

ILUMIEN III and Others: Imaging-Guided PCI Optimization

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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

- Grant/Research Support
- Consulting Fees/Honoraria

Company

- Boston Scientific, St Jude Medical
- Boston Scientific, OCT Medical Imaging Inc.

ILUMIEN III - OPTIMIZE PCI Trial - 450 Patients requiring PCI

R

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graph TD; R((R)) --> OCT[OCT guided PCI  
N=150]; R --> IVUS[IVUS guided PCI  
N=150]; R --> Angio[Angio guided PCI  
N=150];
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OCT guided PCI
N=150

IVUS guided PCI
N=150

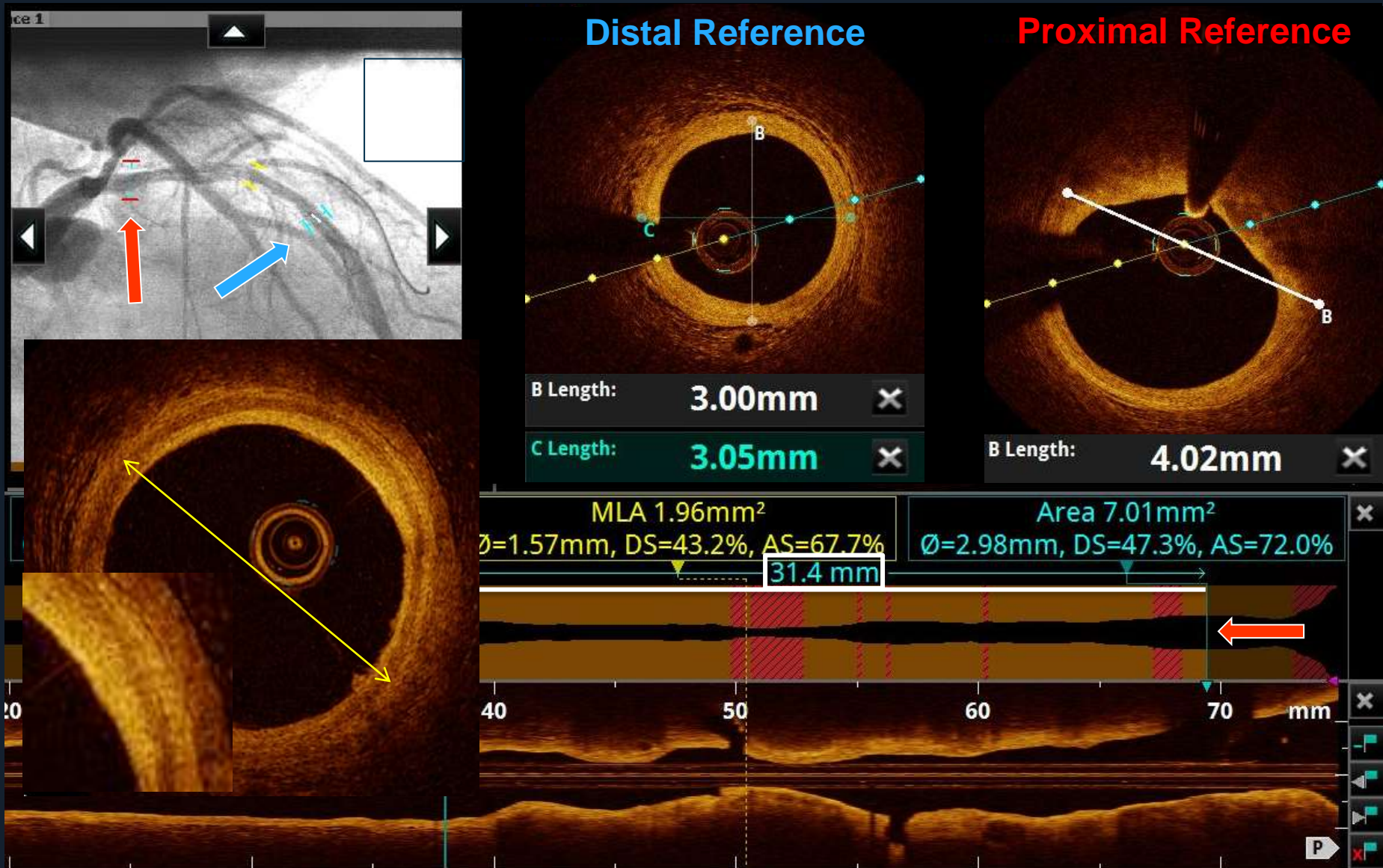
Angio guided PCI
N=150

OCT Guided Stent Sizing
& Optimization Algorithm

Primary endpoint: Minimum stent area by OCT

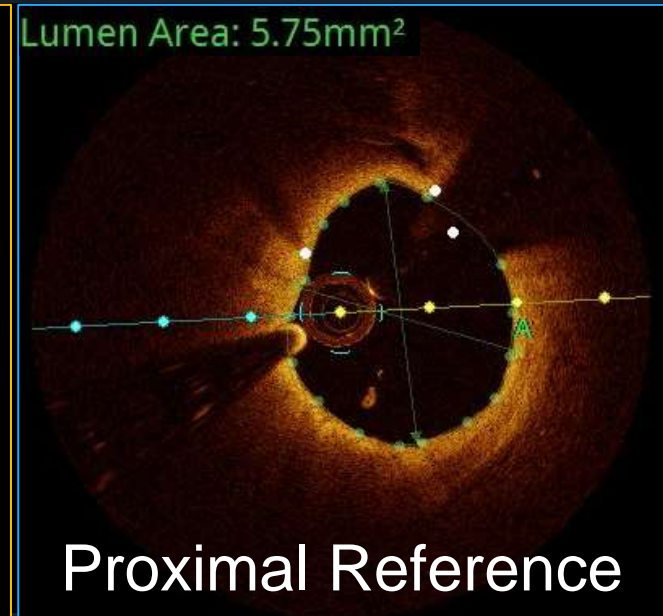
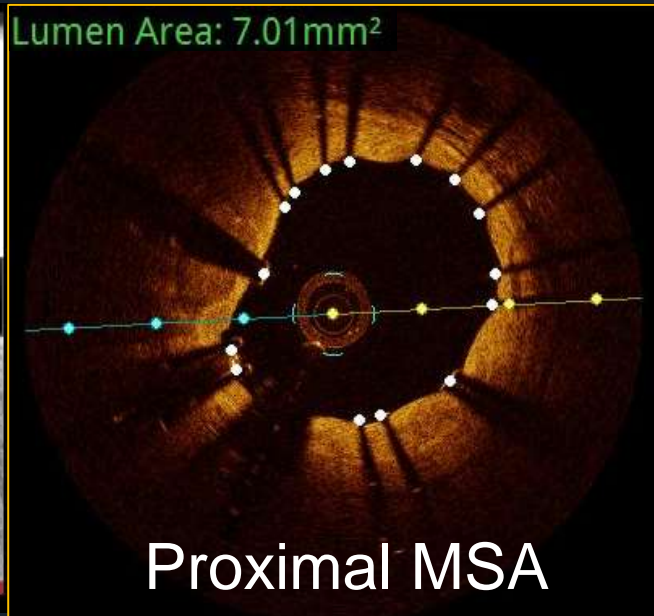
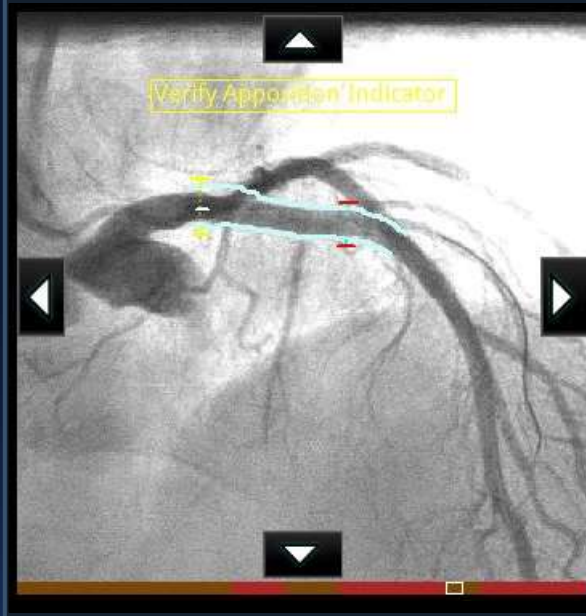
- Non-inferiority compared to IVUS-guidance
- Superiority compared to Angio-guidance

OCT Stent Sizing Algorithm



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

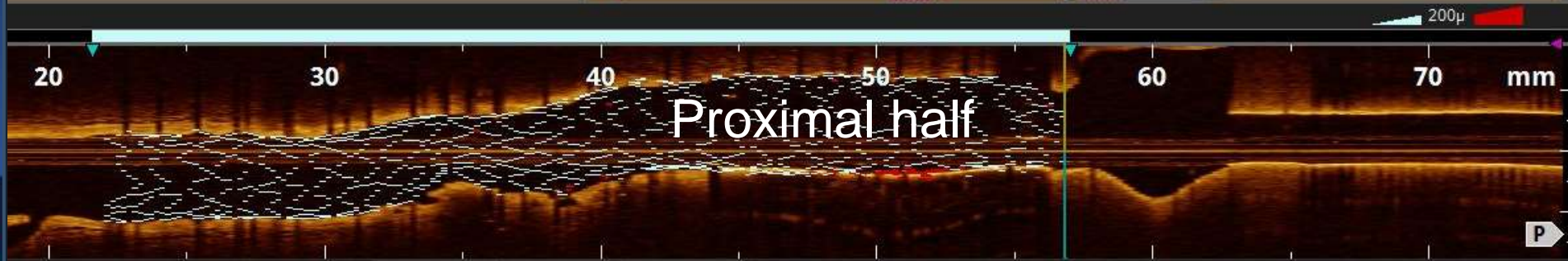
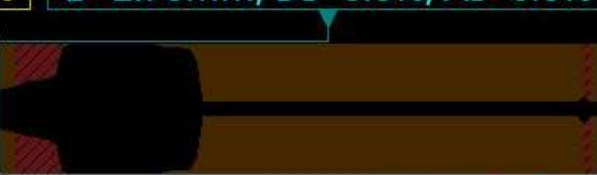
OCT Stent Optimization Algorithm



