

# Impact of peri-procedural IVUS on OCT outcome parameters: IDEAL-LM Study

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**I have the following potential conflicts of interest to report:**

- Institutional grant/research support: Boston Scientific, Abbott Vascular
- Study funded by Boston Scientific

# Why this study

- Meta-analysis of non-randomized trials showed benefit of IVUS-guidance during LM PCI.
- Difference in baseline characteristics and non-captured patient characteristics
- Larger stents?, larger balloons?, better expansion at implant (QCA, IVUS)
- No information on impact after initial healing

Ye Y, et al PLoS One. 2017 Jun 22;12(6):e0179756. [Percutaneous coronary intervention in left main coronary artery disease with or without intravascular ultrasound: A meta-analysis.](#)

Andell P, Erlinge D. et al Circ Cardiovasc Interv. 2017 May;10(5). Intravascular Ultrasound Guidance Is Associated With Better Outcome in Patients Undergoing Unprotected Left Main Coronary Artery Stenting Compared With Angiography Guidance Alone

Tan Q, Et al. Saudi Medical Journal. 2015; 36(5):549±53. [25935174](#)

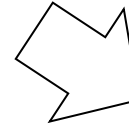
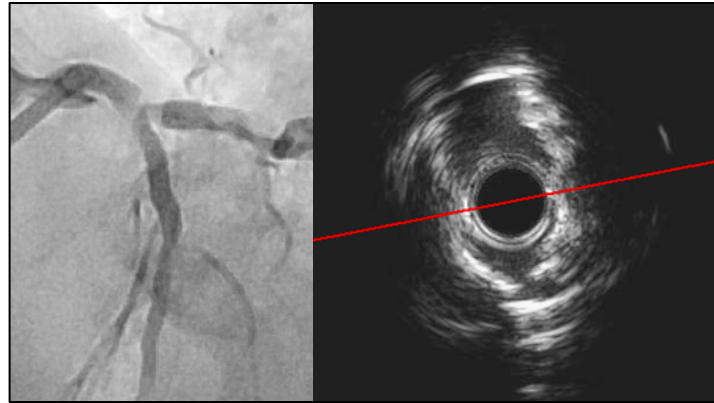
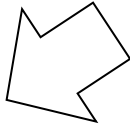
# IDEAL-Left Main:

Improved Drug Eluting stent for ALL comers Left Main

818 Patients: MACE 2 years

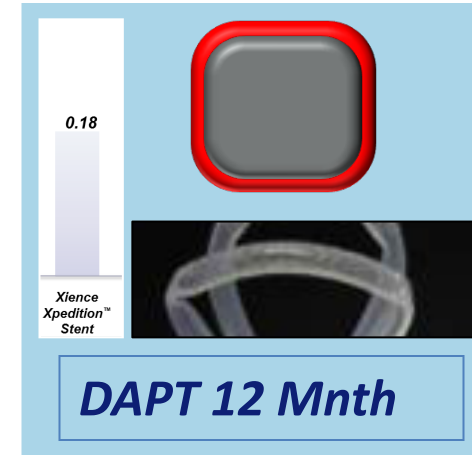
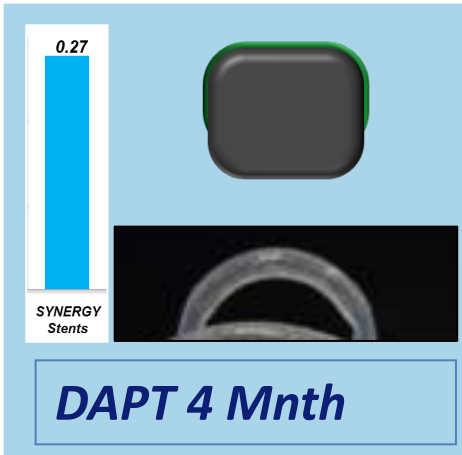
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**Sponsor:**

