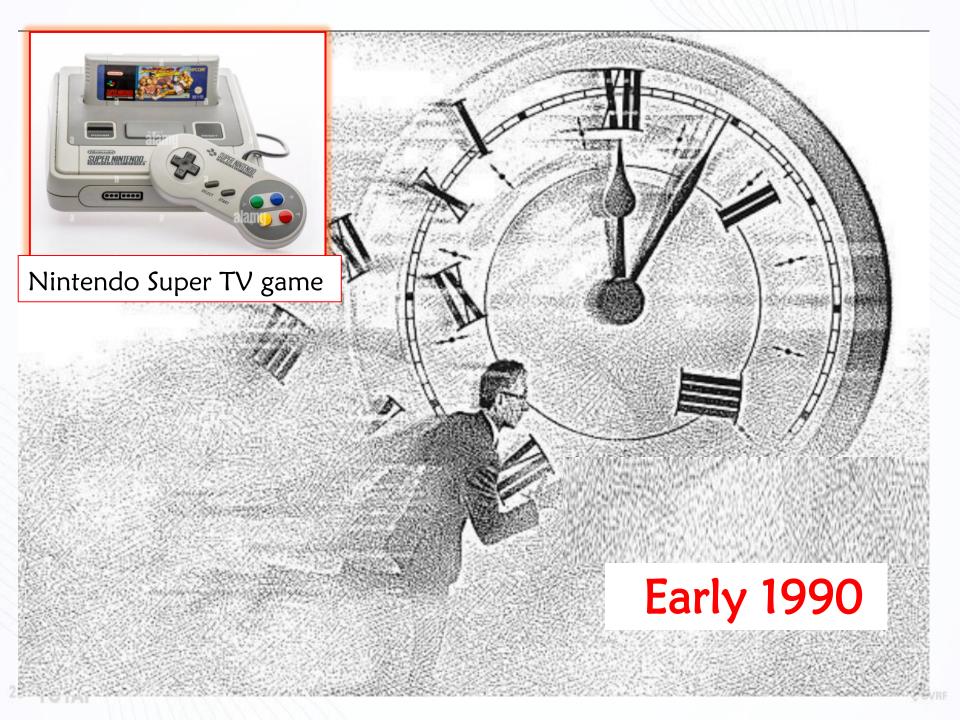
Usefulness of Directional Atherectomy for LMT Bifurcation Followed by DCB

Sunao Nakamura MD PhD

FACC, FESC, FAHA, FSCAI

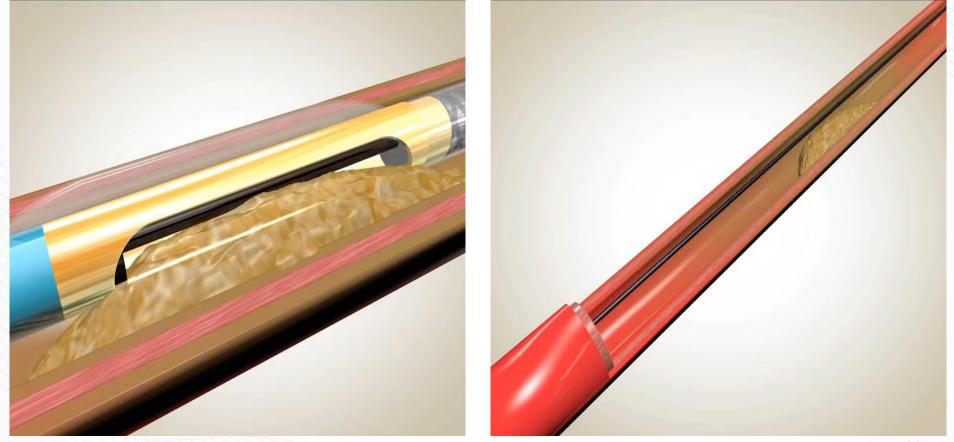
Shotaro Nakamura MD, Naoyuki Kurita MD, Hisaaki Ishiguro MD, Satoko Tahara MD
Masaaki Okutsu MD, Tomohiko Sato MD, Toru Naganuma MD, Satoru Mitomo M.D.
Hiroyoshi Kawamoto MD, Kentaro Tanaka MD, Satoshi Matsuoka MD, Tatsuya Amano MD,
Hiroaki Nakajima MD, Hirokazu Onishi MD, Kenjiro Tani MD, Yusuke Watanabe MD,
Koji Hozawa M.D., Toru Ohuti M.D., Hiroto Yabushita MD,

The New Tokyo Hospital ; Japan Tokyo

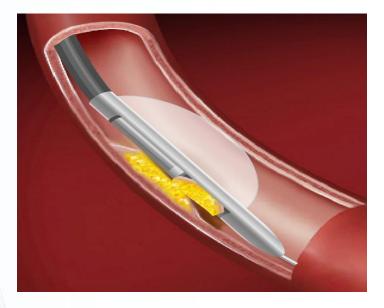


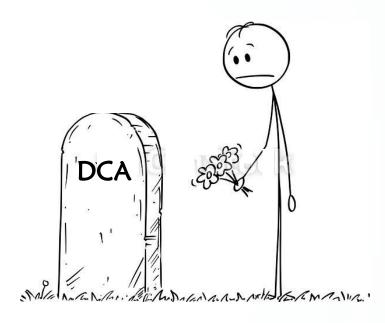
Directional Coronary Atherectomy (DCA)

- He come to the stage just before the STENT-



DCA (Directional Coronary Atherectomy) Went into Grave - Even he would not to like to go -





CABEAT trial ; Topol EJ NEJM 1993 OARS trial ; Simonton CA Circulation 1998

BOAT trial ; Blaim DS Circulation 1998 ABACAS trial ; SUZUKI TAKAHIKO JACC 1999



DCB: Body of Evidence : A Certainly Growing : ISR

TABLE 2 Randomized Controlled Trials of DCBs in ISR

Study Name (Ref. #)	Comparators to PCB	n	Follow-Up Duration	Angiographic Follow-Up	p Value	MACE (%)	p Value	TLR (%)	p Value
BMS ISR									
PACOCATH ISR I and II (14)	POBA	108	6 months (angio) 12 months (clinical)	LLL 0.03 \pm 0.48 mm vs. 0.74 \pm 0.86 mm	0.0002	4 vs. 31	0.01	0 vs. 23	0.02
			5 yrs (clinical)			27.8 vs. 59.3	0.009	9.3 vs. 38.9	0.004
PEPCAD II (97)	PES	131	6 months (angio) 12 months (clinical)	LLL 0.17 \pm 0.42 mm vs. 0.38 \pm 0.61 mm	0.03	9 vs. 22	0.08	6 vs. 15	0.15
			3 yrs (clinical)			34.8 vs. 41.5			
RIBS V (98)	EES	189	6-9 months (angio) 12 months (clinical)	LLL 0.14 \pm 0.5 mm vs. 0.04 \pm 0.5 mm, binary	0.14 0.22	8 vs. 6	0.60	6 vs. 1	0.09
			3 yrs (clinical)	restenosis 9.5% vs. 4.7%		12 vs. 10	0.64	8 vs. 2	0.04
SEDUCE (99)	EES	50	9 months (angio) 12 months (clinical)	LLL 0.28 mm vs. 0.07 mm, proportion uncovered struts (OCT) 1.4% vs. 3.1%	0.1 0.025			4.2 vs. 8	0.576
TIS (100)	EES	136	12 months	LLL 0.02 mm vs. 0.19 mm	0.0004	10.3 vs. 19.1	0.213	7.4 vs. 16.2 (TVR)	0.110
DES ISR									
PEPCAD-DES (101)	POBA	110	6 months (angio and clinical)	LLL 0.43 \pm 0.61 mm vs. 1.03 \pm 0.77 mm,	<0.001 0.001	16.7 vs. 50.0	<0.001	15.3 vs. 36.8	0.005
			3 yrs	restenosis 17.2% vs. 58.1%		20.8 vs. 52.6	0.001	19.4 vs. 36.8	0.046
PEPCAD CHINA ISR (102)	PES	220	9 months (angio) 12 months (clinical)	LLL 0.46 \pm 0.51 mm vs. 0.55 \pm 0.61 mm	0.0005*	16.5 vs. 16 (TLF)	0.92	15.6 vs. 12.3	0.48
			2 yrs (clinical)			16.8 vs. 18.6 (TLF)	0.73	15.9 vs. 13.7	0.66
ISAR DESIRE III (103)	PES vs. POBA	402	6–8 months (angio) 12 months (clinical)	Diameter stenosis 38% vs. 37.4%	0.007*	23-5 vs. 19-3 vs. 46-2	0.5 (PCB vs. PES)	22·1 vs. 13·5 vs. 43·5	0.09 (PCB vs. PES)
			3 yrs (clinical)			38.0 vs. 37.7 vs. 55.7	0.91 (PCB vs. PES)	33.3 vs. 24.2 vs. 50.8	0.11 (PCB vs. PES)
ISAR DESIRE IV (29)	Scoring and PCB	252	6-8 months (angio) 12 months (clinical)	LLL 0.31 \pm 59 mm vs. 0.41 \pm 0.74 mm	0.27	18.4 vs. 23.3	0.35	16.2 vs. 21.8	0.26
RIBS IV (104)	EES	309	6-9 months (angio) 12 months (clinical)	Binary restenosis 19% vs. 11%	0.06	18 vs. 10	0.04	16 vs. 8	0.035
RESTORE (105)	EES	172	9 months (angio) 12 months (clinical)	LLL 0.15 \pm 0.49 mm vs. 0.19 \pm 0.41 mm	0.54	7.0 vs. 4.7	0.51	5.8 vs. 1.2	0.10
FIM LIMUS DCB (25)	SCB	50	6 months (angio)	LLL 0.21 \pm 0.54 mm vs. 0.17 \pm 0.55 mm	0.794	16 vs. 12	> 0.99	16 vs. 12	>0.99
Mixed ISR									
BIOLUX (106)	SES	229	6 months (angio) 12 months (clinical)	LLL 0.03 \pm 0.40 mm vs. 0.20 \pm 0.70 mm	0.40	16.9 vs. 14.2 (TLF)	0.65	12.5 vs. 10.1	0.82
DARE (107)	EES	278	6 months (angio) 12 months (clinical)	MLD 1.71 \pm 0.51 mm vs. 1.74 \pm 0.61 mm	<0.0001*	10.9 vs. 9.2	0.66	7.1 vs. 8.8 (TVR)	0.65
A 100 A 4 10 A									

DCB: Body of Evidence : A Further Take a Step: SMALL CORONARY

Study Name (Ref. #)	Comparators	n	Follow-Up Duration	Angiographic Follow-Up	p Value	MACE (%)	p Value	TLR (%)	p Value
PICCOLETO (58)	Dior PCB vs. TAXUS Liberté PES	57	6 months (angio) 9 months (clinical)	MLD 1.11 \pm 0.65 mm vs. 1.94 \pm 0.72 mm	0.0002	35.7 vs. 13.8	0.054	32.1 vs. 10.3	0.15
BELLO (59,66)	IN.PACT Falcon PCB vs. TAXUS Liberté PES	182	6 months (angio) 12 months (clinical) 3 yrs (clinical)	LLL 0.08 \pm 0.38 mm vs. 0.29 \pm 0.44 mm	0.001	10 vs. 16.3 14.4 vs. 30.4	0.21 0.015	4.4 vs. 7.6	0.37
RESTORE SVD (61)	Restore PCB vs. Resolute Integrity ZES	230	9-12 months (angio) 12 months (clinical)	LLL 0.26 \pm 0.42 mm vs. 0.30 \pm 0.35 mm, diameter stenosis 29.6 \pm 2.0% vs. 24.1 \pm 2.0%	0.41, <0.001	9.6 vs. 9.6	1.0	4.4 vs. 2.6	0.72
BASKET- SMALL 2 (60)	Sequent Please PCB vs. TAXUS Element PES and Xience EES	758	6 months (angio)* 12 months (clinical)	LLL 0.13 mm (–0.14 to 0.57 mm) vs. 0.10 mm (–0.16 to 0.34 mm)	0.72	8 vs. 8	0.918, 0.0152†	3.4 vs. 4.5	0.438