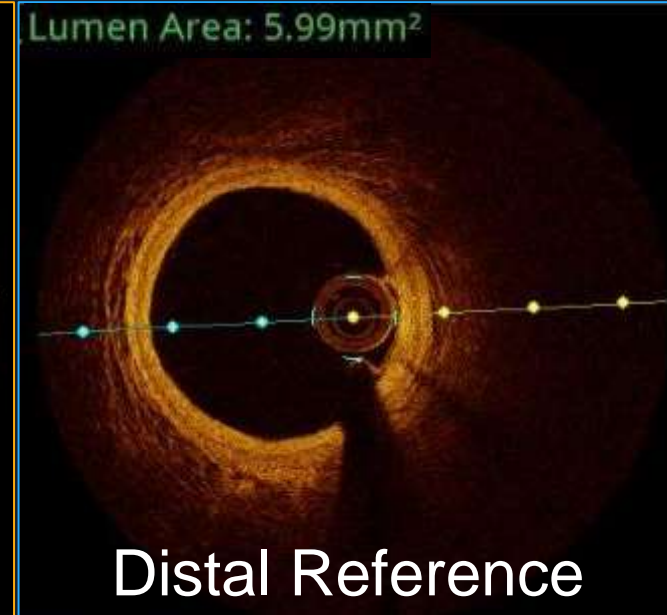
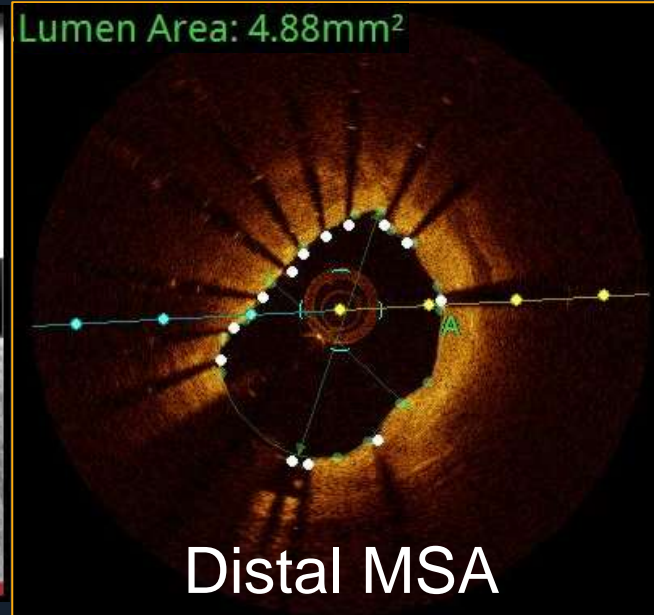
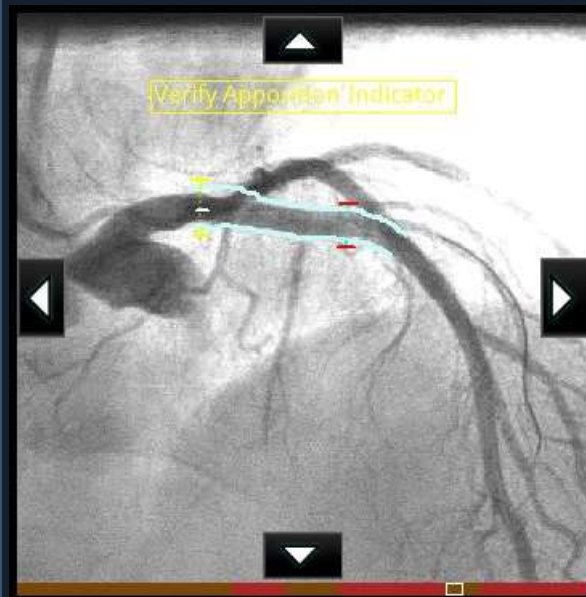
121% Expansion

