Advantage of OCT-guided PCI in complex coronary lesions: Diffuse, severe calcification, or LM bifurcation





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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

- Grant/Research Support
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- : Abbott Vascular Japan Daiichi-Sankyo Pharmaceutical Inc. Nipro Inc. Terumo Inc.





ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial

revascularization

Recommendations on intravascular imaging for procedural optimization

The Task Force on myocardial revascularization Society of Cardiology (ESC) and Euro **Cardio-Thoracic Surgery (EACTS)**

Developed with the special contributi Association for Percutaneous Cardiov

Authors/Task Force Members: Franz-Josef New (Germany), Miguel Sousa-Uva*¹ (EACTS Chai (Sweden), Fernando Alfonso (Spain), Adrian P. (UK), Robert A. Byrne (Germany), Jean-Philip

ety of Cardiology (ESC) and European Asso io-Thoracic Surgery (EACTS)	Recommendations	Class ^a	Level ^b	
loped with the special contribution of the I ciation for Percutaneous Cardiovascular In	IVUS or OCT should be considered in selected patients to optimize stent implantation. ^{603,612,651–653}	lla	В	
rs/Task Force Members: Franz-Josef Neumann* (ESC any), Miguel Sousa-Uva ^{*1} (EACTS Chairperson) (Po en), Fernando Alfonso (Spain), Adrian P. Banning (U Robert A. Byrne (Germany), Jean-Philippe Collet (Fr	IVUS should be considered to optimize treatment of unprotected left main lesions. ³⁵	lla	в	© ESC 2018
Restenosis			H	
DES are recommended for the treatment of in-stent restenosis of BN	1	А		
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES. ^{373,375,378,379}				
In patients with recurrent episodes of diffuse in-stent restenosis, CAI a new PCI attempt.	lla	с		
IVUS and/or OCT should be considered to detect stent-related med	lla	С		

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CLINICAL RESEARCH Interventional cardiology

Optical frequency domain imaging vs. intravascular ultrasound in percutaneous coronary intervention (OPINION trial): one-year angiographic and clinical results

Takashi Kubo¹, Toshiro Shinke², Takayuki Okamura³, Kiyoshi Hibi⁴, Gaku Nakazawa⁵, Yoshihiro Morino⁶, Junya Shite⁷, Tetsuya Fusazaki⁶, Hiromasa Otake², Ken Kozuma⁸, Tetsuya Ioji⁹, Hideaki Kaneda⁹, Takeshi Serikawa¹⁰, Toru Kataoka¹¹, Hisayuki Okada¹², and Takashi Akasaka¹*; on behalf of the OPINION Investigators[†]



ased, high-resolution intravascular imaging l imaging technique for guiding percutaneriority of OFDI-guided PCI compared with

trolled, non-inferiority study to compare generation drug-eluting stent. The primary
death, target-vessel related myocardial

infarction, and ischaemia-driven target vessel revascularization until 12 months after the PCI. The major secondary endpoint was angiographic binary restenosis at 8 months. We randomly allocated 829 patients to receive OFDI-guided PCI (n = 414) or IVUS-guided PCI (n = 415). Target vessel failure occurred in 21 (5.2%) of 401 patients undergoing OFDI-guided PCI, and 19 (4.9%) of 390 patients undergoing IVUS-guided PCI, demonstrating non-inferiority of OFDI-guided PCI to IVUS-guided PCI (hazard ratio 1.07, upper limit of one-sided 95% confidence interval 1.80; $P_{non-inferiority} = 0.042$). With 89.8% angiographic follow-up, the rate of binary restenosis was comparable between OFDI-guided PCI and IVUS-guided PCI (in-stent: 1.6% vs. 1.6%, P = 1.00; and in-segment: 6.2% vs. 6.0%, P = 1.00).

Conclusion The 12-month clinical outcome in patients undergoing OFDI-guided PCI was non-inferior to that of patients undergoing IVUS-guided PCI. Both OFDI-guided and IVUS-guided PCI yielded excellent angiographic and clinical results, with very low rates of 8-month angiographic binary restenosis and 12-month target vessel failure.