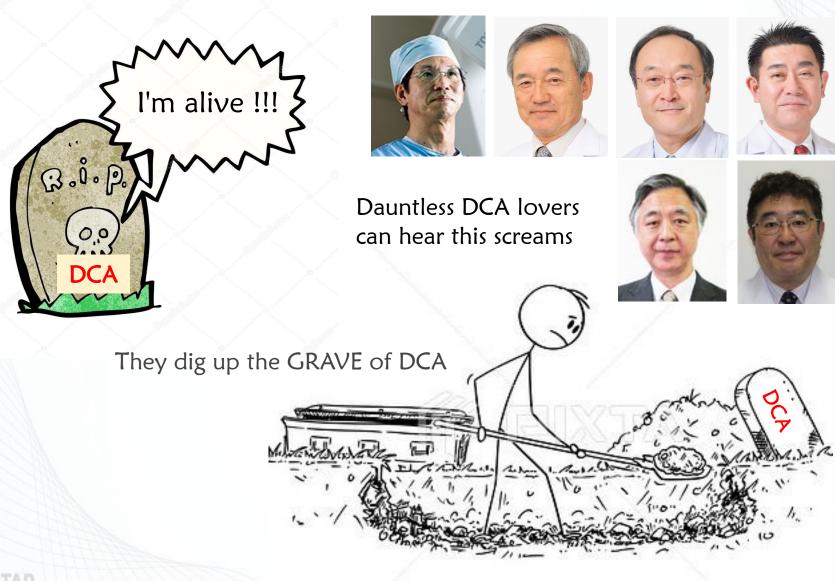
NO 1721

DCB: Body of Evidence : More Further : LARGE CORONARY

Study Name/ First Author et al. (Ref. #)	DCB	n	≥2.75-mm DCB (%)	≥3.0-mm DCB (%)	Bailout Stent (%)	MACE (%)	TLR (%)
DELUX (70)	Pantera Lux	105		23	22	9.4 (12 months)	3.1 (12 months) (TVR)
FALCON (69)	In.Pact Falcon	326	25		4.8	8.0 (12 months)	4.9 (12 months)
Venetsanos et al. (53)	SeQuent Please, In.Pact Falcon, Pantera Lux	985		6	8		3 (12 months)
Rosenberg et al. (54)	Sequent Please	731	21		6	5.6 (9 months)	2.3 (9 months)
Uskela et al. (68)	Sequent Please	463	79	60	12	6.1 (stable CAD, 12 months)	1.4 (stable CAD, 12 months)
Yu et al.(108)	Sequent Please	595	36		0.5	0 (10 months)	0 (10 months)
DEBUT (57)	Sequent Please vs. BMS (RCT)	103	76	64	2	1.9 (9 months)	0 (9 months)
PEPCAD-NSTEMI (62)	Sequent Please vs. BMS and DES (RCT)	104			17.4	3.8 (9 months)	1.0 (9 months)

CAD = coronary artery disease; RCT = randomized controlled trial; other abbreviations as in Tables 1 and 2.

DCA : Forgotten ? Hidden?



CVRF

DCA : Resurrection with new plat form

The First Clinical Experience with a Novel Directional Coronary Atherectomy Catheter: Preliminary Japanese Multicenter Experience

Maoto Habar, Etsuo Tsuchikane, Takahiko Suzuki et al CCI 2016

The Role of Revived Directional Coronary Atherectomy

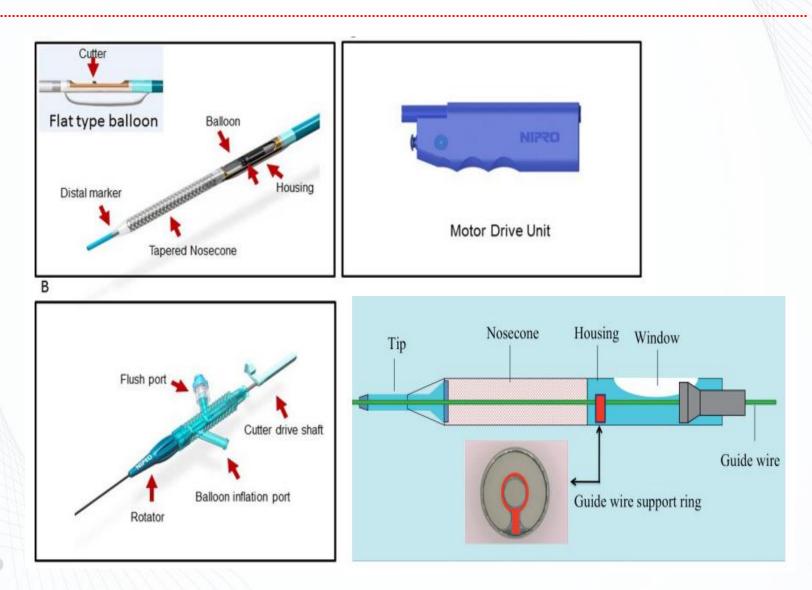
Michihiro Kijima

J Jpn Coron Assoc 2016



DCA : Resurrection with new plat form

- Capacity Expansion by New Plat Form -



DCA : Resurrection with new plat form

ATHEROCUT [®] (a novel catheter) Short cutter	FLEXI-CUT [®] (previous catheter) Long cutter
DLC; diamond like carbon coating	Titan coating
(Vickers hardness : 900)	(Vickers hardness : 550)
1.95 mm (0.077 in.)	2.10 mm (0.083 in.)
6 mm/9 mm (2 type)	9 mm
3.0-4.4 mm (3 size)	2.5-4.0 mm (3 size)
Tapered nose cone with tip (0.032 mL)	0.030 mL
≧7 Fr	\geq 8 Fr
6,000 rpm	3,500 rpm
Flat type	Circular type
	Short cutter DLC; diamond like carbon coating (Vickers hardness : 900) 1.95 mm (0.077 in.) 6 mm/9 mm (2 type) 3.0–4.4 mm (3 size) Tapered nose cone with tip (0.032 mL) ≧7 Fr 6,000 rpm

Very Sharp Cutter, Smaller Catheter, Tapered Nose Cone(more flexible) Smaller compatible catheter (7Fr), High MDU: 6000 rpm, Better Balloon

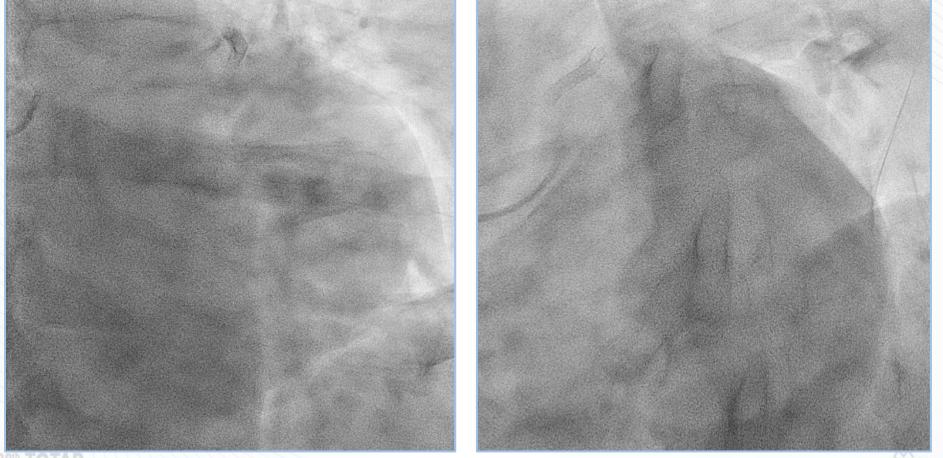
Advantage

28th TCTAP



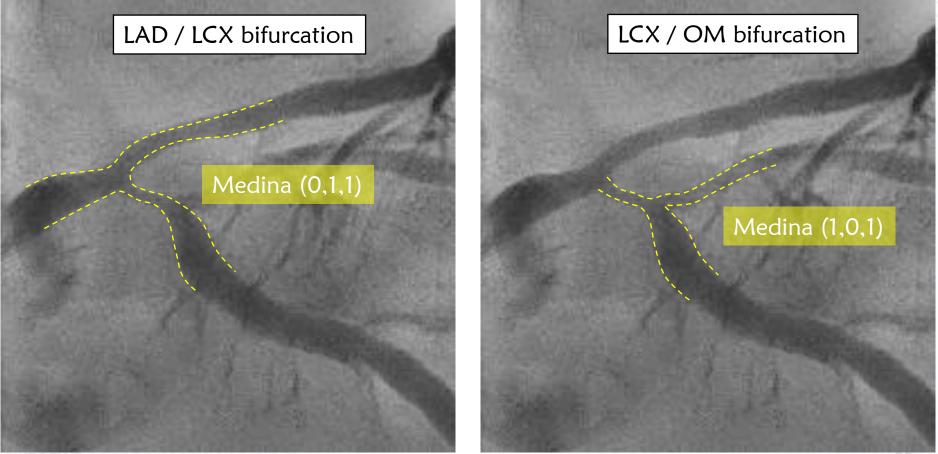
Case 1: 83yo: M LMT true bifurcated Disease

LMT distal true bifurcated Lesion (1.1.1.) Prox. LCx 90%, Prox.LAD diffuse 80% with Cal.



Case 1: 83yo: M LMT true bifurcated Disease

Double true bifurcated lesion with LAD/LCX and LCX/OM



How would you treat this lesion?

1. Provisional Stenting

Highly probable TAP ???



2. DK Crush

DK CRUSH 1.2.3.4.5.....





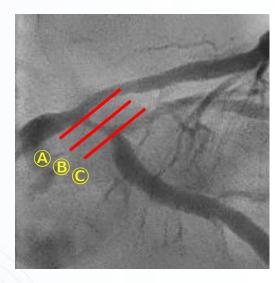


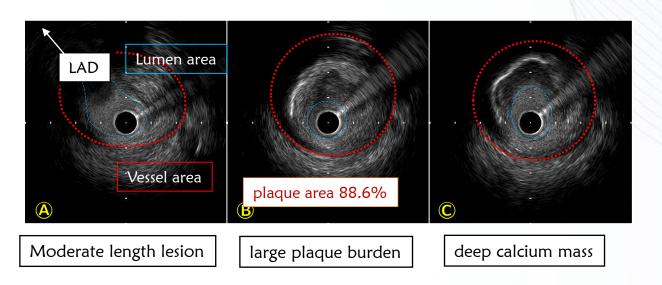


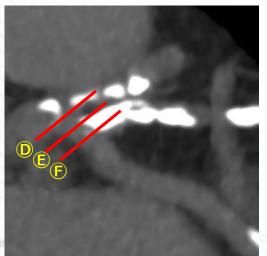
28th TCTAP

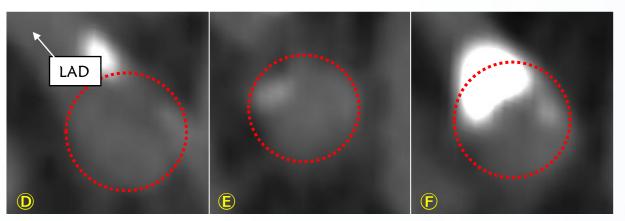
No Calcification in LCX ost~Prox.