MLA 5.75mm²
Ø=2.70mm, DS=4.9%, AS=9.9%

Area 5.75mm²
Ø=2.70mm, DS=0.0%, AS=0.0%



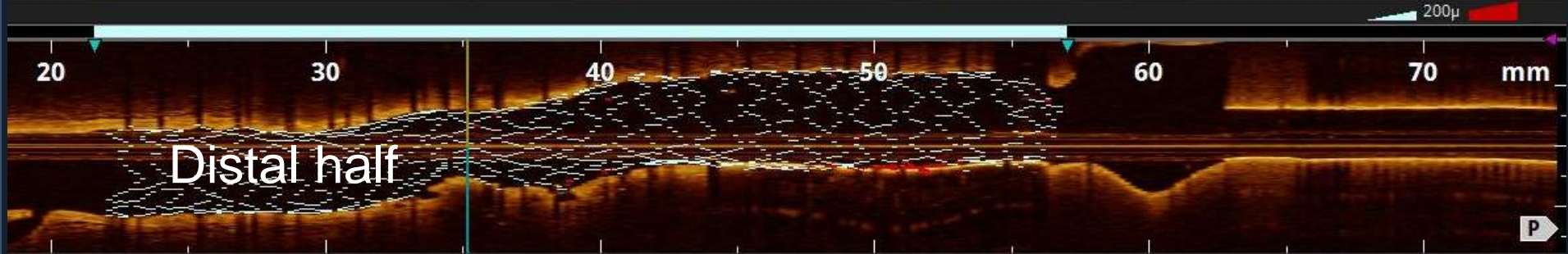
OCT Stent Optimization Algorithm



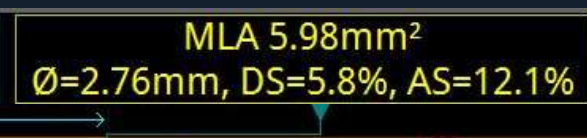
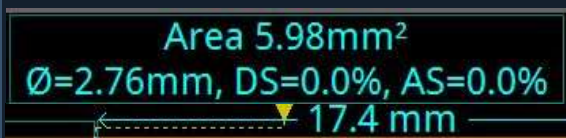
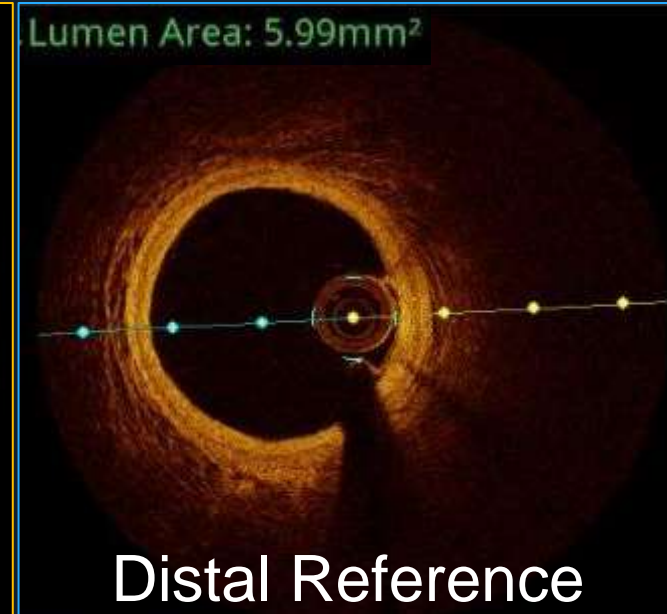
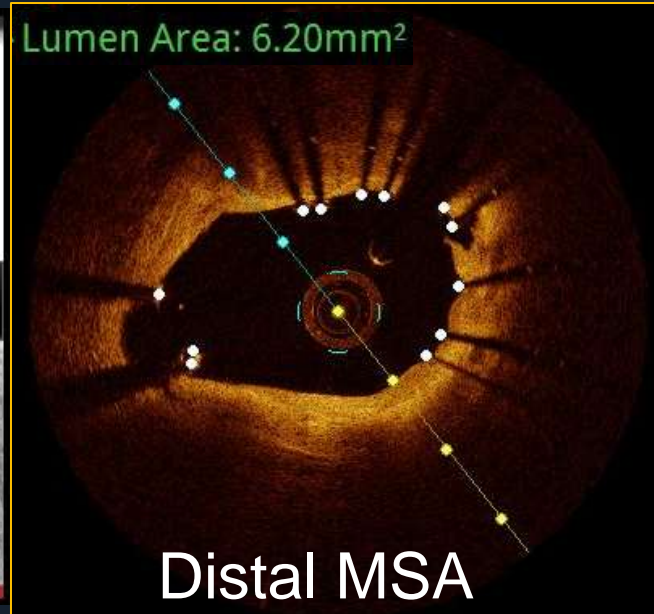
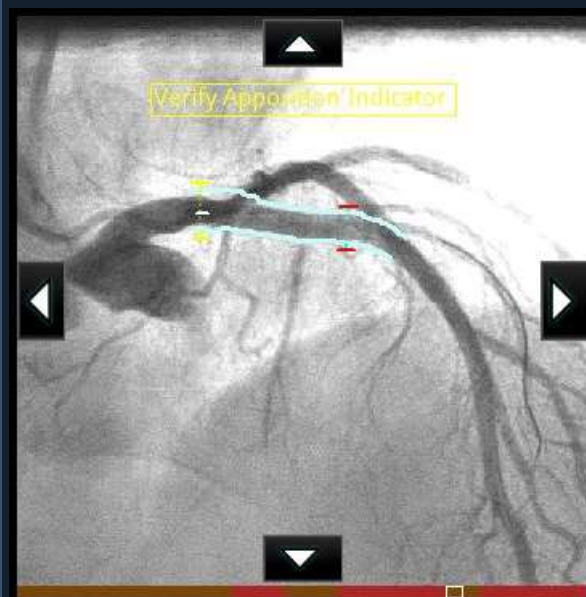
Area 5.99mm²
Ø=2.76mm, DS=10.5%, AS=18.5%

MLA 4.88mm²
Ø=2.47mm, DS=13.0%, AS=23.3%

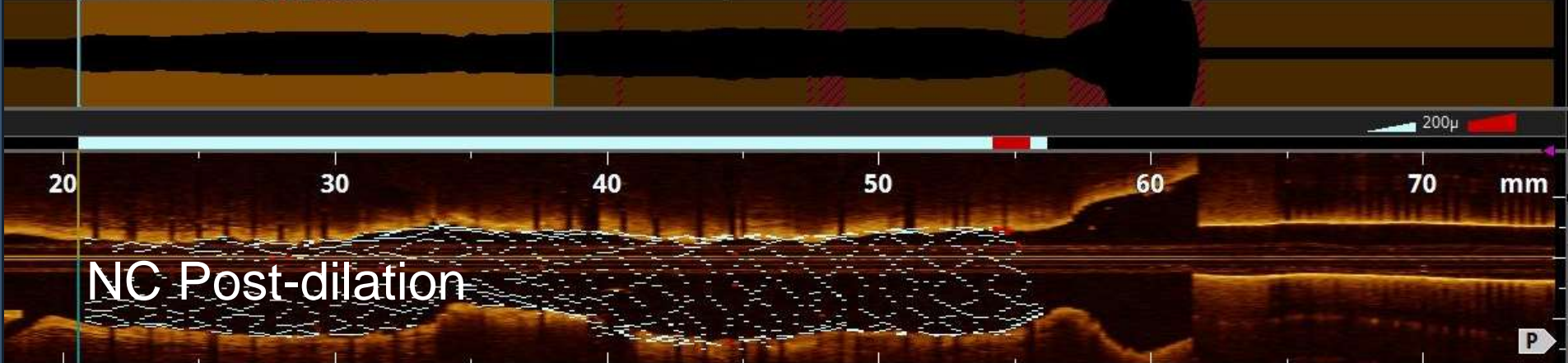
81.5% Underexpansion



OCT Stent Optimization Algorithm



104% Expansion



Angio and Procedure Characteristics

	OCT (n=158)	IVUS (n=146)	Angio (n=146)	<i>P</i> OCT vs IVUS	<i>P</i> 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

