2019 euro PCR

A randomized trial evaluating On-line three-dimensional OFDI guided PCI vs. angiography guided PCI in bifurcation lesions OPTIMUM study

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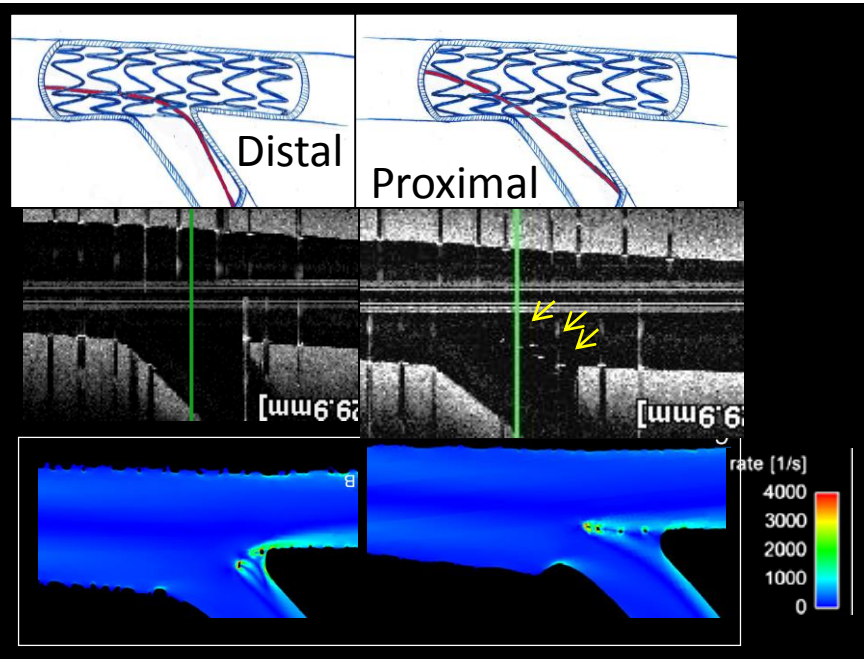
On behalf of the OPTIMUM investigators

Why this study?

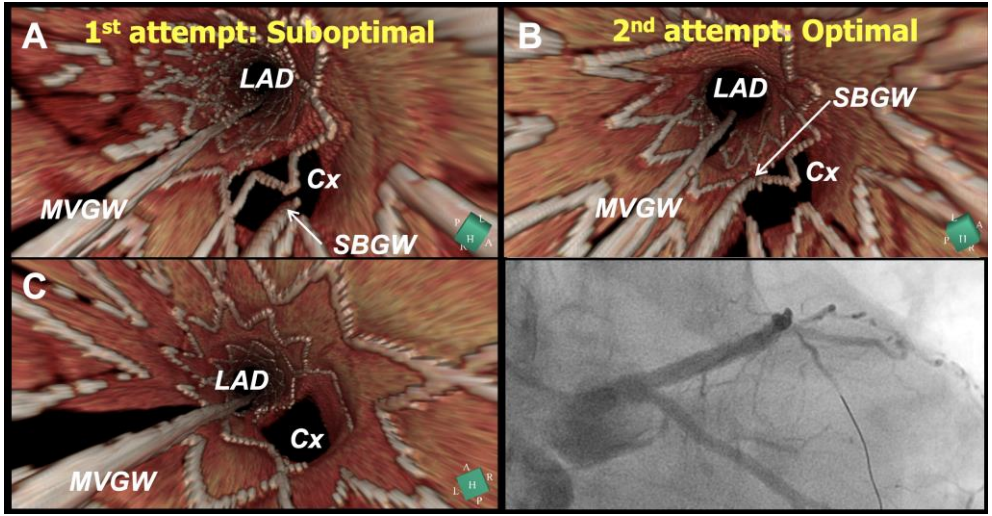


- In bifurcation PCI, re-crossing the distal cell with a wire after main vessel stenting is important to avoid creating a de novo metal carina[1]. Those protruded/malapposed struts result in lower tissue strut coverage of the side branch ostium and more overhanging metal into the main branch after implantation of the stent[2].
- Angiography guided PCI is limited in recognizing the recrossing position, while intracoronary imaging during PCI has a potential to visualize the recrossing point and to optimize the acute results.
- The feasibility of **off-line** 3-dimensional optical frequency domain imaging (OFDI) in bifurcation and its potential benefits were demonstrated in retrospective studies[3,4].
- However, the feasibility and efficacy of **on-line 3D OFDI guided** PCI in bifurcation lesion has not yet been fully investigated.

1. Lassen JF, et al. EuroIntervention 2016;12(1):38-46.
2. Onuma Y, Okamura T et al. EuroIntervention 2015;11 Suppl V:V71-4.
3. Okamura, et al. EuroIntervention. 2014 Dec;10(8):907-15.
4. Alegría-Barrero, et al. EuroIntervention. 2012 Jun 20;8(2):205-13.

What did we study?

To determine whether bifurcation PCI guided by on-line 3D-OFDI is superior to bifurcation PCI with angiographic guidance in terms of **incomplete stent apposition (ISA) in bifurcation segment.**



Okamura T, Onuma Y et al.
EuroIntervention 2014;10:907-915

How was the study executed?

Design

- A multi-centre, open-label, prospective **randomized** investigator-driven trial

Primary endpoints

- Post-procedural **percentage of malapposed struts** assessed by OFDI in bifurcation segment.

Major eligibility criteria

- Patients who undergoes bifurcation PCI with evidence of ischemia, excluding patients presented with STEMI
- Angiographically significant stenosis (>50%) in de novo, native, previously unstented **bifurcation lesion**(s) with a **sidebranch of >2.0mm** in diameter, which is appropriate to be treated by **PCI with a single stent strategy**

How was the study executed?

