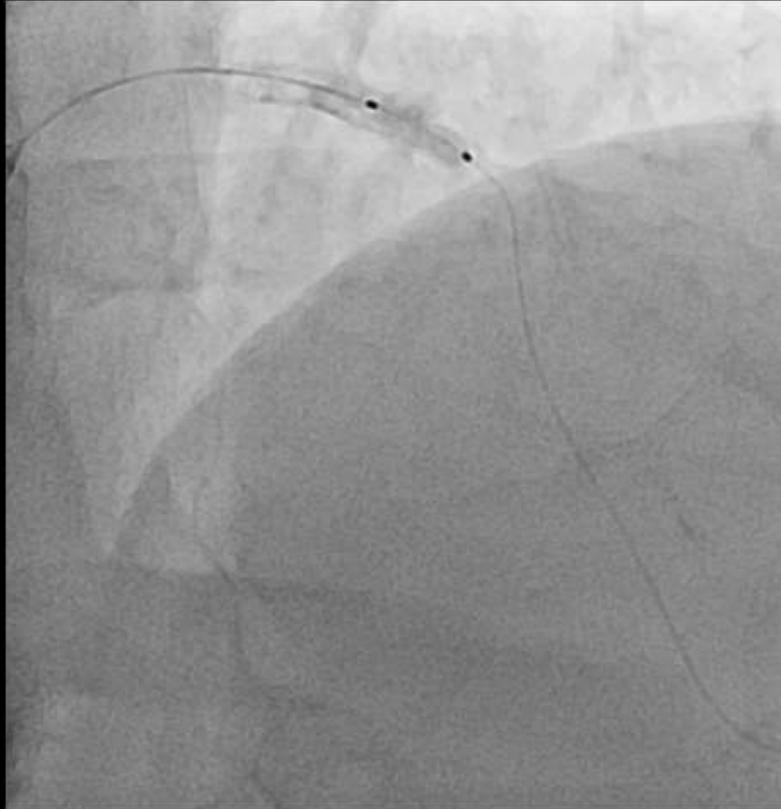
ISR with Neoatherosclerosis



ISR with Under-expansion

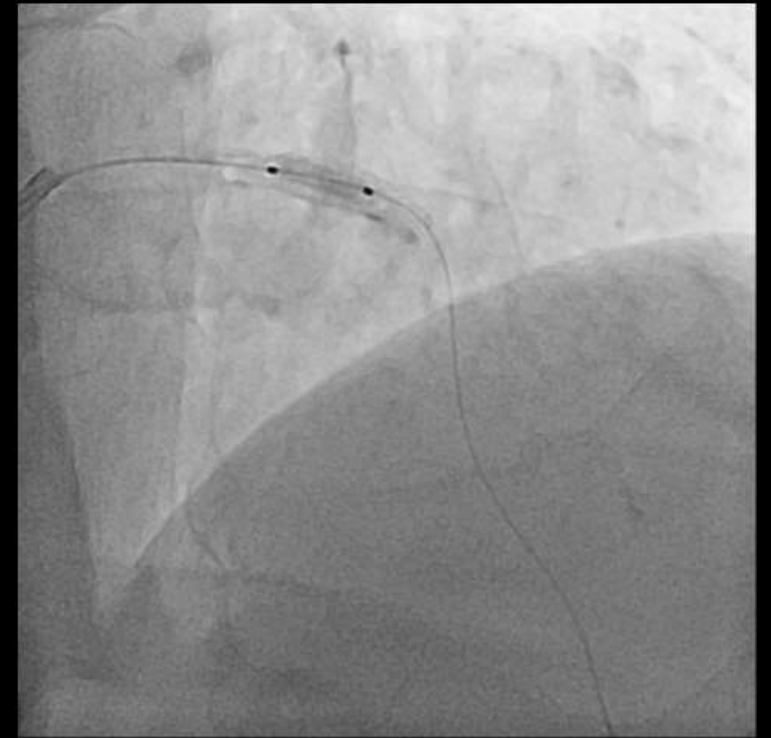
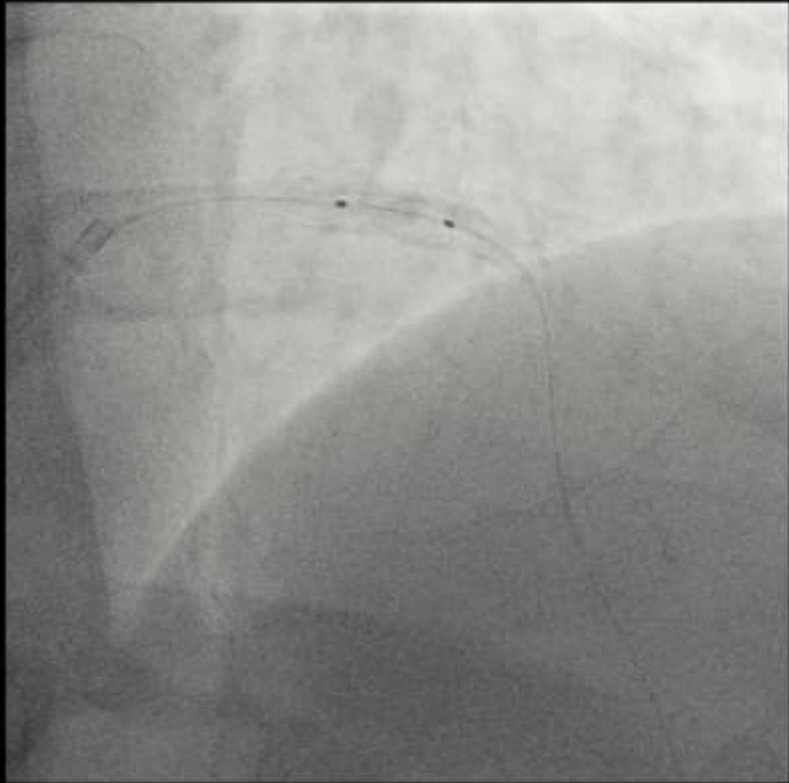


Cutting Balloon



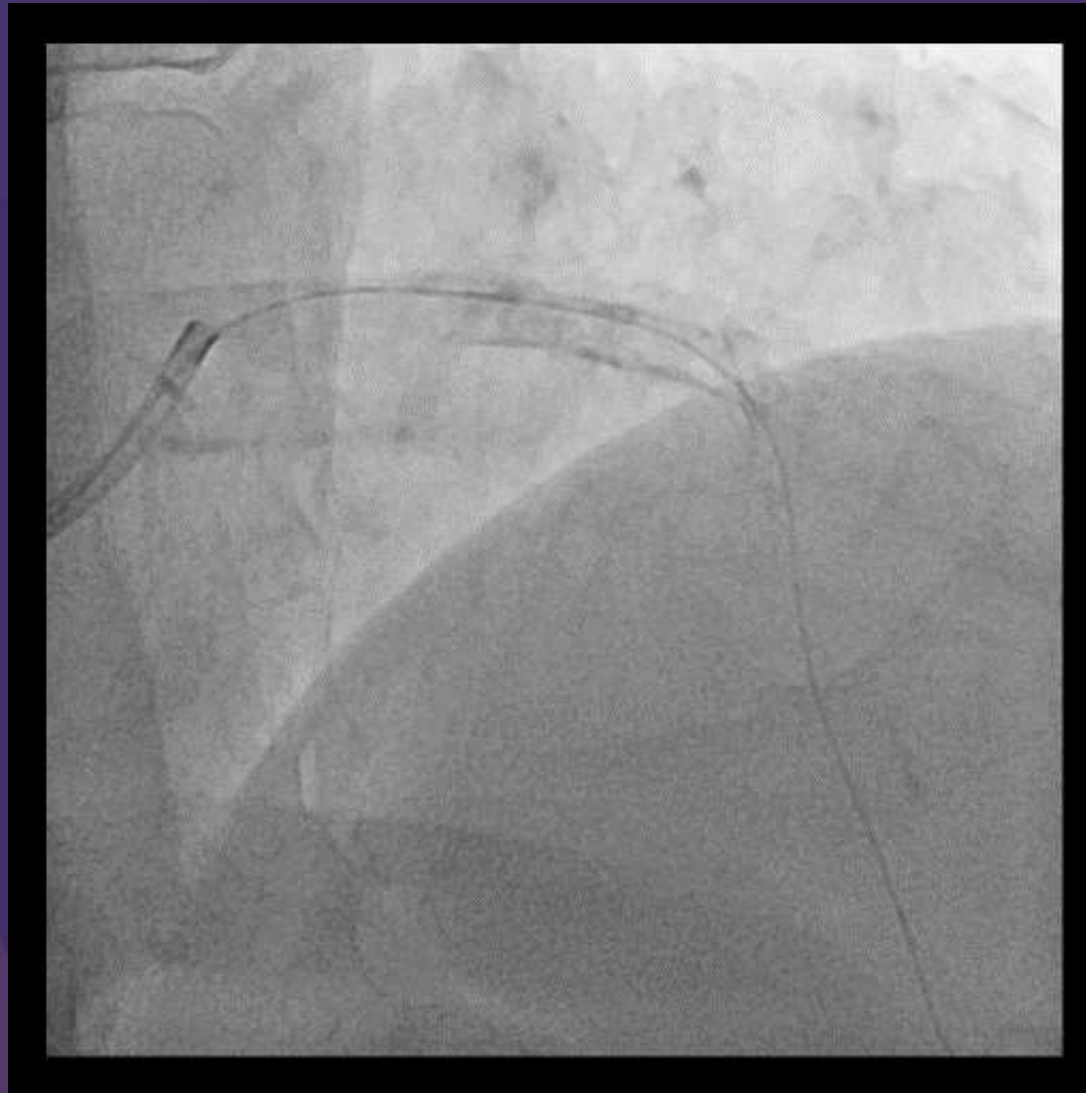
Flextome Cutting balloon 3 x 10 mm upto 20 atm

