OCT-Guided PCI: OPINION, DOCTORS, ILUMIEN III and IV

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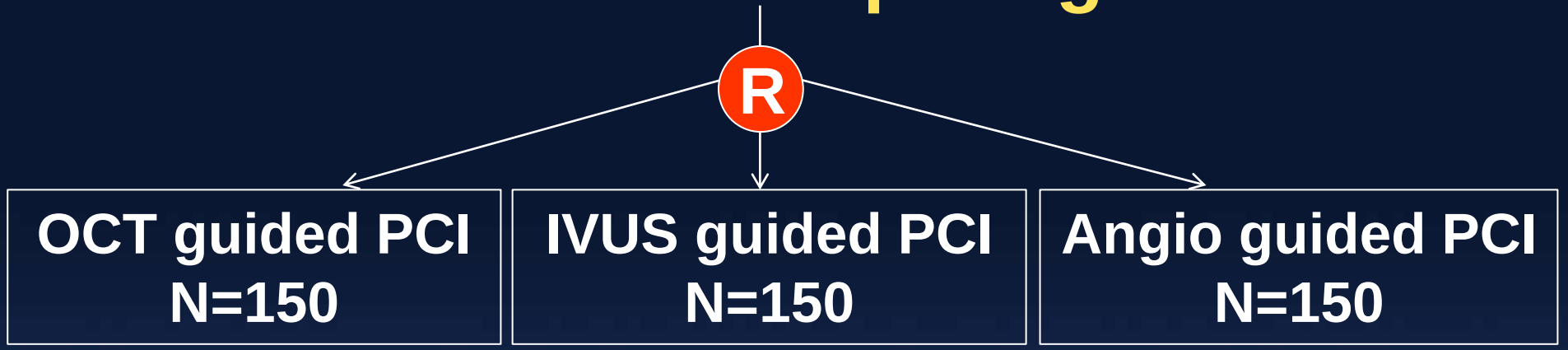
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Boston Scientific, St Jude Medical
• Consulting Fees/Honoraria	• Boston Scientific, OCT Medical Imaging Inc.