Study Chairmen of the OPTIMUM study

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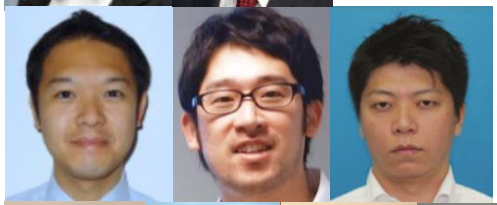
CRO: Meditrix, Tokyo, JP
Imaging OFDI Corelab: Cardialysis, Rotterdam, NL
Grant Giver: TERUMO
NCT02972489



4 Japanese Centres

CARDIALYSIS
Clinical Trial Management · Core Laboratories

TERUMO

How was the study executed?

Sample size calculation

Assumptions for sample size determination are based on previous registries [1, 2].

1. Okamura, et al. EuroIntervention. 2014 Dec;10(8):907-15.
2. Alegría-Barrero, et al. EuroIntervention. 2012 Jun 20;8(2):205-13.

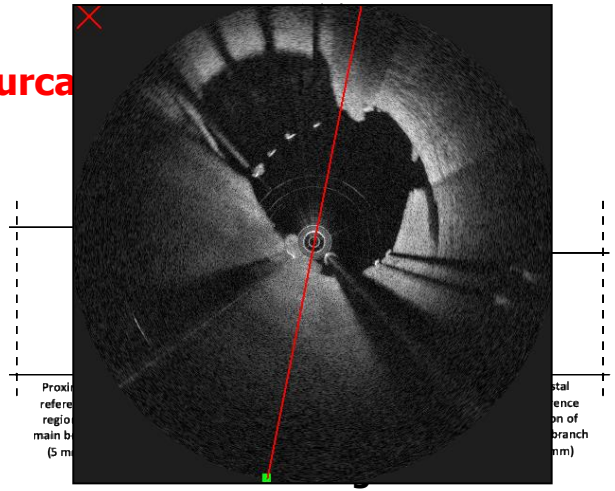
Assumption:

- Malapposition rate in bifurcation by angio-guidance is 26%.
- 3D-OFDI guidance reduces malapposition by 50%
- Common standard deviation: 20%

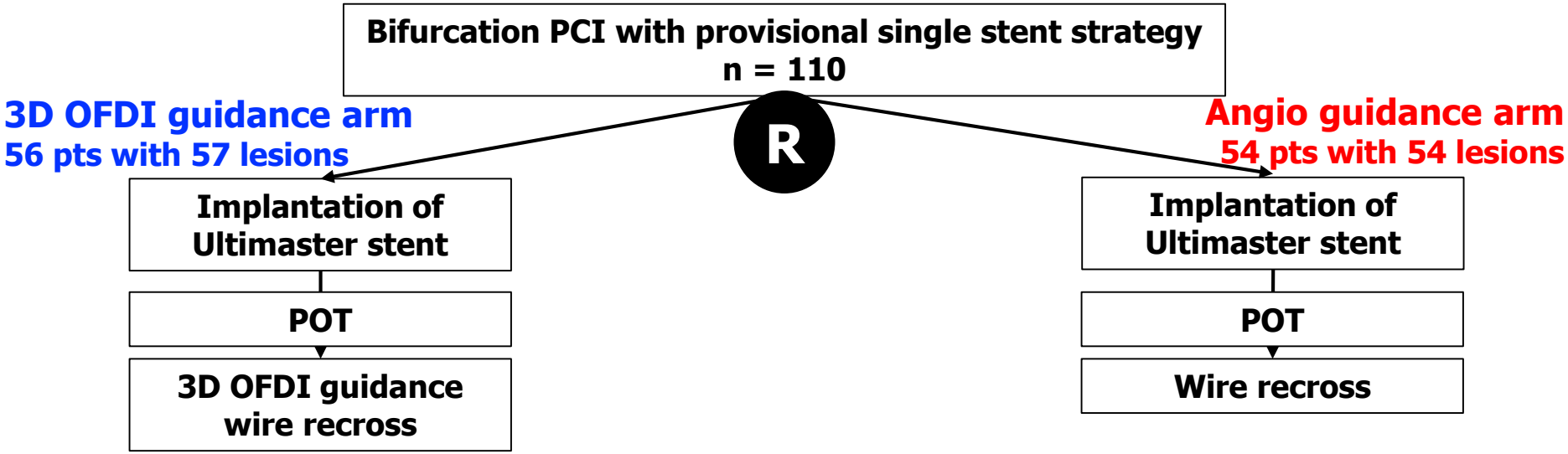
Sample size:

- Alpha = 0.05 (2-sided)
- Power 90%
- 5% of insufficient quality OFDI
- N= 53 x 2

106 subjects are to be randomized.



Study Flow Chart



Study Flow Chart

Bifurcation PCI with provisional single stent strategy
n = 110

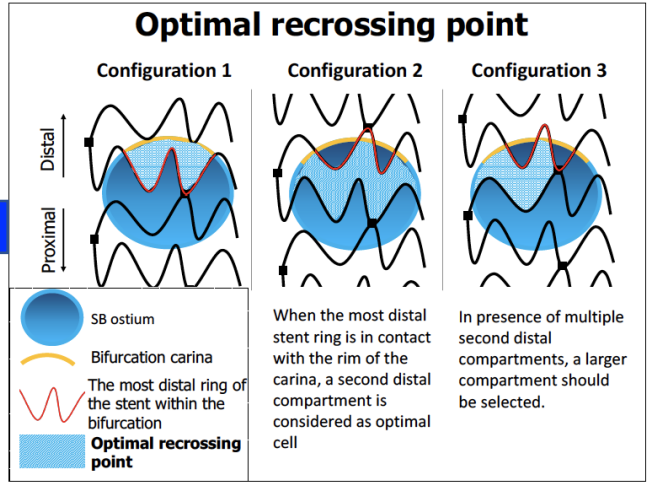
R

3D OFDI guidance arm
56 pts with 57 lesions

- **Implantation of Ultimaster stent**
- **POT**
- **3D OFDI guidance wire recross**