Cutting Balloon

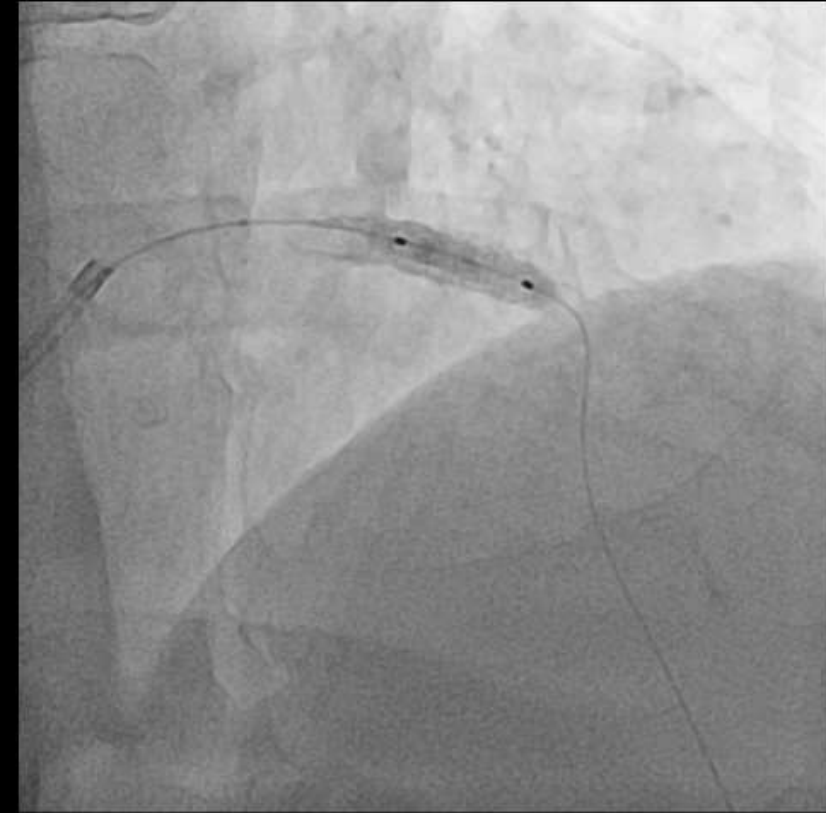
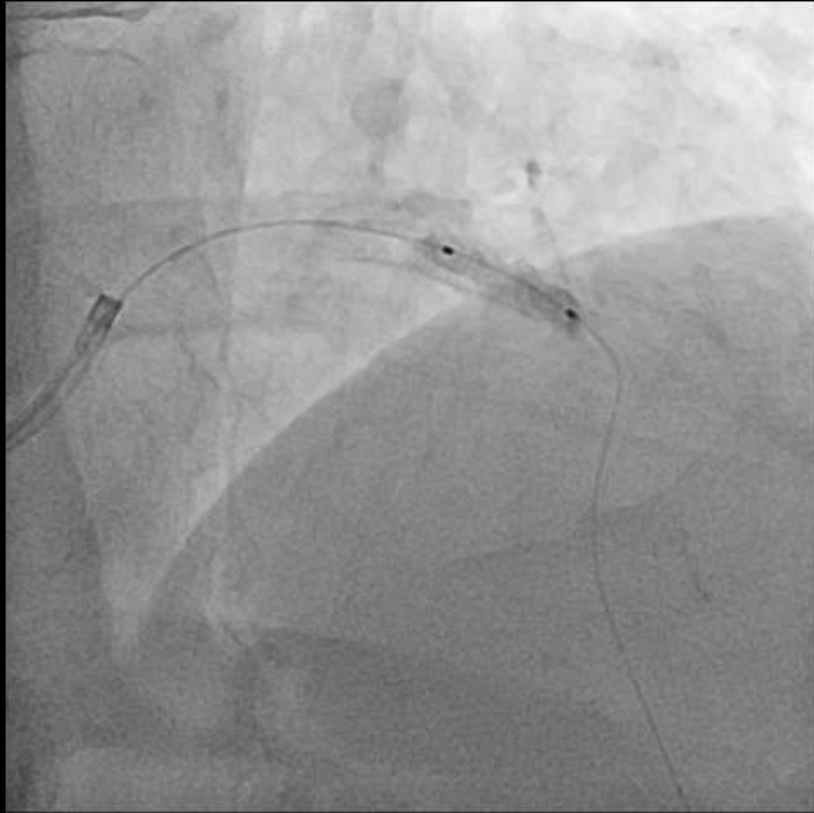


Again & again...

After Cutting Balloon



Non-Compliant 3.5 x 15 mm Balloon upto 26 atm



Then, How to Treat?

DCB vs DES, Which is Better?

: Meta-analyses comparing DCB vs DES

Percutaneous coronary intervention treatment of in-stent restenosis: a

George C M Siontis, Giulio G Stefanini, Dimitris Mavridis, Konstantinos C Siontis, Fe Adnan Kastrati, Bernhard Meier, Georgia Salanti, Peter Juni, Stephan Windecker

	EES	DCB	SES	PES	VBT
EES	99.6 (0-98)	-9.0% (-15.8 to -2.2)	-9.4% (-17.4 to -1.4)	-10.2% (-18.4 to -2.0)	-19.2% (-28.2 to -10.2)
DCB	"	73.7 (0-00)	-0.2% (-6.2 to 5.6)	-1.2% (-6.4 to 4.2)	-10.2% (-17.0 to -3.4)
SES	"	"	72.8 (0-01)	-0.8% (-6.4 to 4.6)	-10.0% (-15.4 to -4.6)
PES	"	"	"	67.7 (0-01)	-9.0% (-15.6 to -2.4)
VBT	"	"	"	"	38.9 (0-00)
BMS	"	"	"	"	"
BA	"	"	"	"	"
ROTA	"	"	"	"	"

Estimates are expressed as differences in percent diameter stenosis, with 95% CIs in parentheses; estim appendix. Negative differences show that the intervention listed in the left column is more beneficial th efficacy ranking. Surface under the cumulative ranking curve values are given in the diagonal, with the surface under the cumulative ranking curve value, the better the treatment. EES=everolimus-eluting stents; PES=paclitaxel-eluting stents; VBT=vascular brachytherapy; BMS=bare metal stents; BA=balloon angioplasty; ROTA=rotational atherectomy.