ILUMIEN III - OPIMIZE PCI Trial -

450 Patients requiring PCI

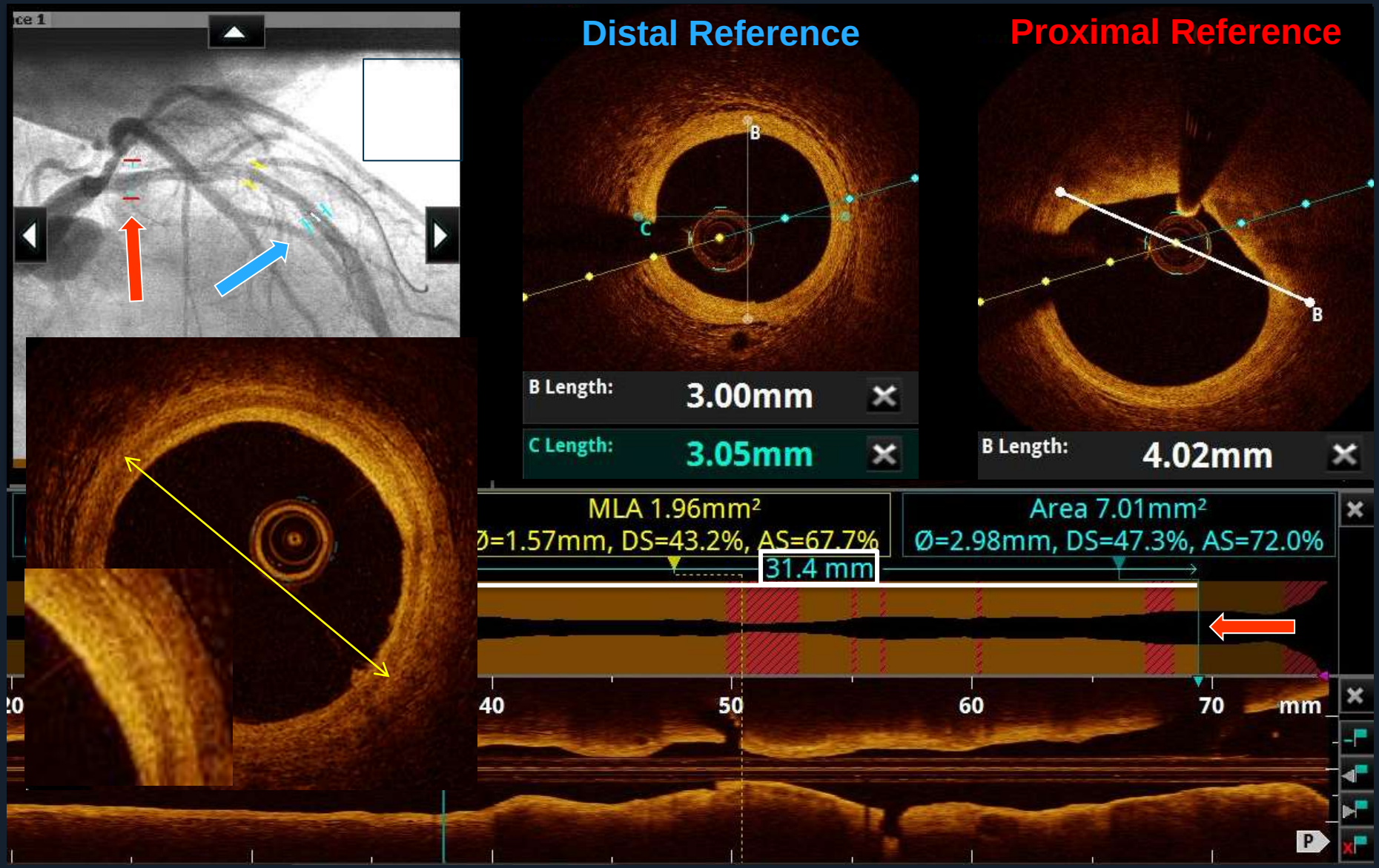


OCT Guided Stent Sizing & Optimization Algorithm

Primary endpoint: Minimum stent area by OCT

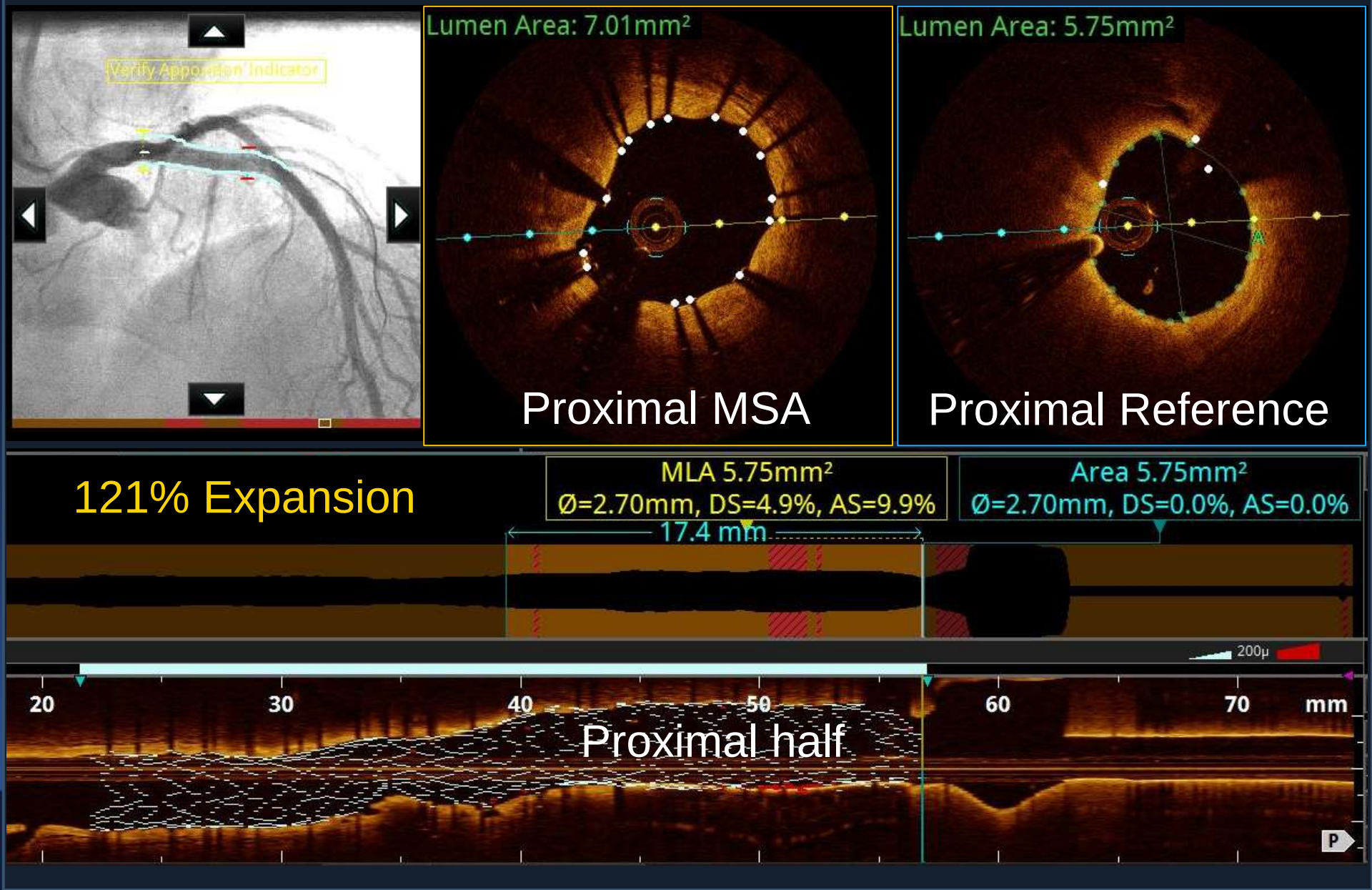
- **Non-inferiority compared to IVUS-guidance**
- **Superiority compared to Angio-guidance**