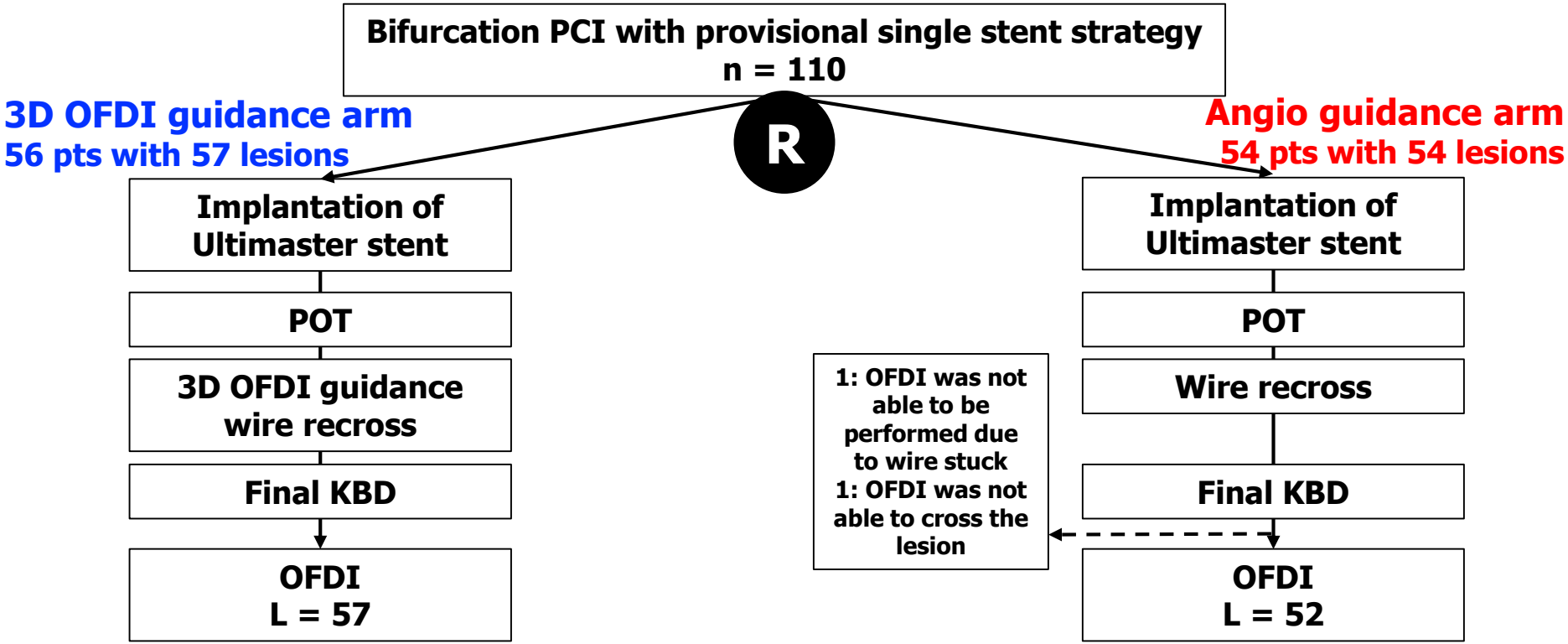
Angio guidance arm
54 pts with 54 lesions