*Glasgow Jubilee National Hospital*

**Principal Investigators:**

*Professor Keith Oldroyd, MD(Hons)*

*Professor Robert-Jan van Geuns, MD, PhD*

**CRO + CEC:** *Venn Life Sciences*

**Biostatistics and Datamanagement:** *Diagram BV*

**Corelab:** *Cardialysis BV*

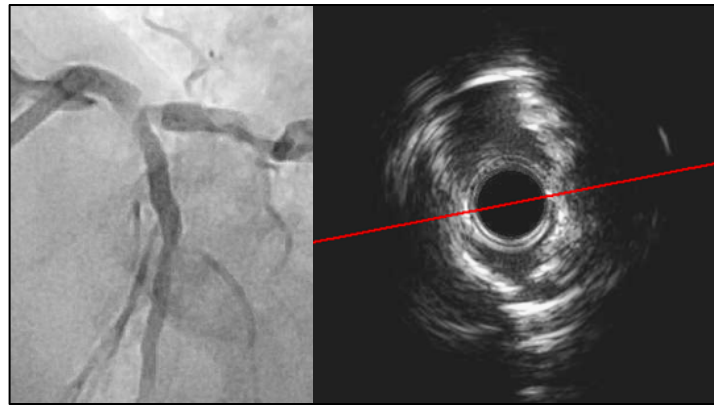
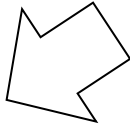
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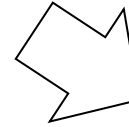
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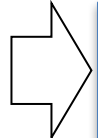


0.27

SYNERGY Stents

**DAPT 4 Mnth**

50



**Invasive Substudy**

**OCT 3 months**

**Target N=100**

**Healing score**

**EARLY HEALING**  
2 month OCT images of SYNERGY in a complex patient  
Source: Dr. J. M. de la Torre

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0.18

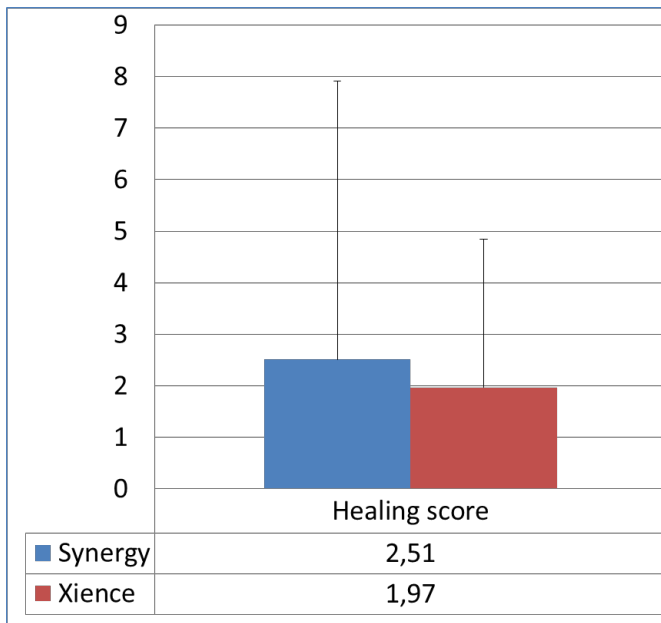
Xience Xpedition™ Stent

**DAPT 12 Mnth**

- Glasgow, UK
- Rotterdam, NL
- Poznan, Poland
- Moscow, Russia
- Cardiff, UK
- Novosibirsk, Russia

# Summary

- First randomized study comparing two types of DES in LM on apposition and coverage.
- No difference in Healing Score
- 100% coverage at 3 months for both DES types
- Very low % malapposition for both DES types



	Malapposed (%)	Uncovered (%)
Proximal main	2.47 ± 4.33	0.00 ± 0.00
Bif. Region	2.60 ± 8.25	0.03 ± 0.30
Distal Main	2.39 ± 5.29	0.01 ± 0.11