Table 2: Estimated differences of the effect of interventions on percent diameter stenosis

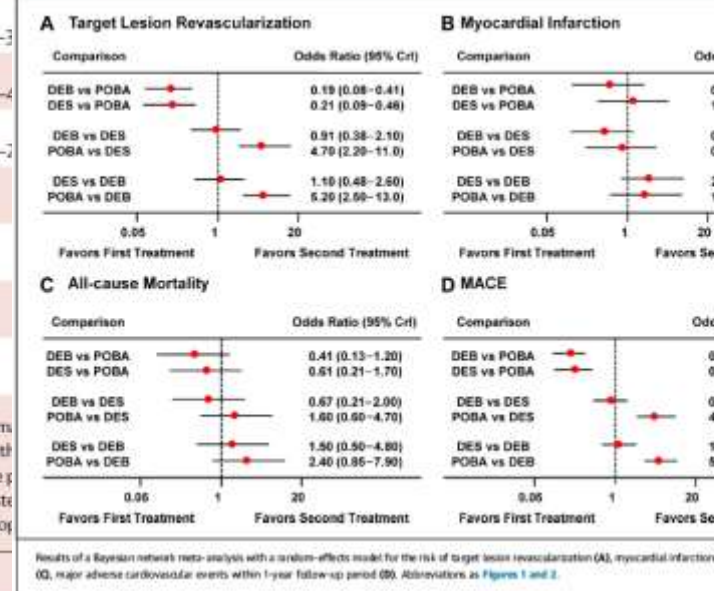
Siontis GC et al., Lancet, 2015

Comparison Among Drug-Eluting Balloons, Drug-Eluting Stent, and Plain Balloon Angioplasty for the Treatment of In-Stent Restenosis

A Network Meta-analysis of 11 Randomized, Controlled Trials

Joo Myung Lee, MD, MPH,* Jonghanne Park, MD,* Jeehoon Kang, MD,* Ki-Hyun Jeon, MD,* Ji Sang Eun Lee, MD, PhD,* Jung-Kyu Han, MD, PhD,* Hack-Lyoung Kim, MD, PhD,* Han-Mo Yan Kyung Woo Park, MD, PhD,* Hyun-Jae Kang, MD, PhD,* Bon-Kwon Koo, MD, PhD,* Hyo-Soo Ki

FIGURE 1 Results of Bayesian Network Meta-analysis for 1-Year Rates of Clinical Outcomes in Random Effects Model



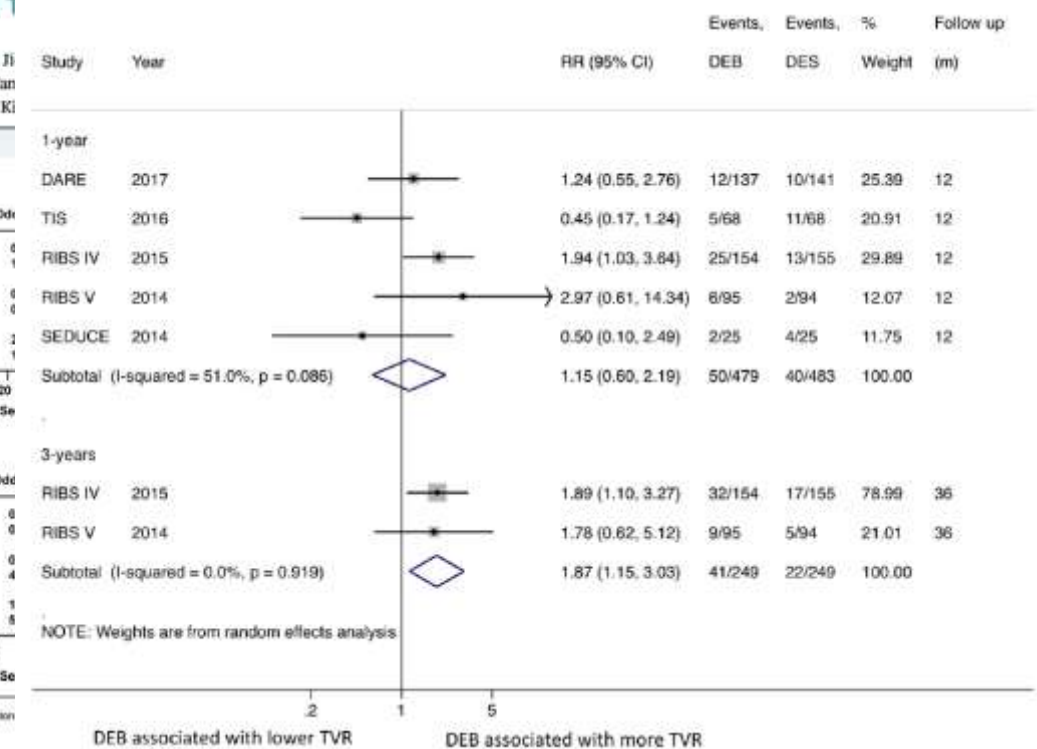
Results of a Bayesian network meta-analysis with a random-effects model for the risk of target lesion revascularization (A), myocardial infarction (B), major adverse cardiovascular events within 1-year follow-up period (C). Abbreviations as Figures 1 and 2.

Lee et al., JACC CV Interv. 2015

Drug-eluting balloons versus everolimus-eluting stents for in-stent restenosis: A meta-analysis of randomized trials*

Islam Y. Elgendy ^{a,*}, Ahmed N. Mahmoud ^a, Akram Y. Elgendy ^a, Mohammad K. Mojadidi ^a, Ayman Elbadawi ^b, Parham Eshtehardi ^c, María José Pérez-Vizcayno ^d, Siddharth A. Wayangankar ^a, Hani Jneid ^e, R. David Anderson ^a, Fernando Alfonso ^f

^a Division of Cardiovascular Medicine, Department of Medicine, University of Florida, Gainesville, FL, United States of America
^b Department of Medicine, Rochester General Hospital, Rochester, NY, United States of America

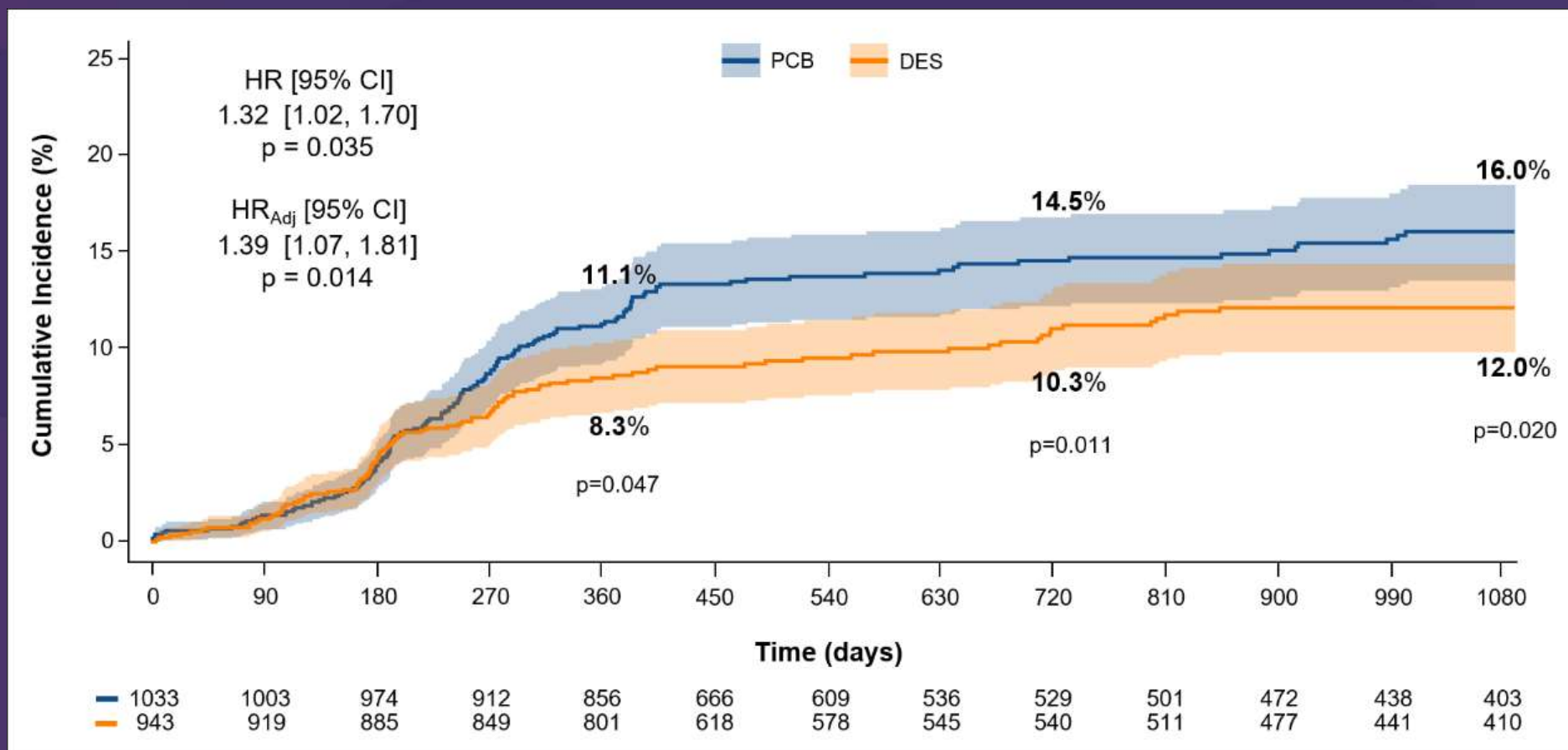


Elgendy IY, Alfonso F et al., Cardiovasc Revasc Med. 2018

DCB vs DES, Which is Better?