- **Implantation of Ultimaster stent**
- **POT**
- **Wire recross**

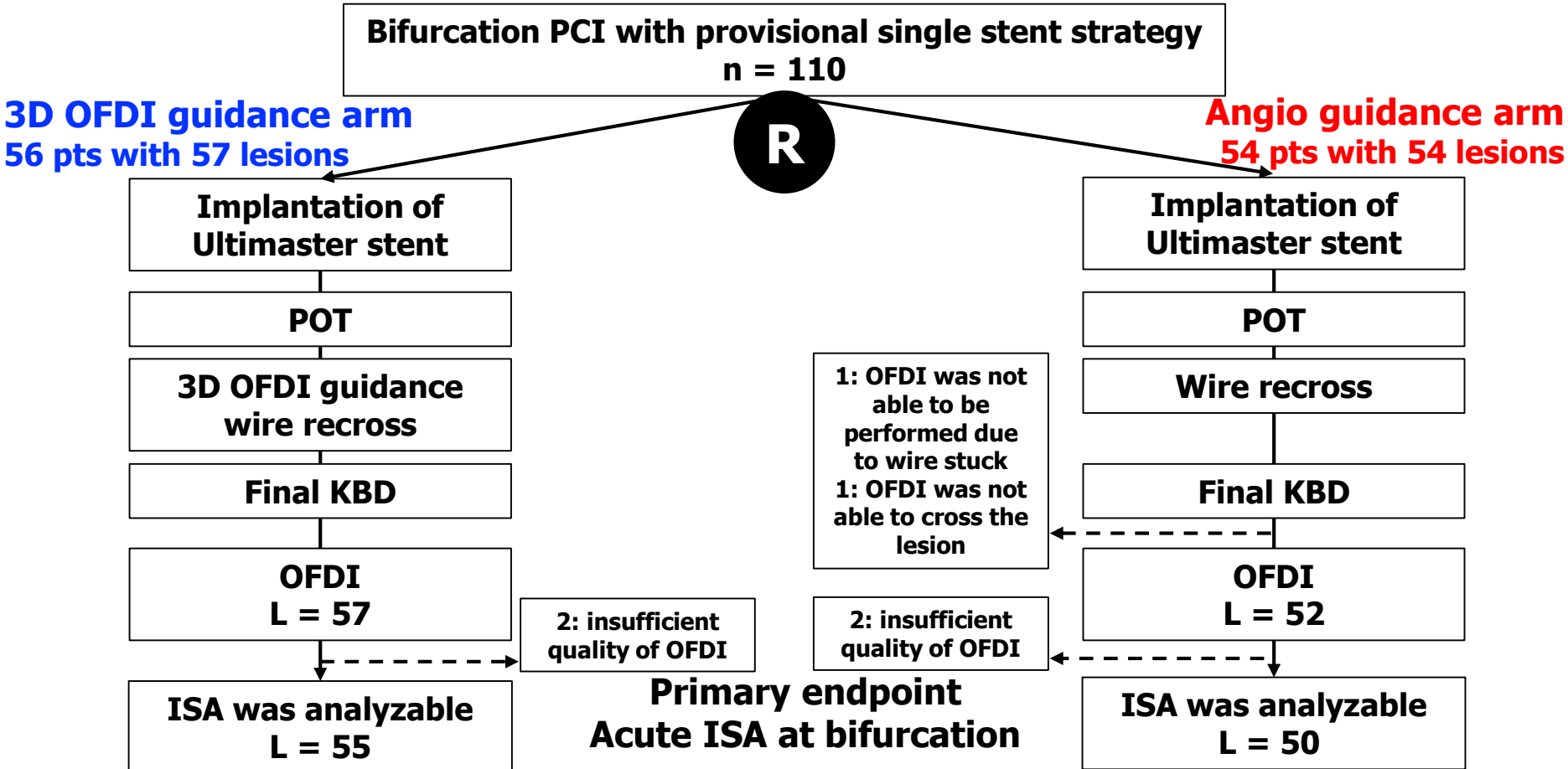


Onuma Y, Katagiri Y, et al. EuroIntervention 2018.

Study Flow Chart



Study Flow Chart



Baseline characteristics

	OFDI-guided PCI N=56	Angio-guided PCI N=54	p value
Age	68.9 ± 10.2	69.4 ± 11.6	0.83
Male	79%	74%	0.58
Medical history			
Diabetes mellitus	52%	46%	0.56
Hypertension	77%	74%	0.74
Hypercholesterolemia	86%	85%	0.94
Current smoker	55%	59%	0.68
Previous MI	16%	15%	0.86
Previous PCI	4%	0%	0.26
Previous CABG	21%	35%	0.06
Serum creatinine, mg/dL	0.79 (0.70-0.95)	0.81 (0.70-0.99)	0.78
Ejection fraction, %	60.8 ± 14.3	59.7 ± 11.8	0.67
Clinical presentation			
Non-STEMI	2%	2%	0.74
Unstable angina	7%	4%	0.36
Stable angina/Silent ischemia	91%	94%	0.38

Data are mean ± SD, median (IQ1,3) or percentage.

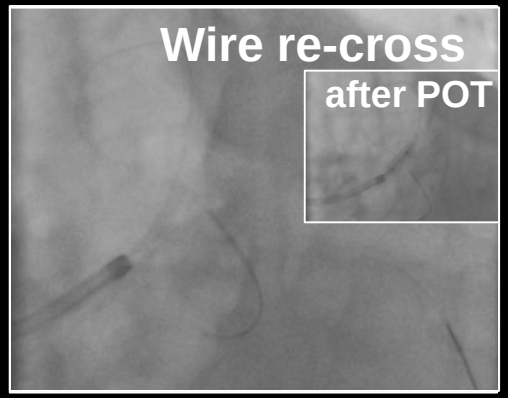
Procedural characteristics

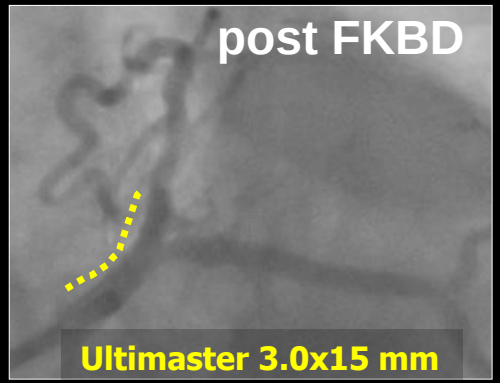
	OFDI L=57	Angio L=54	p value
Target bifurcation			
LMT or LAD-Dx	75%	67%	0.31
LCx-OM or PL	16%	15%	0.89
RCA PD-PL	9%	19%	0.13
Medina classification			
(1, 1, 1) or (0, 1, 1)	14%	6%	0.14
Ultimaster stent implantation	100%	100%	NA
Size, mm	2.76 ± 0.38	2.72 ± 0.33	0.51
Length, mm	30.0 ± 7.3	28.8 ± 7.3	0.36
POT was performed	**98%**	**98%**	0.74
Balloon size, mm	3.29 ± 0.47	3.30 ± 0.54	0.94
Pressure, atm	13.6 ± 3.2	13.9 ± 3.8	0.58

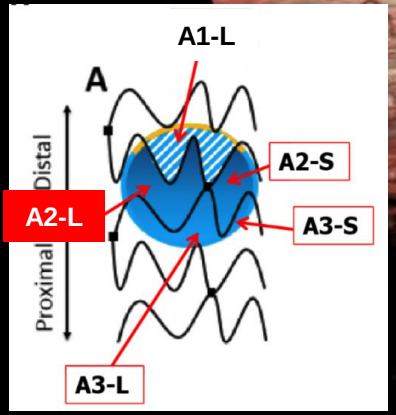
Data are mean ± SD or percentage.

