

# ILUMIEN II

## A Retrospective Evaluation of Stent Expansion with OCT Guidance vs. IVUS Guidance

***Gregg W. Stone MD***

*Professor of Medicine*

*Columbia University Medical Center*

*The Cardiovascular Research Foundation*

# 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
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- None

# ILUMIEN II: Background

- Numerous studies have found that the strongest procedural predictor of stent thrombosis and restenosis is the minimum stent area (MSA) achieved after PCI
- By achieving greater stent luminal dimensions, IVUS guidance has been associated with improved event-free survival compared to angiographic guidance alone
- OCT has superior resolution compared to IVUS, but given limited depth penetration is unable to resolve the EEM in most cases; whether stent expansion (a surrogate of clinical outcomes) is as great with OCT guidance as with IVUS guidance is unknown

# ILUMIEN II: Objective

- To compare the degree of stent expansion achieved after OCT-guidance to that achieved with IVUS-guidance

# ILUMIEN I

Observational Study of Optical Coherence Tomography (OCT) in Patients Undergoing Fractional Flow Reserve (FFR) and Percutaneous Coronary Intervention – Stage I

**418 pts prospectively enrolled**

35 sites in North America, EU, Asia and Australia

Patients with stable angina, unstable angina or NSTEMI plus at least 1 angiographically significant stenosis (>50% by visual estimation) in  $\geq 1$  native coronary artery

Mandatory use of FFR and OCT pre and post PCI;  
PCI strongly recommended for  $\text{FFR} \leq 0.80$



**Clinical FU at 30 days, 1 year**

# ADAPT-DES Study

Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

**8,582 pts prospectively enrolled**  
**No clinical or anatomic exclusion criteria**  
11 sites in US and Germany; IVUS used in 3,349 pts



**PCI with  $\geq 1$  non-investigational DES**  
**Successful and uncomplicated**  
IVUS/VH core lab sub-study: 2,179 pts enrolled



Assess platelet function after adequate DAPT loading and GPI washout: Accumetrics  
VerifyNow Aspirin, VerifyNow P2Y12, and VerifyNow IIb/IIIa assays (results blinded)



**Clinical FU at 30 days, 1 year, 2 year**

# ILUMIEN II

Retrospective comparison of OCT-guidance in ILUMIEN I and IVUS-guidance in ADAPT-DES

## ILUMIEN I

418 pts enrolled

Lesions excluded:

Poor quality (n=45)  
Not received by core lab (n=12)  
BRS (n=5)  
Inconsistent data (n=2)

## ADAPT-DES

2,179 pts enrolled in IVUS substudy

Lesions excluded:

No QCA available (n=1043)  
STEMI (n=378)  
In-stent restenosis (n=191)  
No reference available (n=179)  
Left main (n=99)  
Poor image quality or media issue (n=77)  
Chronic total occlusion (n=75)  
Saphenous vein graft (n=66)  
Unreliable pullback (n=66)  
Not received by core lab (n=12)

← Randomly chosen 1 lesion per patient →

### Overall study population (n=940)

354 patients, 354 lesions

586 patients, 586 lesions

← 1:1 Propensity matching →

RVD, lesion length, calcification,  
reference segment availability

### 1:1 Propensity matched groups (n=572)

286 patients, 286 lesions

286 patients, 286 lesions



# ILUMIEN II: Endpoints

## Primary endpoint

- Post-PCI stent expansion (%) defined as the minimum stent area (MSA) divided by the mean reference lumen area
  - Assessed by OCT in ILUMIEN I and by IVUS in ADAPT-DES