Before IVUS, already-known fact by no contrast coronary CT



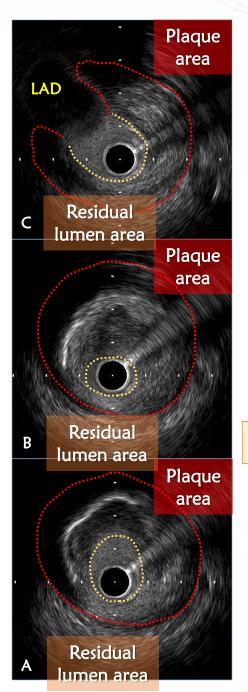






Pre IVUS : Proximal LCx



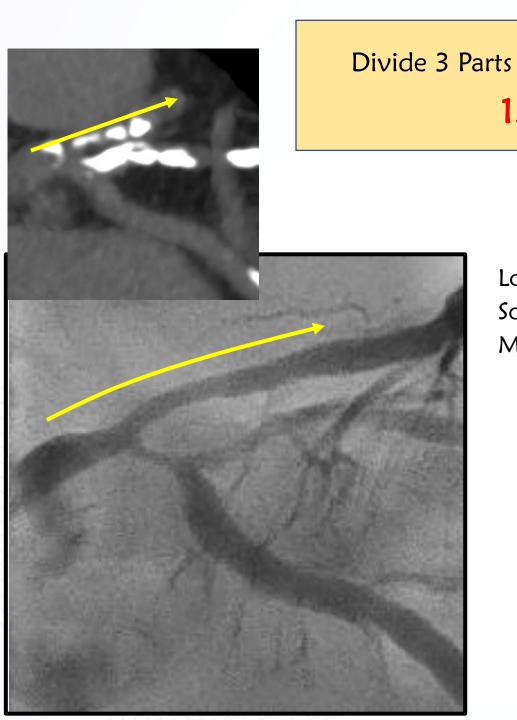


Ostial LCx

Large plaque burden

plaque area 88.6%

Proximal LCx



Long, Diffuse lesion Some superficial calc. Main Vessel

1. LMT- LAD







Divide 3 Parts

2. LCX prox.

Long, Diffuse lesion Some superficial calc. Main Vessel



Short Lesion Few calcification Possible angle for DCA





Divide 3 Parts

3. LCX-OM

Long, Diffuse lesion Some superficial calc. Main Vessel



Short Lesion Few calcification Possible angle for DCA



Long, diffuse lesion Some superficial calc.



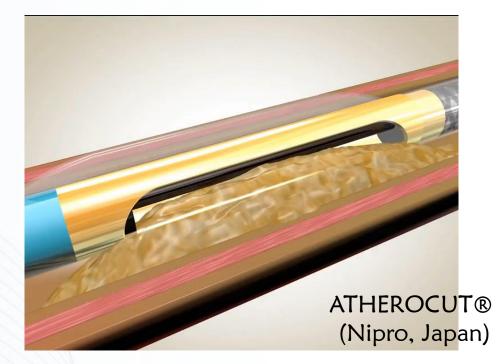




Prevention of neointimal hyperplasia



Plaque reducing effect



SeQuent Please® (B Braun, Germany)

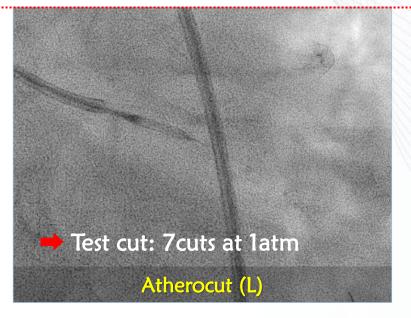
If we combine to use DCA and DCB...

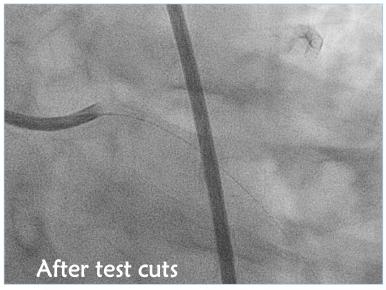
Each of them compensate their drawback by their cross talk Resulting, New concept would be born !!

DCA for the proximal LCx : At first "Test-Cut"



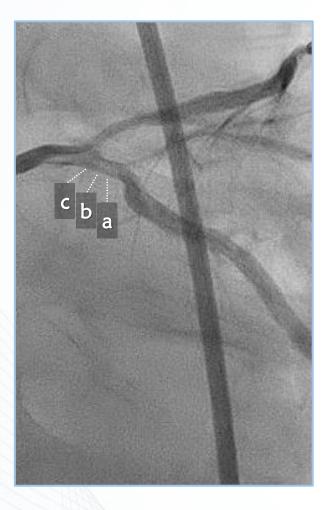
Test Cut for the proximal LCx



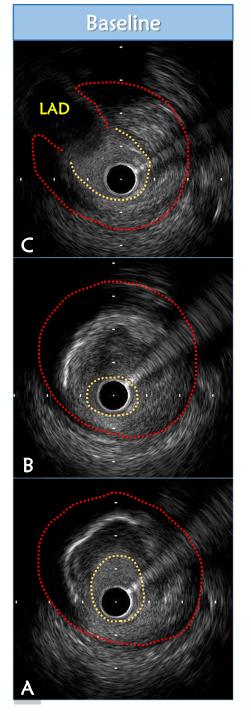


28th TCTAP

IVUS after test cut : proximal LCx

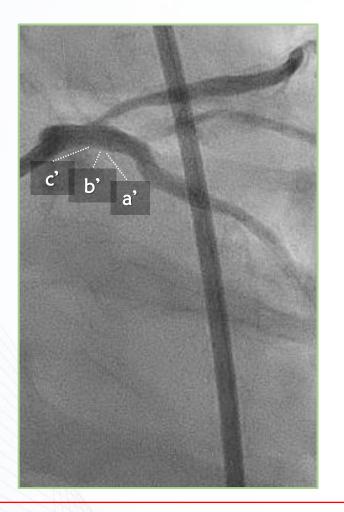


Need to confirm what we have done right or not

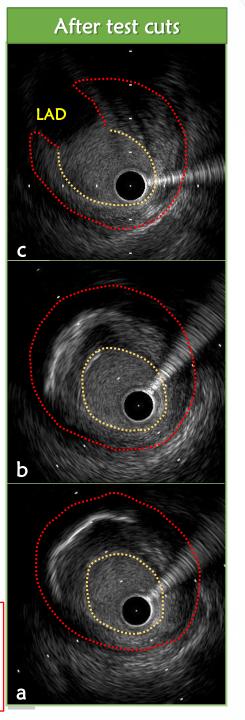


After test cuts LAD С b

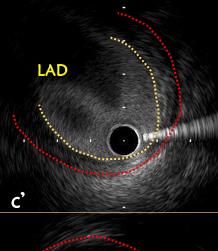
IVUS after multiple DCA for the prox. LCx

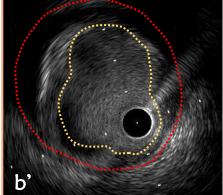


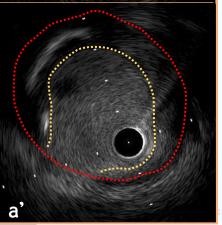
Need to check How much plaque burden already removed And still in safe or not ?



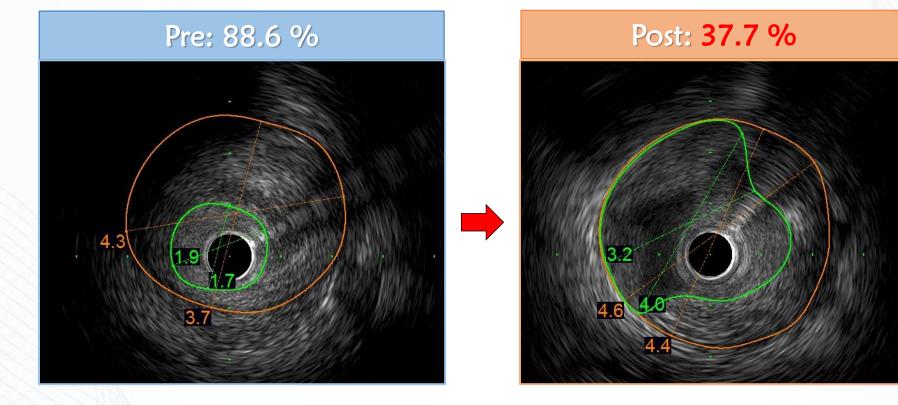
After mutiple cuts





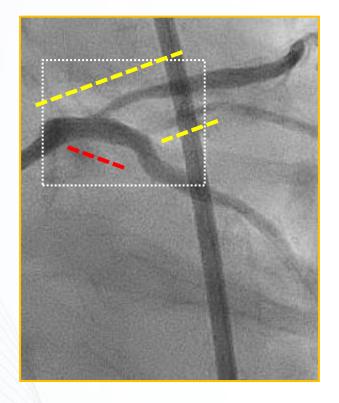


Watch !! Removed Big Plaque Reduction !! By DCA

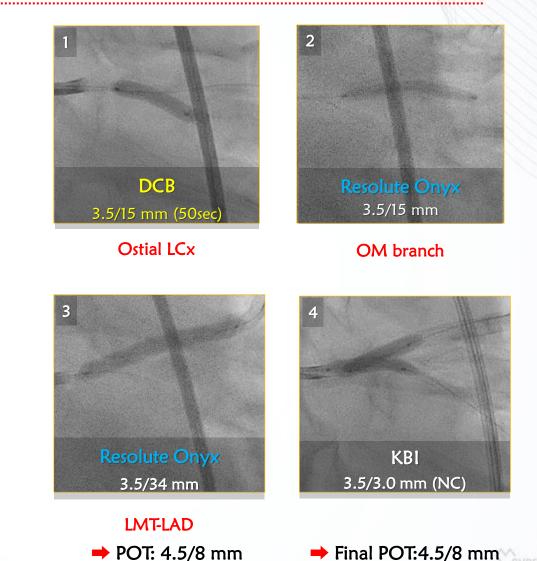


28th TCTAP

Stenting in LAD, OM and DCB in LCx: No Overlapping Stent !!