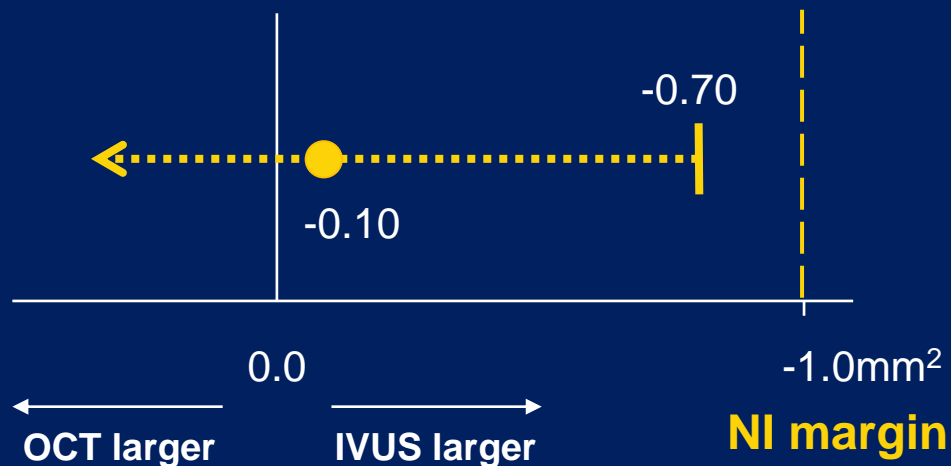
Final post-PCI MSA by OCT

OCT 5.79 mm² [4.54, 7.34]

IVUS 5.89 mm² [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)	<i>P</i> OCT vs IVUS	<i>P</i> 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

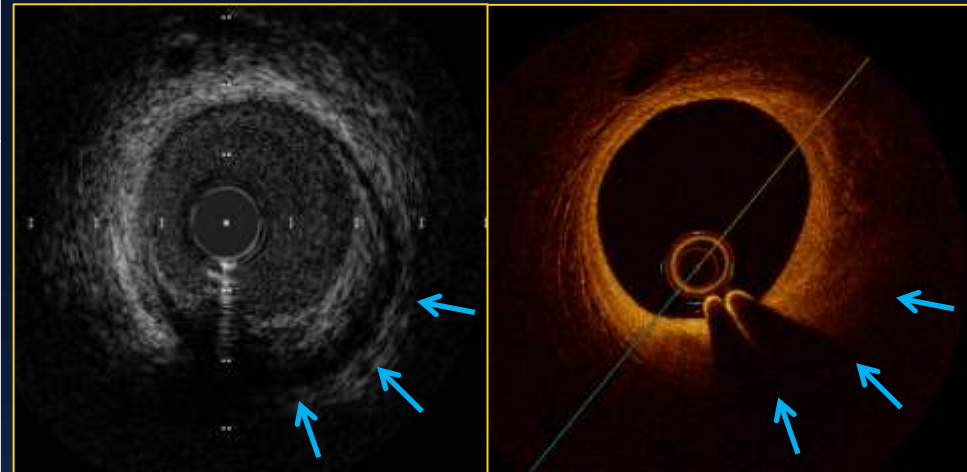
Border and Vessel Visibility

	OCT (n=140)	IVUS (n=135)	<i>P</i> OCT vs IVUS
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EEL visible at either reference segment