# Impact of peri-procedural IVUS on 3 month OCT outcome parameters: A IDEAL-LM Subanalysis

*QCA outcomes:*

*MLD, %DS, LLL*

*OCT parameters:*

*Mean lumen area*

*Minimal lumen area*

*Mean stent area*

*Mean neo-intima areas  $\neq$*

*Uncovered struts (%)*

*Covered >20 micron (%)*

*Malapposed struts (%)*

*Mean ISA area*

# Patient characteristics

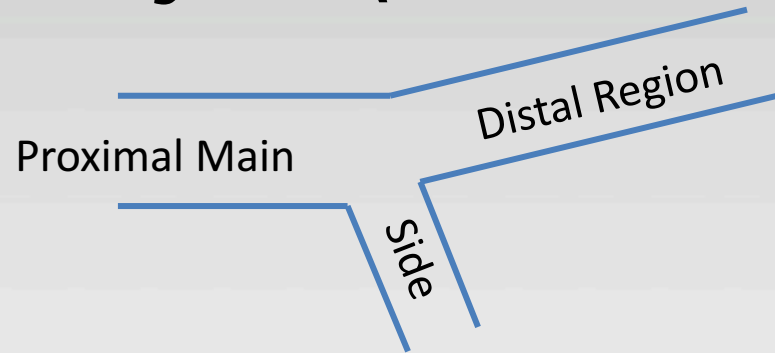
Parameter	Total (N=101)	IVUS (N=47)	No IVUS (N=54)	P value
Age, Mean (SD)	64.2 ± 9.2	63.1 ± 10.2	65.15 ± 8.21	<b>0.1210</b>
Male, n (%)	80 (79.2%)	35/47 (74.5%)	45/54 (83.3%)	<b>0.2735</b>
Prior ACS	50 (49.5%)	19/47 (40.4%)	31/54 (57.4%)	<b>0.0886</b>
Diabetes mellitus	31 (30.7%)	9/47 (19.1%)	22/54 (40.7%)	<b>0.0189</b>
Smoking status				
Current (<30 days)	22 (21.8%)	9/47 (19.1%)	13/54 (24.1%)	<b>0.5497</b>
Former	20 (25.3%)	14/38 (36.8%)	6/41 (14.6%)	<b>0.0233</b>
Hypertension	87 (86.1%)	38/47 (80.9%)	49/54 (90.7%)	<b>0.1514</b>
Hyperlipidemia	88 (87.1%)	42/47 (89.4%)	46/54 (85.2%)	<b>0.5319</b>
Syntax score	20.3 ± 9.0	22.46 ± 10.96	18.41 ± 6.49	<b>0.1656</b>
Low Syntax	69 (68.3%)	25/47 (53.2%)	44/54 (81.5%)	<b>0.0091</b>
Medium Syntax	21 (20.8%)	14/47 (29.8%)	7/54 (13.0%)	
High Syntax	11 (10.9%)	8/47 (17.0%)	3/54 (5.6%)	



# Procedural characteristics

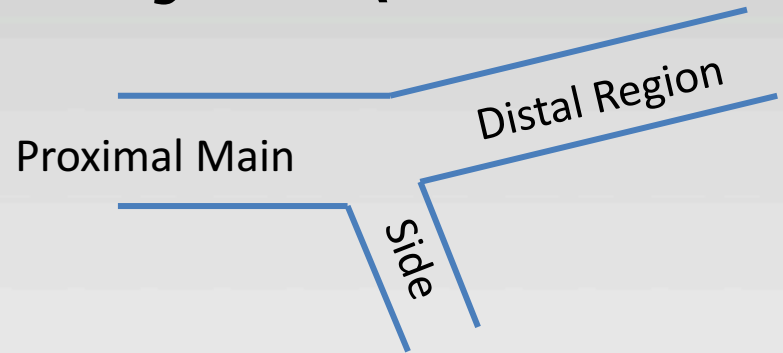
Parameter	Total (N=101)	IVUS (N=47)	No IVUS (N=54)	P value
<b>LM only</b>	31 (30.7%)	14 (29.8%)	17 (31.5%)	<b>0.4656</b>
<b>Left main + One vessel</b>	40 (39.6%)	16 (34.0%)	24 (44.4%)	
<b>Left main + Two vessels</b>	26 (25.7%)	14 (29.8%)	12 (22.2%)	
<b>Left main + Three vessel</b>	4 (4.0%)	3 (6.4%)	1 (1.9%)	
<b># Stents (culprit)</b>	1.23 ± 0.53	1.32 ± 0.66	1.15 ± 0.36	<b>0.2269</b>
<b># Stents (non culprit)</b>	0.59 ± 0.93	0.72 ± 1.10	0.48 ± 0.75	<b>0.5250</b>
<b>Stent Length (culprit)</b>	27.37 ± 13.68	28.68 ± 15.72	26.22 ± 11.66	<b>0.8005</b>
<b>Stent length (total)</b>	41.67 ± 26.58	48.06 ± 31.43	36.11 ± 20.20	<b>0.1062</b>
<b>Stent diameter (culprit)</b>	3.55 ± 0.38	3.54 ± 0.39	3.56 ± 0.37	<b>0.8618</b>
<b>Only pre IVUS</b>		8		
<b>Only post IVUS</b>		17		
<b>Pre and Post IVUS</b>		22		