OCT Stent Sizing Algorithm

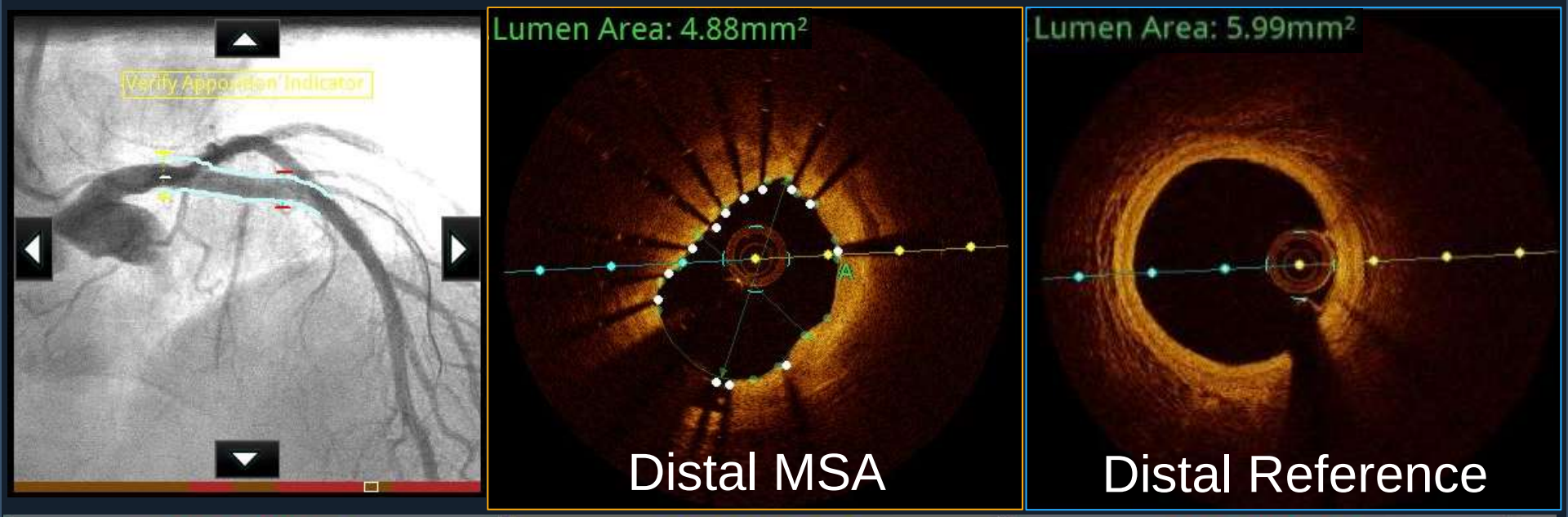


Smallest mean EEL = 3.03 mm ⇒ 3.0 x 34 mm stent chosen

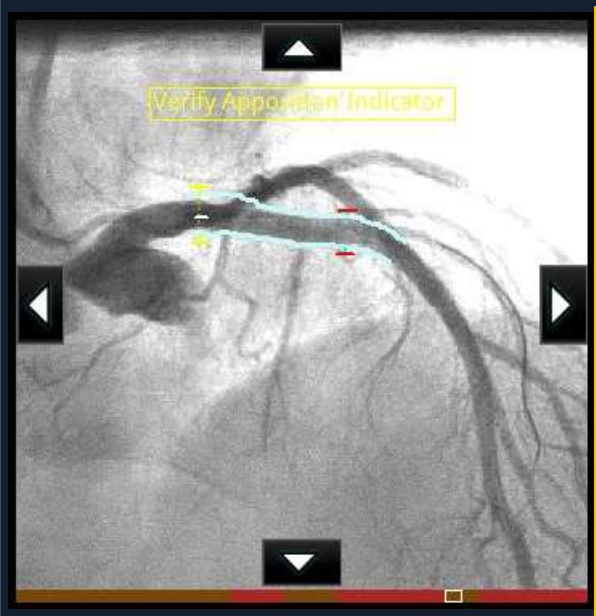
OCT Stent Optimization Algorithm

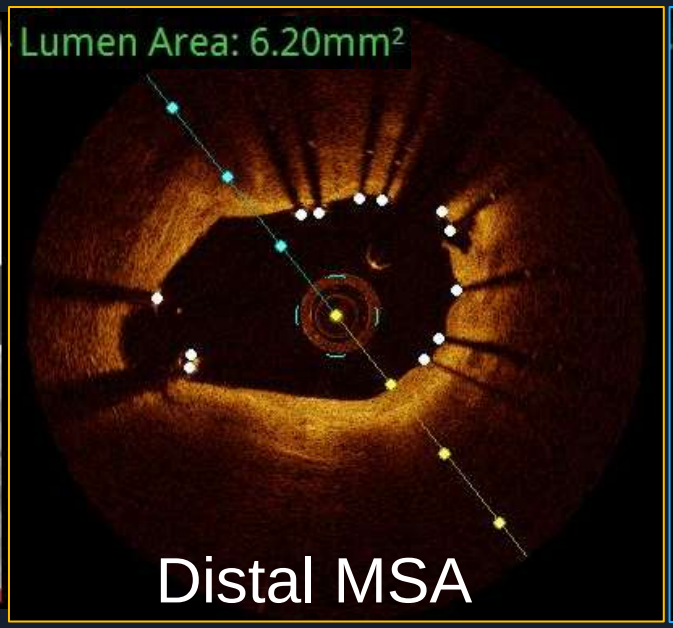


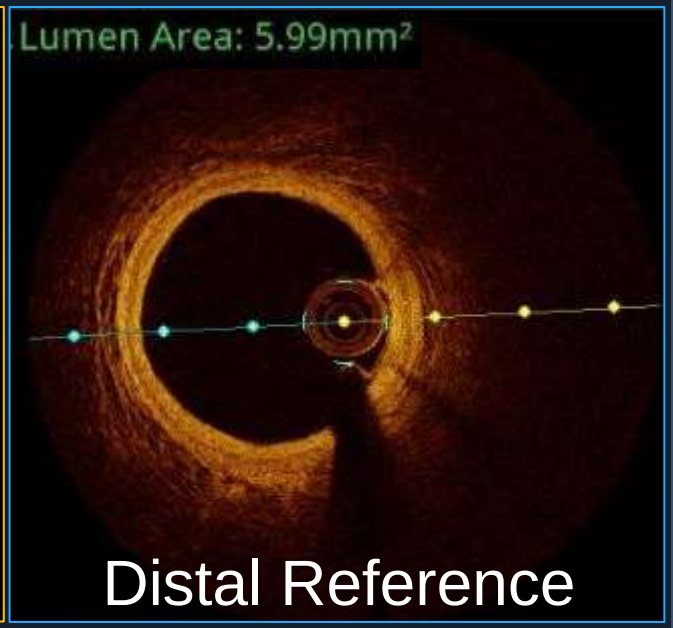
OCT Stent Optimization Algorithm

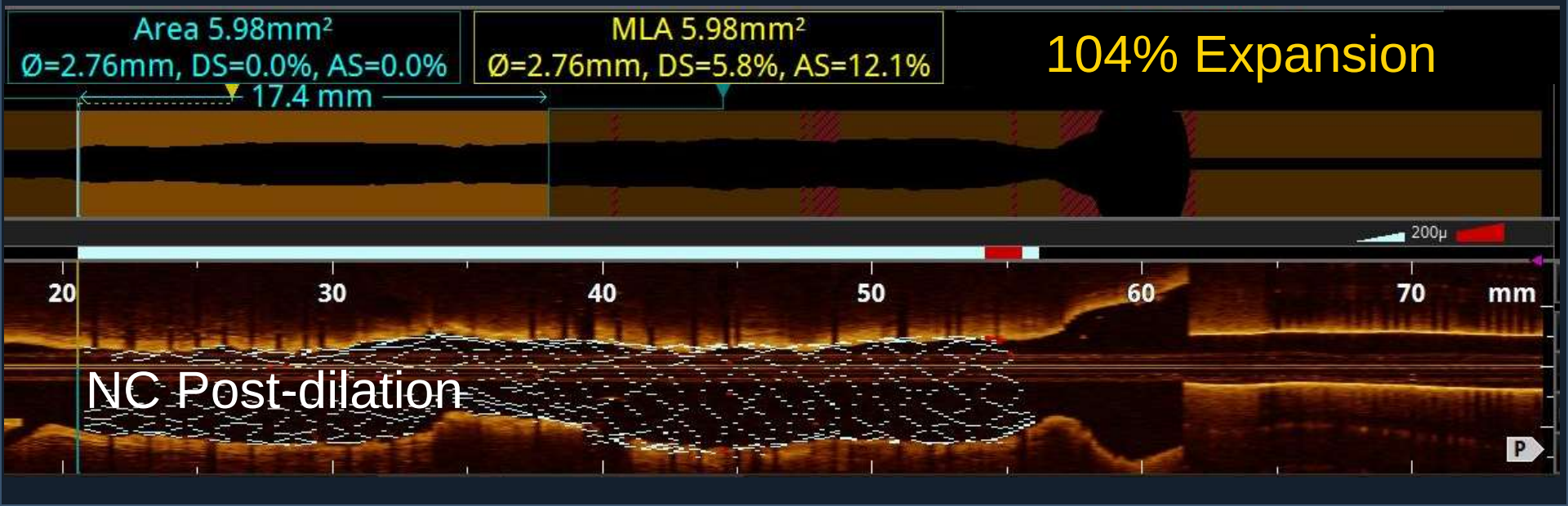


OCT Stent Optimization Algorithm









Angio and Procedure Characteristics

	OCT (n=158)	IVUS (n=146)	Angio (n=146)	*P* OCT vs IVUS	*P* OCT vs Angio
Reference vessel diameter, mm	2.78 [2.42, 3.12]	2.87 [2.56, 3.17]	2.76 [2.50, 3.15]	0.34	0.97
Lesion length, mm	15.5 [11.0, 23.2]	15.3 [11.0, 23.0]	14.8 [10.6, 20.4]	0.99	0.40
Calcification (mod to severe)	20%	16%	26%	0.39	0.23
Stent length, mm	23 [15, 32]	24 [16, 32]	20 [16, 30]	1.00	0.27
Maximal stent diameter, mm	3.00 [2.75, 3.50]	3.00 [2.75, 3.50]	3.00 [2.75, 3.50]	0.36	0.39
Maximum inflation pressure, atm	18 [16, 20]	20 [16, 20]	18 [16, 20]	0.48	0.02
Procedure duration, min	71 [57,101]	73 [54,97]	58 [39,78]	0.99	<0.0001
Contrast volume, mL	222 [164, 285]	190 [140, 250]	183 [140, 250]	0.004	0.001