: Patient-level Pooled analysis of 10 RCTs - DAEDALUS study

Target Lesion Revascularization of ISR

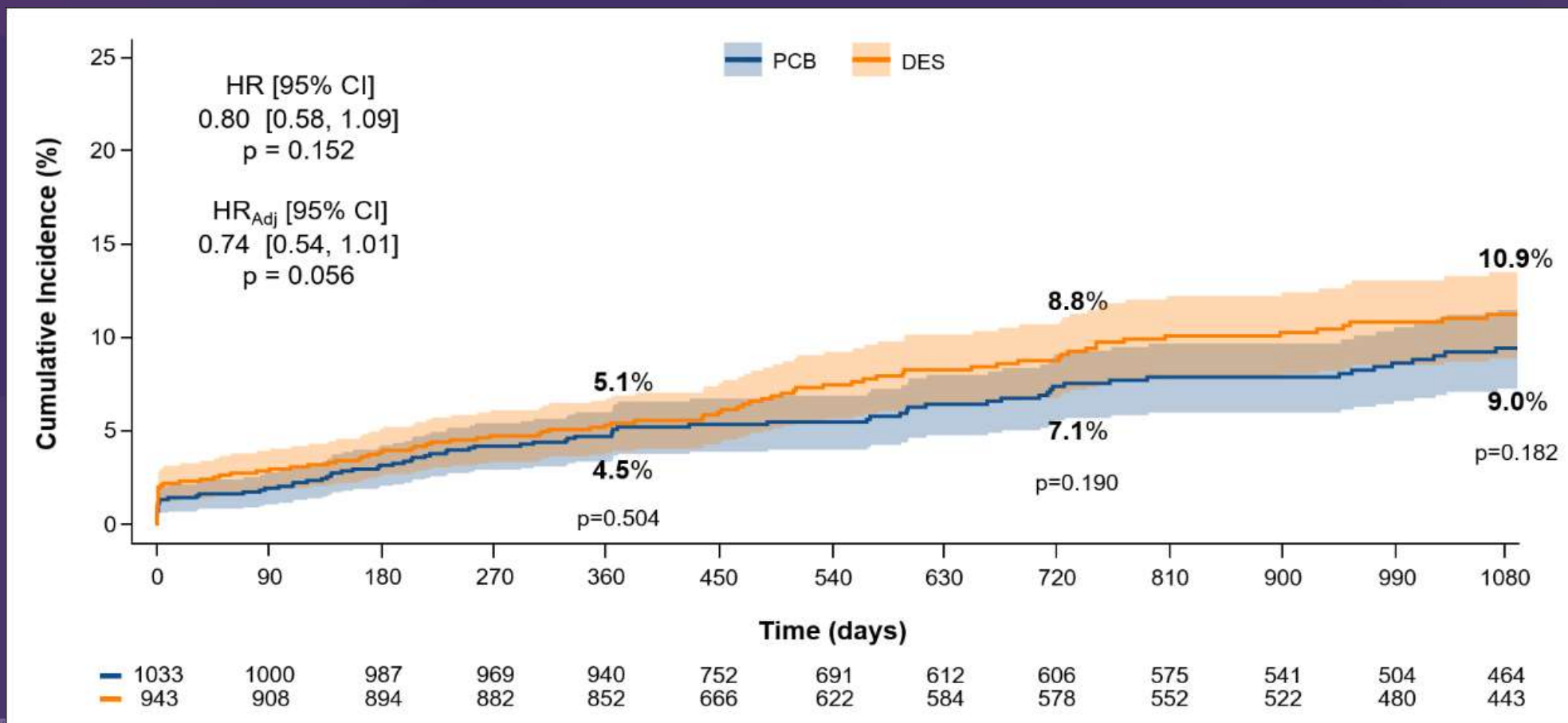


Giacoppo D et al., Eur Heart J. 2020;41(38):3715-3728.

DCB vs DES, Which is Better?

: Patient-level Pooled analysis of 10 RCTs - DAEDALUS study

Composite of all-cause death, MI, or target lesion thrombosis



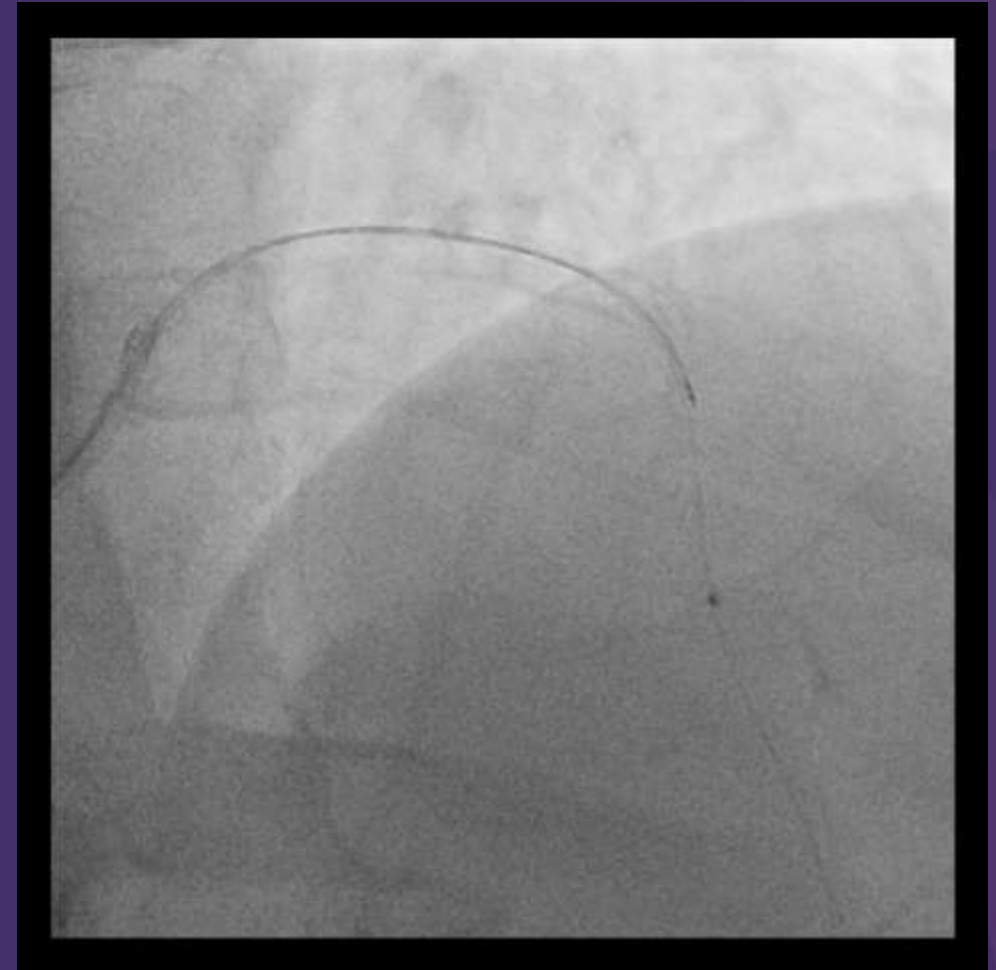
DCB vs DES, Which is Better?

- Data consistently showed,
 - Slightly better angiographic outcomes in DES,
 - More TLR in DCB,
 - Comparable hard outcomes (death, MI, thrombosis).