A Case of Angio-guided PCI

LM bifurcation with Medina 010





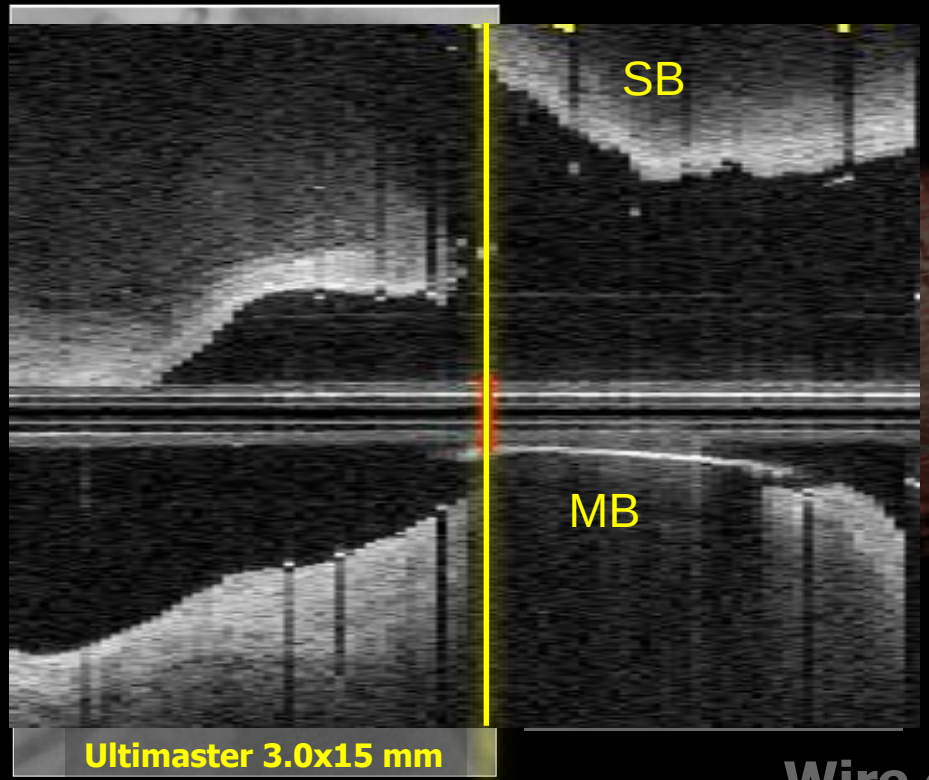


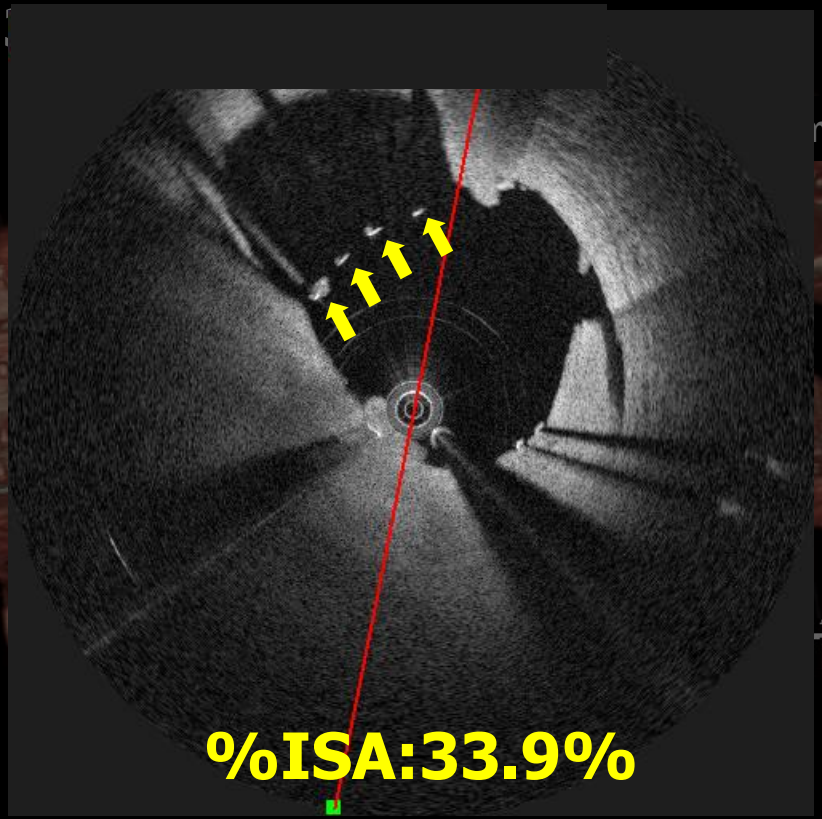
3D OFDI after final KBT

Wire crossed through A2-L segment

A Case of Angio-guided PCI

LM bifurcation with Medina 010

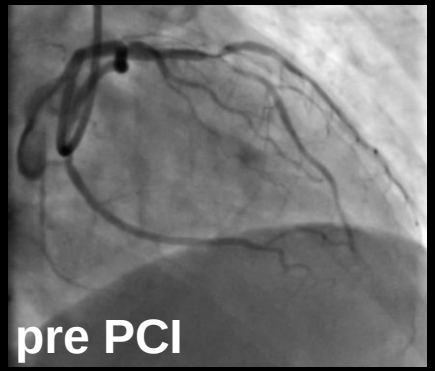


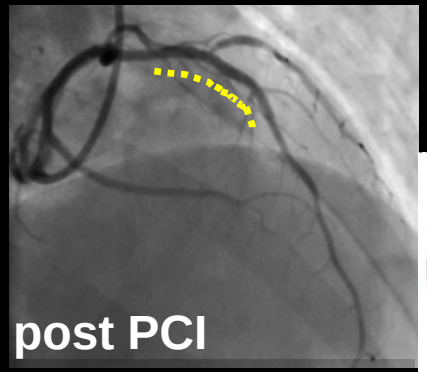