## Secondary endpoints

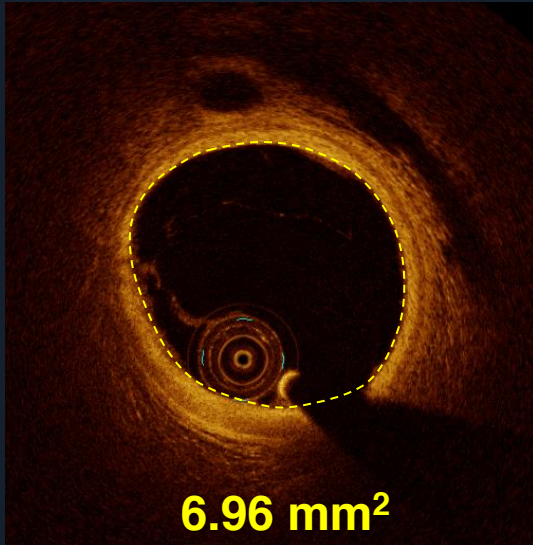
- IVUS and OCT core lab measures
  - Mean stent expansion (defined as stent volume/stent length divided by the mean reference lumen area)
  - Prevalence of major edge dissection ( $\geq 3$  mm in length)
  - Prevalence of major stent malapposition defined as malapposition distance/luminal diameter  $\geq 20\%$
- Angiographic core lab measures (independent of technique)
  - Post-PCI MLD, mean lumen diameter, %DS and acute gain



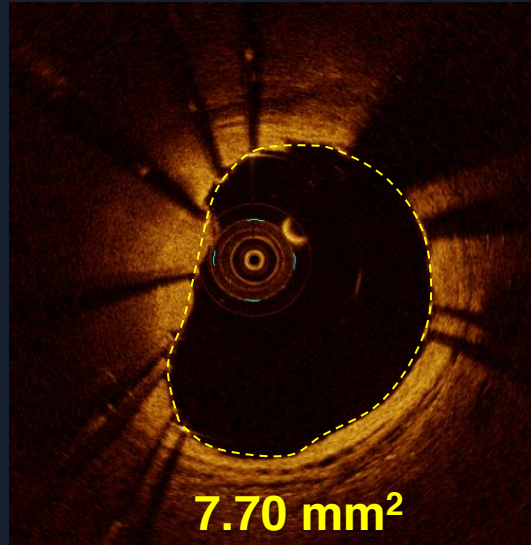
# OCT Imaging and Quantitative Analysis

- St. Jude OCT catheter with automatic pullback (C7 Dragonfly)
- OCT analysis performed at an independent core laboratory (CRF)

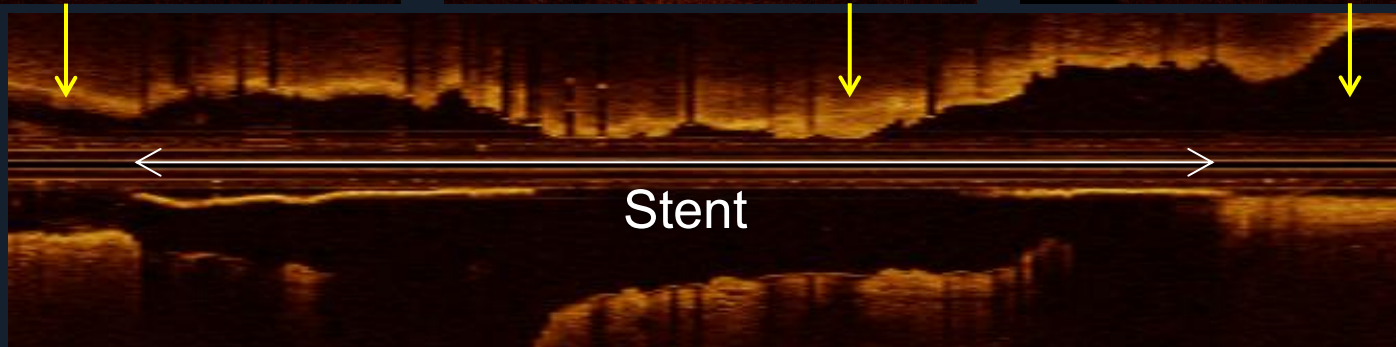
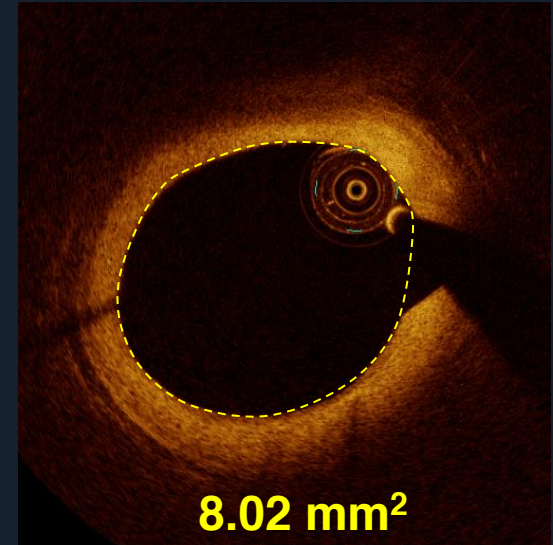
Distal reference



