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

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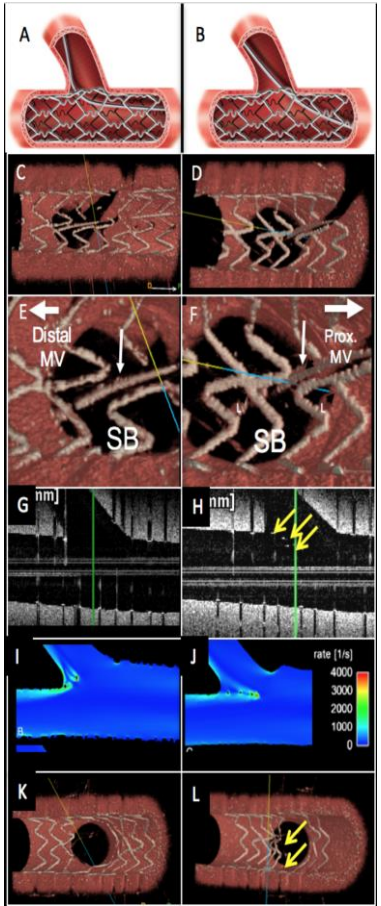
On behalf of the OPTIMUM investigators

Why this study?

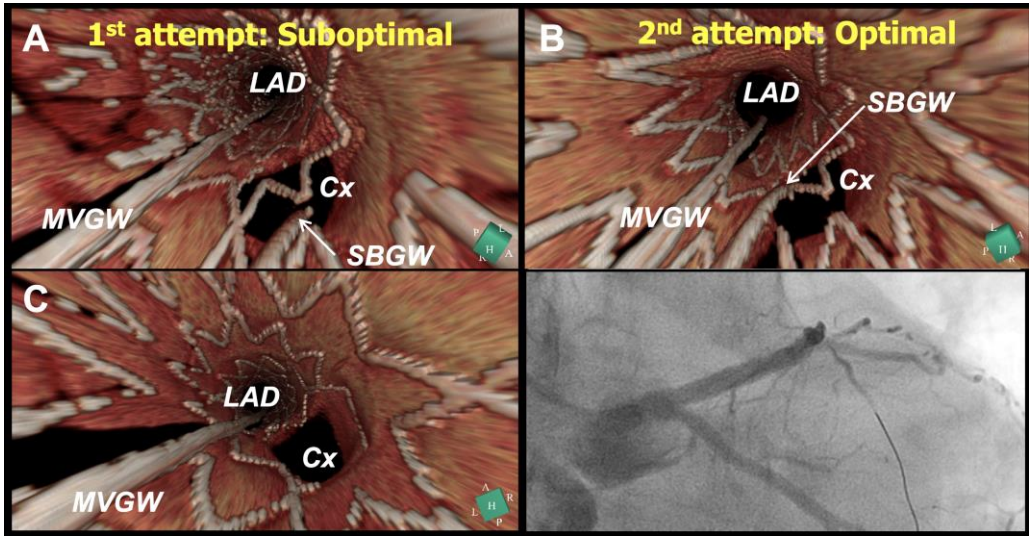


- In bifurcation PCI, re-crossing the distal cell with a wire after main vessel stenting is important to avoid creating a de novo metal carina[1]. Those protruded/malapposed struts result in lower strut coverage of the side branch ostium and more overhanging metal into the main branch over time after implantation of the stent[2].
- Angiography guided PCI is limited in recognizing the recrossing position, while intra coronary image guided PCI has a potential to guide PCI by confirming the recrossing point.
- The feasibility of off-line optical coherence tomography (OCT) guidance in bifurcation (either with 2-dimensional or 3-dimensional images) and its potential benefits were demonstrated in retrospective studies[3,4].
- However, the feasibility and efficacy of 3-D OFDI guidance PCI in bifurcation lesion has not yet been investigated prospectively.

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 stenting guided by on-line three-dimensional optical frequency domain imaging (3D-OFDI) is superior to that with angiographic guidance in terms of incomplete stent apposition (ISA) in the 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
- With a sidebranch of >2.0mm in diameter
- Angiographically significant stenosis (>50%) in de novo, native, previously unstented bifurcation lesion(s) including left main lesion, 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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Rotterdam Academic team
Taku Asano, Yosuke Miyazaki, Yuki Katagiri, Norihiro Kogame, Kuniaki Takahashi, Hidenori Komiyama, Hideyuki Kawashima, Masafumi Ono

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

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.

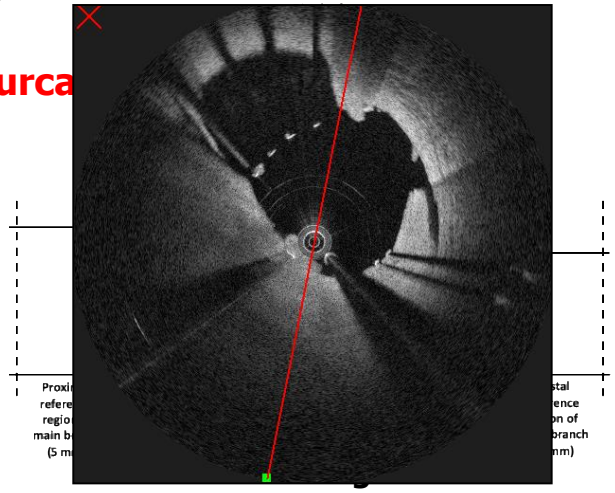
Assumption:

- Malapposition rate in bifurcation by angio-guidance is 26%.
- 3D-OFDI guidance reduces malapposition by 50%
- Malapposition rate in bifurcation by 3D-OFDI guidance: 13%
- Common standard deviation: 20%

