

# OCT vs. Angiography in Complex Lesions : **ILUMIEN 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 ( <i>Institutional</i> )	NIH/NHLBI, Abbott, Philips, Boston Scientific, Abiomed, Opsens, Acist Medical, Medtronic Cardiovascular Systems Inc
Consulting Fees/Honoraria	Amgen, Astra Zeneca, Boston Scientific
Equity	Shockwave Medical

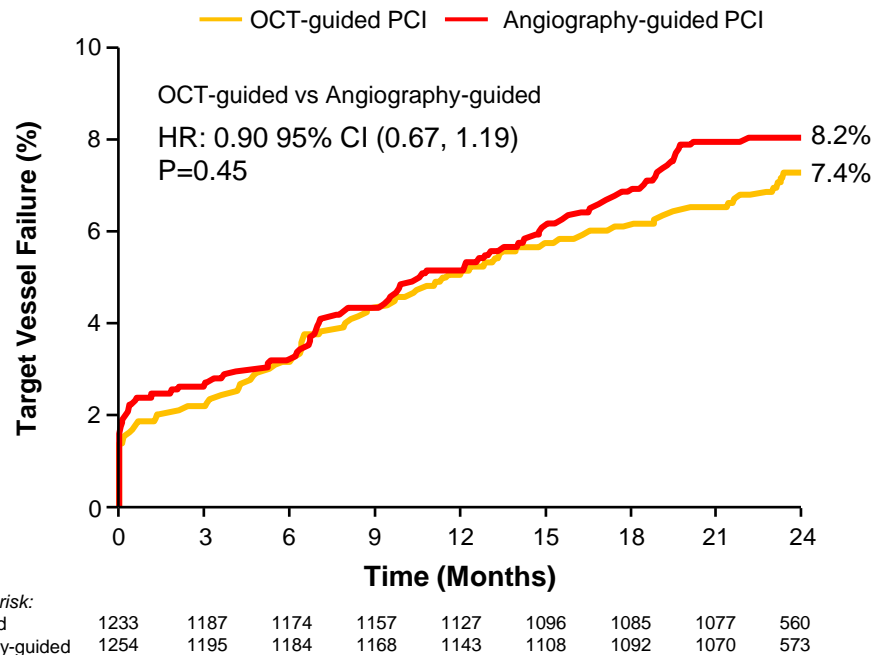
# Background; ILUMIEN IV



## Post-procedure OCT Findings

Variables	OCT L=1222	Angio L=1328	Difference (95% CI)
<b>MSA, mm<sup>2</sup></b>	5.72 ± 2.04	5.36 ± 1.87	0.36 (0.21, 0.51)
Min stent expansion, %	80.8 ± 16.8	78.0 ± 16.7	2.9 (1.6, 4.2)
Mean stent expansion, %	111.3 ± 16.3	103.0 ± 17.2	8.2 (6.9, 9.5)
<b>Stent expansion</b>			
- Acceptable (≥90%)	40.5%	23.3%	17.2% (13.6, 20.8)
<b>Dissection, any</b>			
Major	2.9%	5.1%	-2.2% (-3.9, -0.6)
Minor	22.7%	19.4%	3.3% (-0.1, 6.6)
<b>Malapposition, any</b>			
Major	15.8%	33.2%	-17.4% (-20.6, -14.1)
Minor	39.4%	36.5%	3.0% (-0.8, 6.7)
<b>Tissue Protrusion, any</b>			
Major	5.3%	8.3%	-3.0% (-4.9, -1.0)
Minor	50.6%	38.7%	11.9% (8.1, 15.7)
<b>Reference Disease, any</b>			
Focal	9.5%	12.1%	-2.7% (-5.1, -0.2)
Diffuse	7.8%	8.0%	-0.1% (-2.3, 2.0)