Wire crossed through A2-L segment

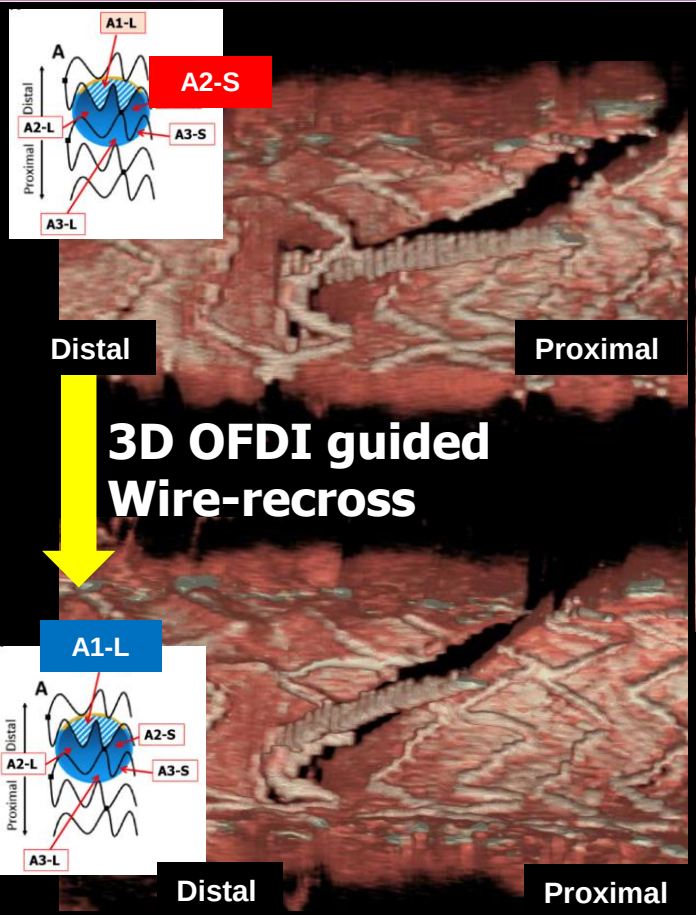
A Case of OFDI-guided PCI

LAD bifurcation with Medina 111

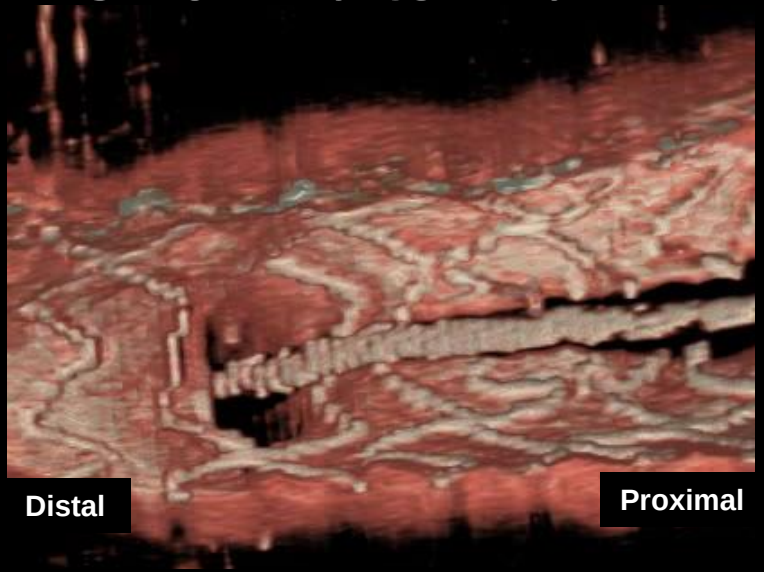




Ultimaster 3.0x28 mm



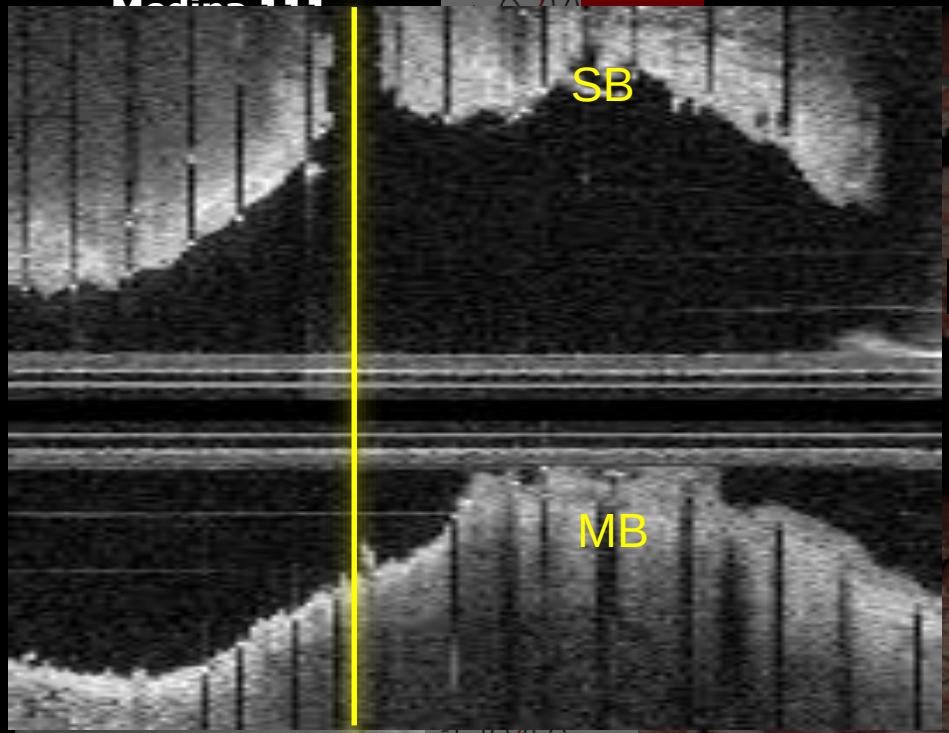
3D OFDI after final KBT

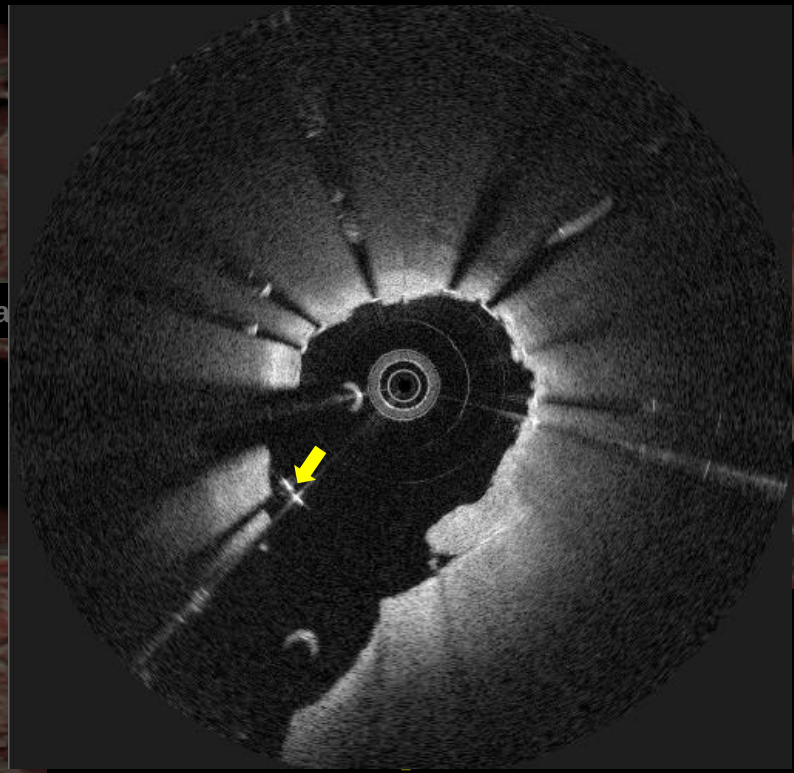


Achieved optimal result!