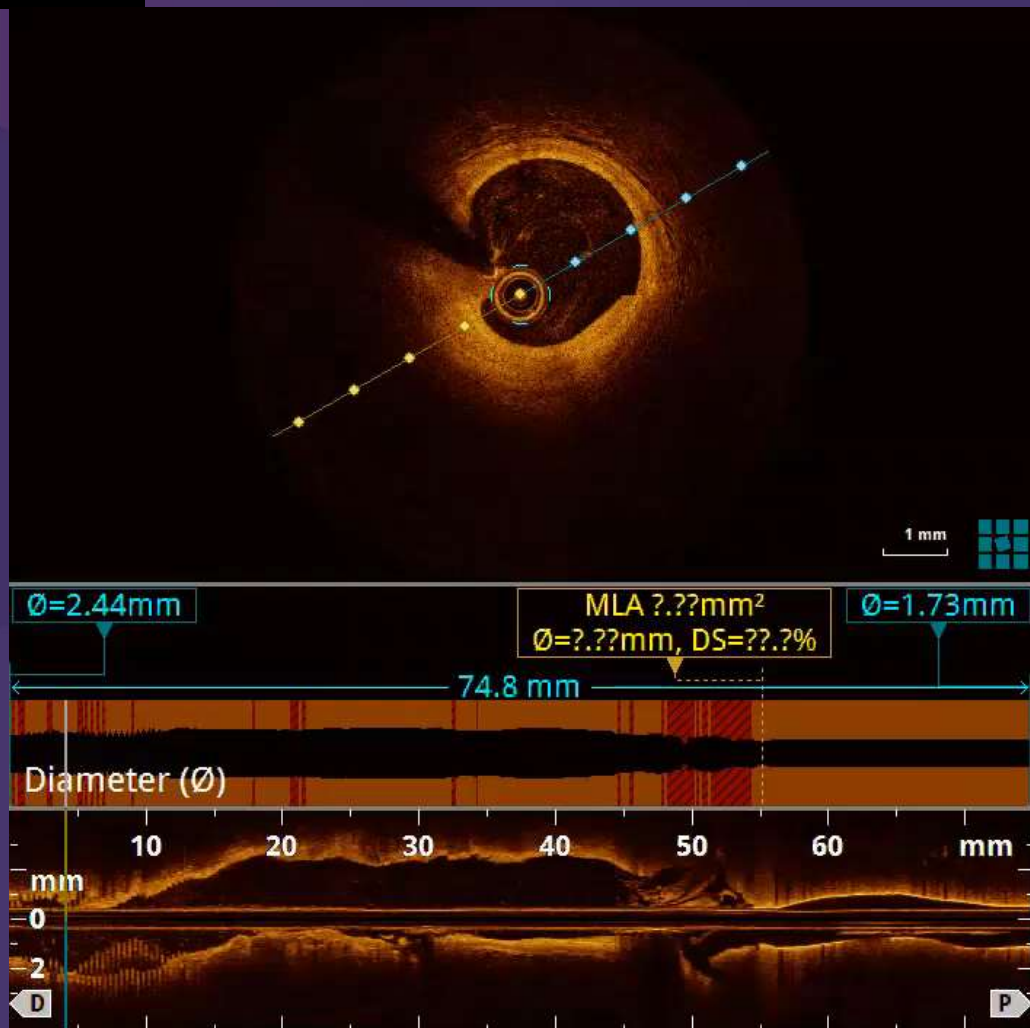
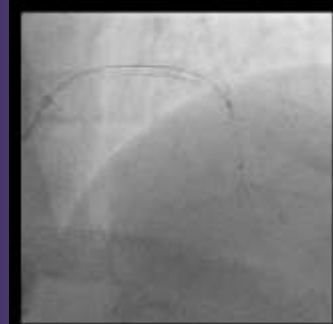
DCB (Paclitaxel) 3.5 x 25 mm at 8 atm for 1 minute



Final OCT / IVUS



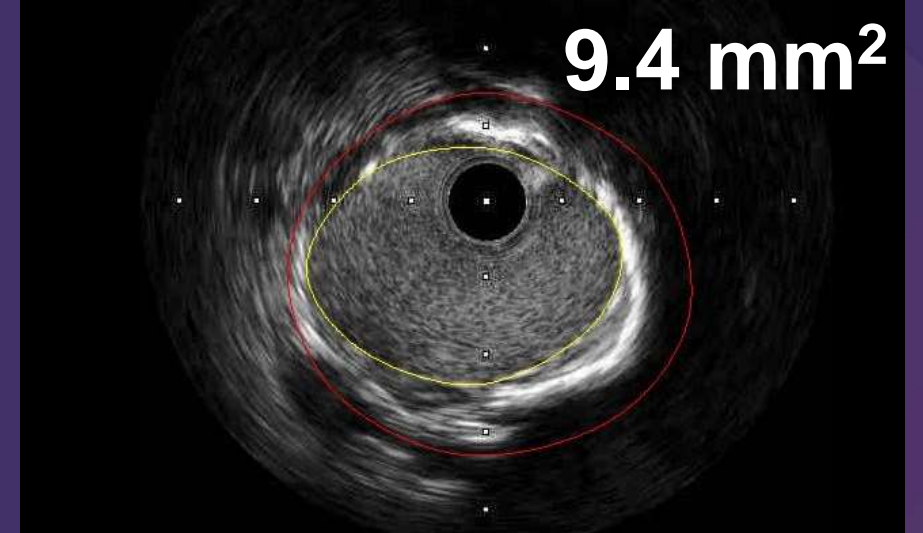
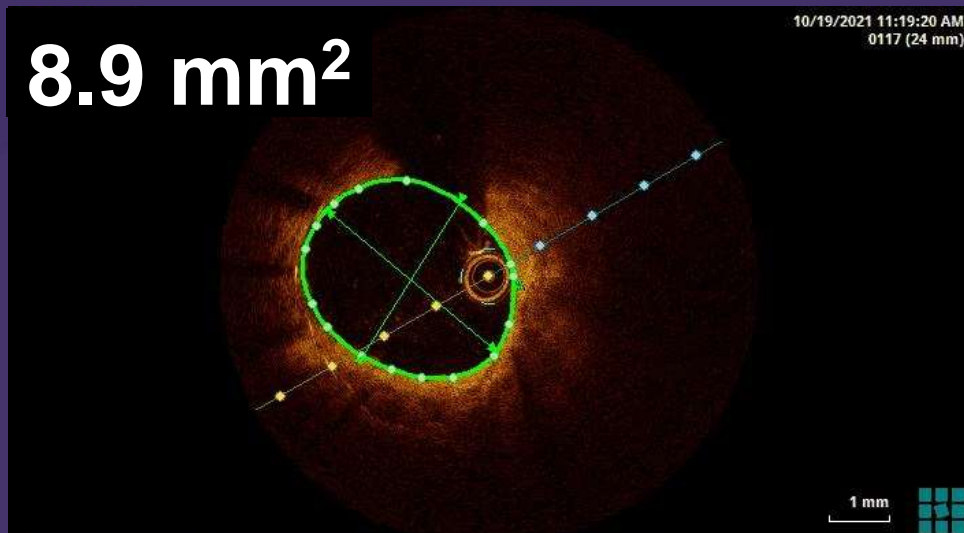
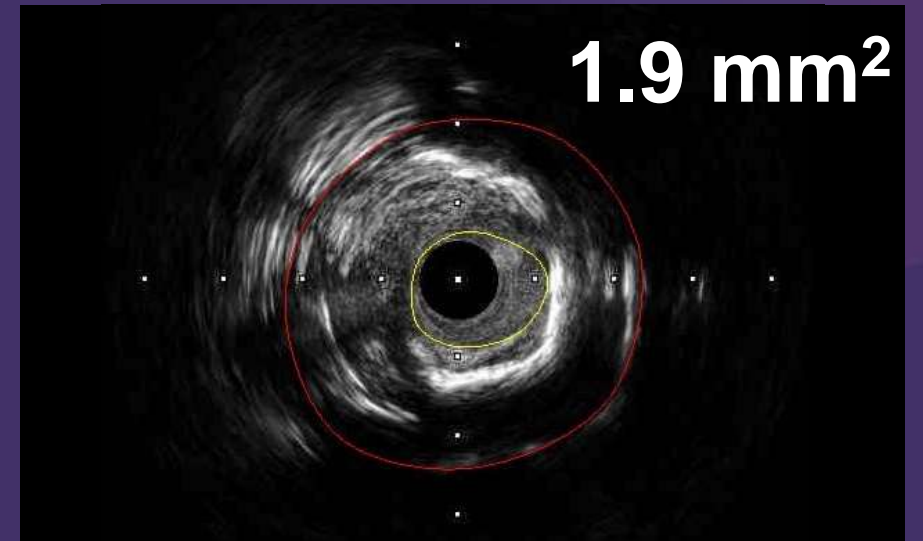
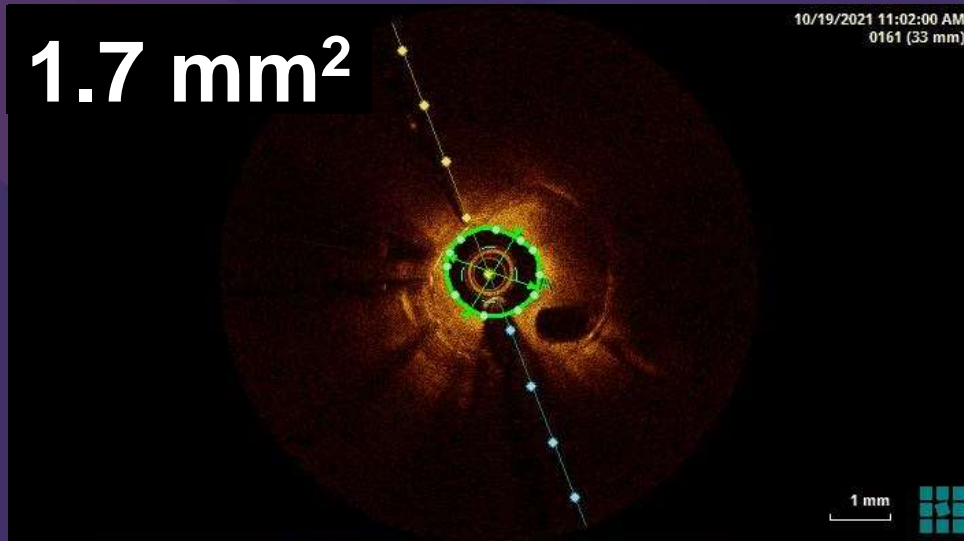
Final OCT / IVUS