Minimum stent area (MSA)



Proximal reference



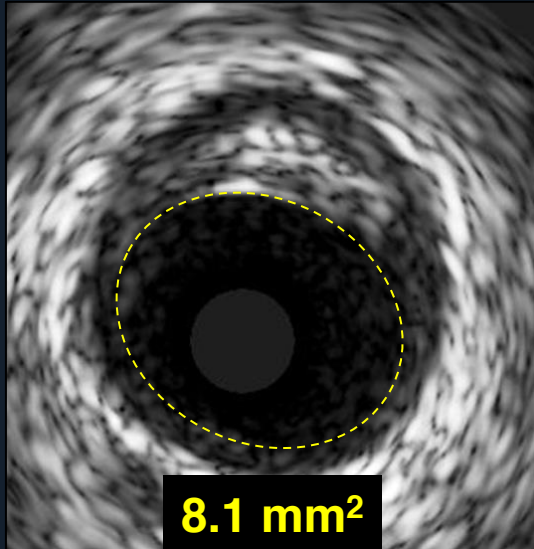
% stent expansion = MSA / average of reference lumen area

$$102.8\% = 7.70 / [(6.96 + 8.02) / 2] * 100$$

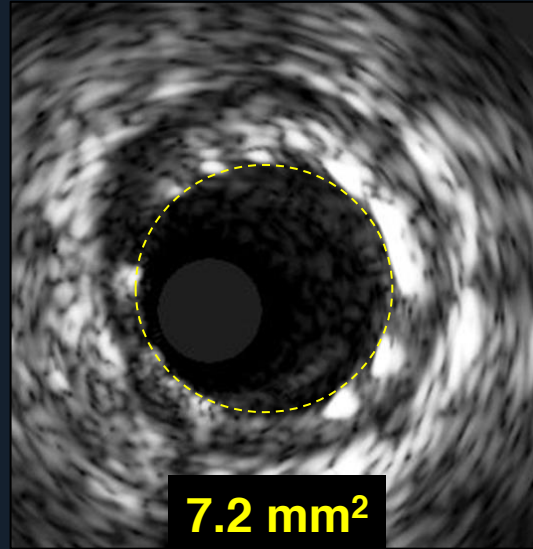
# IVUS Imaging and Quantitative Analysis

- Volcano Eagle Eye IVUS catheter (20MHz) with automatic pullback
- IVUS analysis at independent core laboratory (CRF)