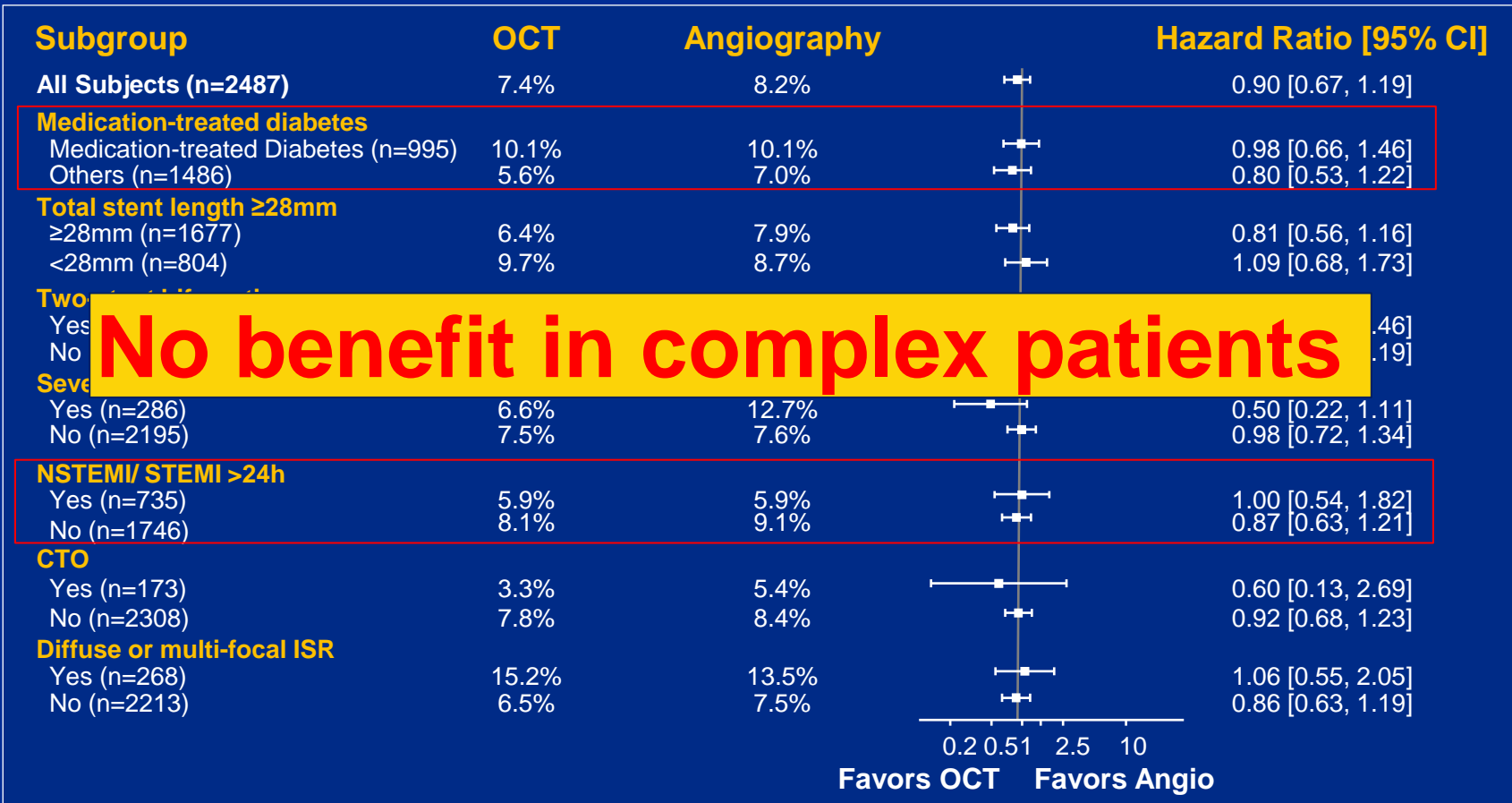
## Target Vessel Failure





**What did we learn?**

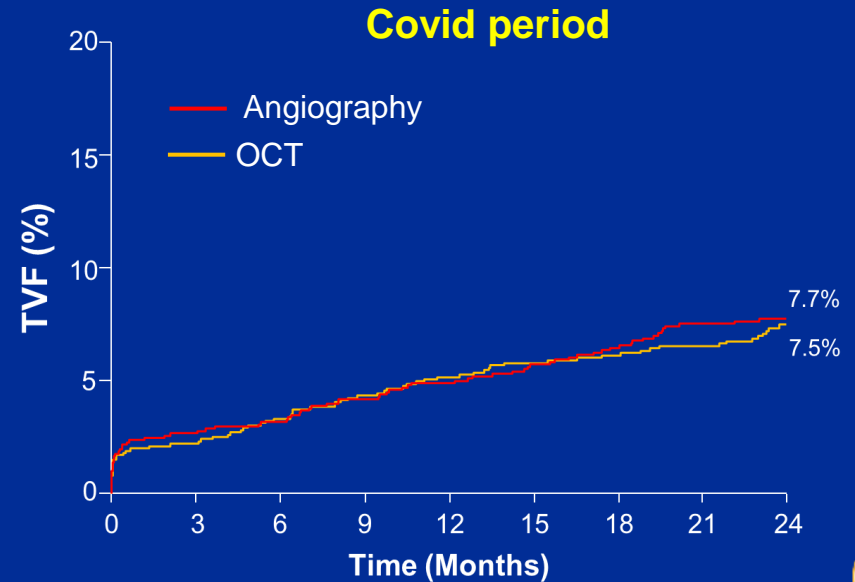
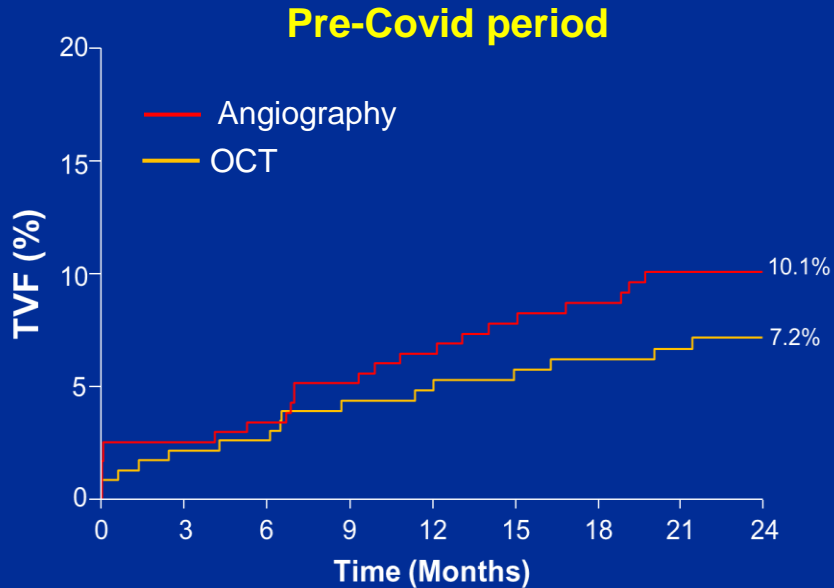
# Sub-group Analysis



**No benefit in complex patients**

# Covid Impact

	OCT	Angiography		Hazard Ratio [95% CI]
<b>Target Vessel Failure</b>			Favors OCT   Favors Angio	
Pre-Covid (n=476)	7.2%	10.1%		0.70 [0.37, 1.32]
Covid (n=2020)	7.5%	7.7%		0.96 [0.69, 1.32]
			0.0 0.5 1 2.5 2.0	





# 2-Year Clinical Outcomes

	OCT (n=1233)	Angio (n=1254)	Hazard Ratio (95% CI)
All-cause mortality	2.7%	3.6%	0.73 (0.47, 1.16)
-Cardiac	0.8%	1.3%	0.57 (0.25, 1.29)
-Vascular	0.3%	0.3%	0.76 (0.17, 3.38)
-Non-cardiovascular	1.7%	2.0%	0.84 (0.46, 1.52)
All MI	4.8%	6.0%	0.80 (0.56, 1.13)
-TV-MI	2.5%	3.3%	0.77 (0.48, 1.22)
-Periprocedural MI	1.4%	1.7%	0.82 (0.43, 1.56)
-Non-periprocedural MI	3.4%	4.4%	0.77 (0.51, 1.17)
All revascularization	9.4%	10.1%	0.94 (0.72, 1.21)
- ID-TVR	5.6%	5.6%	0.99 (0.71, 1.40)
- ID-TLR	4.5%	4.3%	1.05 (0.71, 1.54)
- ID-TVR/non-TLR	1.8%	2.4%	0.79 (0.45, 1.38)