Optical coherence tomography compared with intravascular $\rightarrow M^{\dagger}$ ultrasound and with angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised Summary controlled trial

Background Percutaneous coronary intervention (PCI) is most commonly guided by angiography alone. Intravascular ultrasound (IVUS) guidance has been shown to reduce major adverse cardiovascular events (MACE) after PCI, principally by resulting in a larger postprocedure lumen than with angiographic guidance. Optical coherence tomography (OCT) provides higher resolution imaging than does IVUS, although findings from some studies suggest Ziad A Ali, Akiko Maehara, Philippe Généreux, Richard A Shlofmi that it might lead to smaller luminal diameters after stent implantation. We sought to establish whether or not a novel Fernando Alfonso, Habib Samady, Takashi Akasaka, Eric B Carlso OCT-based stent sizing strategy would result in a minimum stent area similar to or better than that achieved with IVUS guidance and better than that achieved with angiography guidance alone. Ori Ben-Yehuda, Gregg W Stone, for the ILUMIEN III: OPTIMIZE P

Methods In this randomised controlled trial, we recruited patients aged 18 years or older undergoing PCI from 29 hospitals in eight countries. Eligible patients had one or more target lesions located in a native coronary artery with a visually estimated reference vessel diameter of 2.25-3.50 mm and a length of less than 40 mm. We excluded patients with left main or ostial right coronary artery stenoses, bypass graft stenoses, chronic total occlusions, planned two-stent bifurcations, and in-stent restenosis. Participants were randomly assigned (1:1:1; with use of an interactive web-based system in block sizes of three, stratified by site) to OCT guidance, IVUS guidance, or angiography-guided stent implantation. We did OCT-guided PCI using a specific protocol to establish stent length, diameter, and expansion according to reference segment external elastic lamina measurements. All patients underwent final OCT imaging (operators in the IVUS and angiography groups were masked to the OCT images). The primary efficacy endpoint was post-PCI minimum stent area, measured by OCT at a masked independent core laboratory at completion of enrolment, in all randomly allocated participants who had primary outcome data. The primary safety endpoint was

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*Investigators listed in the appendix

New York Presbyterian Hospital and Columbia University, New York, NY, USA (Z A Ali MD, A Maehara MD, T M Nazif MD, O Ben-Yehuda MD. Prof G W Stone MD); Cardiovascular Research Foundation, New York, NY, USA (Z A Ali, A Maehara, P Généreux MD, T M Nazif, M Matsumura BS, M O Ozan MS, G S Mintz MD, O Ben-Yehuda, Prof G W Stone); St Francis Hospital, Roslyn, New York, NY,

Interpretation OCT-guided PCI using a specific reference segment external elastic lamina-based stent optimisation strategy was safe and resulted in similar minimum stent area to that of IVUS-guided PCI. These data warrant a largescale randomised trial to establish whether or not OCT guidance results in superior clinical outcomes to angiography guidance.

> (one-sided 97.5% lower CI -0.70 mm²; p=0.001), but not superior (p=0.42). OCT guidance was also not superior to Madrid, Spain (FAlfonso MD); angiography guidance (p=0.12). We noted procedural MACE in four (3%) of 158 patients in the OCT group, one (1%) of 146 in the IVUS group, and one (1%) of 146 in the angiography group (OCT vs IVUS p=0.37; OCT vs angiography p=0.37).

Emory University Hospital, Atlanta, GA, USA (Prof H Samady MD); Wa Medical University, W kavama Japan (Prof T Aka gy, Greenville, Eastern Cardio NC, USA (E Carlson MD) and Uni ersity of Alabama Birr ngham, AB, USA M A Leesar MD)

Wakayama Medical University

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Similarities & differences between OCT & IVUS

Maehara A, et al. J Am Coll Cardiol Img 2017;10:1487-1503

	OCT				IVUS				
Very good	Good	Feasible	Pre-PCI	Feasible	Good	Very good			
			Severity of calcium						
			Prediction of slow flow						
			Stent sizing by vessel wall						
			Stent length to cover normal to normal						
			Post-PCI						
			Stent expansion						
			Tissue protrusion through strut						
			Stent malapposition						
			Stent deformation (frequently at aorto-ostium)						
			Stent edge dissection						
			Residual disease at stent edge						
			F -11						
			Old stent expansion						
			Tissue coverage						
			Neointimal hyperplasia						
			Stent fracture						
			Stent malapposition						
			Positive remodeling of vessel wall						
			Neoatherosclerosis						
				Wake		na Me	dica l	Unive	21