MLA Before / After PCI

Pre

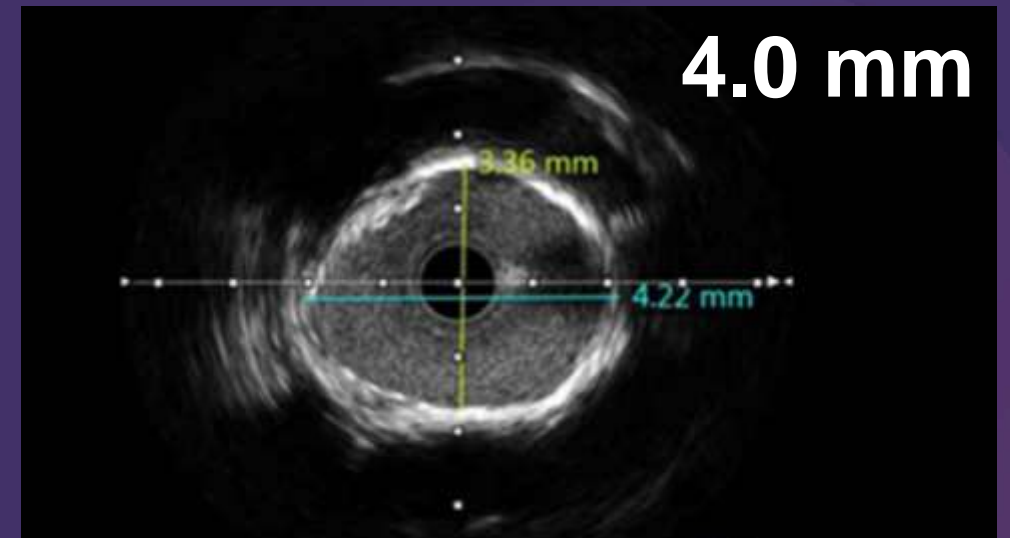
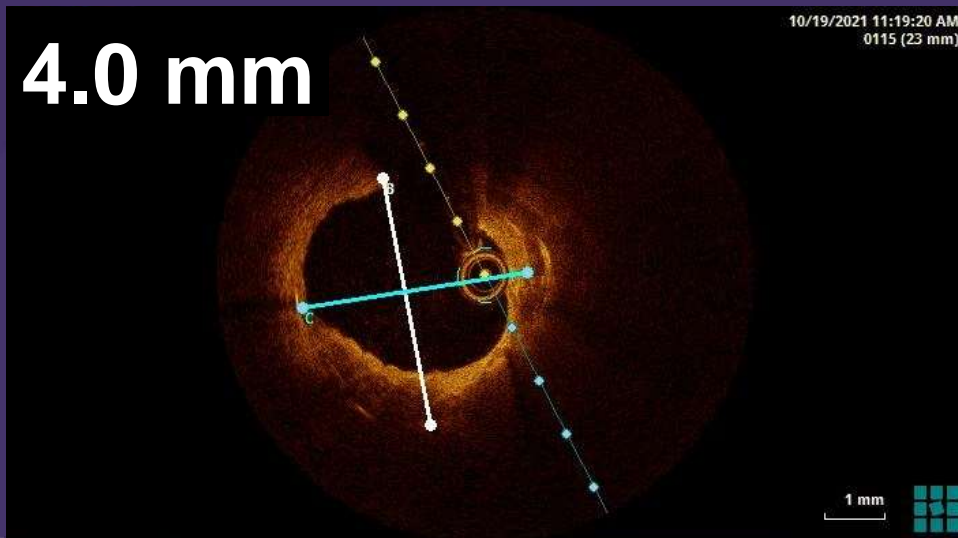
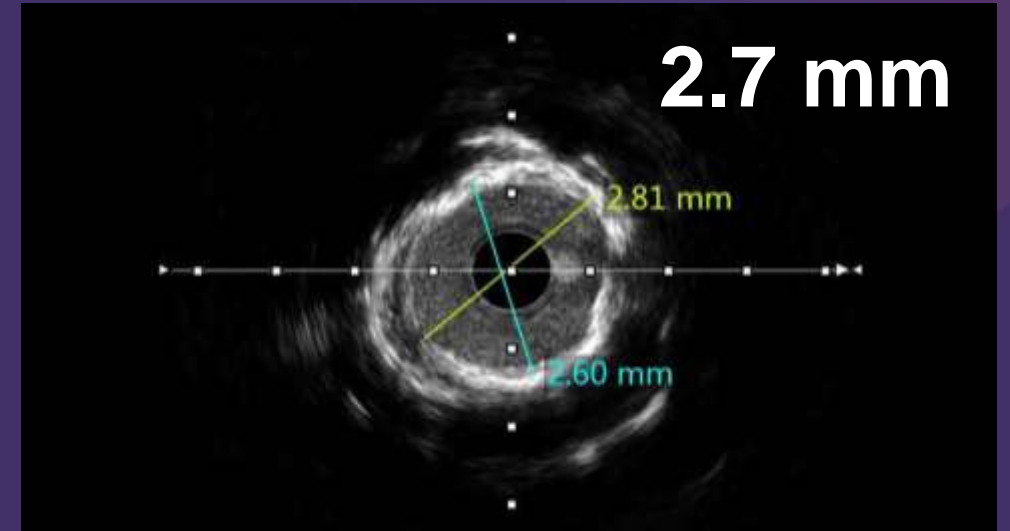
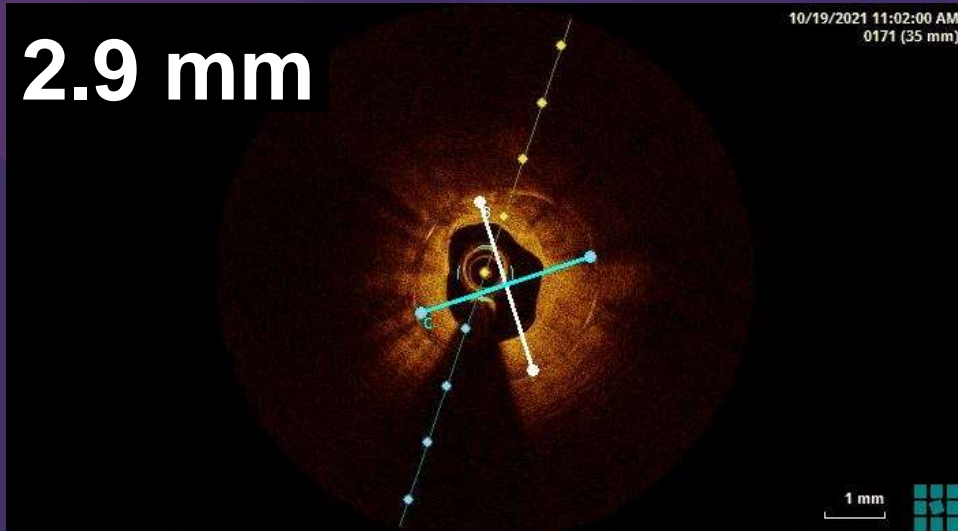
Post