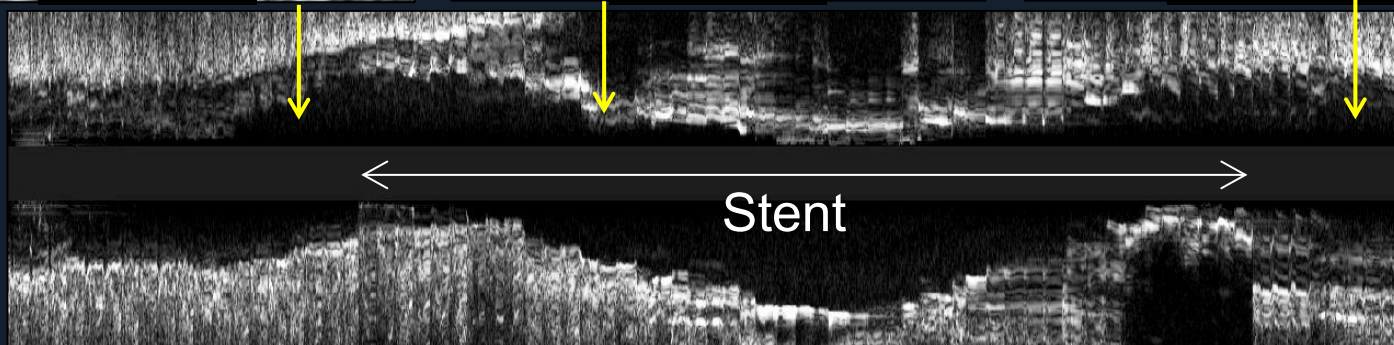
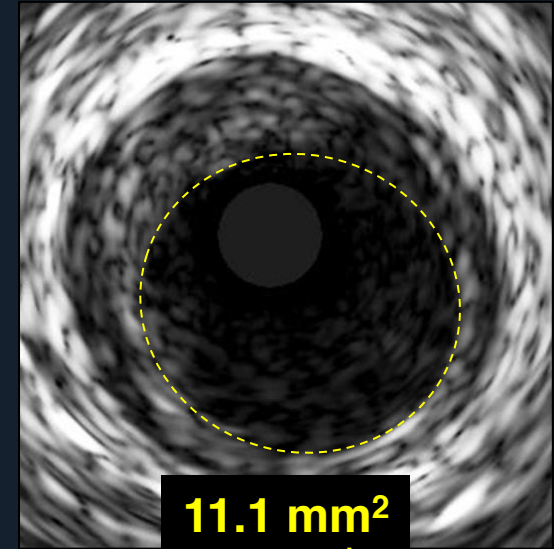
Distal reference



Minimum stent area (MSA)



Proximal reference



% stent expansion = MSA / average of reference lumen area

$$75.0\% = 7.2 / [(8.1 + 11.1) / 2] * 100$$



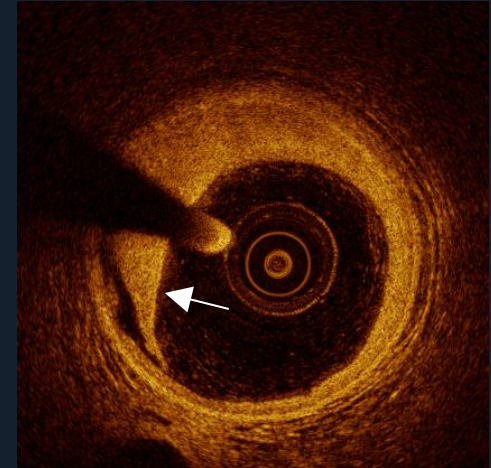
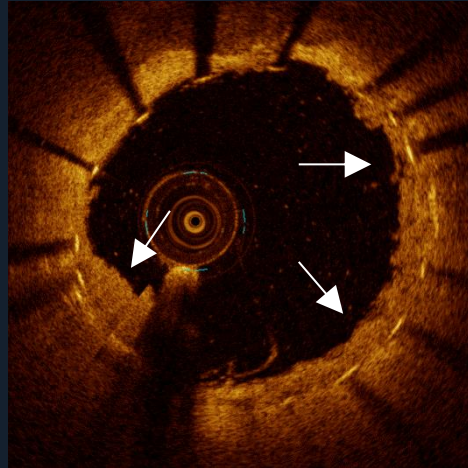
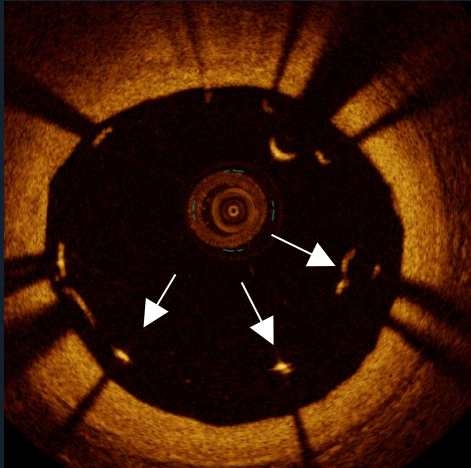
# Examples of Major Post Stent Findings