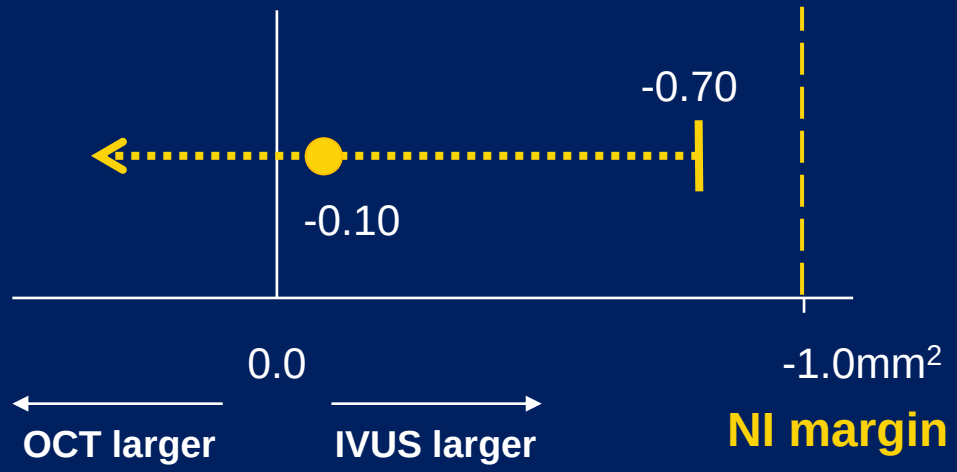
Primary Endpoint

Final post-PCI MSA by OCT

OCT 5.79 mm^2 [4.54, 7.34]

IVUS 5.89 mm^2 [4.67, 7.80]

97.5% one-sided CI: [-0.70, -]



$P_{noninferiority} = 0.001$

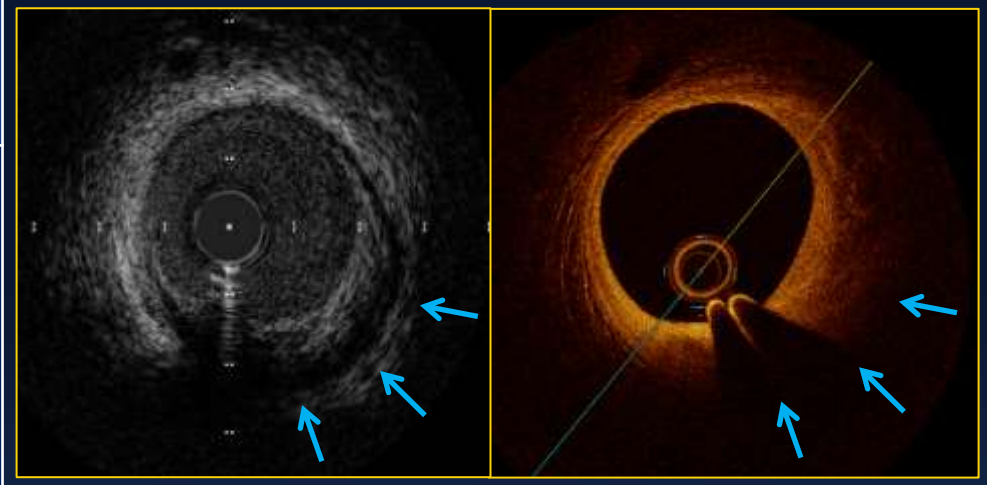
Secondary Endpoints

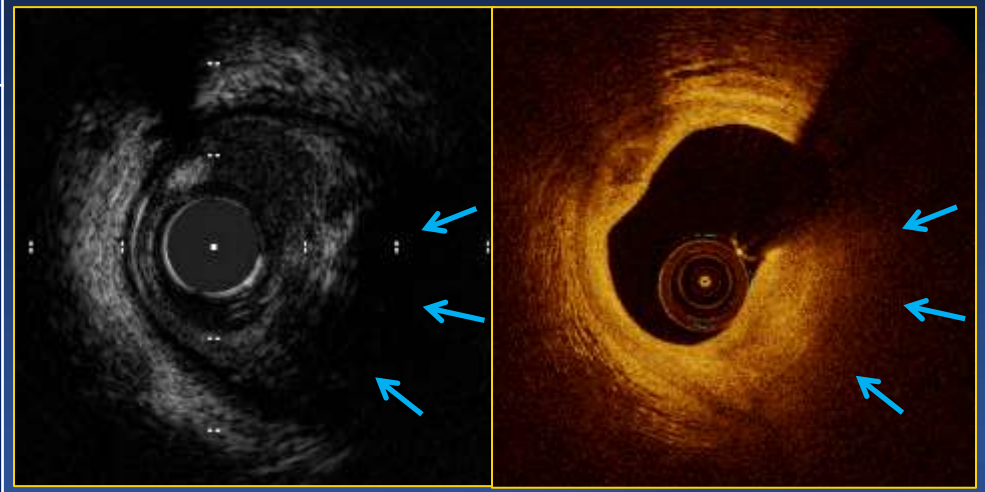
	OCT (n=140)	IVUS (n=135)	Angio (n=140)	*P* OCT vs IVUS	*P* OCT vs Angio
Minimal stent area, mm^2	5.79 [4.54,7.34]	5.89 [4.67,7.80]	5.49 [4.39, 6.59]	0.42	0.12
Min stent expansion, %	88 ± 17	87 ± 16	83 ± 13	0.77	0.02
Mean stent expansion, %	106 [98, 120]	106 [97, 117]	101 [92, 110]	0.63	0.001
Expansion					
- Optimal (>95%)	26%	25%	17%	0.84	0.07
- Acceptable (90 - <95%)	16%	12%	3.7%	0.42	0.0008
- Unacceptable (<90%)	59%	63%	79%	0.45	0.0002