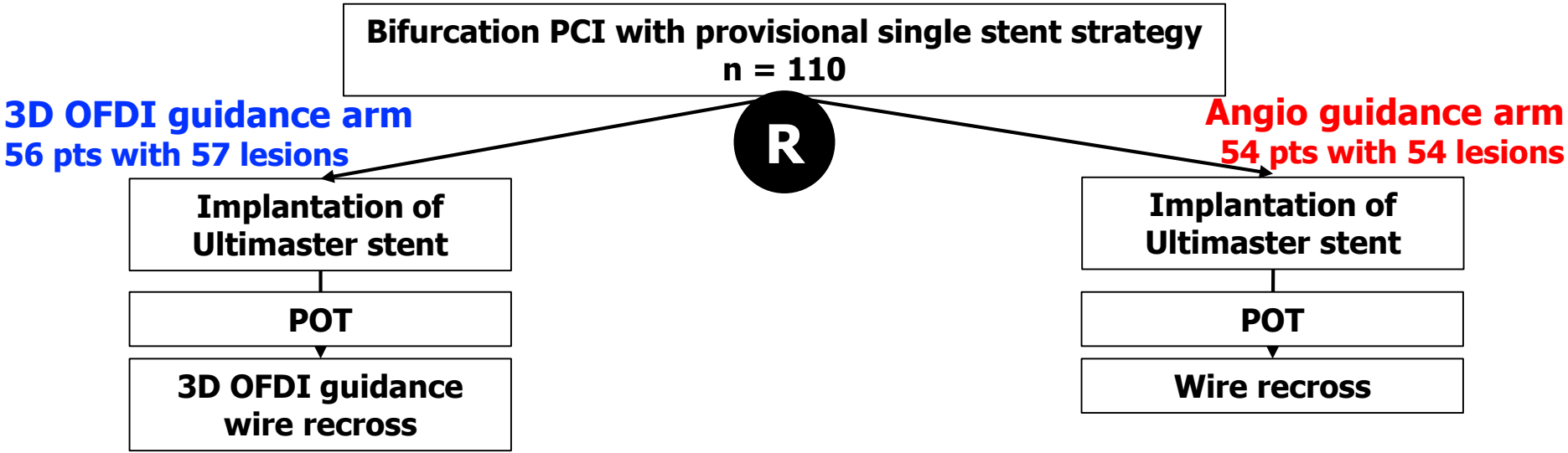
Sample size:

- 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



Primary endpoint
Acute ISA at bifurcation

Study Flow Chart

Bifurcation PCI with provisional single stent strategy
n = 110

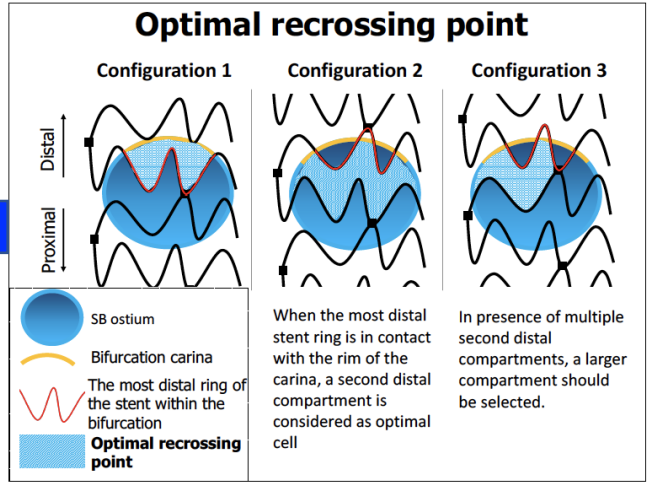
R

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

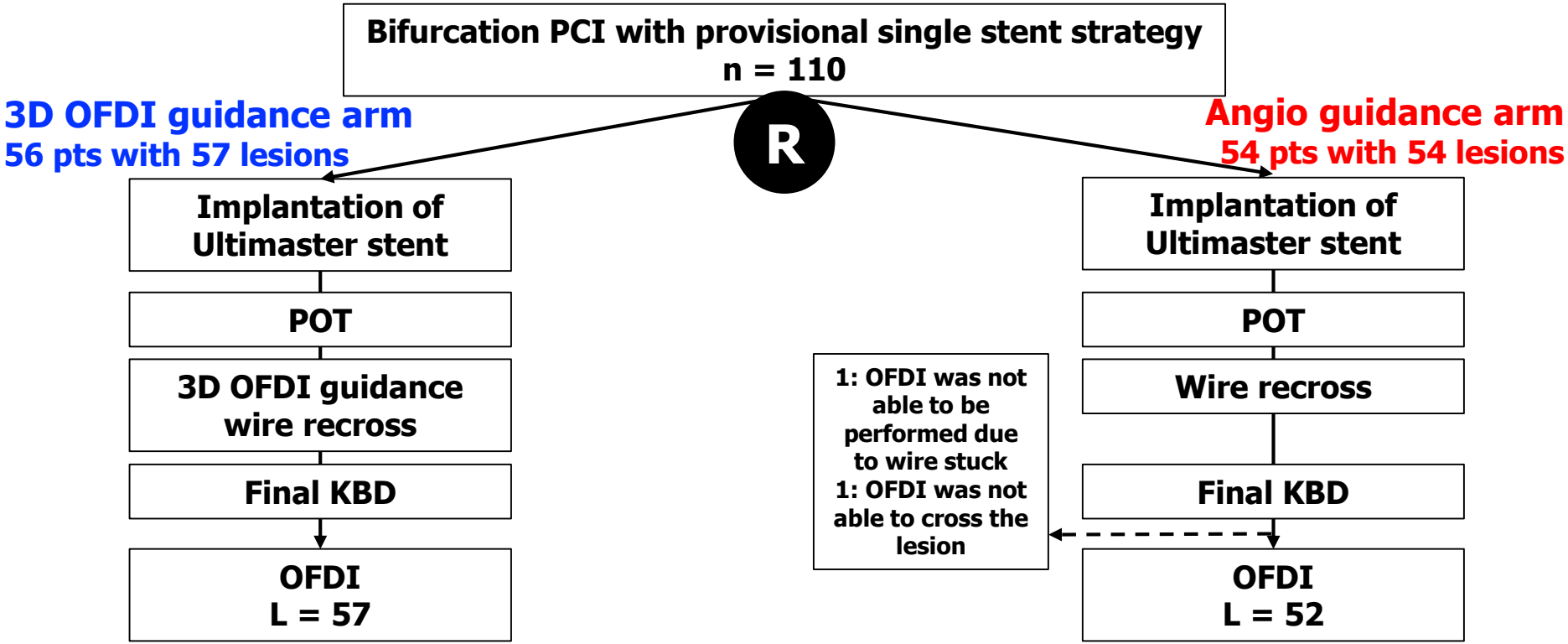
- **Implantation of Ultimaster stent**
- **POT**
- **Wire recross**