>180°

Site	84%	83%	0.78
Core lab	95%	100%	0.02



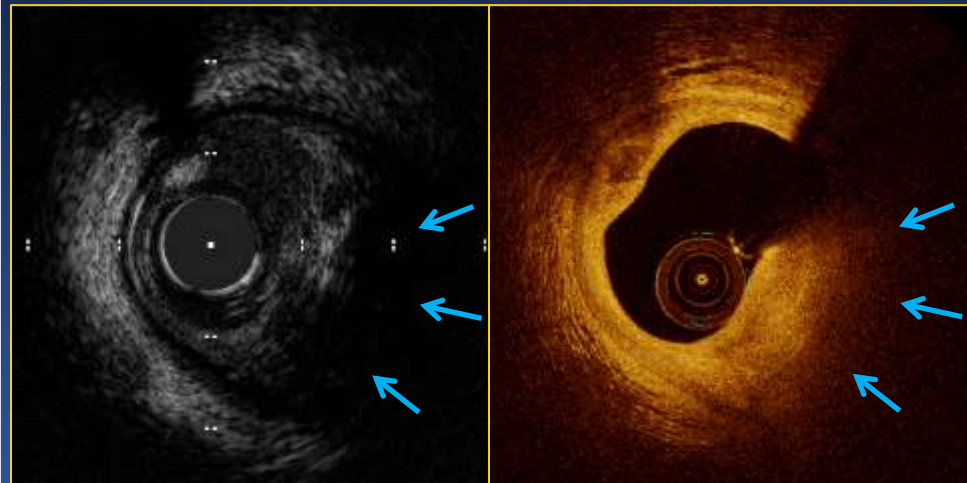
Measurement used to decide stent sizing

Proximal reference

EEL	70%	71%	0.89
Lumen	30%	29%	

Distal reference

EEL	79%	70%	0.09
Lumen	21%	30%	

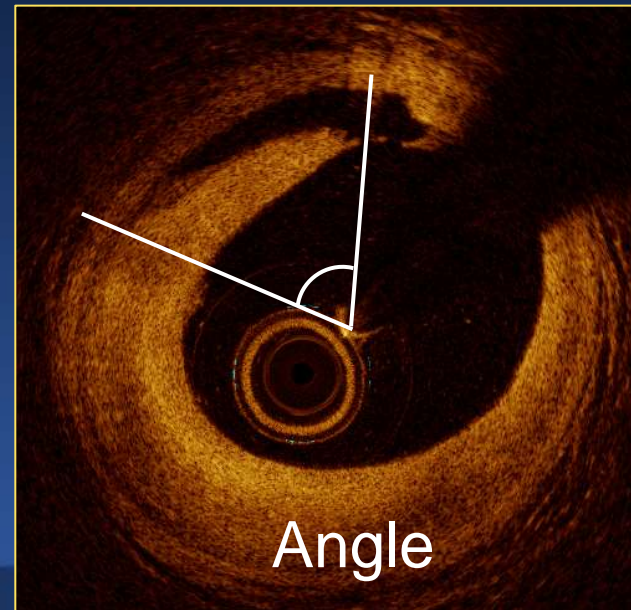
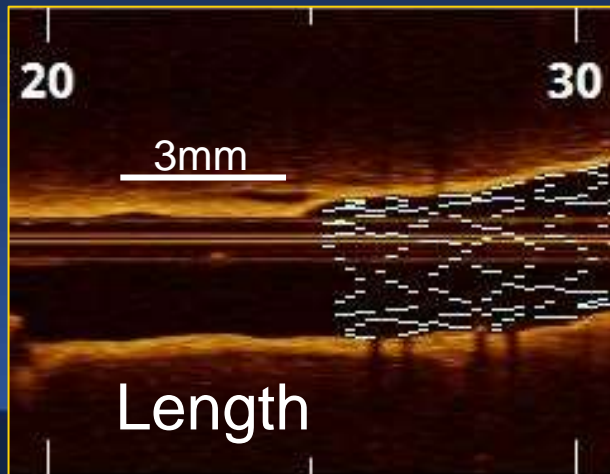


Dissections

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	<i>P</i> OCT vs IVUS	<i>P</i> 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

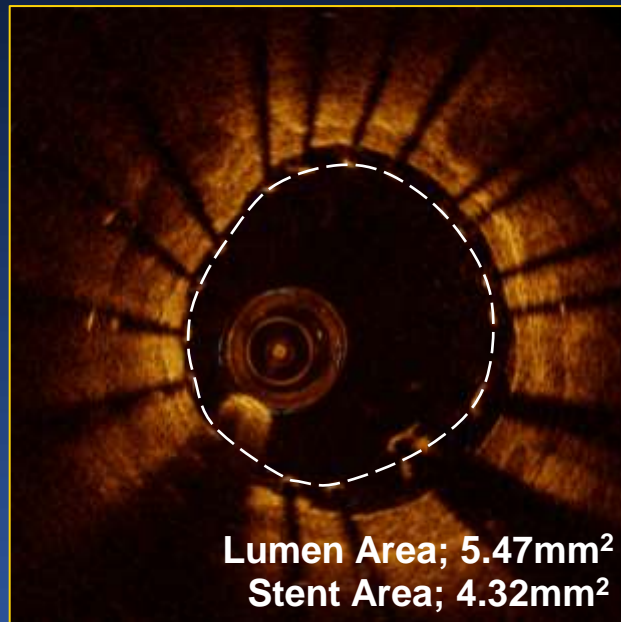
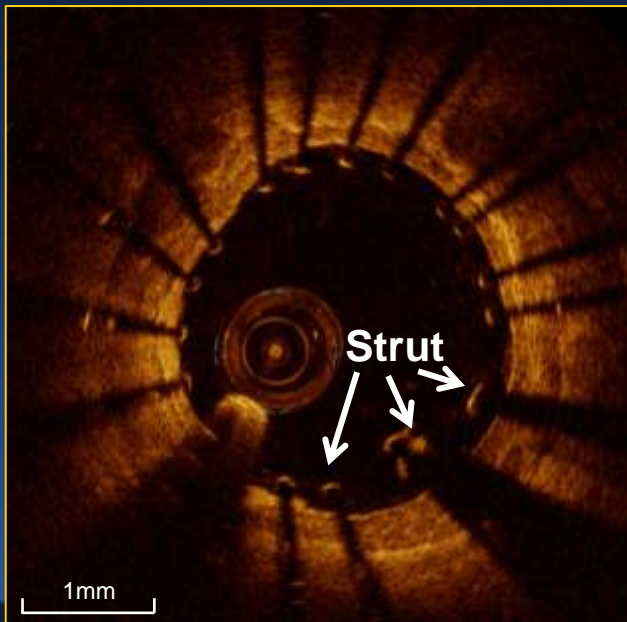
Major Dissection

- 1) Angle $>60^\circ$
- 2) Length >3 mm



Malapposition

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	<i>P</i> OCT vs IVUS	<i>P</i> 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