Border and Vessel Visibility

	OCT (n=140)	IVUS (n=135)	*P* OCT vs IVUS
EEL visible at either reference segment			
>180°			
Site	84%	83%	0.78
Core lab	95%	100%	0.02

Measurement used to decide stent sizing			
Proximal reference			
EEL	70%	71%	0.89
Lumen	30%	29%	
Distal reference			
EEL	79%	70%	0.09
Lumen	21%	30%	



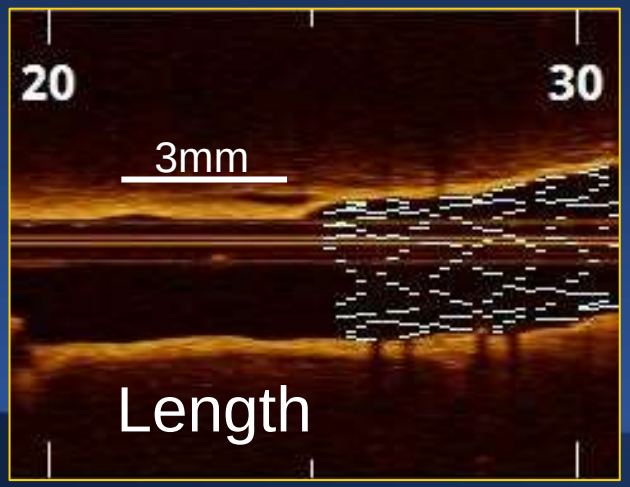


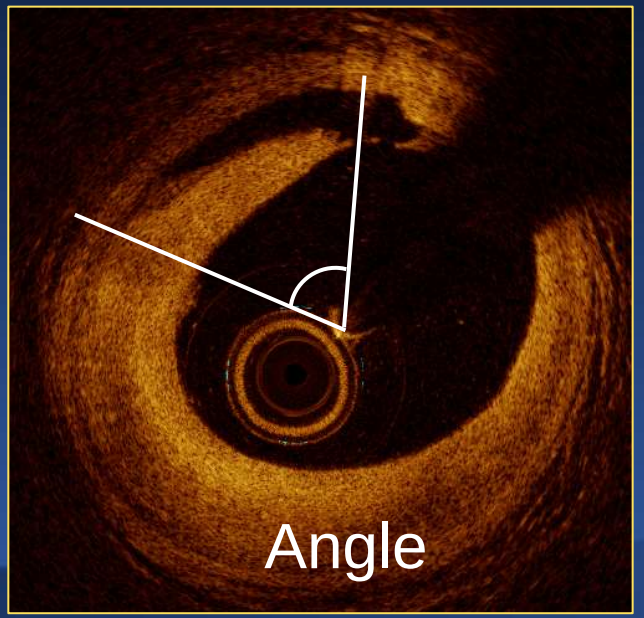
Dissections

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	*P* OCT vs IVUS	*P* OCT vs Angio
Dissection, any	28%	40%	44%	0.04	0.006
Major	14%	26%	19%	0.009	0.25
Minor	14%	13%	25%	0.84	0.02

Major Dissection

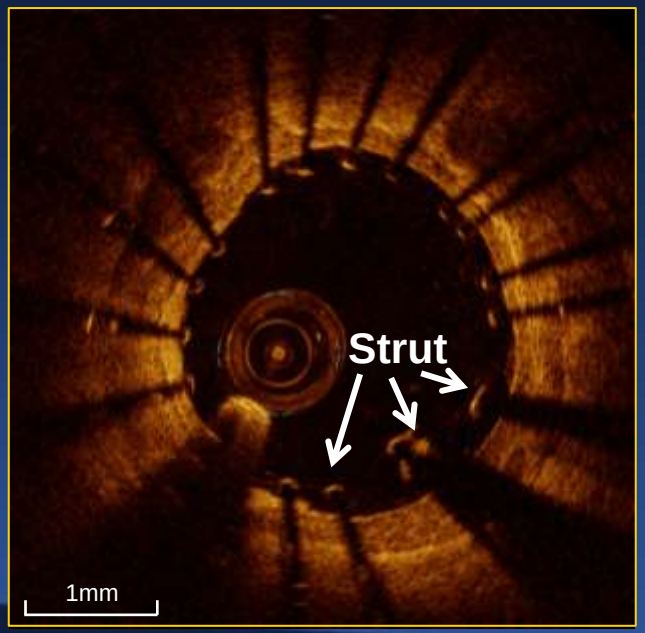
1) Angle >60˚
2) Length >3 mm

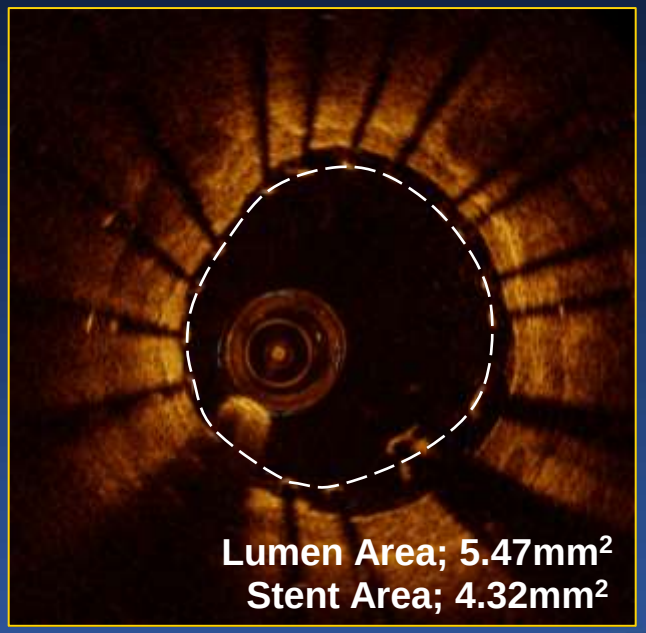




Malapposition

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	*P* OCT vs IVUS	*P* OCT vs Angio
Malapposition, any	41%	38%	59%	0.62	0.002
Major	11%	21%	31%	0.02	<0.0001
Minor	31%	18%	28%	0.01	0.60