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

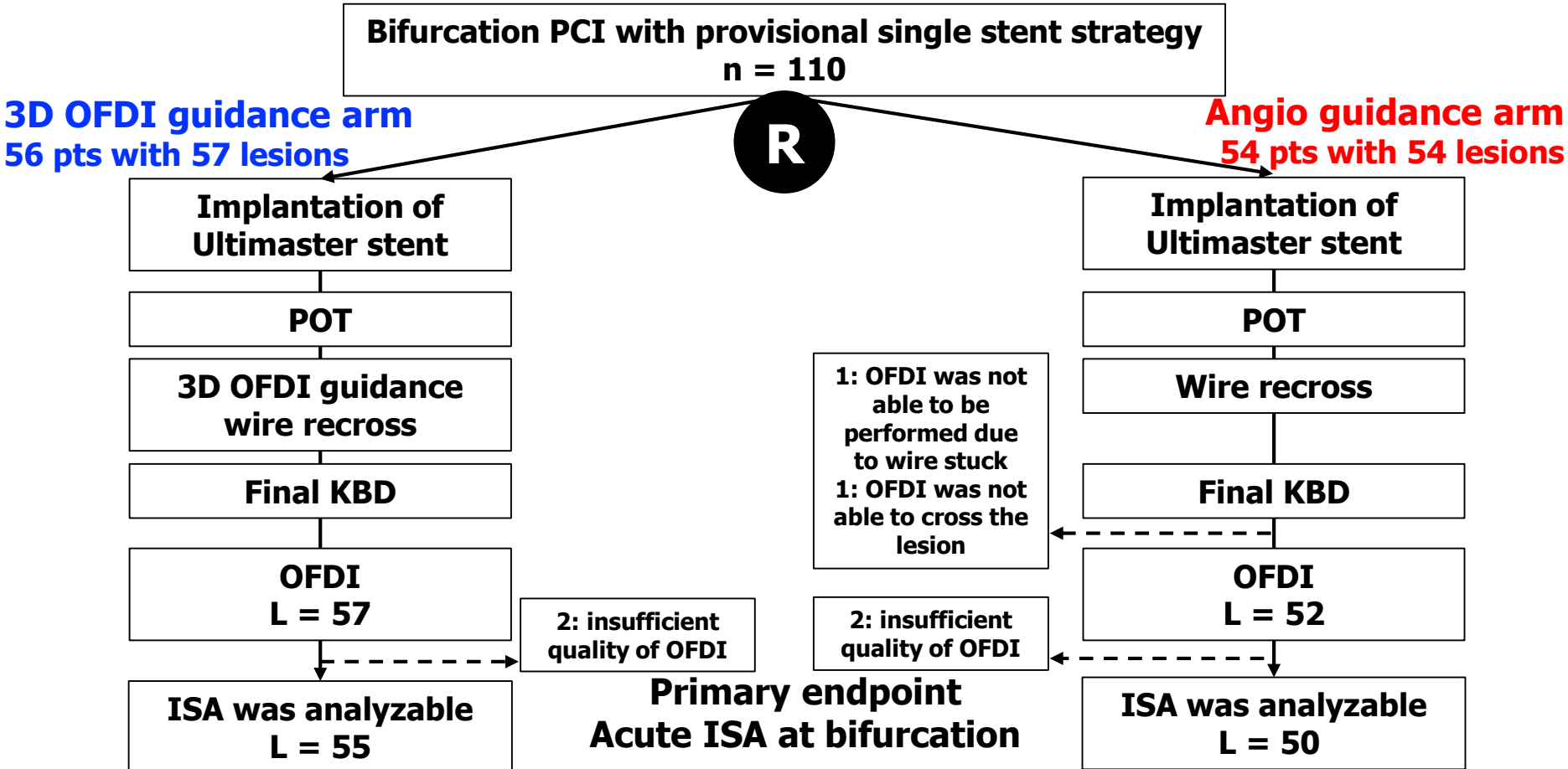
Primary endpoint
Acute ISA at bifurcation

Study Flow Chart



Primary endpoint
Acute ISA at bifurcation

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	36%	32%	0.64

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.