# Study design



## Aim:

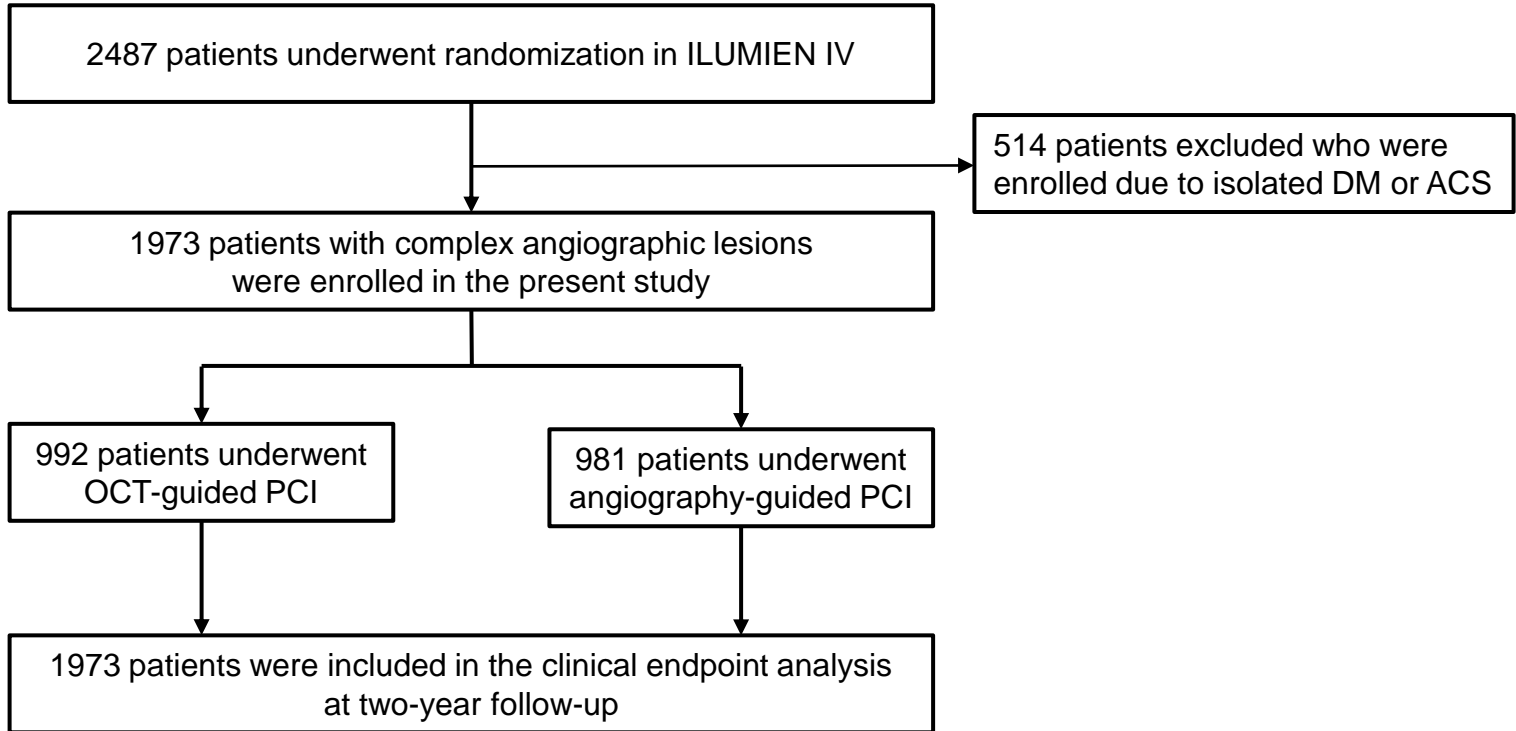
To determine whether OCT-guided PCI improves procedural and clinical outcomes compared with angiography-guided PCI, specifically in **complex angiographic lesions**, assessing for hard endpoints.

## Method:

- This was a pre-specified powered analysis of the ILUMIEN IV: OPTIMAL PCI, a prospective, single-blind randomized trial comparing OCT-guided versus angiography-guided PCI.
- Complex angiographic lesions included;
  1. Long or multiple lesion (stent  $\geq$ 28 mm)
  2. Two-stent bifurcation lesion
  3. Severely calcified lesion
  4. Chronic total occlusion
  5. In-stent restenosis



# Study Flowchart



# Endpoints

## 1. Imaging endpoint:

- Final post-PCI MSA assessed by OCT

## 2. Major clinical endpoints:

- Serious Major Adverse Cardiovascular Events (MACE) during 2-years follow up

(a composite of cardiac death, target-vessel MI, or definite/probable stent thrombosis)

- Target-Vessel Failure (TVF) during 2-years follow-up

(a composite of cardiac death, target-vessel MI, or ischemia-driven TVR)

# Baseline characteristics



	OCT-Guided PCI (N=992)	Angiography-Guided PCI (N=981)	P-value
Age, years	65.6 ± 10.5	65.7 ± 10.4	0.89
Male	792 (79.8%)	750 (76.5%)	0.07
Hypertension	707 (71.3%)	734 (74.8%)	0.08
Dyslipidemia	658 (66.3%)	681 (69.4%)	0.14
Diabetes mellitus	360 (36.3%)	342 (34.9%)	0.51
Current smoker	198/991 (20.0%)	192/980 (19.6%)	0.83
PVD	56 (5.6%)	62 (6.3%)	0.53
<b>Prior MI</b>	<b>211 (21.3%)</b>	<b>255 (26.0%)</b>	<b>0.01</b>
Prior CABG	53 (5.3%)	43 (4.4%)	0.32
Renal insufficiency	86 (8.7%)	90 (9.2%)	0.69
LVEF, %	55.1 ± 8.5	55.0 ± 8.7	0.88
Clinical presentation			
Silent ischemia	140 (14.1%)	151 (15.4%)	0.42
Stable angina	288 (29.0%)	303 (30.9%)	0.37
Unstable angina	297 (29.9%)	281 (28.6%)	0.53
NSTEMI	208 (21.0%)	181 (18.5%)	0.16
Recent STEMI (>24 hours)	59 (5.9%)	65 (6.6%)	0.53