**Major:** Malapposition  
Distance/lumen  $>20\%$

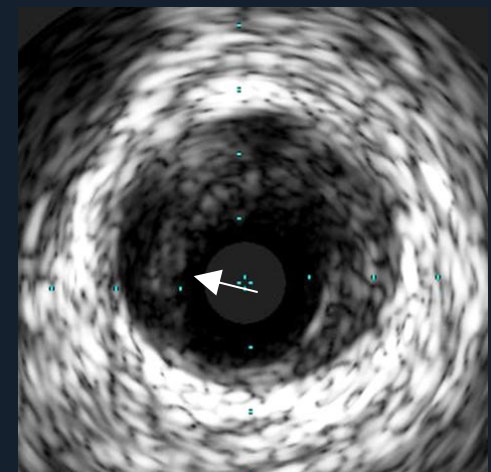
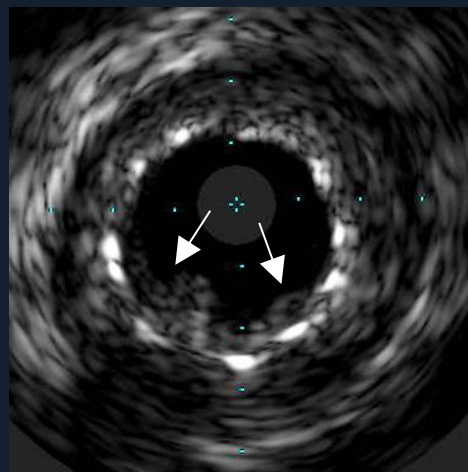
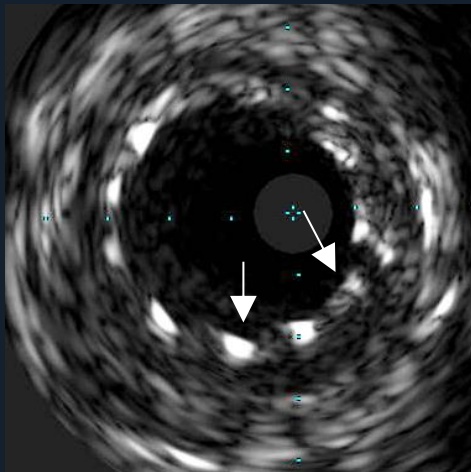
Tissue protrusion  
 $>10\%$