Procedural characteristics

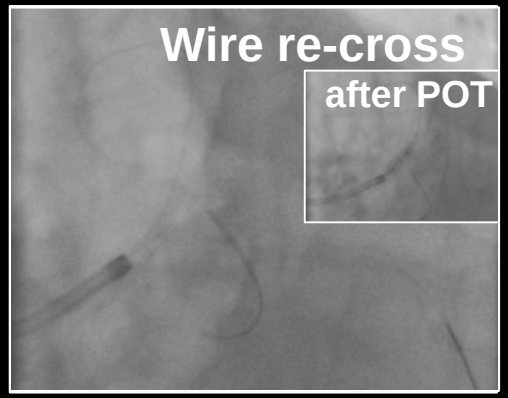
	OFDI N=57	Angio N=54	p value
Vascular access site			
Radial	31 (55)	35 (65)	0.311
Femoral	23 (41)	17 (32)	0.296
Brachial	2 (4)	2 (4)	0.677
GC size			
6F	30 (54)	28 (52)	0.857
7F	24 (43)	26 (48)	0.577
8F	2 (4)	0 (0)	0.257
Target bifurcation			
LMT or LAD-Dx	43(77)	35(67)	0.24
LCx-OM or PL	7 (13)	8 (15)	0.724
RCA PD-PL	5 (9)	10 (19)	0.143

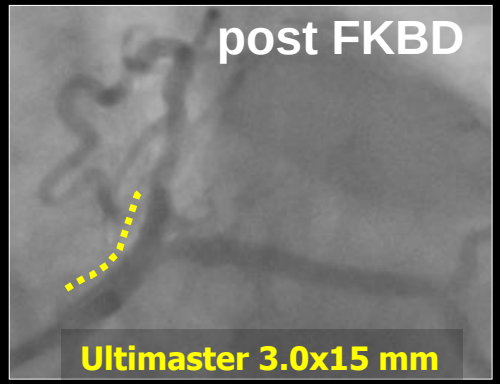
	OFDI N=57	Angio N=54	p value
Medina classification			
(1, 1, 1)	5 (9)	3 (6)	0.379
(1, 1, 0)	28 (50)	35 (65)	0.116
(1, 0, 1)	3 (5)	1 (2)	0.323
(1, 0, 0)	5 (9)	4 (7)	0.523
(0, 1, 1)	2 (4)	0 (0)	0.257
(0, 1, 0)	13 (23)	10 (19)	0.545
(0, 0, 1)	0 (0)	1 (2)	0.491
Calcified lesion	19 (34)	18 (33)	0.947
Thrombotic lesion	1 (2)	1 (2)	0.743
Rotablator	6 (11)	8 (15)	0.519
DCA	2 (4)	0 (0)	0.257

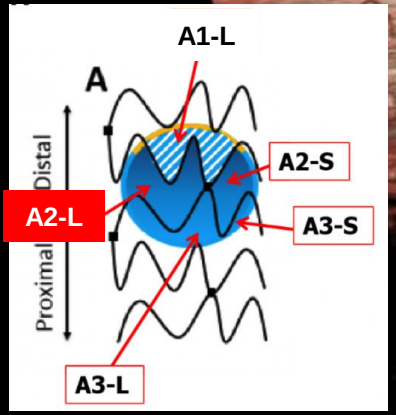
Data are mean ± SD or counts (percentage).