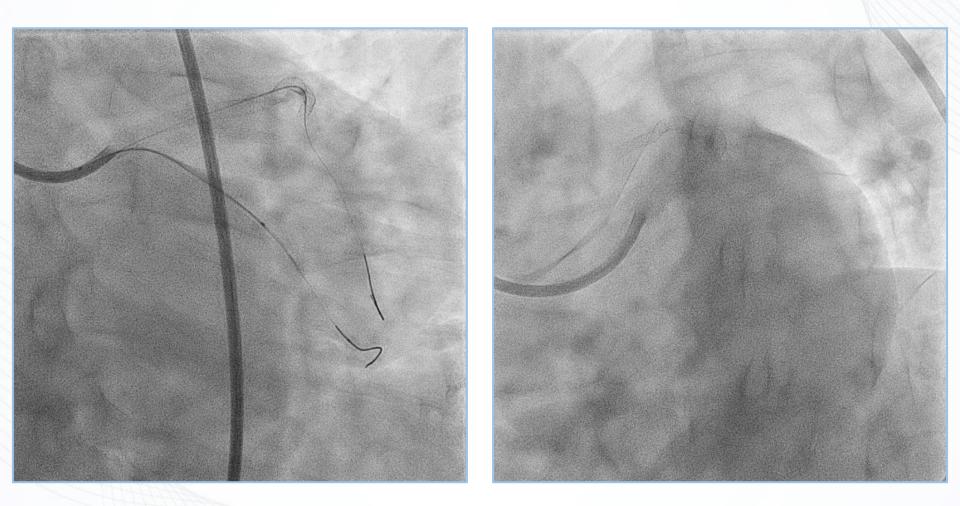


Looks like 0,1,0



28th TCTAP

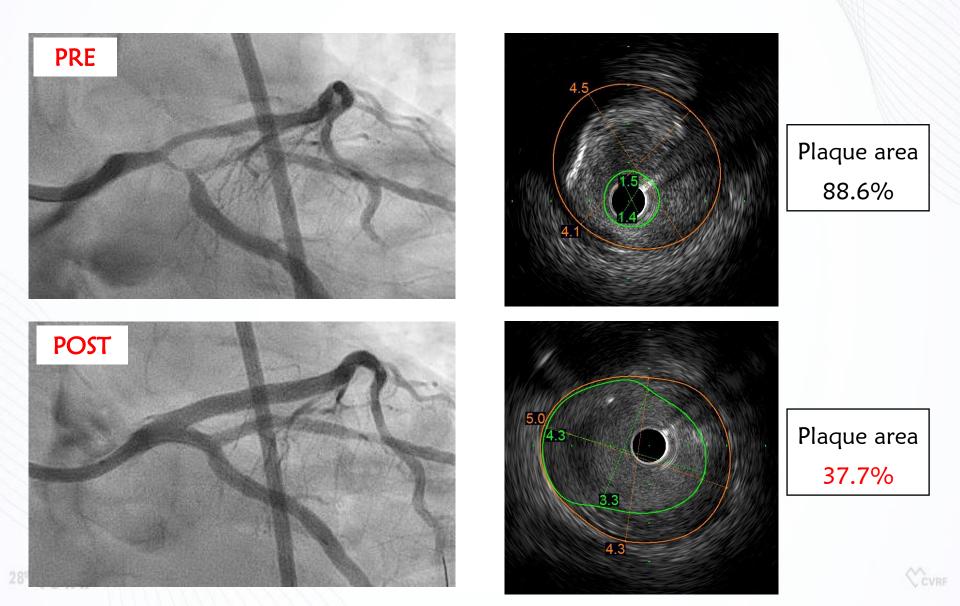
Hybrid Strategy with DCAB and DES Then No Overlapping Stent !!



Final angiography



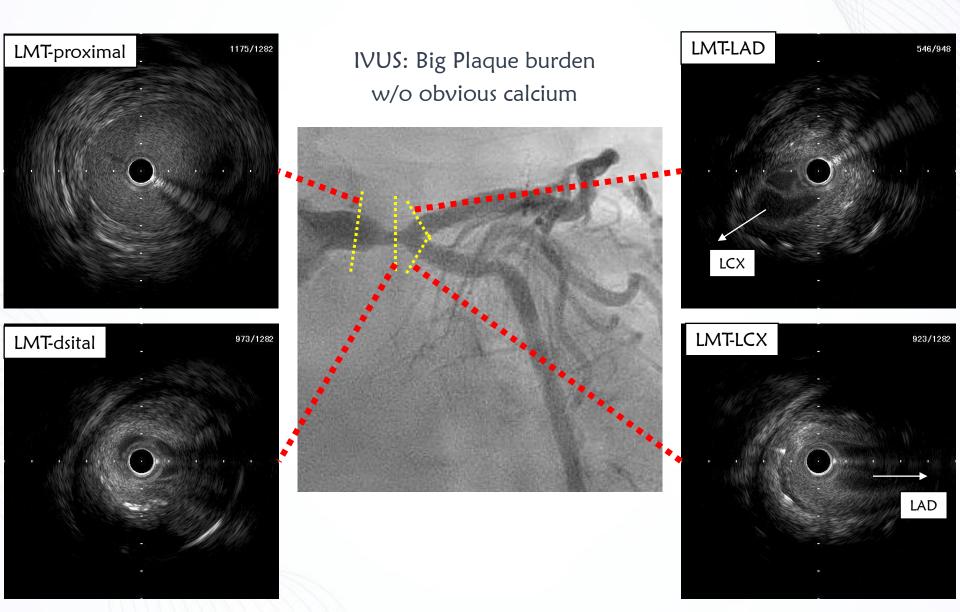
How do you think ???

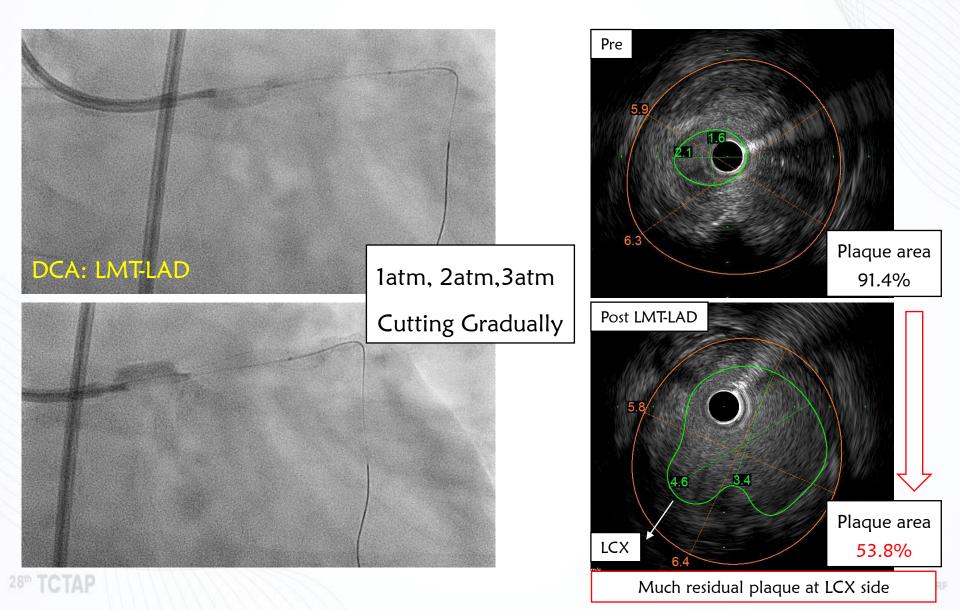


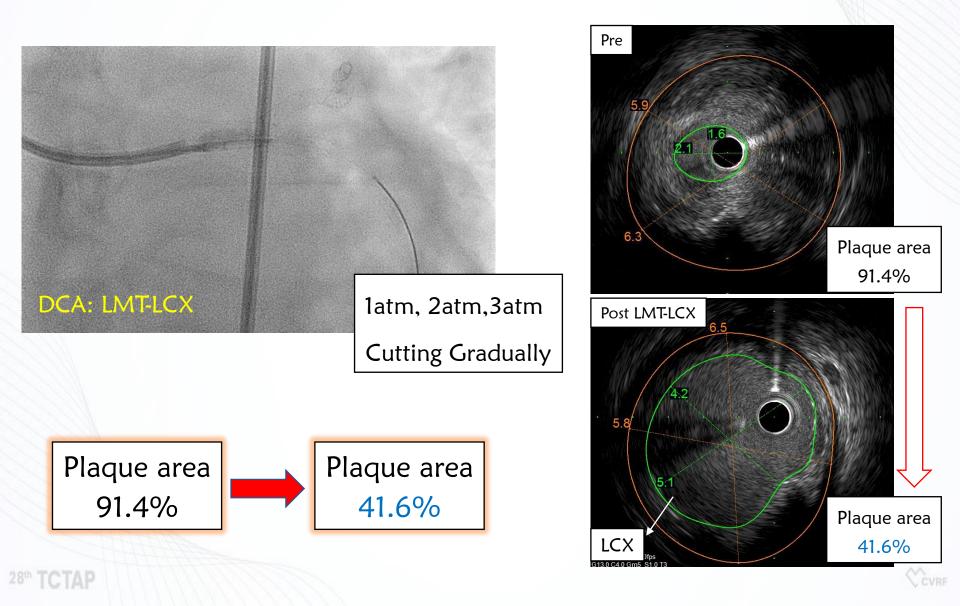
Stenosis in LMT distal just before area of V-stenting in LAD and LCX