# Angiographic analysis (Procedure)



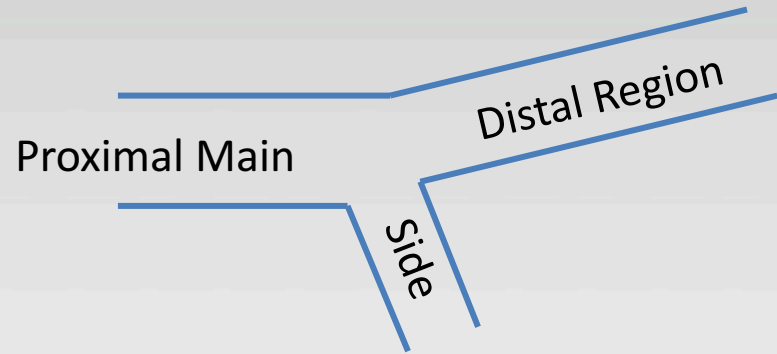
Segment	Length (mm)	Pre RVD (mm)		Post-MLD (mm)		Post-DS (%)		p-Value
		IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	
Proximal Main Branch	8.0 ± 2.9	3.54 ± 0.68	3.61 ± 0.80	3.51 ± 0.49	3.45 ± 0.46	<b>12.04 ± 6.24</b>	<b>15.34 ± 7.56</b>	<b>0.027</b>
Distal Main Branch	15.7 ± 12.0	2.58 ± 0.57	2.51 ± 0.61	2.57 ± 0.60	2.62 ± 0.46	<b>14.07 ± 16.71</b>	<b>11.71 ± 8.41</b>	<b>0.663</b>
Side Branch	9.1 ± 11.2	2.48 ± 0.56	2.46 ± 0.62	2.26 ± 0.50	2.19 ± 0.53	<b>14.16 ± 14.85</b>	<b>15.10 ± 13.89</b>	<b>0.383</b>

# Angiographic analysis (Procedure)



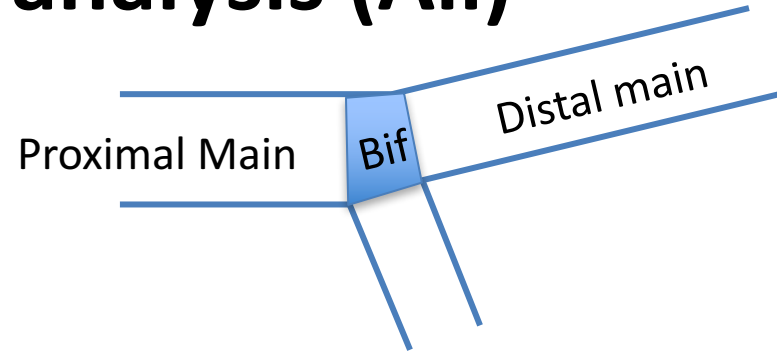
Segment	Length (mm)	Pre-MLD (mm)		Post-MLD (mm)		Acute Gain (mm)		p-Value
		IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	
Proximal Main Branch	8.0 ± 2.9	2.16 ± 0.71	2.07 ± 0.58 ns	3.51 ± 0.49	3.45 ± 0.46 ns	<b>1.36 ± 0.60</b>	<b>1.39 ± 0.47</b>	<b>0.779</b>
Distal Main Branch	15.7 ± 12.0	1.66 ± 0.64	1.73 ± 0.61 ns	2.57 ± 0.60	2.62 ± 0.46 ns	<b>0.87 ± 0.42</b>	<b>0.89 ± 0.61</b>	<b>0.873</b>
Side Branch	9.1 ± 11.2	1.90 ± 0.70	1.72 ± 0.65 ns	2.26 ± 0.50	2.19 ± 0.53 ns	<b>0.36 ± 0.73</b>	<b>0.48 ± 0.67</b>	<b>0.821</b>