A Case of Angio-guided PCI

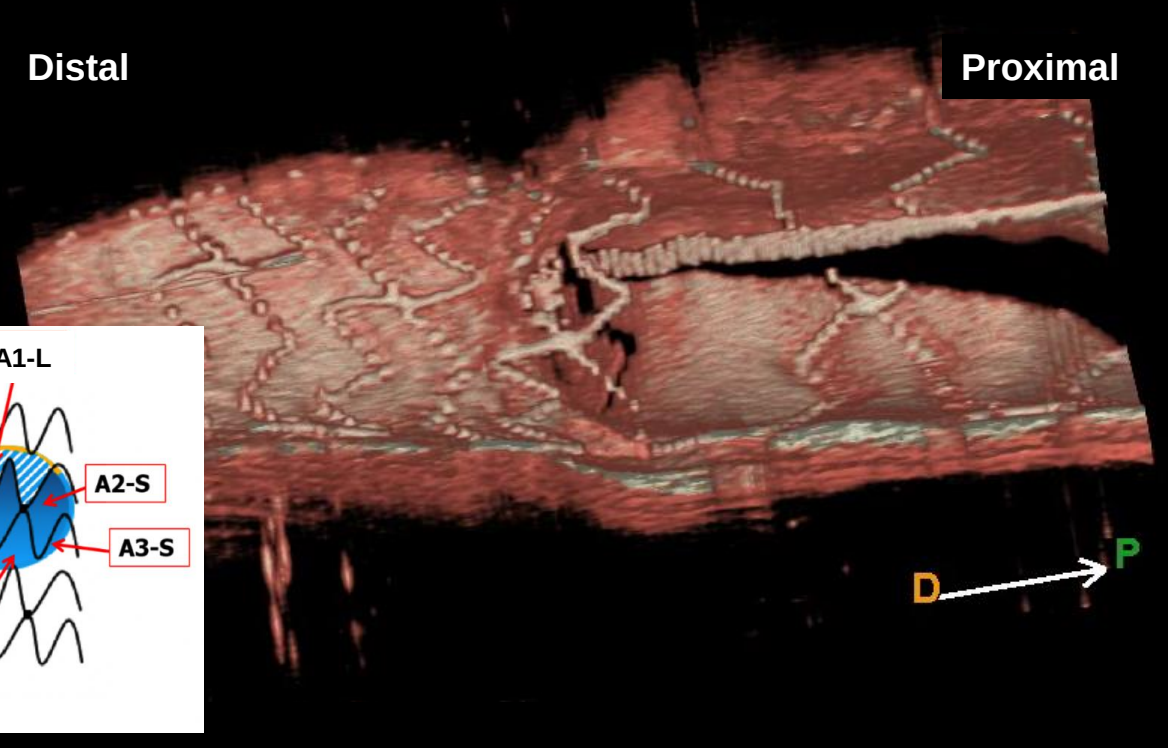
LM bifurcation with Medina 010







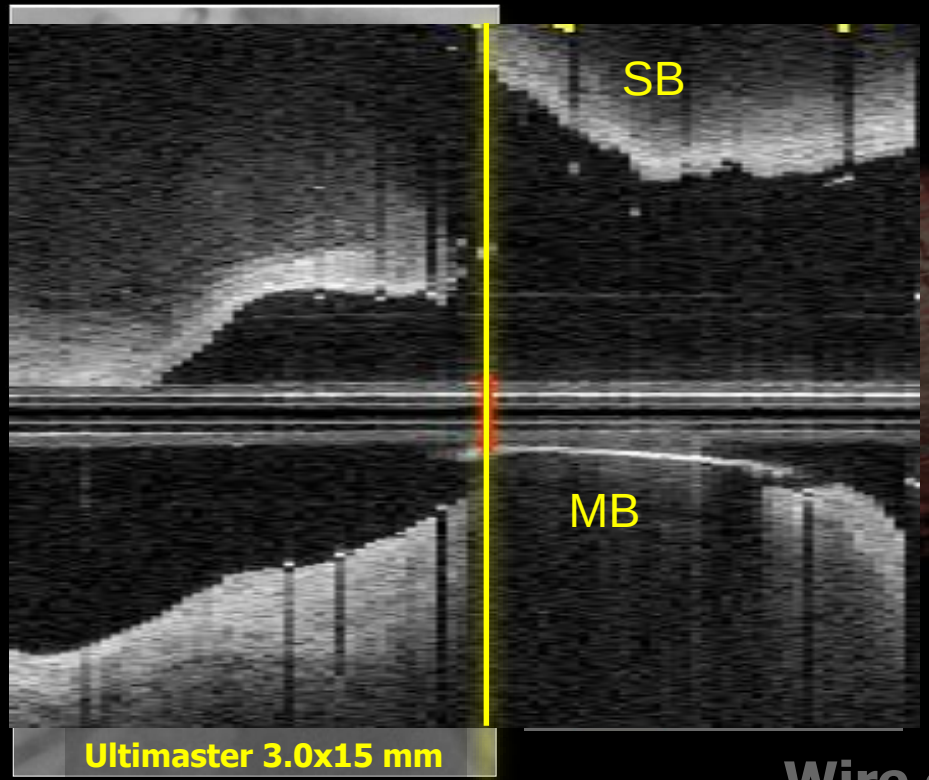
3D OCT after final KBT

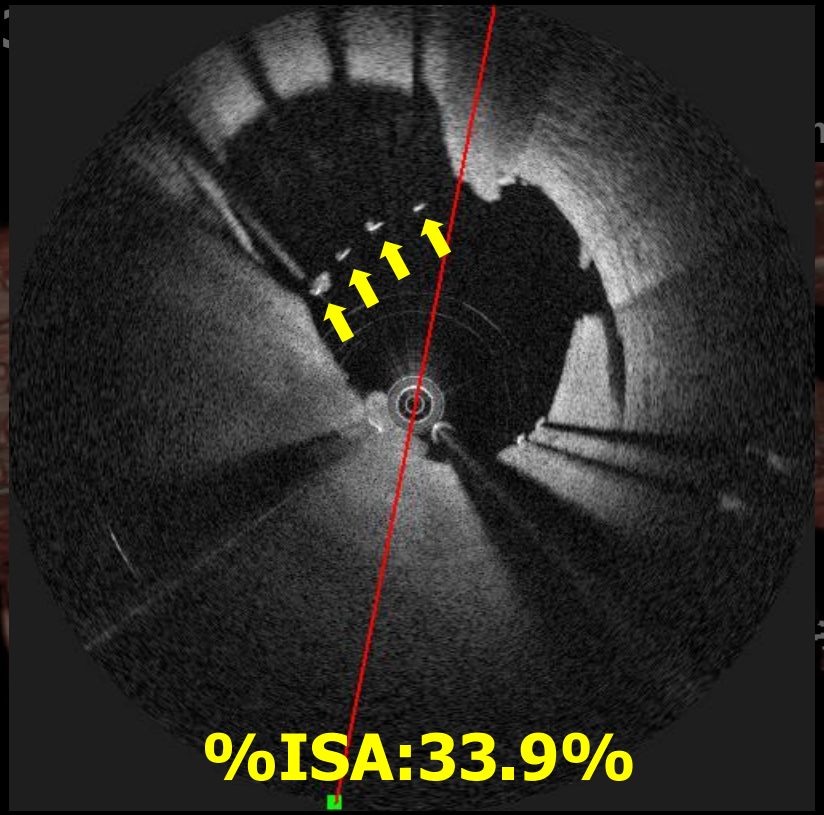


Wire crossed through A2-L segment