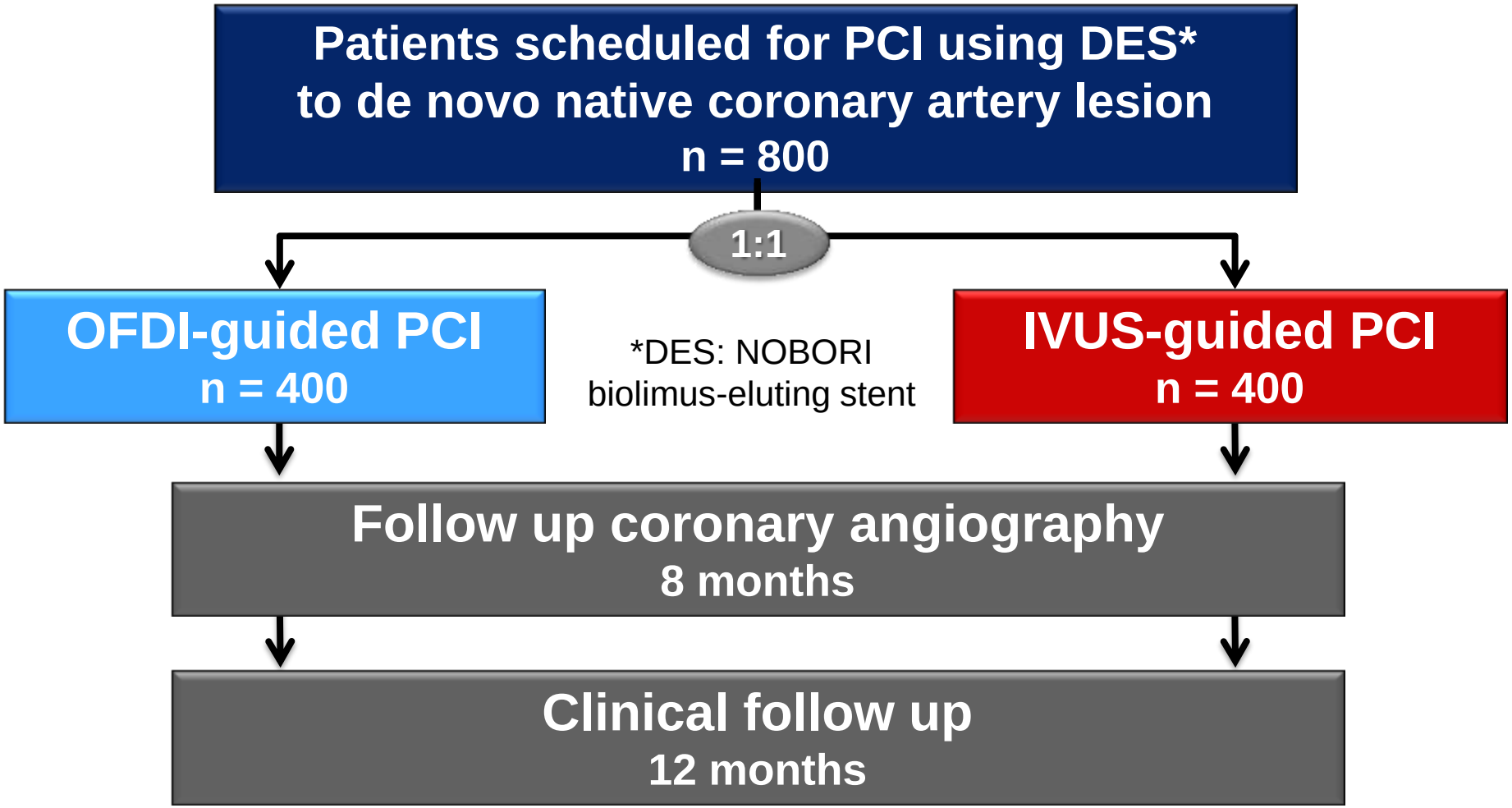


Major

Strut(s) >0.2 mm from vessel edge and stent underexpansion

The OPINION study design

Prospective, multi-center (n=42), randomized (1:1), non-inferiority trial comparing OFDI-guided PCI with IVUS-guided PCI



Primary Endpoint: Target Vessel Failure (TVF) at 12 months after PCI

OFDI and IVUS criteria for PCI

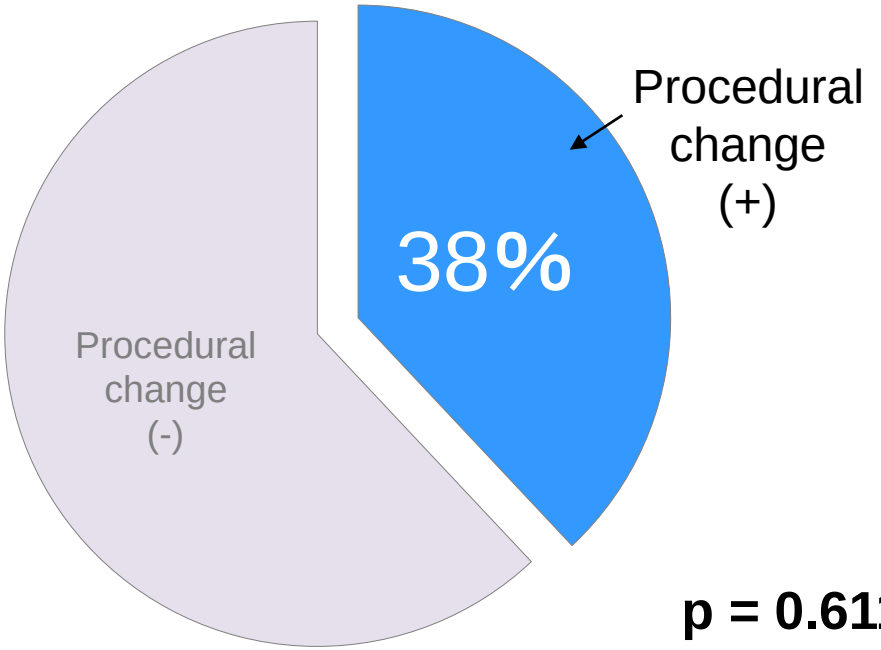
	OFDI-guided PCI	IVUS-guided PCI
Reference site	• Most normal looking • No lipidic plaque	• Largest lumen • Plaque burden < 50%
Determination of stent diameter	• By measuring lumen diameter at proximal and distal reference sites	• By measuring vessel diameter at proximal and distal reference sites
Determination of stent length	• By measuring distance from distal to proximal reference site	
Goal of stent deployment	• In-stent minimal lumen area ≥ 90% of the average reference lumen area • Complete apposition of the stent over its entire length against the vessel wall • Symmetric stent expansion defined by minimum lumen diameter / maximum lumen diameter ≥ 0.7 • No plaque protrusion, thrombus, or edge dissection with potential to provoke flow disturbances	