# Angiographic analysis (FU)



Segment	Post-MLD (mm)		3mth-MLD (mm)		Late Loss (mm)		p-Value
	IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	IVUS (N=47)	NO IVUS (N=54)	
Proximal Main Branch	3.51 ± 0.49	3.45 ± 0.46 ns	3.45 ± 0.48	3.45 ± 0.48	<b>0.05 ± 0.33</b>	<b>0.03 ± 0.33</b>	<b>0.794</b>
Distal Main Branch	2.57 ± 0.60	2.62 ± 0.46 ns	2.49 ± 0.58	2.57 ± 0.52	<b>0.08 ± 0.26</b>	<b>0.04 ± 0.28</b>	<b>0.520</b>
Side Branch	2.26 ± 0.50	2.19 ± 0.53 ns	2.18 ± 0.56	2.09 ± 0.56	<b>0.08 ± 0.29</b>	<b>0.09 ± 0.36</b>	<b>0.918</b>

# 3 Months OCT analysis (All)



	<b>Mean Lumen area</b>	<b>Minimal Lumen Area</b>	<b>Endoluminal: Mean stent area</b>	<b>neo-intima areas ₣</b>	<b>ISA area</b>
Proximal main	12.35 ± 2.85	10.53 ± 2.82	12.88 ± 2.77	0.89 ± 0.47	0.13 ± 0.36
Bifurcation Region	12.66 ± 3.11	11.75 ± 2.93	12.69 ± 3.22	0.85 ± 0.47	0.17 ± 0.68
Distal Main	9.20 ± 2.33	7.08 ± 2.32	9.62 ± 2.11	0.78 ± 0.40	0.15 ± 0.32

	<b>Malapposed (%)</b>	<b>Uncovered (%)</b>
Proximal main	2.47 ± 4.33	0.00 ± 0.00
Bifurcation Region	2.60 ± 8.25	0.03 ± 0.30
Distal Main	2.39 ± 5.29	0.01 ± 0.11



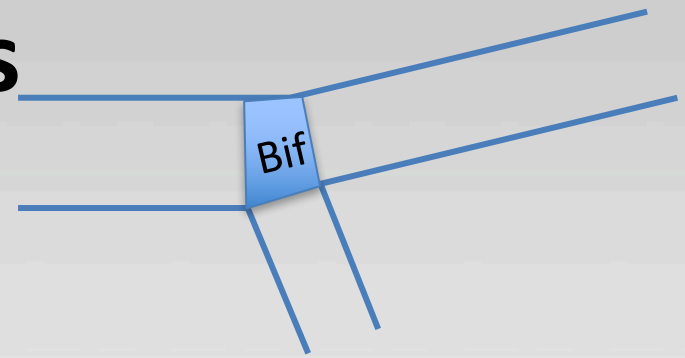
# 3 Months OCT analysis



Distal Main	IVUS (N=43)	NO IVUS (N=48)	p-Value
Mean lumen area	9.19 ± 2.30	9.21 ± 2.38	<b>0.973</b>
Minimal lumen area	6.90 ± 2.15	7.23 ± 2.48	<b>0.500</b>
Endoluminal: Mean stent area	9.69 ± 2.12	9.56 ± 2.13	<b>0.765</b>
Endoluminal: Mean neo-intima areas	0.72 ± 0.31	0.84 ± 0.48	<b>0.912</b>
Uncovered struts (%)	0.02 ± 0.16	0.02 ± 0.16	<b>0.291</b>
Covered >20 micron (%)	96.94 ± 2.92	96.55 ± 3.88	<b>0.758</b>