A Case of Angio-guided PCI

LM bifurcation with Medina 010

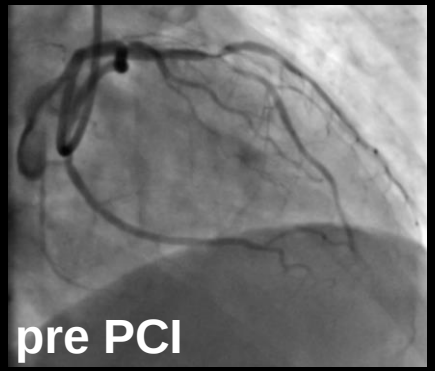


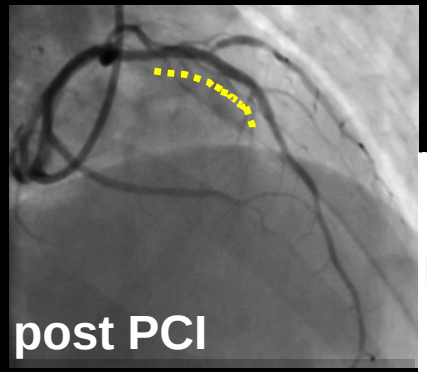


Wire crossed through A2-L segment

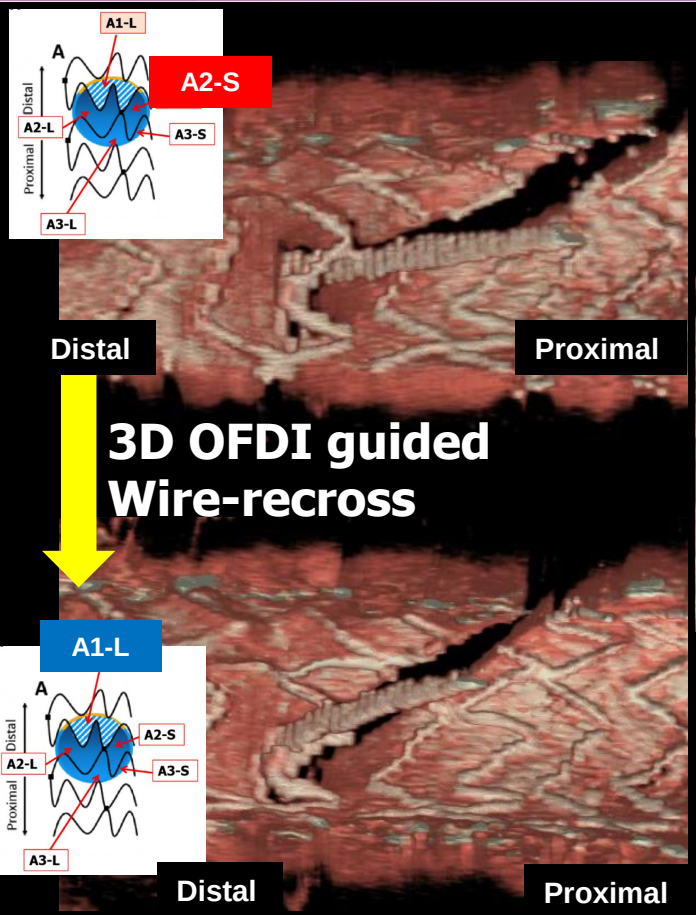