# Qualifying Characteristics



	OCT-Guided PCI (N=992)	Angiography-Guided PCI (N=981)	P-value
Long or multiple lesions	853 (86.0%)	824 (84.0%)	0.22
Two-stent bifurcation	40 (4.0%)	43 (4.4%)	0.70
Severe calcification	140 (14.1%)	146 (14.9%)	0.63
Chronic total occlusion	94 (9.5%)	79 (8.1%)	0.26
Diffuse or multi-focal ISR	130 (13.1%)	138 (14.1%)	0.53

# Baseline Angiographic Characteristics



	OCT-Guided PCI (L=1075)	Angiography-Guided PCI (L=1095)	P-Value
Target vessel			0.69
LAD	571 (53.1%)	575 (52.5%)	
LCX	190 (17.7%)	209 (19.1%)	
RCA	314 (29.2%)	311 (28.4%)	
Thrombus	76/1072 (7.1%)	77/1082 (7.1%)	0.98
Severe calcification	363/1069 (34.0%)	348/1080 (32.2%)	0.39
Reference vessel diameter, mm	2.92 ± 0.43	2.90 ± 0.42	0.28
Minimum lumen diameter, mm	0.87 ± 0.43	0.87 ± 0.43	0.76
Diameter stenosis, %	70.2 ± 14.0	69.8 ± 14.0	0.58
<b>Lesion length, mm</b>	<b>36.0 ± 15.5</b>	<b>33.3 ± 16.1</b>	<b>&lt;0.001</b>
Baseline TIMI III flow	832/1032 (80.6%)	815/1034 (78.8%)	0.31

# Procedural Characteristics per patient



	OCT-Guided PCI (N=992)	Angiography-Guided PCI (N=981)	P-value
Radial access	716 (72.2%)	710 (72.4%)	0.92
Total stent length, mm	49.0 ± 23.5	45.4 ± 24.2	0.001
Procedure duration, min	72.0 ± 39.2	53.9 ± 37.1	<0.001
Fluoroscopy duration, min	22.3 ± 13.9	18.4 ± 12.1	<0.001
Radiation dose, Gy	2.1 ± 1.8	1.6 ± 1.3	<0.001
Contrast volume, mL	237.7 ± 88.8	200.4 ± 82.1	<0.001

# Procedural Characteristics per lesion



	OCT-Guided PCI (L=1105)	Angiography-Guided PCI (L=1116)	P-value
Advanced lesion preparation	163 (14.8%)	101 (9.1%)	<0.001
Maximum stent diameter, mm	3.22 ± 0.47	3.12 ± 0.39	<0.001
Post-dilatation performed	1064 (96.3%)	957 (85.8%)	<0.001
Post-dilatation balloons used	1.7 ± 1.2	1.5 ± 1.2	<0.001
Maximum device size, mm	3.68 ± 0.55	3.39 ± 0.46	<0.001
Maximum inflation pressure,atm	20.0 ± 3.1	18.6 ± 3.4	<0.001
Stent type			
Xience stent	1086/1094 (99.3%)	1106/1112 (99.5%)	0.57
Other or not specified	18/1094 (1.6%)	12/1112 (1.1%)	0.25

# Post-PCI Angiographic Characteristics



	OCT-Guided PCI (L=1075)	Angiography-Guided PCI (L=1095)	P-value
Reference vessel diameter, mm	2.96 ± 0.44	2.93 ± 0.39	0.11
Acute lumen gain, mm	1.75 ± 0.52	1.72 ± 0.52	0.20
Minimum lumen diameter, mm	2.62 ± 0.42	2.60 ± 0.38	0.13
Diameter stenosis,	11.3 ± 6.6	11.3 ± 6.4	0.87
Dissection ≥ type B	15 (1.4%)	19 (1.7%)	0.52
Slow flow or no-reflow	3 (0.3%)	6 (0.5%)	0.51
Final TIMI III flow	997/1022 (97.6%)	1000/1032 (96.9%)	0.37



# Conclusion



The primary results of OCT vs. Angiography in Complex Lesions will be presented at [EuroPCR - May 15, 2024](#)