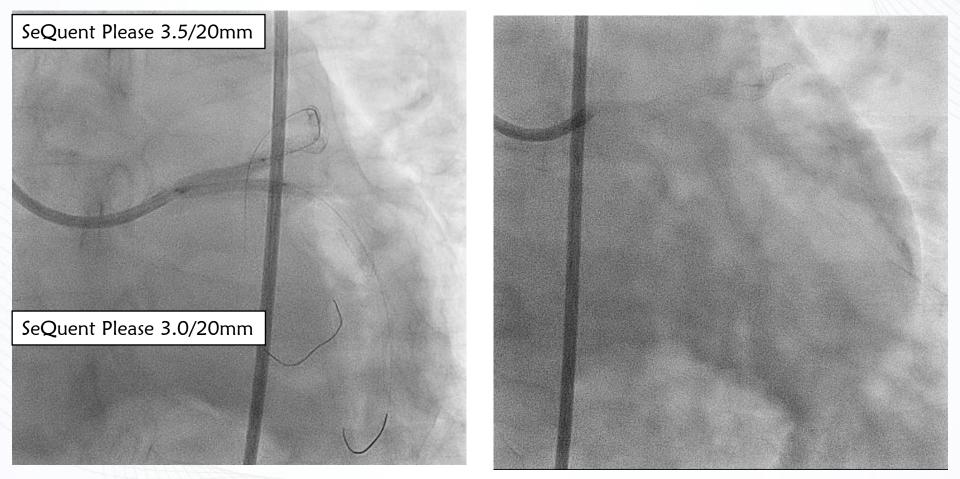




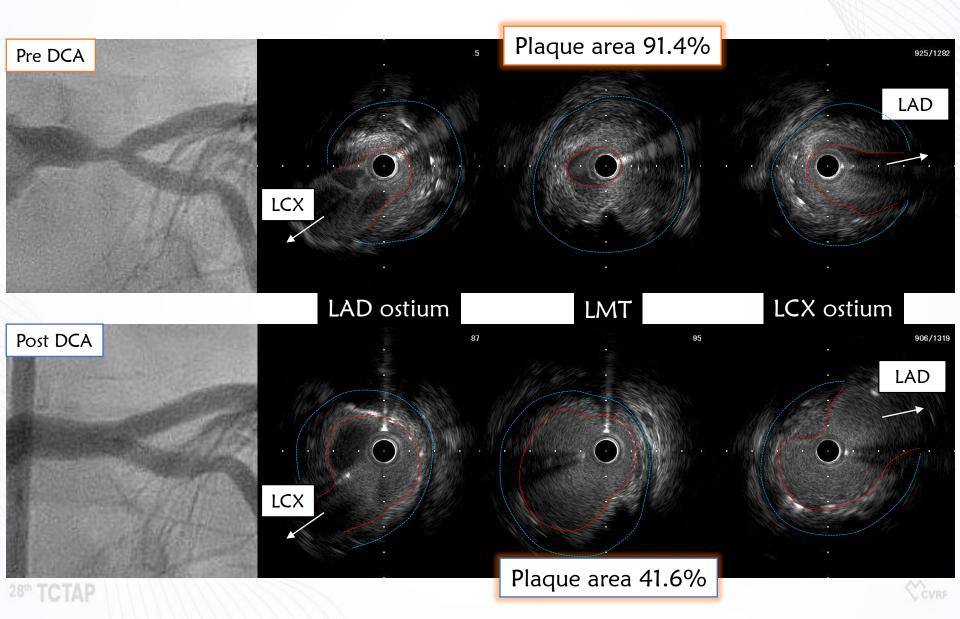


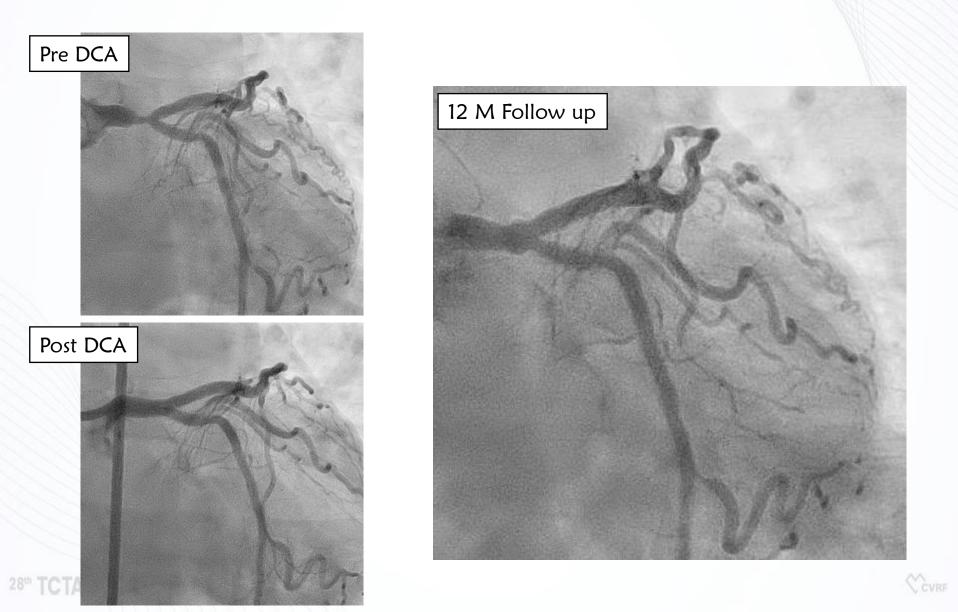


KBT !! With DCBs

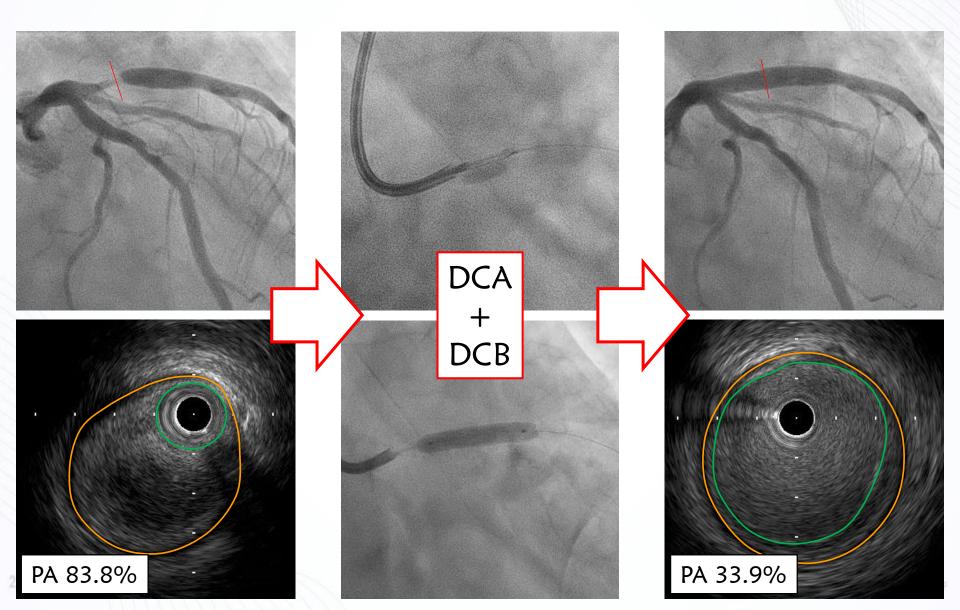








Case 3 : LAD just Prox. DCA case

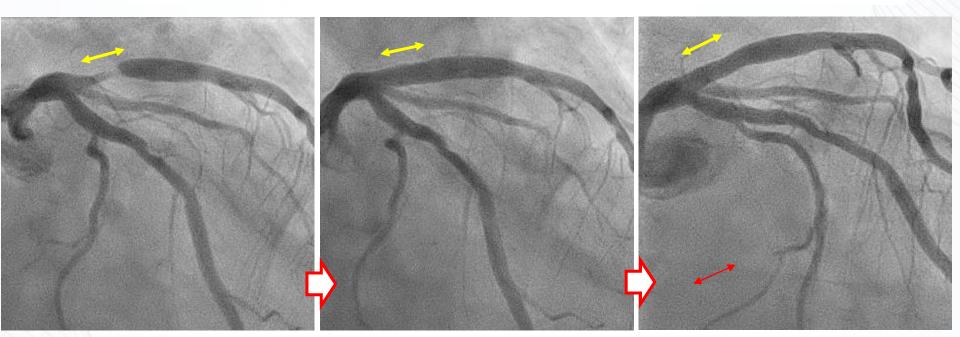


DCA decrease the number of STENT

Pre

Post DCA+DCB

6 months follow up



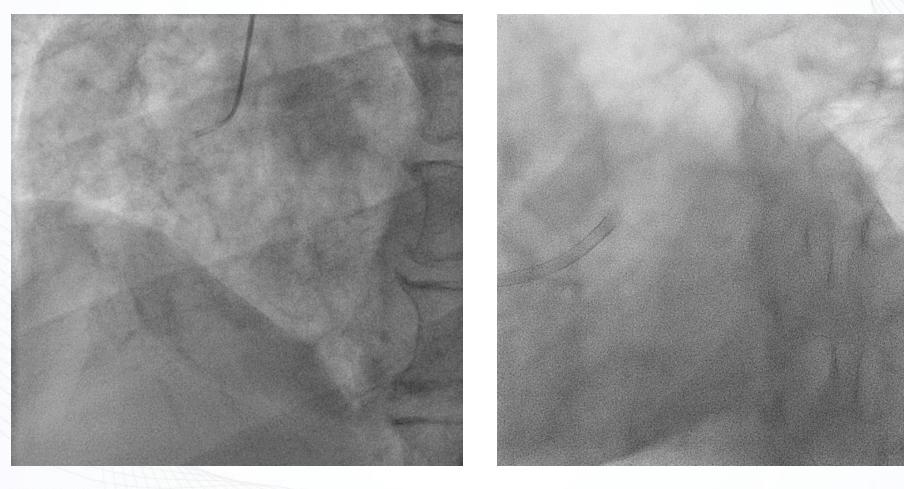


NO STENT !!

28th TCTAP

Case 4 : 66yo: M ; LAD CTO with trifurcation LMT

No significant in RCA and good collateral to LAD and LAD subtotal occlusion





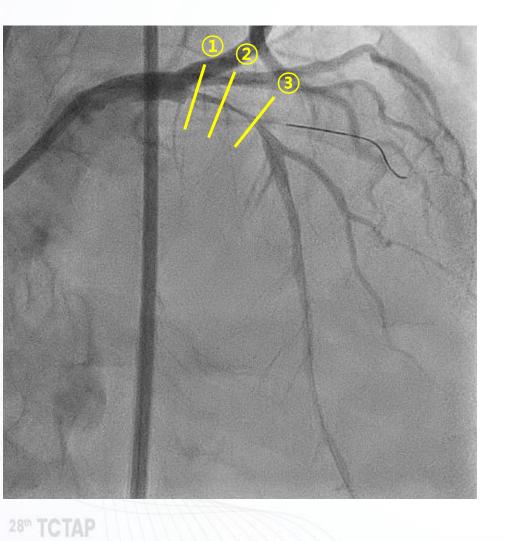
Case 4 : 66yo: M ; LAD CTO with trifurcation LMT

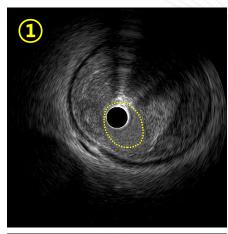
After passing the GWs to LAD and Dx, 1.5 mm ballooning for making space

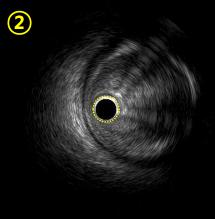


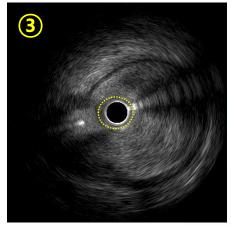


IVUS run 1



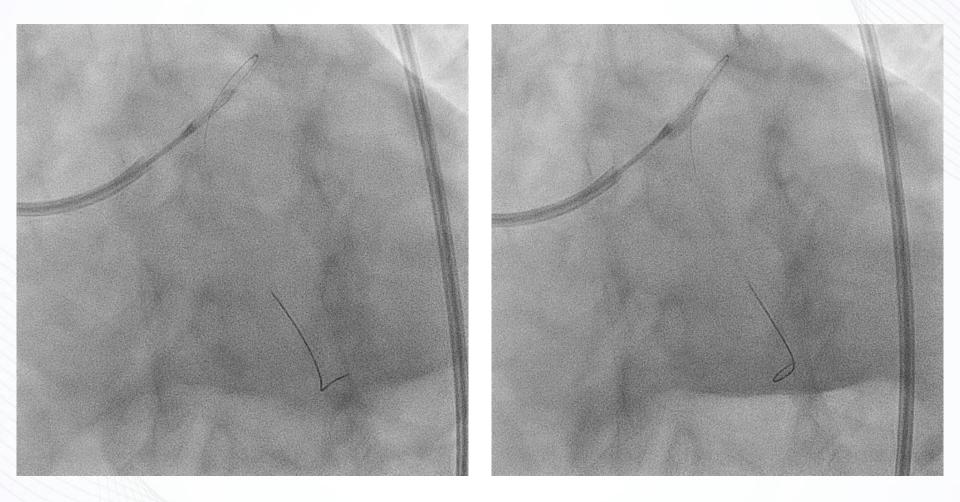






Big Plaque Burden

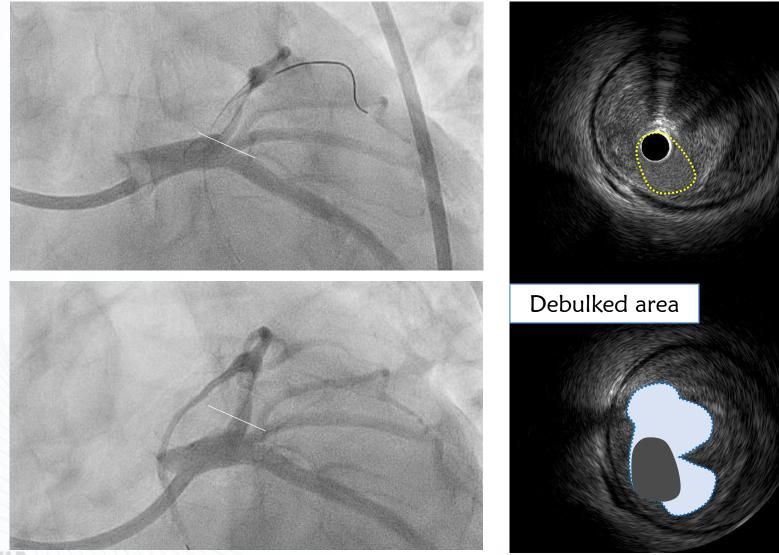
DCA 1st Session @ 1atm



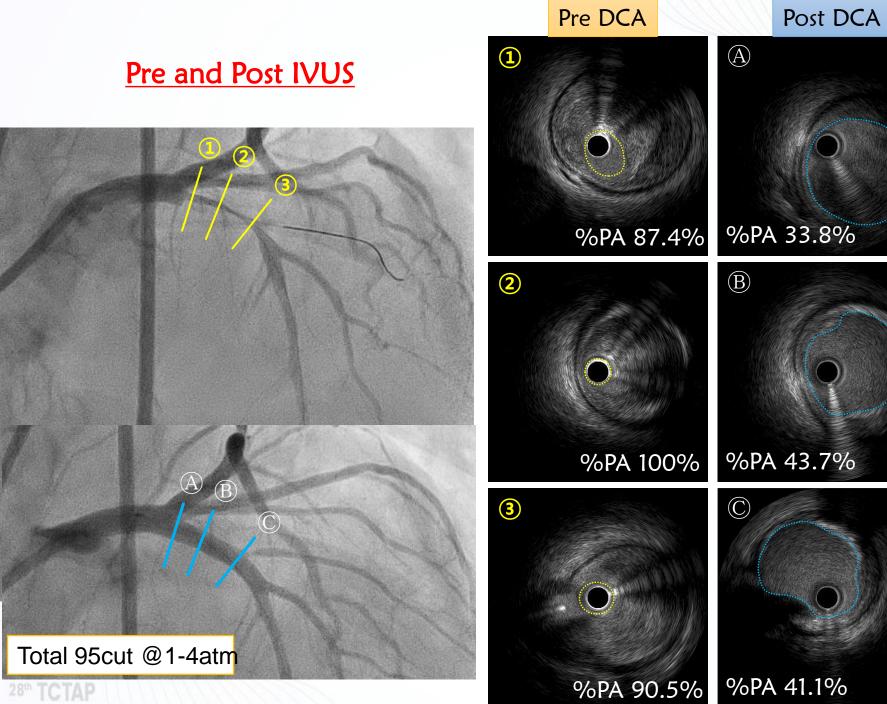
8Fr. Mach1 FCL4.0 DCA: Atherocut (L)