A Case of OFDI-guided PCI

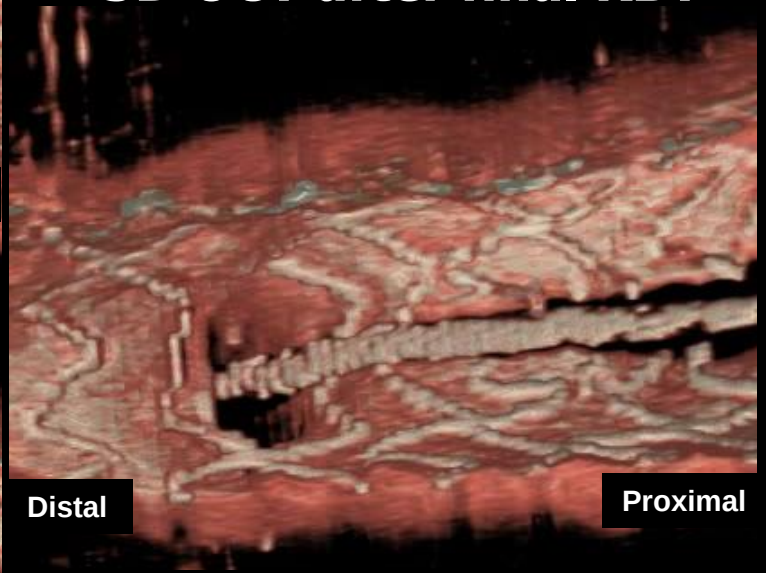
LAD bifurcation with Medina 111





Ultimaster 3.0x28 mm

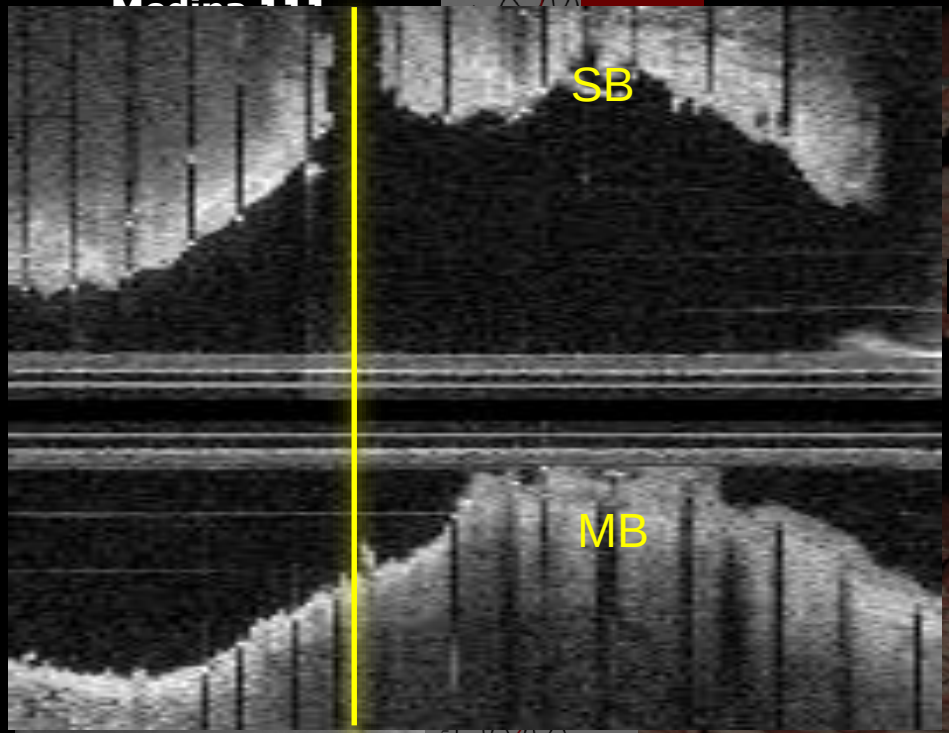


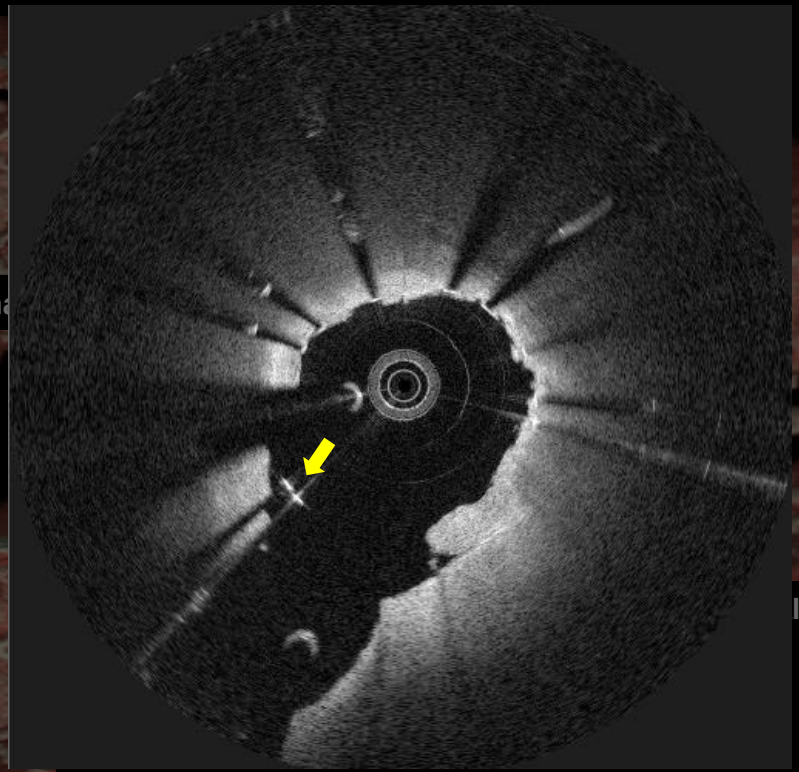


Achieved optimal result!