Comparison between OCT & IVUS in bifurcation treatment

Onuma Y, et al. EuroInterv 2018, doi: 10.4244/EIJ-D-18-00391

Pre- procedure	IVUS	ОСТ
Co-registration with angiogram	++	++
Sizing of vessel	++	+
Sizing of lumen	++	++
Assessment of plaque distribution	++	+
Plaque characterization	++	+
Assessment of side branch ostium in the pullback of main branch	א ו	++
Determination of landing zone & stent length	++	++
During Stent implantation		
Guidance of position of the guidewire toward side branch	X	++
Post-procedure		
Evaluation of stent dimensions according to flow conservation lav	W ++	++
Stent underexpansion	++	++
Edge dissection	+	++
ISA	+	++
During Stent implantation		
LMT lesion	++	+





European Heart Journal - Cardiovascular Imaging Advance Access published September 15, 2015



European Heart Journal – Cardiovascular Imaging doi:10.1093/ehjci/jev229

Multi-laboratory inter-institute reproducibility study of IVOCT and IVUS assessments using published consensus document definitions

Edouard Gerbaud¹, Giora Weisz^{2,3}, Atsushi Tanaka¹, Manabu Kashiwagi¹,

Conclusion In the measurement of lumen CSA, maximum and minimum lumen diameters, stent CSA, and maximum and minimum stent diameters by analysts from two different laboratories, reproducibility of IVOCT was more consistent than that of IVUS.

Akiko Maehara ²		Inter-institute measurement differences magnitude for IVUS	Inter-institute measurement differences magnitude for OFDI	P-value
	Lumen CSA (mm ²)	0.33 (0.12-0.67)	0.10 (0.05-0.22)	< 0.001
	Lumen max. diameter (mm)	0.16 (0.06-0.30)	0.06 (0.03-0.10)	< 0.001
	Lumen min. diameter (mm)	0.12 (0.06-0.27)	0.04 (0.02-0.08)	< 0.001
	Stent CSA (mm ²)	0.26 (0.20-0.50)	0.17 (0.10-0.30)	0.02
	Stent max. diameter (mm)	0.16 (0.09-0.20)	0.05 (0.03-0.09)	< 0.001
	Stent min. diameter (mm)	0.10 (0.03-0.14)	0.04 (0.01-0.08)	0.01
	EEM CSA (mm ²) ^a	0.86 (0.39-1.28)	0.18 (0.05-0.36)	0.007
	Atheroma CSA (mm ²) ^a	0.68 (0.53-1.05)	0.17 (0.06-0.34)	0.02
	Plaque burden (%) ^a	5.6 (2.2-7.3)	1.9 (0.4-2.1)	0.002
	Max. atheroma thickness (mm) ^a	0.14 (0.07-0.20)	0.06 (0.03-0.14)	0.03
	Min. atheroma thickness (mm) ^a	0.07 (0.03-0.10)	0.03 (0.01-0.05)	0.01
M	Atheroma eccentricity index ^a	0.07 (0.04-0.15)	0.06 (0.04-0.11)	0.42



Positioning of OCT Catheter





Advantages of Newly developed FD-OCT system (ILUMIEN OPTIS[™])





FD-OCT and IVUS criteria of optimal stent deployment

	FD-OCT-guided PCI	IVUS-guided PCI			
Reference site	Most normal lookingNo lipidic plaque	 Largest lumen Plaque burden < 50% 			
Determination of stent diameter	 By measuring lumen diameter at proximal and distal reference sites 	 By measuring vessel diameter at proximal and distal reference sites 			
Determination of stent length	 By measuring distance from 	By measuring distance from distal to proximal reference site			
Goal of stent deployment	 In-stent minimal lumen area reference lumen area Complete apposition of the s the vessel wall Symmetric stent expansion diameter / maximum lumen No plaque protrusion, throm potential to provoke flow disc 	 In-stent minimal lumen area ≥ 90% of the average reference lumen area Complete apposition of the stent over its entire length against the vessel wall Symmetric stent expansion defined by minimum lumen diameter / maximum lumen diameter ≥ 0.7 No plaque protrusion, thrombus, or edge dissection with potential to provoke flow disturbances 			
Kubo T, et al. J Cardiol 2016;68:455-460					



Pre-PCI assessment, #6 90%, (DES 4.0×15mm)



Precursor lesion of stent edge restenosis

In 744 stent (EES) edge segments, OCT was used to evaluate morphological characteristics of the coronary plaques that developed stent edge restenosis.





Both stent edges (n = 744)

(A) Immediately after EES implantation, OCT images showed lipid rich plaque at the proximal stent edge (a, b).(B) At 10-month follow-up, angiography demonstrated stent edge restenosis at the proximal edge of the stent.

Conclusion: Lipidic plaque in the stent edge segments at post- PCI was a predictor of late stent edge restenosis.