Post 1st Session @ 1atm

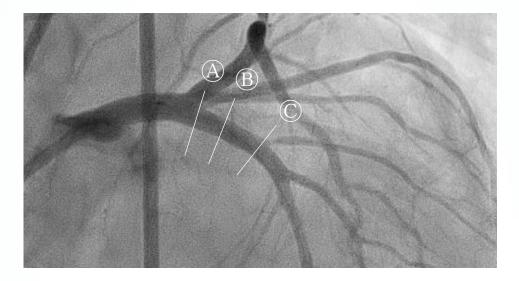


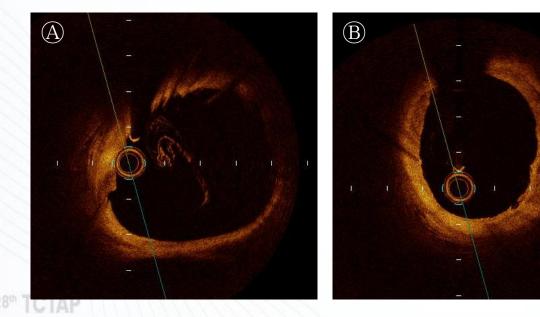
CVRF

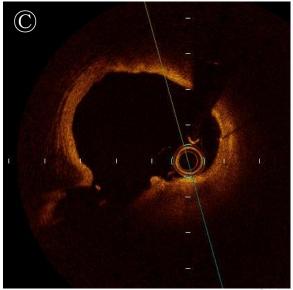


%PA 33.8% %PA 43.7%

OCT study after DCB 4.0×20mm

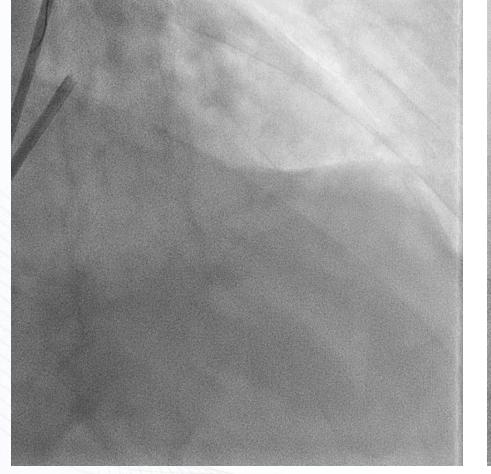


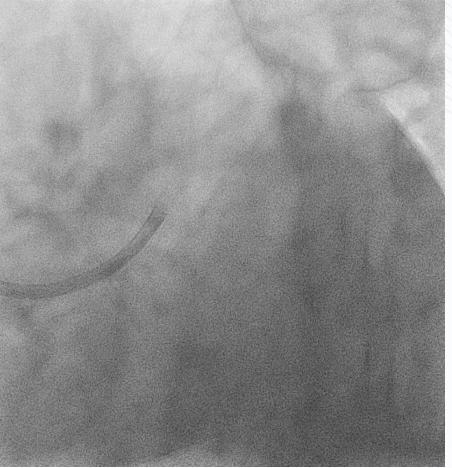




Case 4 : 66yo: M ; LAD CTO with trifurcation LMT

Final Angiogram







Advantage

1. Decreasing the number of the stent in LMT true bifur. area

2. Possibility of avoiding overlapping 2 stents

3. Quick discontinuation of antiplatelet therapy



Impact of directional coronary atherectomy followed by drug-coated balloon strategy to avoid the complex stenting for bifurcation lesions

Okutsu M, Sunao Nakamura et al Heart and Vessel 2022



Short-term outcome of percutaneous coronary intervention with directional coronary atherectomy followed by drug-coated balloon: a preliminary report

Akihiko Sato, Mikihiro Kijima et al Cardiovascular Intervention and Therapeutics 2019

Efficacy of drug-coated balloon angioplasty after directional coronary atherectomy for coronary bifurcation lesions (DCA/DCB registry)

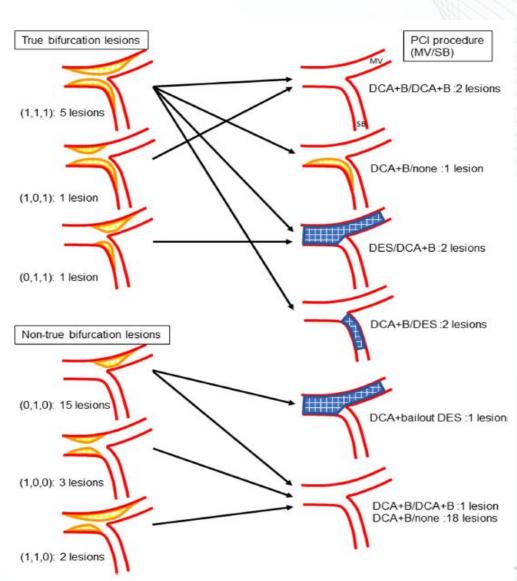
Shunsuke Kitani, Mikihiro Kijima et al CCI 2021

Stentless Strategy by Drug-Coated Balloon Angioplasty following Directional Coronary Atherectomy for Left Main Bifurcation Lesion

Norihiko Kobayashi Journal of Interventional Cardio. 2021

Impact of directional coronary atherectomy followed by drug-coated balloon strategy to avoid the complex stenting for bifurcation lesions Heart and Vessel 2022

LMT AREA 28 case	es 31 lesion
	n=26
IVUS	
Pre procedure	
MLA, mm ²	2.6 ± 1.4
VA, mm ²	14.6 ± 5.0
PA, %	80.4 ± 10.5
Post DCA	
MLA, mm ²	9.9 ± 2.6
VA, mm ²	16.7 ± 5.5
PA, %	41.0 ± 9.7
Post DCB	
MLA, mm^2	10.6 ± 2.8
VA, mm ²	17.8 ± 4.4
PA, %	39.0 ± 11.5
Acute gain, mm ²	7.9 ± 3.3
Deep cut	8 (30.8)



28th TCTAP

Intra-Coronary Imaging

IVUS	34 lesions
Pre procedure	
MLA, mm ²	2.7±1.6
VA, mm ²	14.9±5.3
PA, %	80.5±10.9
Post DCA	
MLA, mm ²	9.7±2.8
VA. mm ²	16.5±5.3
PA, %	42.2±8.9
Post DCB	
MLA, mm ²	10.4±2.9
VA, mm²	17.5±4.5
PA, %	39.6±10.5
Acute gain, mm ²	7.7±3.3
Deep cut	11 (32.3)

ОСТ	34 lesions
Pre procedure	
MLA, mm ²	2.2±1.7
Post procedure	
MLA, mm ²	8.7±2.9
Acute gain, mm ²	6.7±3.0
6M-follow-up	
MLA, mm ²	6.3±3.3
Late lumen loss, mm ²	2.5±3.0

8º TC

Clinical F/U Result

In-hospital MACE			
Cardiac death	0		
Procedural cardiac tamponade	0		
Target vessel-rerated MI	0		
Unplanned TVR	0		
6M-MACE			
Cardiac death	0		
Target vessel-rerated MI	0		
Ischemia driven TVR	3 (10	.7)	

Potential...

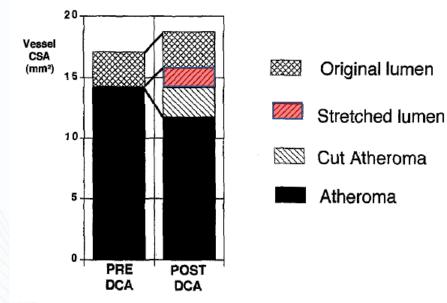
"DCA makes Vessel can move very freely whatever he want" ???



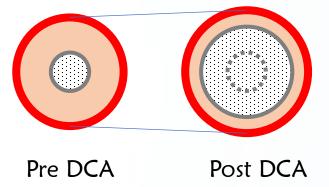


Unique advantages of no stent strategy with DCA

Vessel enlargement

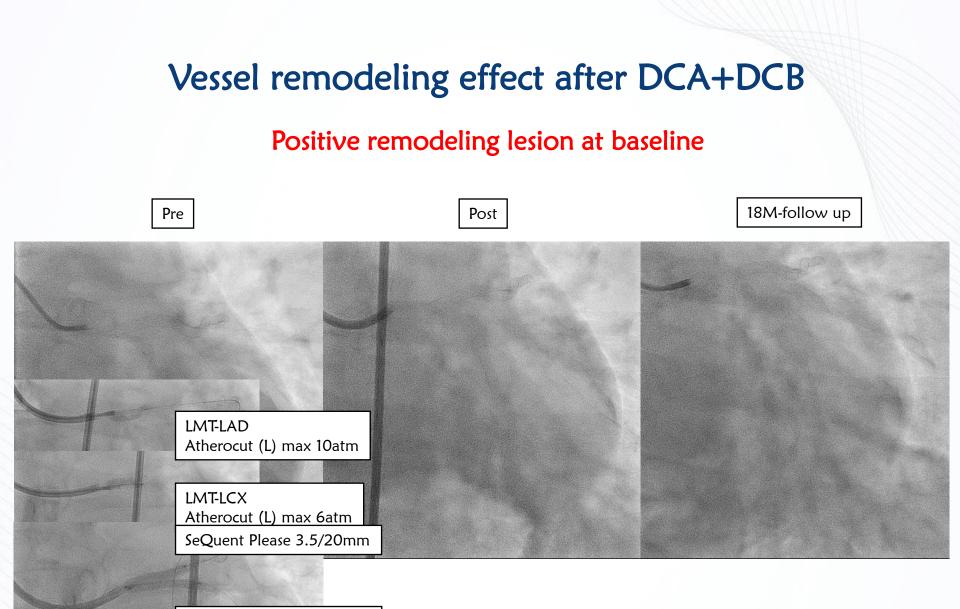


(Shigeru Nakamura, et al. Am Heart J 1995)