Proximal Main	IVUS (N=38)	NO IVUS (N=53)	p-Value
Mean lumen area	11.99 ± 3.21	12.61 ± 2.57	<b>0.309</b>
Minimal lumen area	10.15 ± 2.95	10.80 ± 2.72	<b>0.284</b>
Endoluminal: Mean stent area	12.62 ± 3.22	13.06 ± 2.41	<b>0.453</b>
Endoluminal: Mean neo-intima areas	0.91 ± 0.47	0.88 ± 0.48	<b>0.982</b>
Uncovered struts (%)	0.00 ± 0.00	0.00 ± 0.00	
Covered >20 micron (%)	96.44 ± 4.13	96.88 ± 3.71	<b>0.738</b>

# 3 Months OCT analysis



Bif	IVUS (N=43)	NO IVUS (N=50)	p-Value
<i>Mean lumen area</i>	12.38 ± 3.49	12.90 ± 2.74	<b>0.420</b>
<i>Minimal lumen area</i>	11.38 ± 3.35	12.07 ± 2.52	<b>0.261</b>
<i>Endoluminal: Mean stent area</i>	12.13 ± 3.72	13.17 ± 2.66	<b>0.125</b>
<i>Endoluminal: Mean neo-intima areas</i> †	0.82 ± 0.47	0.89 ± 0.48	<b>0.363</b>
<i>Uncovered struts (%)</i>	0.07 ± 0.44	0.00 ± 0.00	<b>0.281</b>
<i>Covered &gt;20 micron (%)</i>	97.24 ± 4.46	96.48 ± 4.94	<b>0.862</b>

† Median test on original data

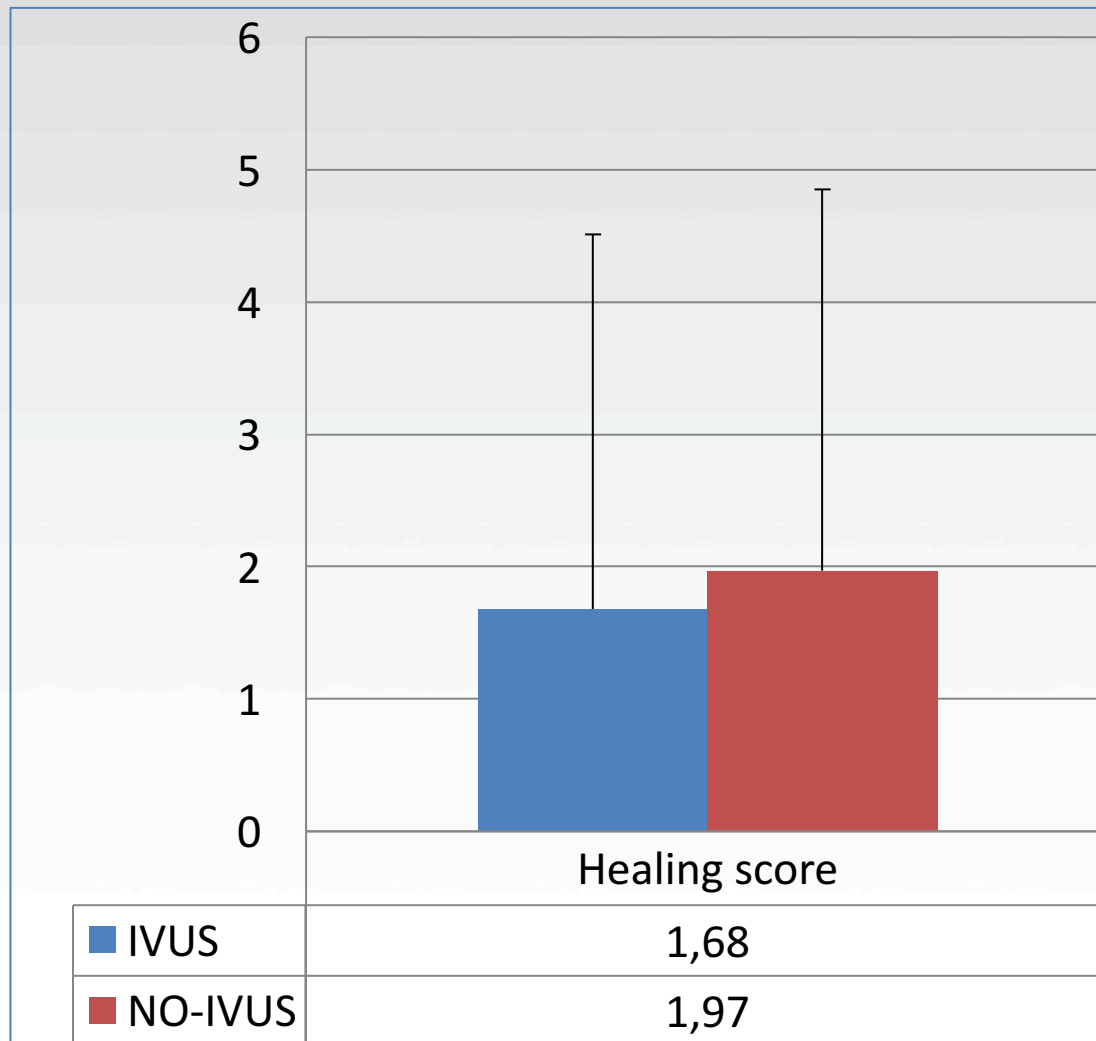
# Malapposition, ISA??