Angiographic and procedure findings

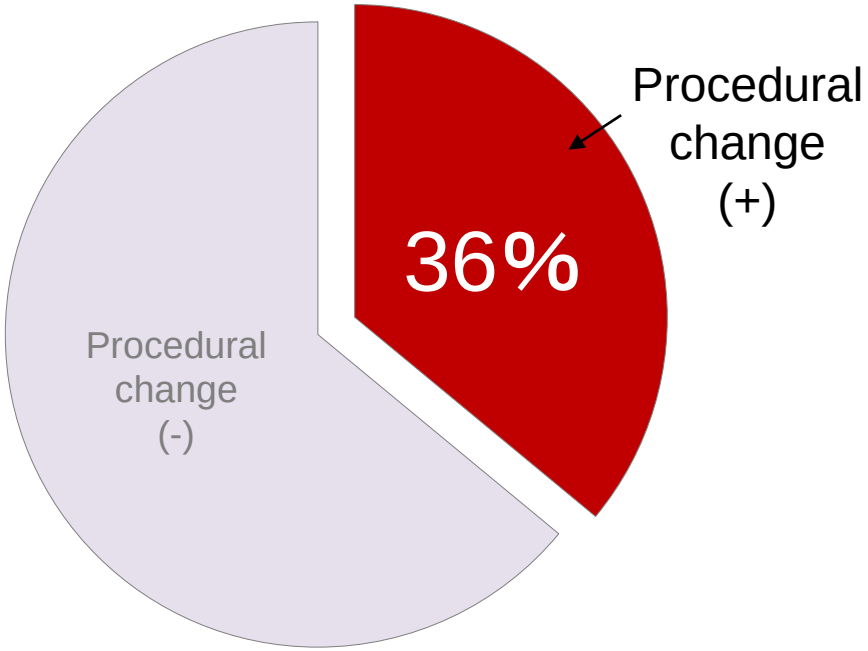
	OFDI	IVUS	*p*-value
ACC/AHA classification B2/C	80%	80%	0.860
Reference vessel diameter, mm	2.62 ± 0.53	2.59 ± 0.57	0.259
Final Min. lumen diameter, mm	2.25 ± 0.53	2.27 ± 0.52	0.776
Final Diameter stenosis, %	22 ± 10	22 ± 9	0.885
Stent diameter, mm	2.92 ± 0.38	3.00 ± 0.37	0.007
Total stent length, mm	26 ± 13	25 ± 13	0.059
Post dilatation	77%	75%	0.624
Max. balloon diameter, mm	3.1 ± 0.8	3.3 ± 1.2	0.058
Max. inflation pressure, atm	16 ± 4	16 ± 4	0.697

Procedural change by OFDI/IVUS

OFDI guidance



IVUS guidance

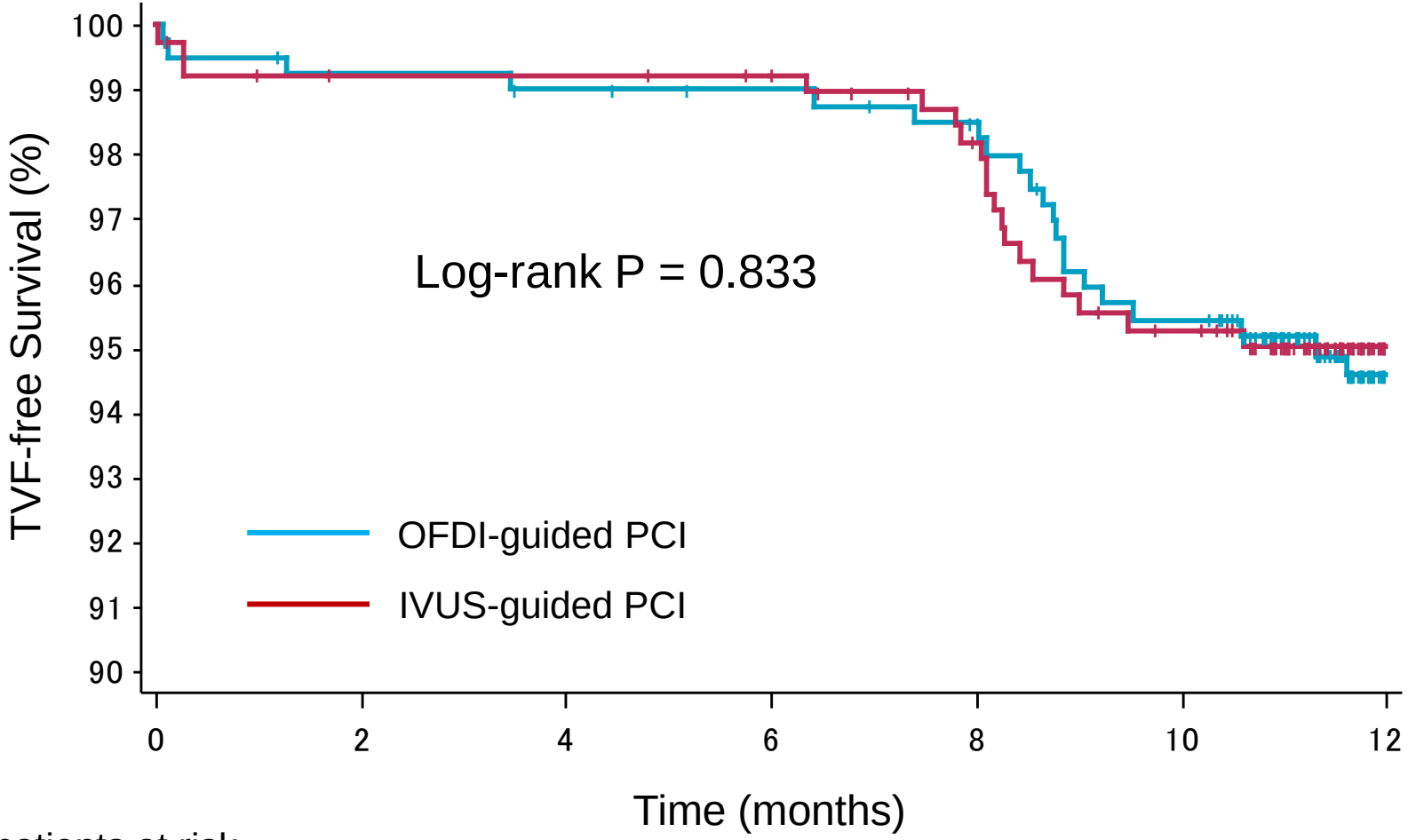


p = 0.611

Pre-dilatation: Balloon size/pressure up (11% vs. 10%)
Rotablator, Cutting balloon (3% vs. 4%)
Distal protection (4% vs. 3%)
Post-dilatation: Balloon size/pressure up (31% vs. 28%)
Additional stent (4% vs. 3%)
Others (1% vs. 2%)