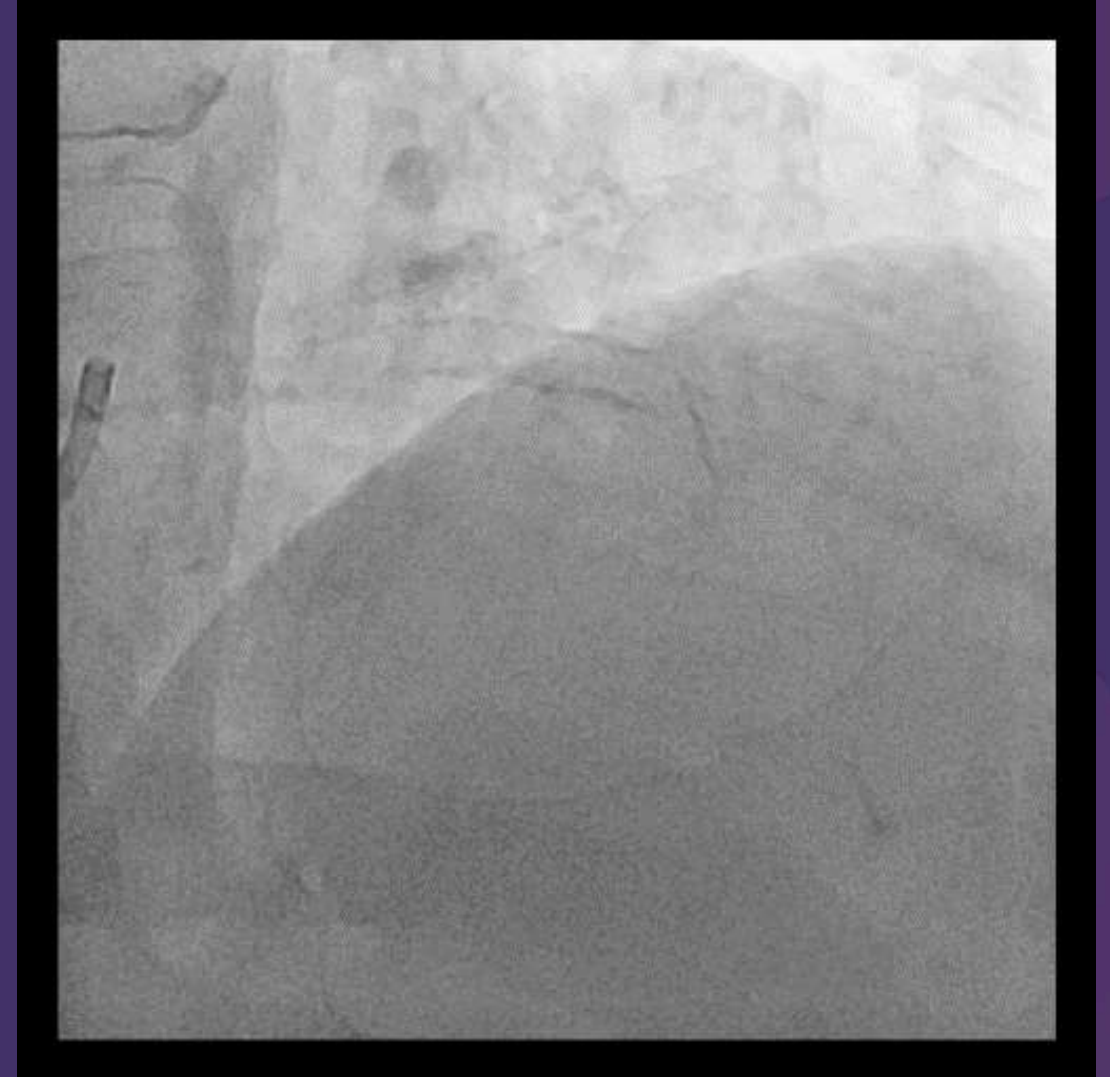
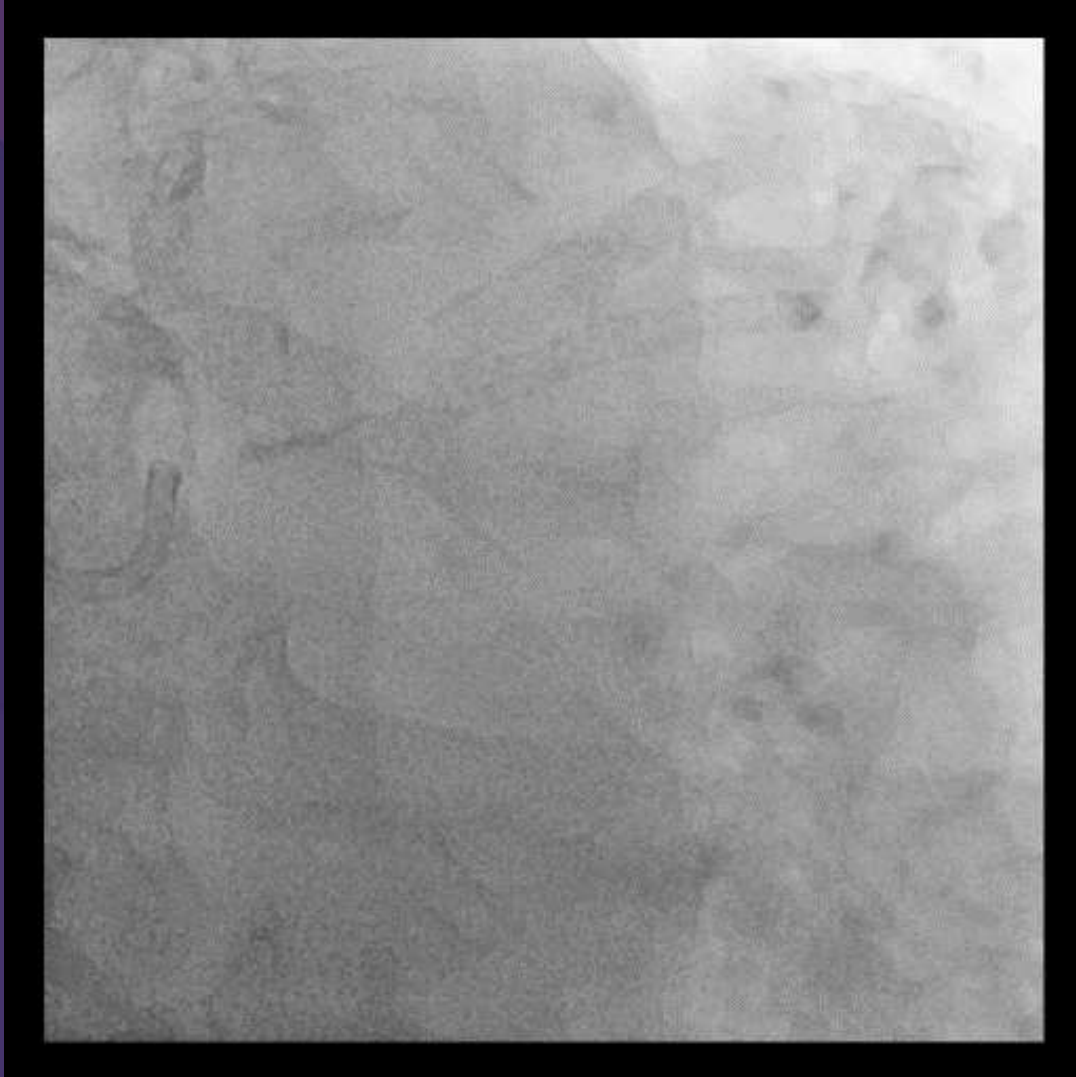
Stent Diameter Before / After PCI