Distal Main	IVUS (N=43)	NO IVUS (N=48)	p-Value
Malapposed struts (%)	1.78 ± 3.19	2.93 ± 6.63	<b>0.598</b>
Endoluminal: Mean ISA area	0.11 ± 0.23	0.18 ± 0.39	<b>0.912</b>
Mean lumen eccentricity index	0.81 ± 0.05	0.80 ± 0.05	<b>0.253</b>
Mean stent eccentricity index	0.86 ± 0.05	0.86 ± 0.05	<b>0.468</b>

Proximal Main	IVUS (N=38)	NO IVUS (N=53)	p-Value
Malapposed struts (%)	1.65 ± 3.33	3.05 ± 4.88	<b>0.037</b>
Endoluminal: Mean ISA area	0.06 ± 0.13	0.18 ± 0.45	<b>0.037</b>
Mean lumen eccentricity index	0.78 ± 0.08	0.77 ± 0.09	<b>0.028</b>
Mean stent eccentricity index	0.83 ± 0.09	0.81 ± 0.08	<b>0.350</b>



# Healing score

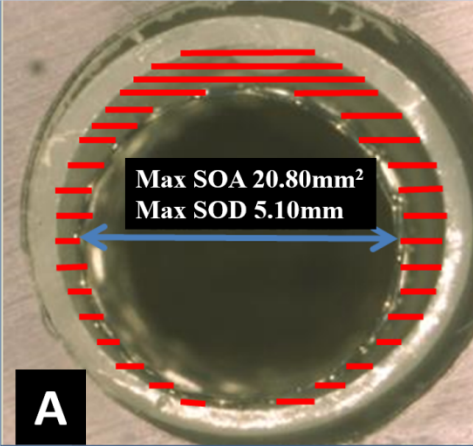
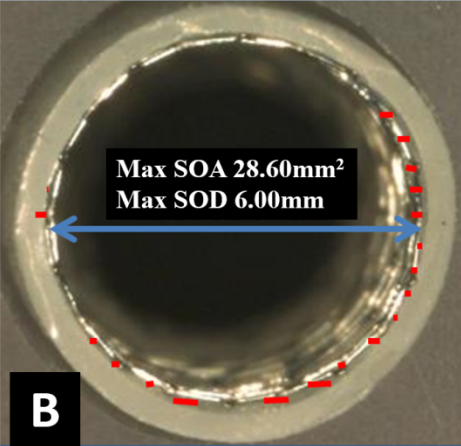
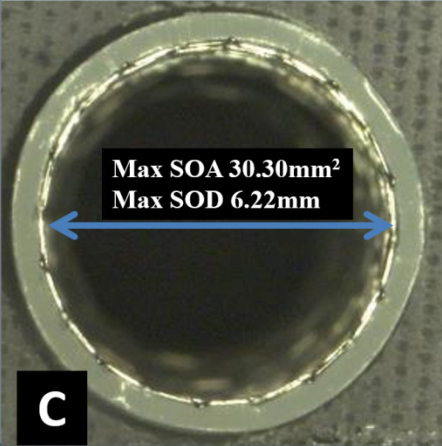
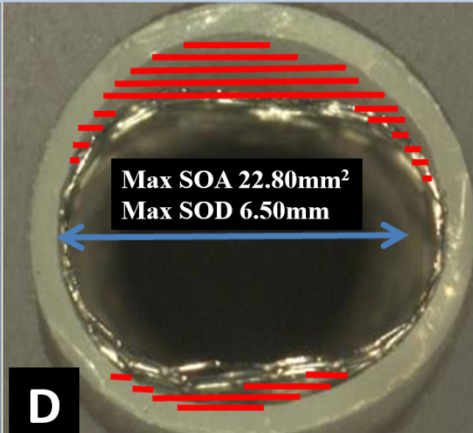
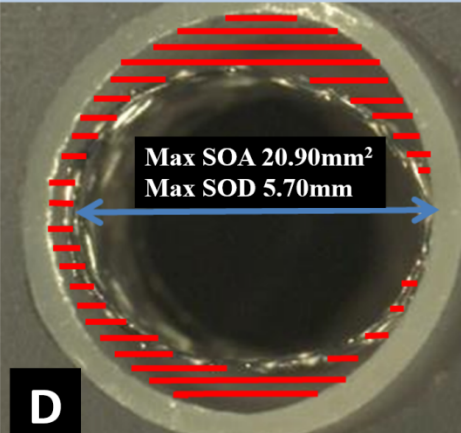
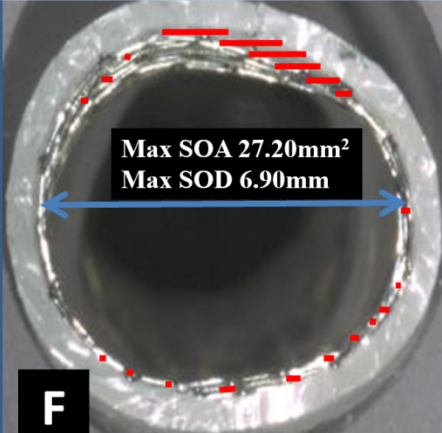