Target vessel failure (TVF)-free survival curves

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



No. of patients at risk

OFDI-guided PCI	401	396	394	392	387	374	265
IVUS-guided PCI	390	384	384	381	373	360	285

Secondary endpoints

	OFDI	IVUS	*p*-value
Cardiac death	0 (0%)	1 (0.2%)	0.496
MI	2 (0.5%)	3 (0.7%)	0.684
Clinically-driven TVR			
TLR	11 (2.7%)	12 (3.0%)	0.835
Non-TLR	9 (2.2%)	5 (1.2%)	0.420
Stent thrombosis	1 (0.2%)	2 (0.5%)	0.621
Stroke	4 (1.0%)	1 (0.2%)	0.374
Contrast-induced nephropathy	0 (0%)	0 (0%)	-

QCA results at follow-up

	OFDI	IVUS	*p*-value
In-stent			
Min. lumen diameter, mm	2.38 ± 0.51	2.44 ± 0.52	0.136
Diameter stenosis, %	16 ± 11	15 ± 10	0.948
Late loss, mm	0.19 ± 0.29	0.17 ± 0.26	0.532
Binary restenosis (DS>50%)	6 (1.6)%	6 (1.6)%	1.000
In-segment			
Min. lumen diameter, mm	2.15 ± 0.56	2.16± 0.55	0.799
Diameter stenosis, %	24 ± 13	24 ± 12	0.517
Late loss, mm	0.10± 0.46	0.10± 0.45	0.691
Binary restenosis (DS>50%)	23 (6.2)%	22 (6.0)%	1.000

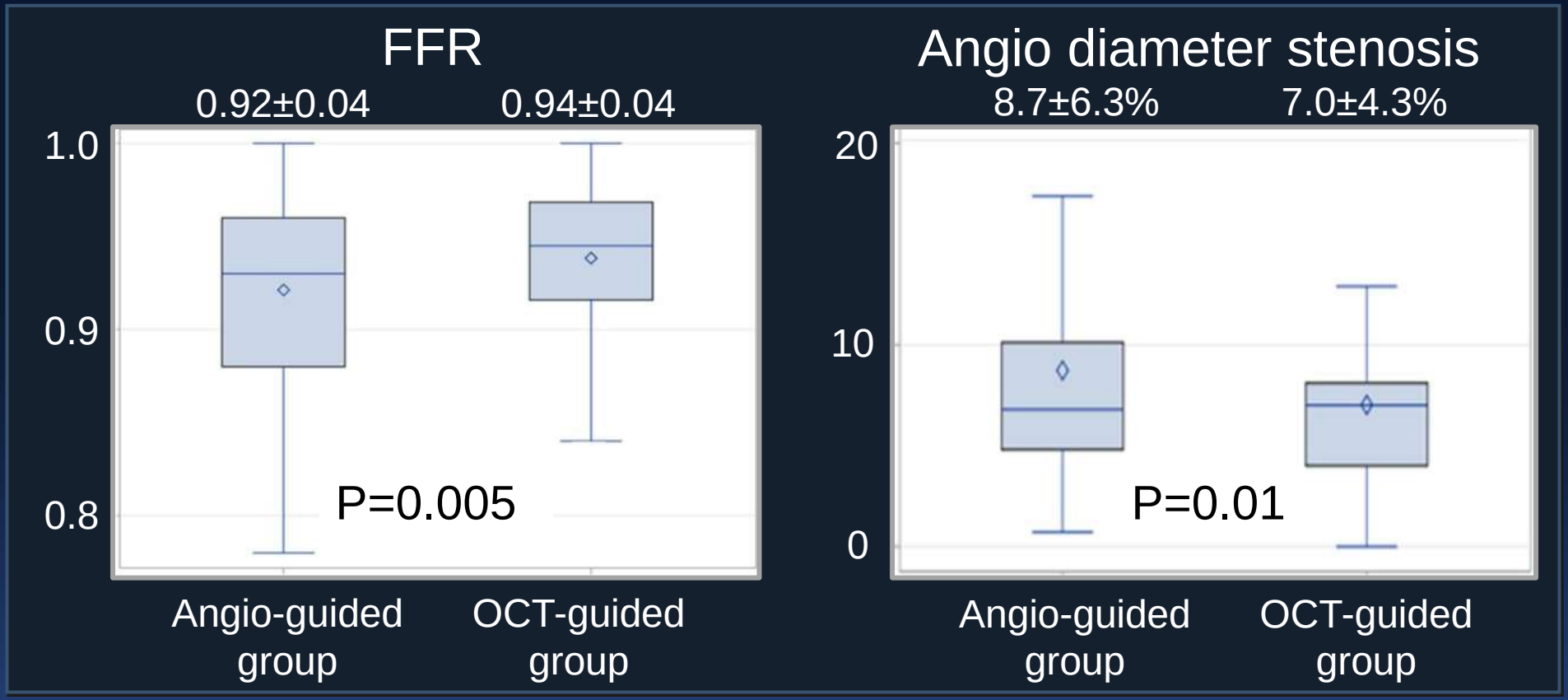
OCT vs Angio Guided PCI - DOCTORS -

- Multicenter, randomized trail to compare OCT vs Angio (n=240)
- **Endpoint: Post-procedural FFR**
- OCT guidance recommendation
  - Pre-OCT; stent size, length, presence of calcium, thrombus
  - Post-stent
    - **Stent underexpansion≤80% (MLA/reference lumen area)**
    - Malapposition, intra-stent thrombus, tissue
    - Incomplete stent coverage, edge dissection
- OCT use led to a change in procedural strategy in 50% of cases

	Post-Stent	Post-Optimization
Minimum lumen area (mm^2)	5.99±2.11	6.41±1.99
Stent expansion (%)	78.9±12.4	84.1±7.3

Meneveau N, et al. Circulation 2016;134:906-17.

OCT vs Angio Guided PCI - DOCTORS -



Post-PCI FFR to predict future event

* Vessel-oriented cardiac event

Trial, Study	# of pts	Outcome	Cut off
FAME I and II	644	2year VOCE*	<0.92
Meta-analysis	7470	MACE	<0.90
Agarwal et al	574	MACE	≤0.86

Piroth et al. TCT2016, Rimac G, et al. AHJ 2017: 183;1-9. Agarwal SW JACC Interv 2016 9: 1022-31.

Summary

1. OCT-guided PCI was confirmed as non-inferior compared to IVUS-guided PCI.
2. OCT-guided PCI seems to be superior to angio-guided PCI by choosing appropriate size and length of stent, optimizing stent expansion, and correcting acute complication.
3. These data will lead us to move ILUMIEN IV trial to prove OCT-guided PCI to improve long term outcome in complex lesion cohort compared to angiography-guidance.