A Case of OFDI-guided PCI

LAD bifurcation with





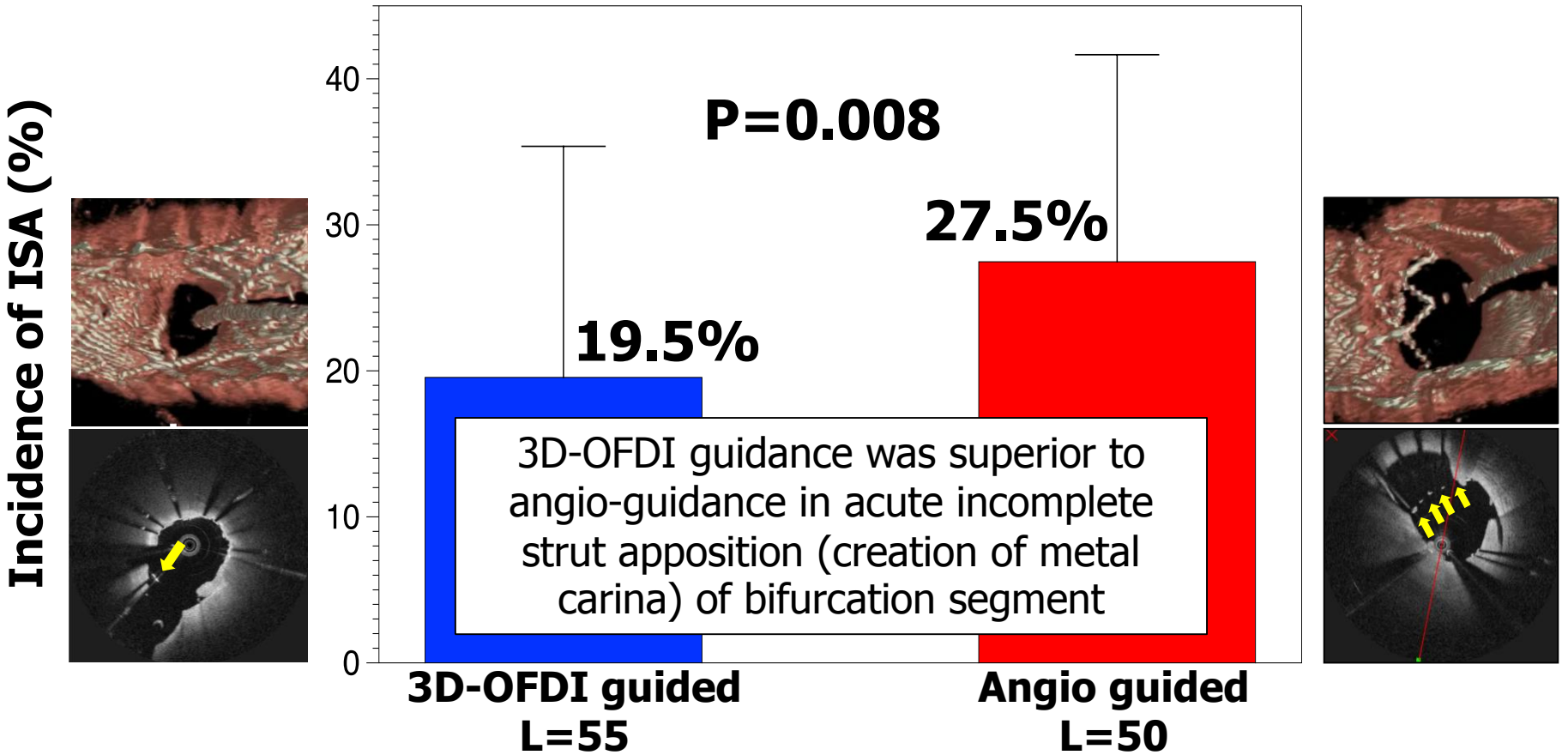
post PCI

Ultimaster 3.0x28 mm

Distal

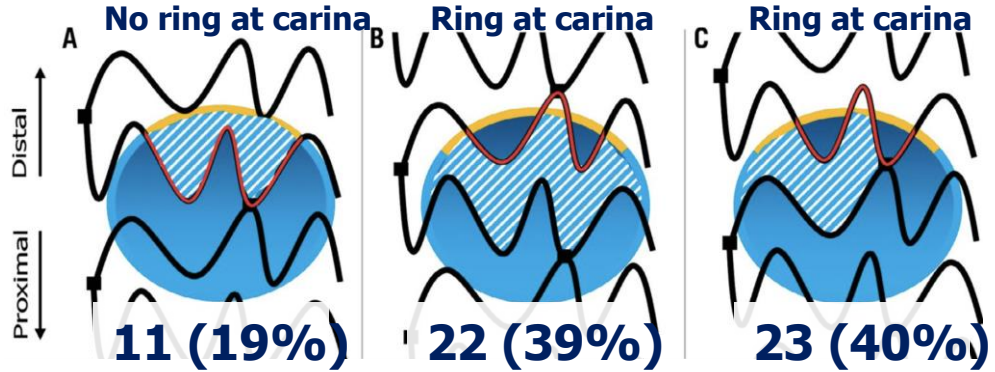
Proximal

Primary endpoint:
Incomplete Stent Apposition at bifurcation



Summary of 3-D OFDI guided wire recrossing

- **Feasibility of on-line 3D-OFDI:**
  - **56/57 (98%)**
- **Re-crossing position after POT was suboptimal in 45%, requiring 2nd attempt**
- **With 3D-OFDI guidance, optimal wire re-crossing was achieved in 100%.**
- **Distribution of configurations of overhanging struts**



with multiple 2nd distal compartments

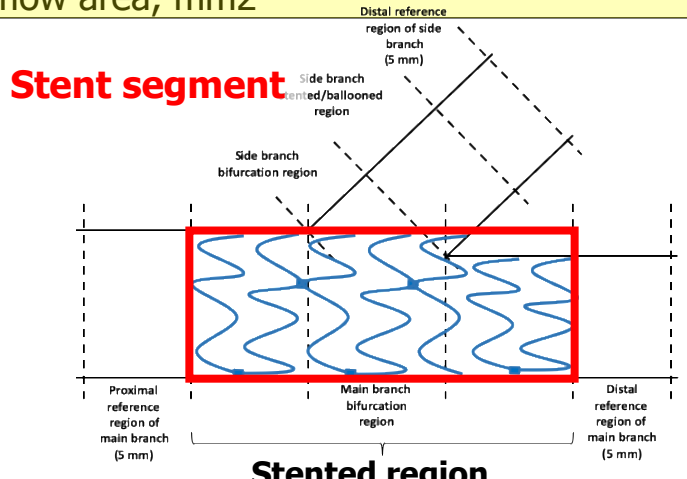
- **Use of total contrast volume was not different between two arms.**

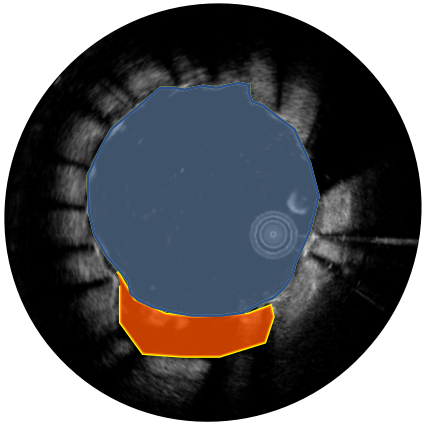
	OFDI, N=56	Angio, N=54	p value
Contrast volume, ml (Median)	175.0 (146.3-210.0)	175.0 (125.0-230.0)	0.87

Secondary OFDI endpoints

Quantitative OFDI measurement of stented segments

	OFDI guidance L=55	Angio guidance L=50	p value
Mean ISA area, mm2	0.23 ± 0.20	0.27 ± 0.27	0.39
Mean stent area, mm2	6.48 ± 1.61	6.20 ± 1.65	0.38
Mean intrastent defect attached to/free from the vessel wall, mm2	0.11 ± 0.09	0.09 ± 0.06	0.15
Minimum flow area, mm2	4.72 ± 1.36	4.63 ± 1.24	0.70
Mean flow area, mm2	6.85 ± 1.63	6.67 ± 1.78	0.60





Conclusion

- In the randomized trial of bifurcation PCI, 3D-OFDI guidance was superior to angio-guidance in acute incomplete strut apposition (creation of metal carina) of bifurcation segment (3D-OFDI 19.5±15.8% vs. angio: 27.5%±14.2%, p=0.008).

- Excellent feasibility of online 3D-OFDI was demonstrated (98%).

- After mandatory POT, the first wiring position was not optimal in 45% of cases, requiring 2nd attempt to redirect the wire into the optimal cell when 3D-OFDI guidance was used.

- On-line 3D OFDI images help operator to undergo rewiring to the optimal cell, resulting in a lower rate of malapposition compared with angiography guided PCI.

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