# Summary

- **Overall large stent areas and MLA at OCT FU**
- **Larger stent areas in proximal main vs distal main**
- **Frequent use of IVUS in substudy (approx. 50%)**
- **Use of IVUS no impact on stent size.**
- **Use of IVUS no difference in mean LA or MLA**
- **Late malapposition similar in bifurcation and distal main branch**
- **Without IVUS: More late malapposition, larger ISA in proximal main branch**

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# Overview for 6mm tubing

	SC 6 ATM	SC 14 ATM	NC: 24 ATM
POT 6 mm	MA: 8.40mm <sup>2</sup> , EI 1.0	MA: 1.10mm <sup>2</sup> , EI 1.0	MA: 0mm <sup>2</sup> , EI 1.0
	 <p><b>A</b></p>	 <p><b>B</b></p>	 <p><b>C</b></p>
FKBD	MA: 6.20mm <sup>2</sup> , EI 1.5	MA: 8.20mm <sup>2</sup> , EI 1.2	MA: 1.80mm <sup>2</sup> , EI 1.2
	 <p><b>D</b></p>	 <p><b>D</b></p>	 <p><b>F</b></p>
	<b>3.5 + 4.0 12 ATM</b>	<b>4.0 + 5.0 4 ATM</b>	<b>4.0 + 5.0 12 ATM</b>

# Study flow