Pre

Post



Final Angiography



Intravascular Imaging in ISR PCI can Help to

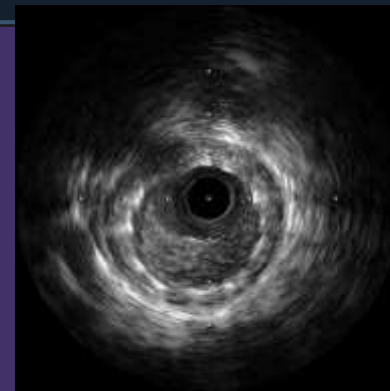
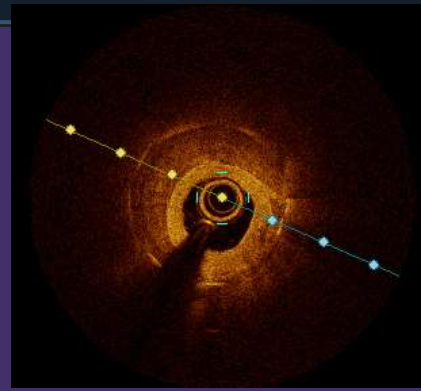
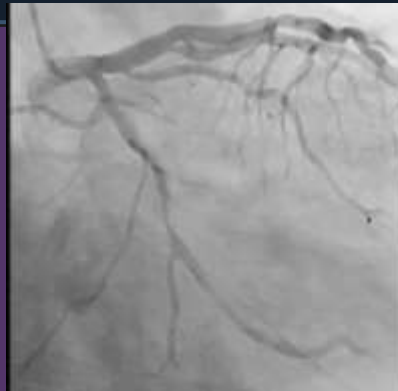
- Identify the mechanism of restenosis
- Select the optimal treatment modality
 - High-pressure balloon for underexpansion
 - DES for fracture, gap, or edge problems
 - DEB/DES for neointimal hyperplasia
 - Atherectomy / lithotripsy for undilatable ISR
- Optimize the ISR PCI (lumen area, complication assessment)
- Give instant feedback to the operator

OCT vs. IVUS for ISR Imaging

OCT can visualize in more detail,

- Stent strut coverage,
- Discrimination between stent and calcium,
- Dissection, edge problem, other complications,
- Bioresorbable scaffold

However, it needs contrast filling,
it has difficulty in ostial visualization.



Ongoing OCTIVUS Trial

- Pragmatic RCT
- All-comer PCI including LM, Bifurcation, CTO, ISR...
- 6 academic hospitals in Korea
- 96% enrolled on Oct 2021
- NCT03394079

Optical Coherence Tomography versus Intravascular Ultrasound
Guided Percutaneous Coronary Intervention

OCTIVUS Trial

Patients with CAD undergoing PCI (N=2,000)

R

OCT-guided PCI
(N=1,000)

IVUS-guided PCI
(N=1,000)

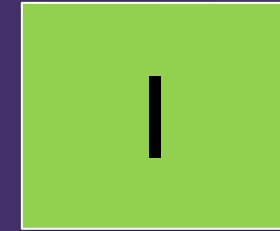
Primary Endpoint: Target Vessel Failure at 1 year
(Composite of cardiac death, target-vessel MI and ischemia-driven TVR)

Clinical follow-up at 1, 6, 12 months, then 3 and 5 years

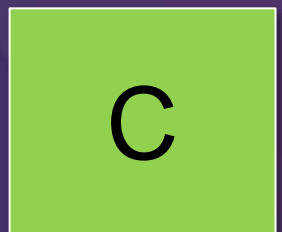
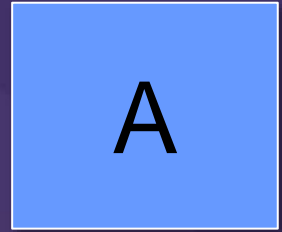
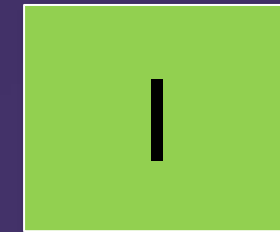
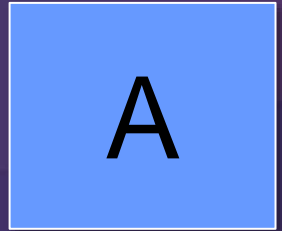
2018 ESC Guideline for ISR Treatment

- **DES** are recommended for the treatment of in-stent restenosis of BMS or DES.
- **Drug-coated balloons** are recommended for the treatment of in-stent restenosis of BMS or DES
- **IVUS and/or OCT** should be considered to detect **stent-related mechanical problems** leading to restenosis

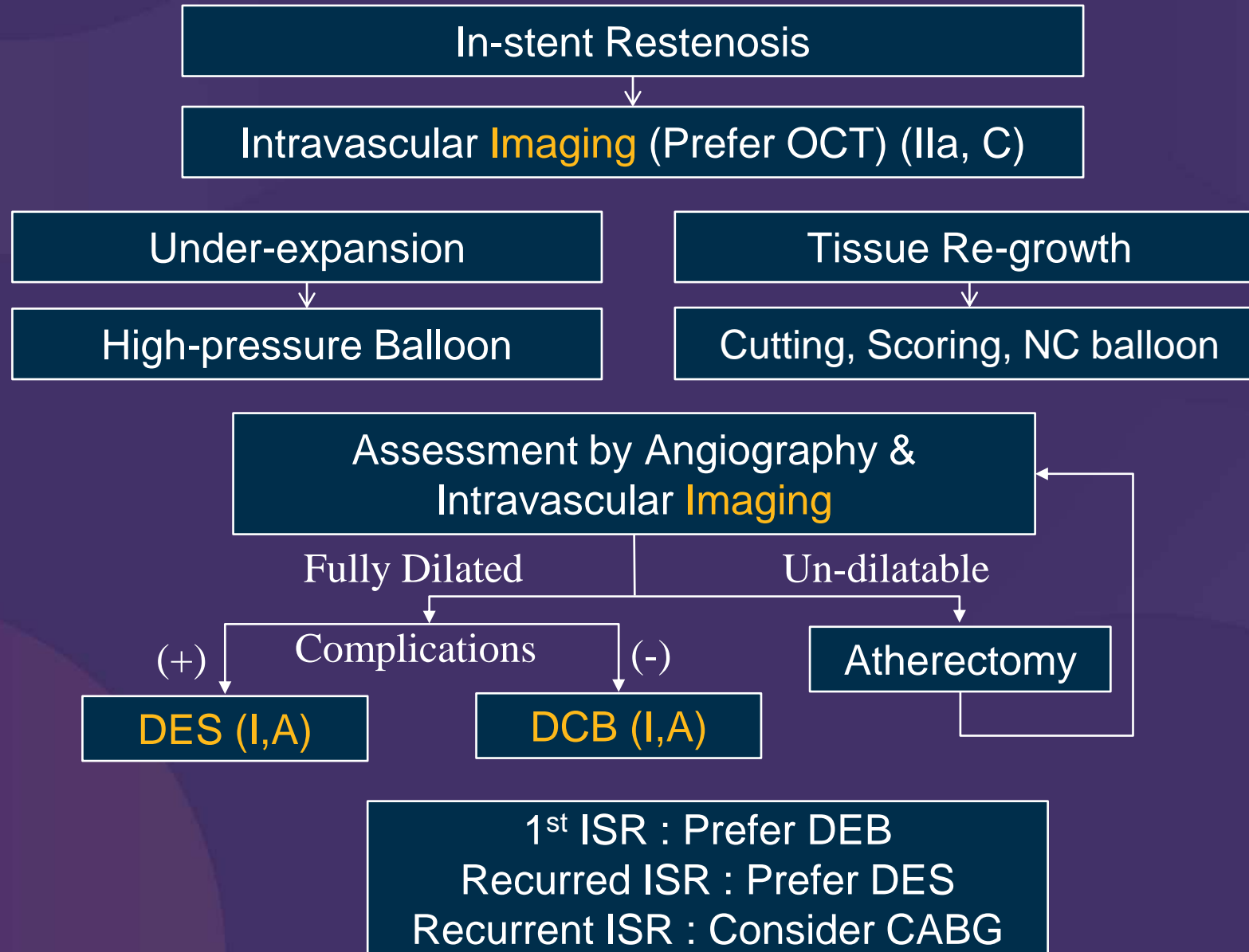
COR



LOE



My Treatment Strategy for ISR



Conclusion

- Intravascular imaging help to Identify the mechanism of ISR, to Select optimal treatment modality, and to Optimize the acute result of the ISR-PCI.
- DCB and DES both are recommended as 1st line Tx for ISR.
- Prevention is better than cure. Intravascular imaging-guided optimal stenting at initial PCI would minimize the ISR.