Ino Y, et al. Cric CV Interv 2016;9:e004231 DOI:10.1161/CIRCINTERVENTIONS.116.004231.

Post-PCI assessment, #6 90%, (DES 4.0 × 15mm)



MLA ≥ 90% of the average reference lumen area



Stent sizing



FASTTRACK CLINICAL RESEARCH Coronary artery disease

Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions

Endorsed by the Chinese Society of Cardiology

Lorenz Räber¹, Gary S. Mintz², Konstantinos C. Koskinas¹, Thomas W. Johnson³, Niels R. Holm⁴, Yoshinubo Onuma⁵, Maria D. Radu⁶, Michael Joner^{7,8}, Bo Yu⁹, Haibo Jia⁹, Nicolas Meneveau^{10,11}, Jose M. de la Torre Hernandez¹², Javier Escaned¹³, Jonathan Hill¹⁴, Francesco Prati¹⁵, Antonio Colombo¹⁶, Carlo di Mario¹⁷, Evelyn Regar¹⁸, Davide Capodanno¹⁹, William Wijns²⁰, Robert A. Byrne²¹, and Giulio Guagliumi²²*

Coordinating editor: Prof Patrick W. Serruys, MD, PhD, Imperial College, London, UK Document Reviewers: Fernando Alfonso²³, Ravinay Bhindi²⁴, Ziad Ali²⁵, Rickey Carter²⁶

- The beneficial effect of imaging-guided PCI does not appear to be strictly linked to the algorithm used for stent sizing by IVUS or OCT.
- From a practical standpoint, a distal lumen reference based sizing may represent a safe and straightforward approach with subsequent optimization of the mid and proximal stent segments. Specifically, the mean distal lumen diameter with up rounding stent (0–0.25 mm) may be used (e.g. $3.76 \rightarrow 4.0$ mm), or the mean EEM (2 orthogonal measurements) with down rounding to the nearest 0.25 mm stent size (e.g. $3.76 \rightarrow 3.5$ mm).
- When using OCT, an EEM reference based sizing strategy appears feasible, although more challenging than a lumen based approach for routine clinical practice.
- Appropriate selection of the landing zone is crucial as residual plaque burden (<50%) and particularly lipid rich tissue at the stent edge is associated with subsequent restenosis.
- Co-registration of angiography and IVUS or OCT is a useful tool to determine stent length and allows for precise stent placement.

Raber L, et al. Eur Heart J 2018 May 22. doi: 10.1093/eurheartj/ehy285





Post PCI optimization



Raber L, et al. Eur Heart J 2018 May 22. doi: 10.1093/eurheartj/ehy285



Optimal vs Suboptimal IVUS-guided PCI (ULTIMATE trial)

PCI results

TVF at 12 months





Zhang J, et al. J Am Coll Cardiol 2018;DOI:10.1016/j.jacc2018.09.013

Coronary angio. (Pre PCI)



















Volumetric Stent Expansion Assessment

Nakamura D, et al. J Am Coll Cardiol Intv 2018;11:1467-1478



Major side-branch

Representative Case with One Bifurcation



Normalized Expansion Index Value=actual lumen area/ideal lumen area X 100 MEI=cross section with lowest expansion index along the entire stented segment Nakamura D, et al. J Am Coll Cardiol Intv 2018;11:1467-1478



Correlation of %AS with Final FFR Value for Conventional Method and New Volumetric Method

Nakamura D, et al. J Am Coll Cardiol Intv 2018;11:1467-1478









Definition of incomplete stent appostion (ISA)







ROC curve analysis identified a maximum ISA distance of EES > 355μ m with as separating persistent from resolved ISA (sensitivity 100%, specificity 75%, area under the curve = 0.905; 95%CI, 0.812 to 0.999).

ROC curve analysis identified a maximum ISA distance of SES > 285μ m with as separating persistent from resolved ISA (sensitivity 93%, specificity 80%, area under the curve = 0.947; 95%CI, 0.878 to 1.015).



Shimamura K. et al, Eur Heart J CV Imaging 2015;16:23-28

New Development in OCT



3-D reconstruction and color coded auto-detection of stent incomplete apposition can be demonstrated as fly through image by new OCT.

Step by step calcium ablation by OCT-guide

Non-stent strategy was selected because of subsequent colon cancer operation. Wakayama Medical University

Making calcium fractures after rotablator by OCT-guide

Broken calcium plate

Broken calcium plate

Stent malappsoition

Prediction of calcium plate fracture by ballooning

OFDI was performed to assess vascular response immediately after high pressure ballooning in 61 patients with severe calcified coronary lesion.