Stent edge dissection  
Length  $\geq 3$  mm

**OCT**



**IVUS**



# ILUMIEN II: Pre-PCI QCA

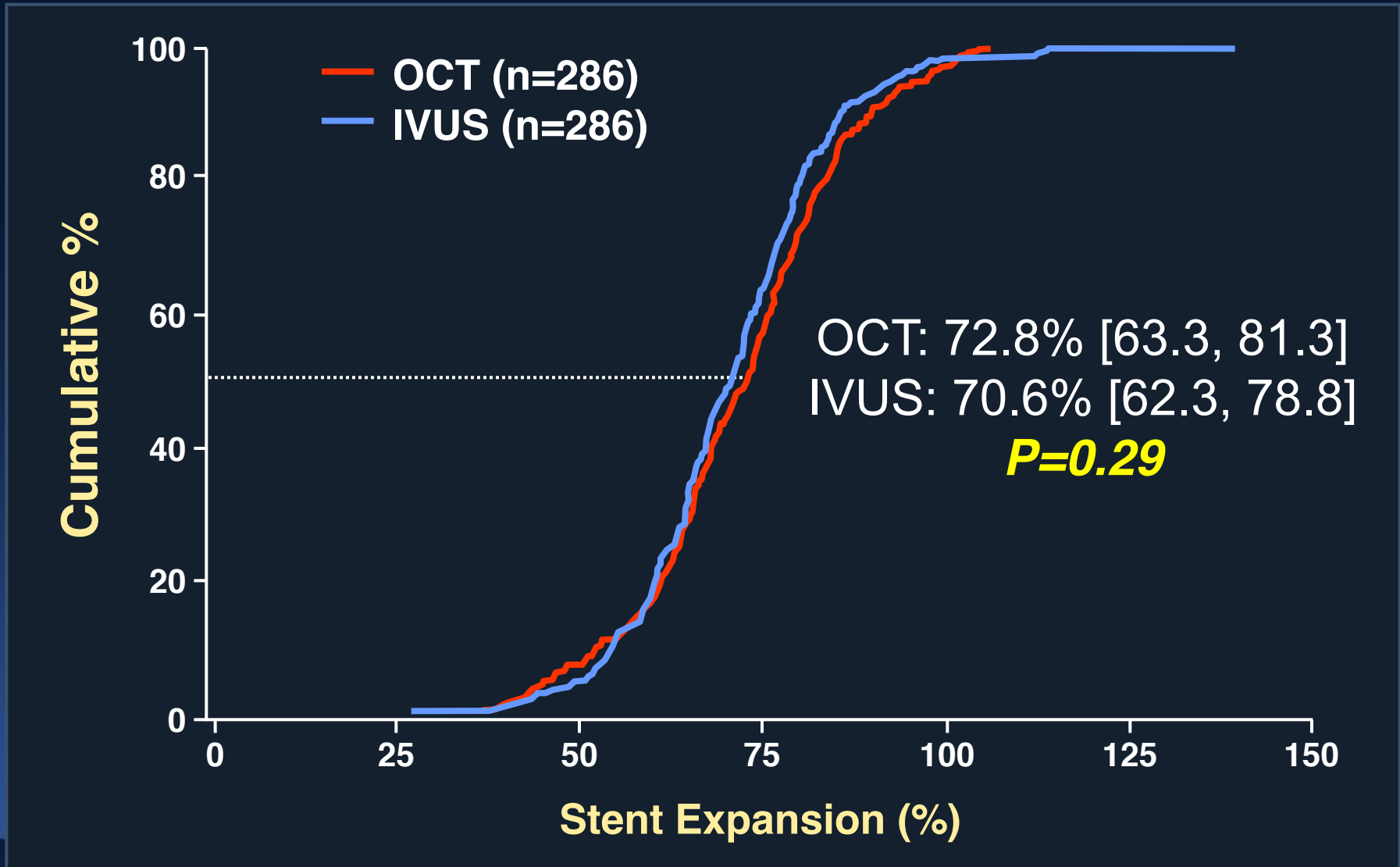
	OCT guidance (n=286)	IVUS guidance (n=286)	P Value
Calcification (moderate or severe)*	60 (21.0%)	56 (19.6%)	0.63
Thrombus	8 (2.8%)	20 (7.0%)	0.02
Bifurcation	97 (33.9%)	93 (32.5%)	0.71
Angulation (moderate or severe)	21 (7.3%)	23 (8.0%)	0.75
Tortuosity (moderate or severe)	21 (7.8%)	23 (8.0%)	0.75
TIMI-3 flow	257 (89.9%)	255 (89.2%)	0.78
RVD, mm*	2.7 (2.3, 3.0)	2.7 (2.4, 3.0)	0.17
MLD, mm	0.9 (0.7, 1.2)	0.9 (0.6, 1.2)	0.12
Diameter stenosis, %	64.3 (57.0, 72.1)	64.0 (56.9, 75.5)	0.03
Lesion length, mm*	14.9 (10.9, 21.3)	14.1 (9.8, 23.5)	0.54