**Patients scheduled for PCI using DES*
to de novo native coronary artery lesion
n = 800**

1:1

**OFDI-guided PCI
n = 400**

*DES: NOBORI
biolimus-eluting stent

**IVUS-guided PCI
n = 400**

**Follow up coronary angiography
8 months**

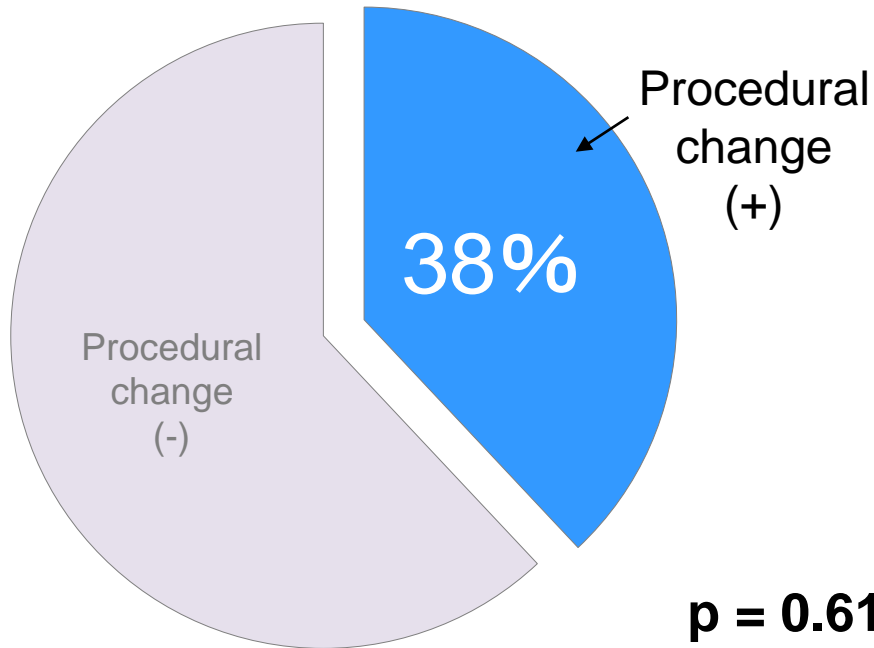
**Clinical follow up
12 months**

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

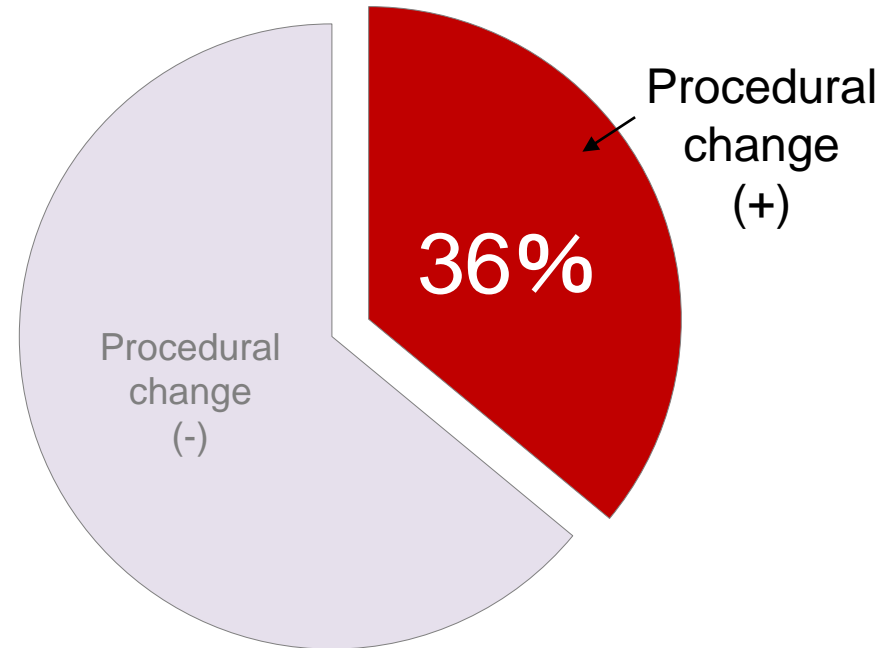
	OFDI-guided PCI	IVUS-guided PCI
Reference site	<ul style="list-style-type: none"> • Most normal looking • No lipidic plaque 	<ul style="list-style-type: none"> • Largest lumen • Plaque burden < 50%
Determination of stent diameter	<ul style="list-style-type: none"> • By measuring lumen diameter at proximal and distal reference sites 	<ul style="list-style-type: none"> • By measuring vessel diameter at proximal and distal reference sites
Determination of stent length	<ul style="list-style-type: none"> • By measuring distance from distal to proximal reference site 	
Goal of stent deployment	<ul style="list-style-type: none"> • In-stent minimal lumen area $\geq 90\%$ 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 	