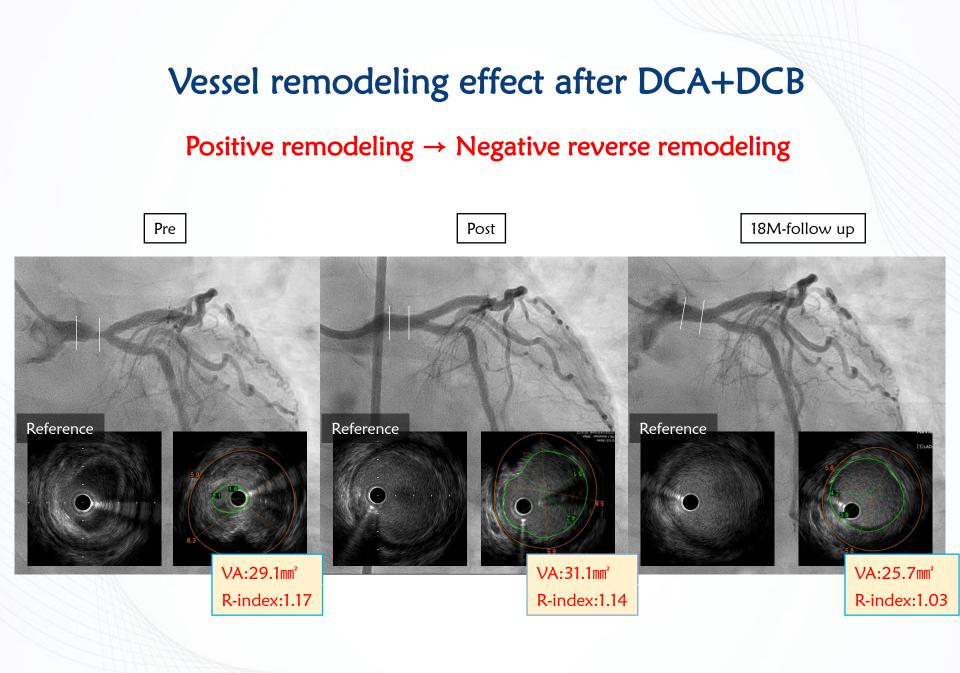
28th TCTAP



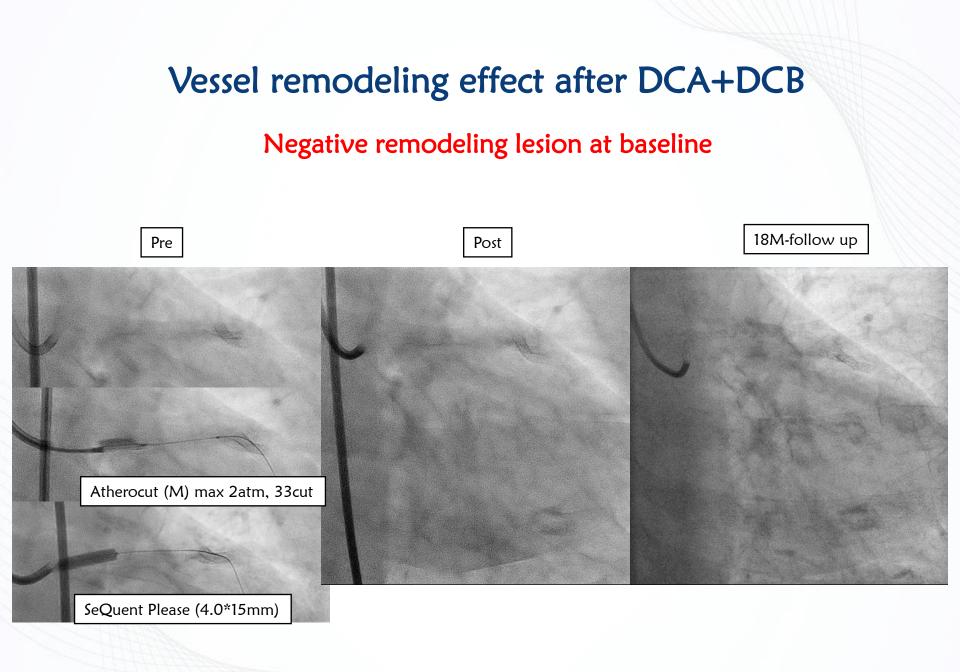


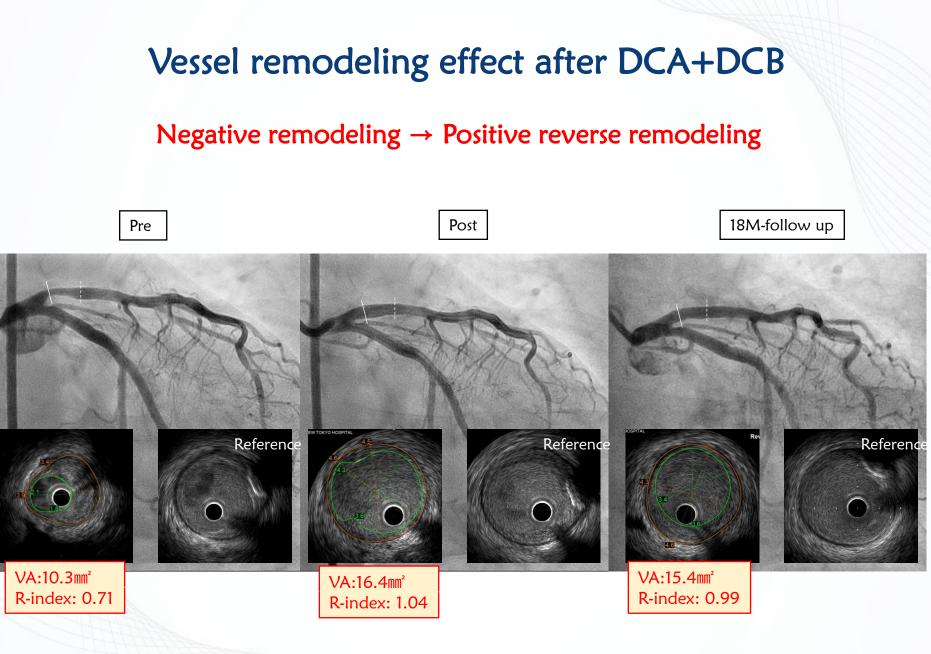
SeQuent Please 3.0/20mm





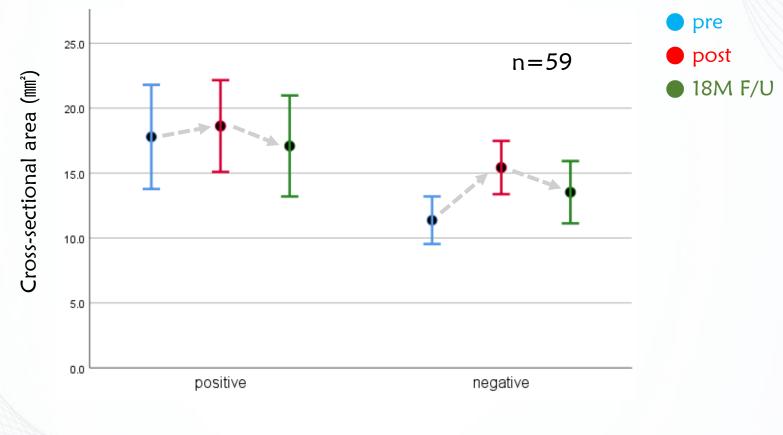






Vessel area change after DCA+DCB

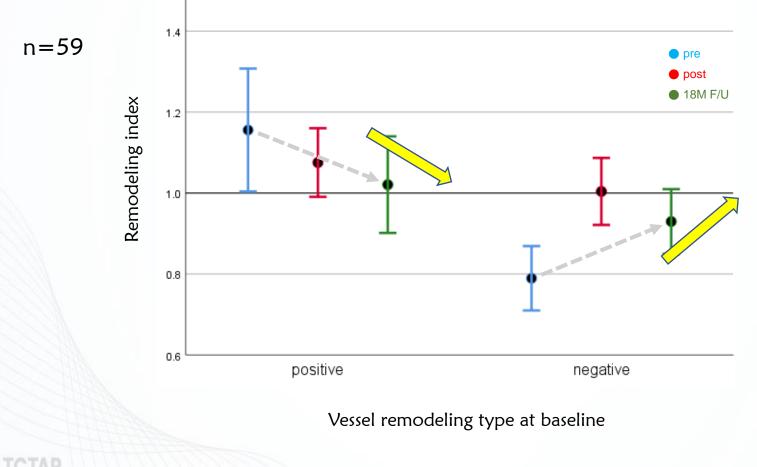
Both positive, negative remodeling vessel increased in area once and then decreased



Vessel remodeling type at baseline

Vessel remodeling index after DCA+DCB

Both positive and negative remodeling lesions seems to return to normal size.



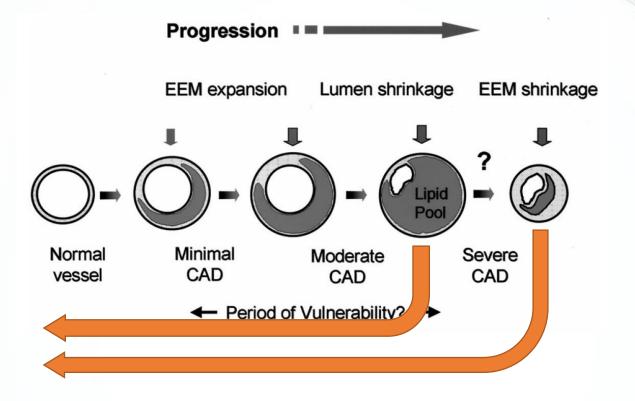
Potential...

"DCA makes Vessel can move very freely whatever he want" ???



28th TCTAP

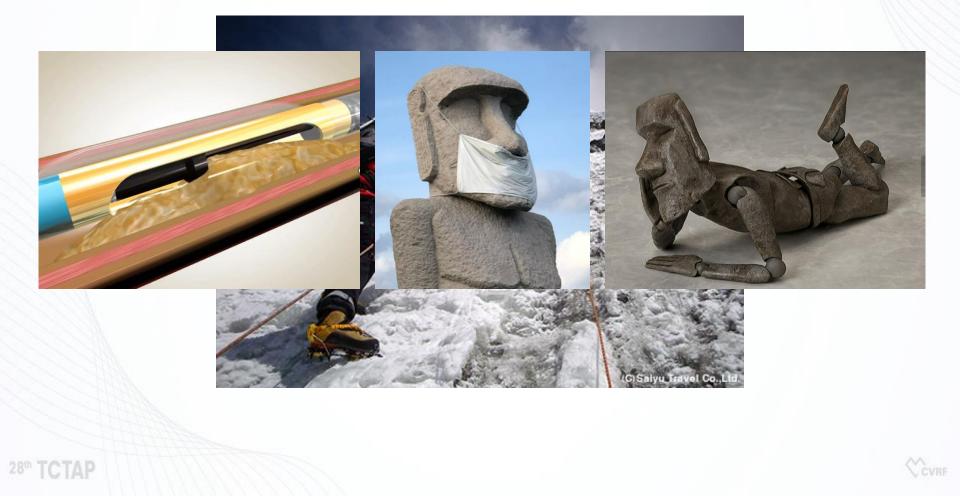




(Schoenhagen et al. J Am Coll Cardiol 2001)

DCA has a potential of reverse remodeling towards normal vessel size in both positive and negative remodeling lesions at baseline

We are still on the way to solve "unclarified validity "and "effectiveness" of DCA-B