\*Matching parameter

# ILUMIEN II: Post-PCI QCA

	OCT guidance (n=286)	IVUS guidance (n=286)	P Value
RVD, mm	2.6 (2.3, 2.9)	2.7 (2.4, 3.0)	0.12
<b>In-stent measures</b>			
MLD, mm	2.5 (2.3, 2.9)	2.6 (2.3, 2.8)	0.78
Mean LD, mm	2.9 (2.6, 3.2)	2.9 (2.7, 3.2)	0.76
Acute gain, mm	1.6 (1.3, 1.9)	1.6 (1.4, 1.9)	0.60
Diameter stenosis, %	6.3 (2.8, 9.6)	6.4 (2.9, 11.9)	0.07
<b>In-segment measures</b>			
MLD, mm	2.2 (2.0, 2.6)	2.3 (2.1, 2.6)	0.01
Acute gain, mm	1.3 (1.0, 1.6)	1.4 (1.1, 1.7)	0.005
Diameter stenosis, %	13.0 (8.6, 19.8)	12.3 (8.2, 17.3)	0.07
Proximal stent edge MLD, mm	2.8 (2.5, 3.2)	2.8 (2.5, 3.2)	0.046
Distal stent edge MLD, mm	2.3 (2.0, 2.6)	2.4 (2.1, 2.8)	<0.0001

# Illumien II: Cumulative Frequency Distribution of Minimum Stent Expansion



# ILUMIEN II: Post-PCI Imaging

	OCT guidance (n=286)	IVUS guidance (n=286)	P value
<b>Any finding</b>			
- Malapposition	76 (26.6%)	39 (13.6%)	0.0002
- Tissue protrusion	182 (63.6%)	78 (27.3%)	<0.0001
- Stent edge dissection	66 (23.1%)	15 (5.2%)	<0.0001
<b>Major finding</b>			
- Malap distance/lumen >20%	4 (1.4%)	2 (0.7%)	0.69
- Tissue protrusion >10%	33 (11.5%)	23 (8.0%)	0.17
- Dissection with length $\geq$ 3 mm	7 (2.4%)	3 (1.0%)	0.29



# ILUMIEN II: Multivariable Analysis

- Entire study population (n=940) -

	Stent expansion (%)	Mean stent expansion (%)	QCA DS In-stent (%)	QCA DS in-segment (%)
Measurements by OCT (n=354)	72.6 (63.5, 81.4)	89.6 (79.2, 98.5)	6.4 (2.7, 9.9)	13.3 (8.9, 20.2)
Measurements by IVUS (n=586)	70.5 (62.1, 79.5)	86.8 (77.1, 96.8)	6.4 (3.0, 10.7)	11.2 (7.6, 17.2)

## Adjusted p-values

<b>OCT vs. IVUS guidance</b>	<b>0.84</b>	<b>0.30</b>	<b>0.19</b>	<b>0.009</b>
Age	0.04	*	*	*
Prior myocardial infarction	*	*	0.04	*
Lesion length	<0.0001	0.0009	<0.0001	*
Reference vessel diameter	*	0.07	*	0.04
Bifurcation	0.0006	*	*	0.07
Tortuosity (moderate or severe)	0.01	*	*	*
Calcification (moderate or severe)	*	0.0007	*	*
LAD location	*	*	0.02	*
Reference availability	<0.0001	<0.0001	*	*

\*P>0.1 and thus not selected in the final model

# ILUMIEN II: Limitations

- Retrospective comparison from 2 different study databases, with different patients, sites and operators (although same angio/IVUS/OCT core laboratory – CRF)
- Lesions were relatively non-complex
- Despite propensity matching, study groups may differ in unmeasured confounders
- Stent type and inflation pressure were not collected in Illumien I
- Techniques for IVUS and OCT guidance were not pre-specified
- Given differences in dimension measurements between OCT and QCA, the primary endpoint was stent expansion (not MSA)

# ILUMIEN II: Conclusions

- In the present comparison of pts undergoing OCT-guided stenting from ILUMIEN I and IVUS-guided stenting from ADAPT-DES, OCT-guidance was associated with comparable stent expansion, slightly greater in-segment %DS, and similar rates of major stent malapposition, tissue protrusion, and stent edge dissection as IVUS-guidance
- The results of angiography-guided, IVUS-guided and OCT-guided stent implantation are currently being evaluated in the prospective, multicenter, randomized **ILUMIEN III: OPTIMIZE PCI** trial