	OFDI	IVUS	<i>p</i> -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

OFDI guidance



IVUS guidance

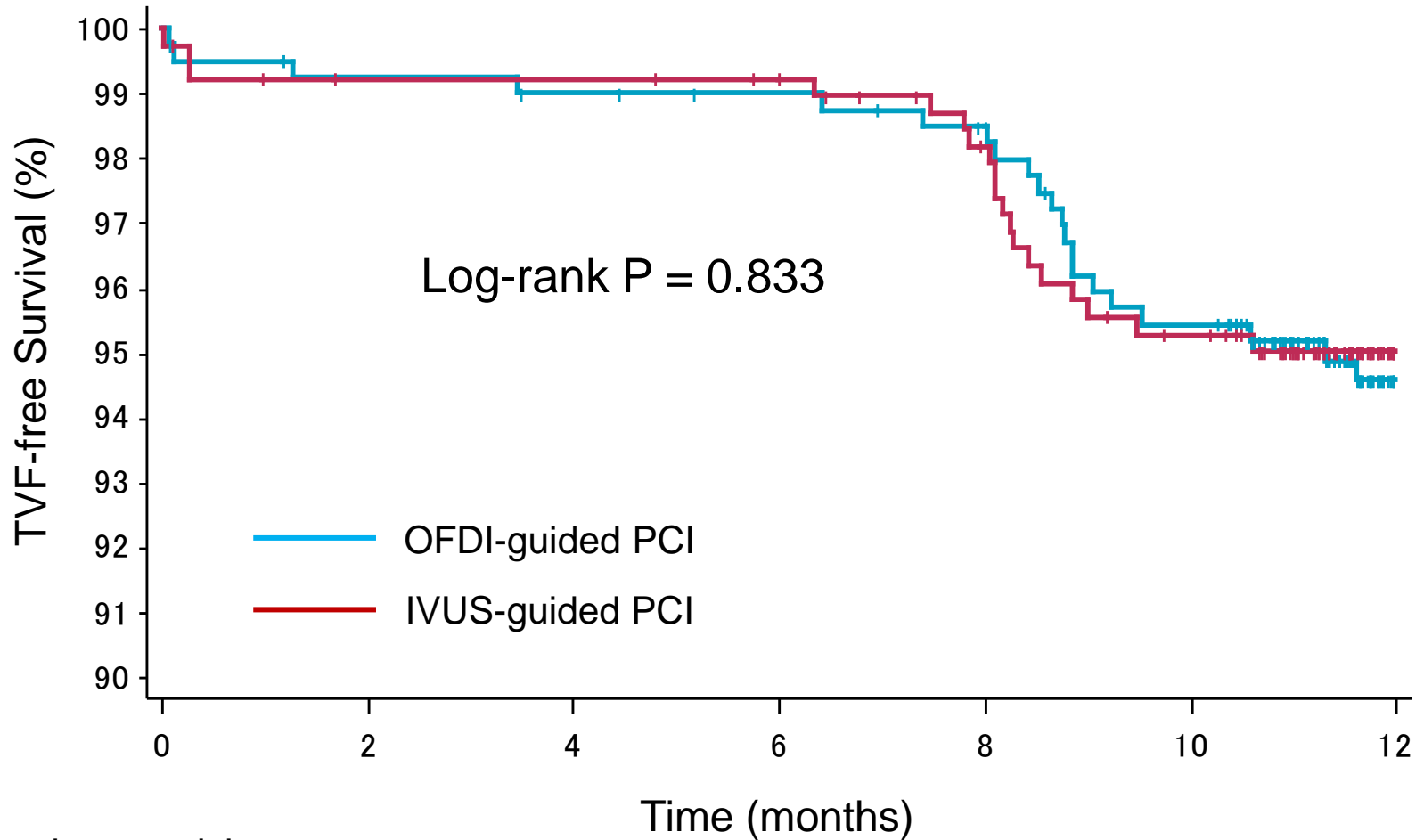


p = 0.611

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

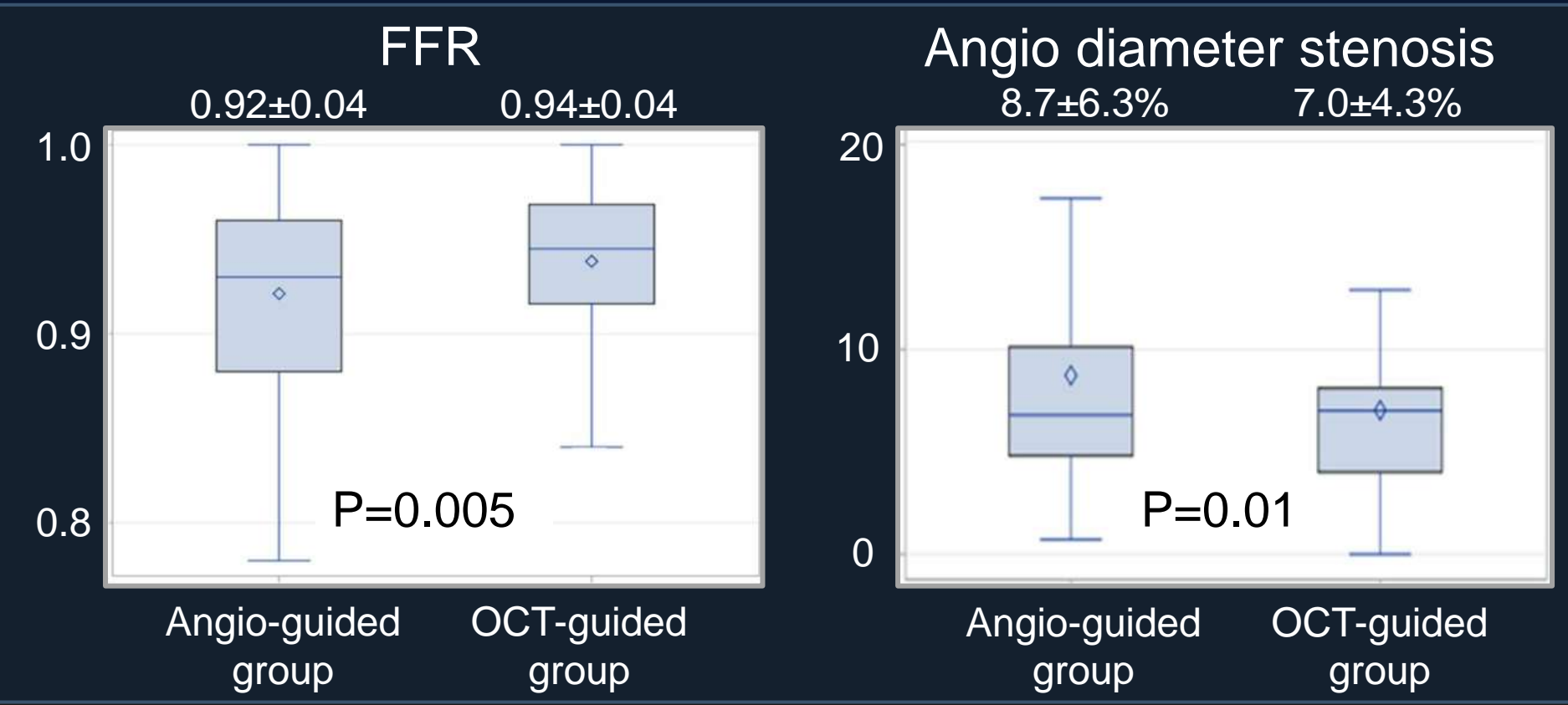
	0	2	4	6	8	10	12
OFDI-guided PCI	401	396	394	392	387	374	265
IVUS-guided PCI	390	384	384	381	373	360	285

OCT vs Angio Guided PCI - DOCTORS -

- Multicenter, randomized trial 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 $\leq 80\%$ (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

OCT vs Angio Guided PCI - DOCTORS -



Post-PCI FFR to predict future 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

* Vessel-oriented cardiac event

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.**