A Case of OFDI-guided PCI

LAD bifurcation with





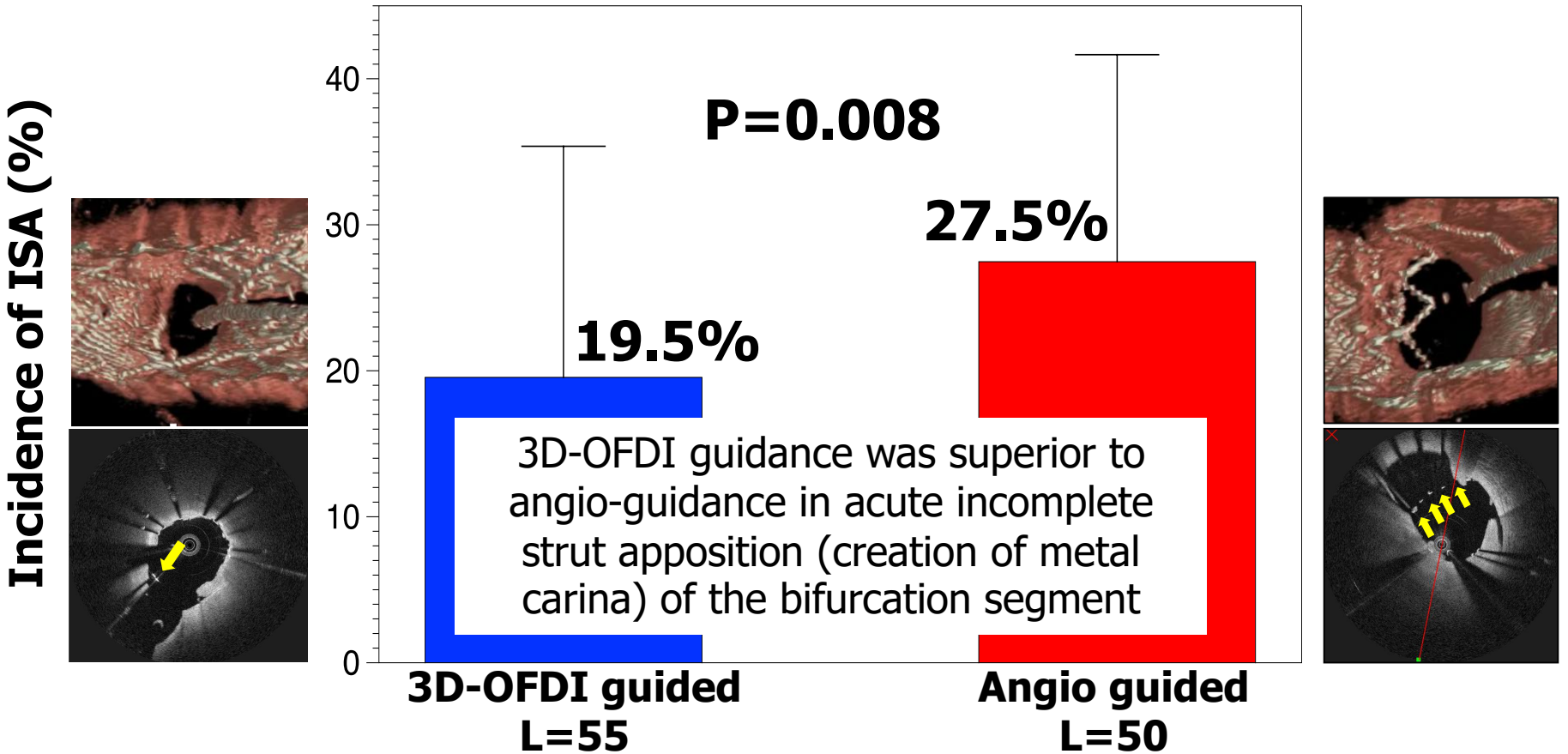
post PCI

Ultimaster 3.0x28 mm

Distal

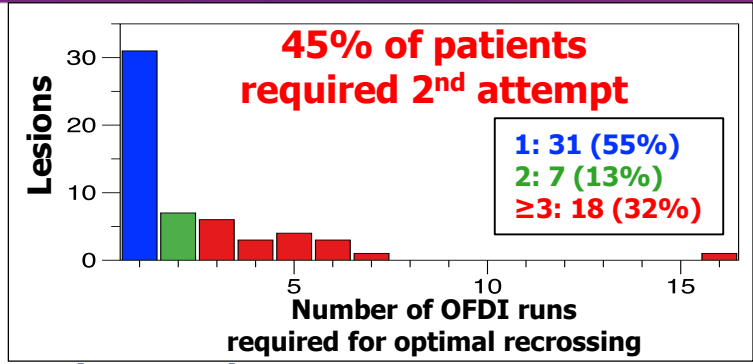
Proximal

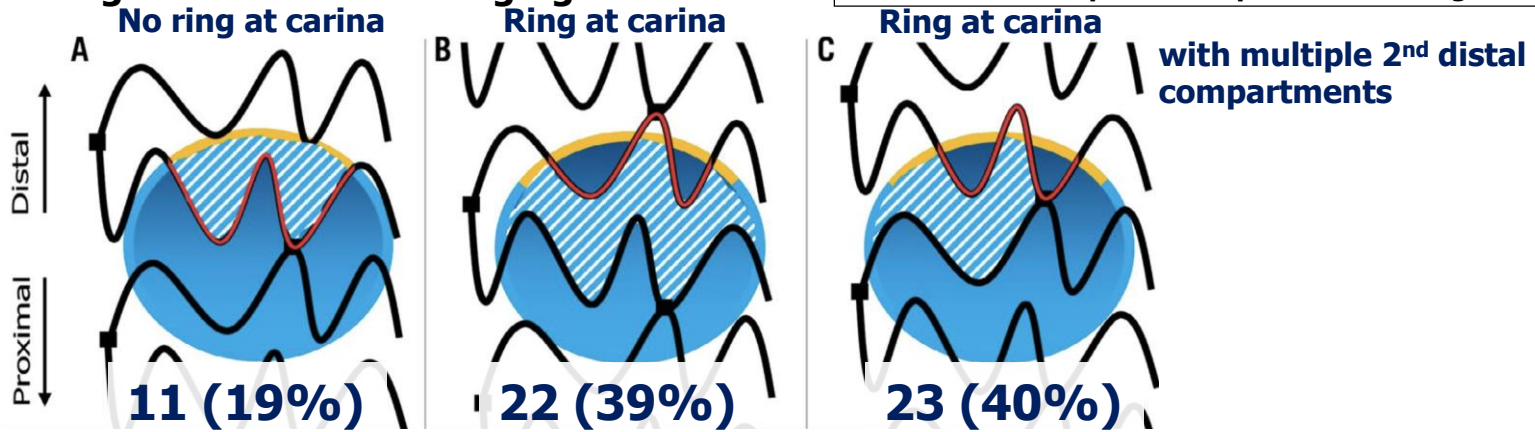
Primary endpoint:
Incomplete Stent Apposition at bifurcation



Summary of 3-D OFDI guided wire recrossing

- **Feasibility of on-line 3D-OFDI:**
  - **56/57 (98%)**
- **Number of OFDI runs required for optimal wire recrossing:**
  - **1 (Median, IQ: 1 to 3)**
- **Optimal wire recrossing identified by OFDI**
  - **56/56 (100%)**
- **Distribution of configurations of overhanging struts**



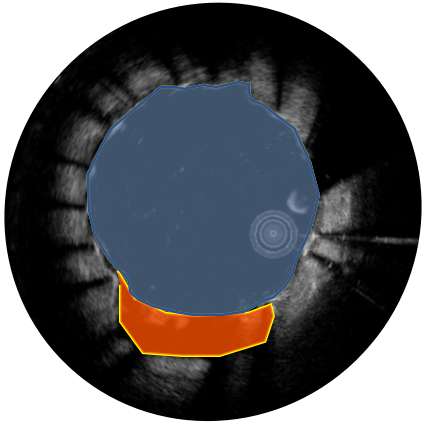


	OFDI, N=56	Angio, N=54	p value
Contrast volume, ml (Median)	175.0 (146.3-210.0)	175.0 (125.0-230.0)	0.87

Secondary OCT endpoints

In stent region

	OFDI L=55	Angio 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

- 3D-OFDI guided bifurcation PCI demonstrated superiority to angio guided PCI in terms of incidence of acute ISA (creation of metal carina) in bifurcation segment.

- Online 3D-OFDI demonstrated excellent feasibility in the present prospective trial (98%, only one case).

- In 3D-OFDI guided arm, 45% of lesions required 2nd attempt to redirect the wire to the optimal cell.

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