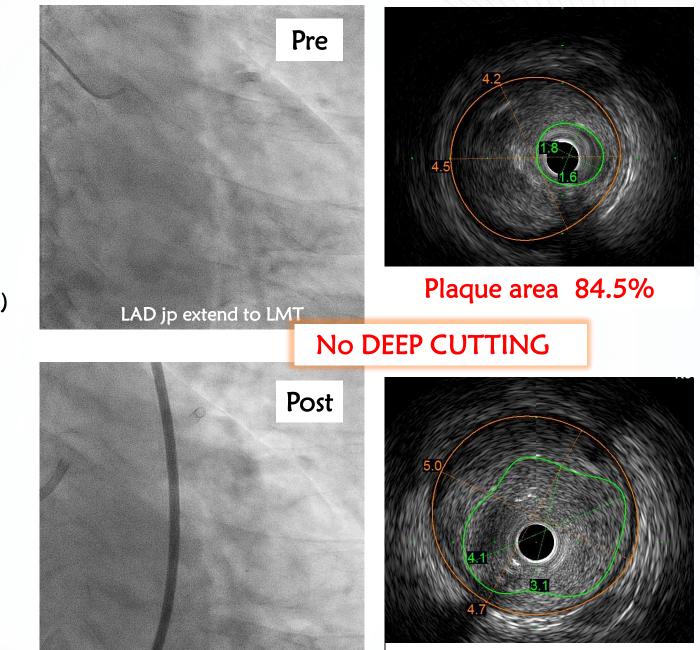


Reverse remodeling after DCA+DCB IVUS cross sectional area n=59 Positive remodeling at baseline Negative remodeling at baseline stretched lumen 20 MLA Negative Plaque area \$ stretched lumen **Reverse** remodeling original lumen 15 Positive Cross-sectional area (mm²) **Reverse remodeling** ¢Ľ cut plaque original lumen net gain 10 net gain cut plaque plaque area 5 plaque area 0 18-month 18-month post post pre pre

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<u>Case 1</u>

Unstable angina HT+, DL+, DM-, CKD-, Smoke-LDL-C: 66mg/dl (at PCI) ⇒ 68mg/dl (6M)

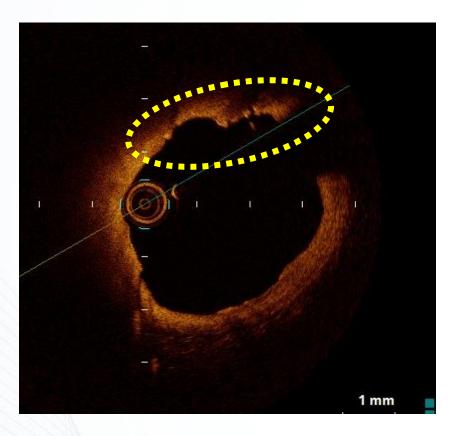


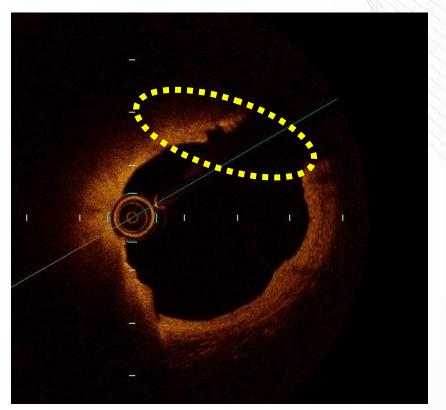
28th TCTAP

Plaque area 45.8%

Case 1

Post PCI OCT (DCA + DCB)



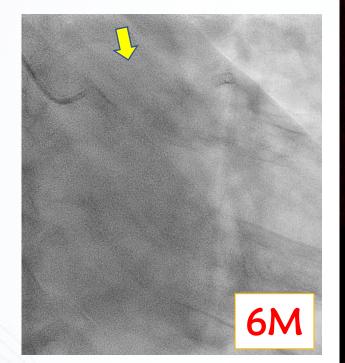


Surface Irregularity and Distorted shape of lumen, Surface of Vessel is uneven and stratum like appearance.

28th TCTAF

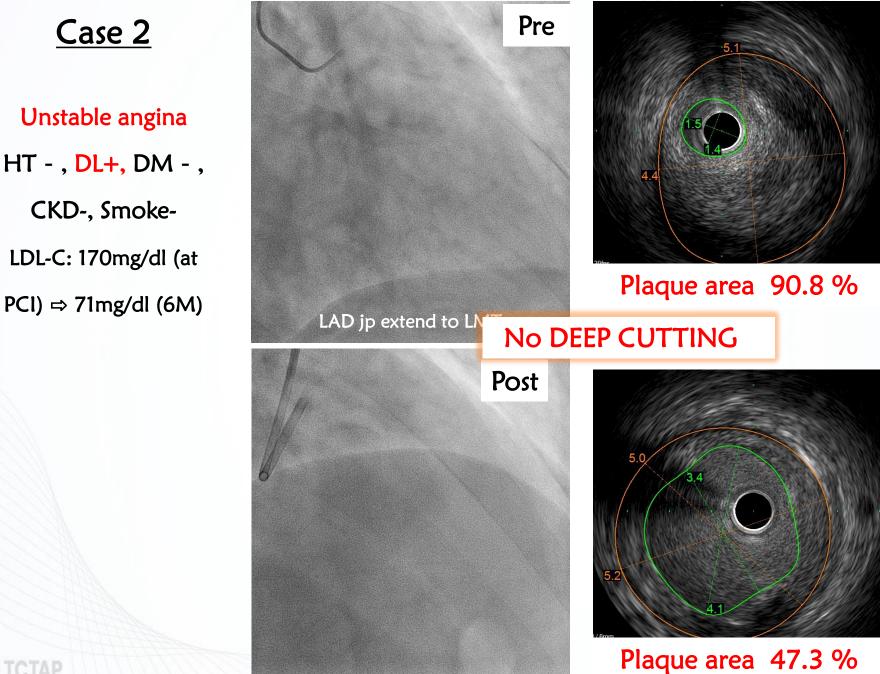
CVRF

OCT at F/U : 6M



Inflammation (MQ), Microchannel, and Multiple healing events (multi-layer) may be associated with TLR.

Macrophages **Microchannel** Multiple layer

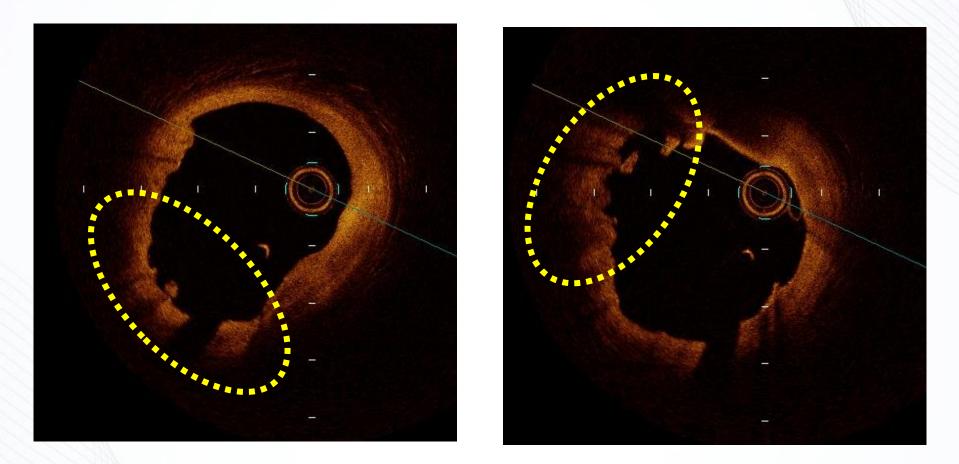


28th TCTAP

CVR

Case 2

Post PCI OCT (DCA + DCB)



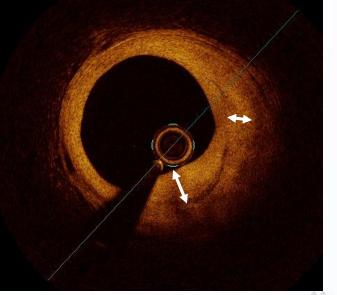
Surface Irregularity and Distorted shape of lumen, Surface of Vessel is uneven and stratum like appearance.



OCT at F/U : 6M

<u>Multiple healing events</u> (multi-layer) and <u>microchannel</u> or its disruption (micro-hemorrhage between layer) <u>may be associated with TLR</u>.

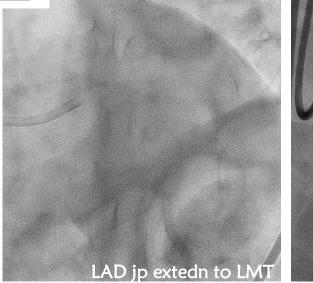
Microchannel or micro-hemorrhage?

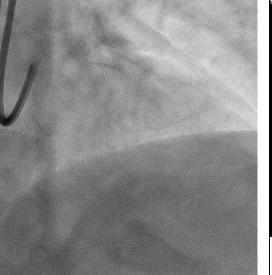


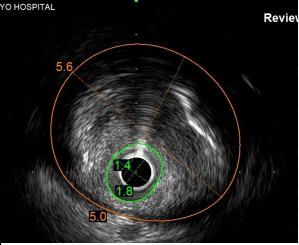
Multiple layer

Case 3

Pre







Plaque area 90.6 %

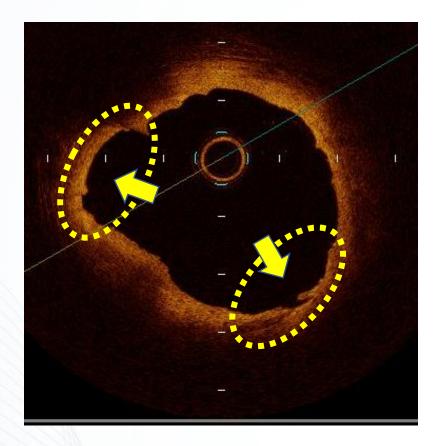
No DEEP CUTTING

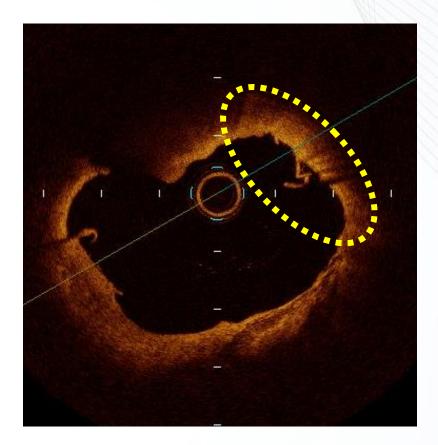


28th TCTAP

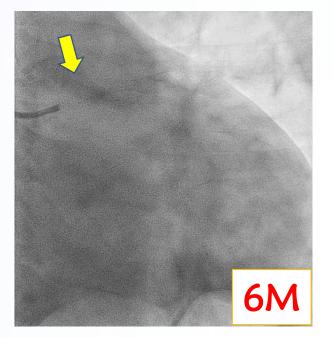
Case 3

Post PCI OCT (DCA + DCB)

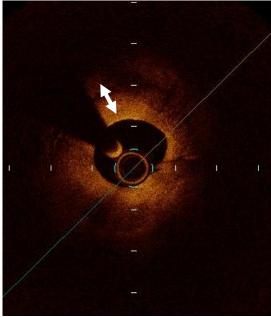




Surface Irregularity and <u>Distorted shape of lumen</u>, Surface of Vessel is uneven and <u>Stratum like appearance</u>.

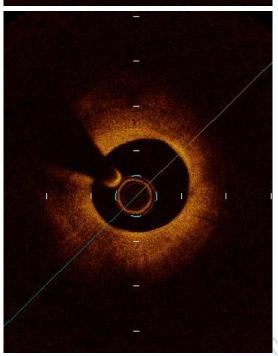






OCT at F/U : 6M

Excessive layer (thick neointima) formation may be another mechanism for TLR.



28th TCTAP

Consideration

- 1. Clinical presentation (e.g. UAP) and Co.Risk factors can be associated with plaque progression after DCA + DCB
- 2. Multiple healing events, which form multiple layer, may be one of the mechanisms for plaque progression after DCA + DCB.
- 3. Microstructures such as microchannel (and micro-plaque homorrhage between layers) can relate to plaque progression.
- 4. Inflammation (macrophages) and excessive healing (thick-neointima) may be also mechanisms for plaque progression after DCA + DCB.

We supposed Distorted shape of lumen, Uneven Surface ; Stratum like appearance Might cause Un-Even Endothelialization. Which means resulting "Multilayer Healing"