Conclusion: A calcium plate thickness < 505 µm was the corresponding cut-off value for predicting calcium plate fracture by high pressure ballooning.

Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Stent expansion at post-PCI

0 0 Calcium fracture (+) Calcium fracture (-) Calcium fracture (+) Calcium fracture (-) (n = 29)(n = 32)(n = 29)(n = 32)Minimum stent area and stent expansion index were significantly greater in the group with calcium fracture compared with the group without calcium fracture.

 (mm^2)

 5.02 ± 1.43

6

4

2

Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Restenosis and TLR at 10 months follow-up

The frequency of binary restenosis and target lesion revascularization was significantly lower in the group with calcium fracture compared with the group without calcium fracture.

Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

3D-OCT demonstration Link connecting to carina type GW recross distal cell

suboptimal

GW recross proximal cell

We cannot control the rink position on the side branch orifice, and it should be by chance. Wakayama Medical University

Impact of the rewiring position Strut malapposition & shear stress

Comparison of % reduction of the side branch flow area

Wakayama Medical University

Onuma Y, et al. EuroInterv 2018, doi: 10.4244/EIJ-D-18-00391 Comparison among each jailed type

Frequency of jailing configuration & GW rewiring position Okamura T, et al. EuroIntervention 2018;13: e1785 – e1793

Incidence of ISA at each segment

Okamura T, et al. EuroIntervention 2018;13:e1785-e1793

Angiographic ISR at 9 Month

Okamura T, et al. EuroIntervention 2018;13:e1785-e1793

	All	Optimal	Suboptimal	P value
n	87	48	39	
ISR	12(13.8%)	4(8.3%)	8(20.5%)	0.1254
PMV	0(0%)	0(0%)	0(0%)	-
DMV	1(1.1%)	1(2.1%)	0(0%)	1.0000
Side Br Orifice	12(13.8%)	4(8.3%)	8(20.5%)	0.1254

Japanese registry for 3-D OCT guided bifurcation stenting

Study population

600 bifurcation lesions

Side branch opening guided by 3-D OCT:400 Optimal Suboptimal

No side branch opening:200

Primary endpoint

Incidence of side branch restenosis at 1 year.

Secondary endpoint

MACE at 3 years

Optimal rewiring point in side branch ostium accoroding to different configurations of overhanging struts

2018 ESC/EACTS Guidelines on myocardial revascularization

European Heart Journal (2018) 00, 1-96

The Task Force on myocardial revascularization of the European Society of Cardiology (ESC Cardio-Thoracic Surgery (dural optimization

Developed with the special Association for Percutanec

European Society doi:10.1093/eurhearti/ehv394

of Cardiology

Authors/Task Force Members: Fr (Germany), Miguel Sousa-Uva*¹ (Sweden), Fernando Alfonso (Spa (UK), Robert A. Byrne (Germany (Germany), Stuart J. Head¹ (The Adnan Kastrati (Germany), Akos Josef Niebauer (Austria Dirk Sibbing (Germany (Switzerland), Rashmi Yadav¹ (Ul Document Reviewers: William Wijns (ESC Co-ordinator) (Canada), Victor Aboyans ((Norway), Felicita Andreotti (Italy), Eman

(Canada), Héctor Bueno (Spain), Patrick A

Recommendations	Class ^a	Level ^b
IVUS or OCT should be considered in selected patients to optimize stent implantation. ^{603,612,651–653}	lla	B
OCT should be considered to optimize treatment of unprotected left main lesions. ³⁵	lla	В

Take home message

- Pre- & post-PCI lesion morphology can be assessed easily and precisely by OCT because of higher resolution with high frame rate, auto-pullback & auto-measurement systems, and 3D reconstruction, etc.
- Improvement of clinical outcomes in bifurcation lesion PCI can be expected by the guidance of 3D-OCT, although there are not enough data to support the reduction of the adverse clinical events using OCT guided PCI for bifurcation lesions at the moment.
- Randomized prospective studies with greater number of study population should be planned to demonstrate the improvement of clinical outcome by OCT-guided PCI for specific lesions such as diffuse lesion, severe calcified lesion, and LM bifurcation lesions in the near future.

Change Practice!! JCS2020

The 84th Annual Scientific Meeting of the Japanese Circulation Society

March 13(Fri)-15(Sun),2020

Kyoto International Conference Center
 Grand Prince Hotel Kyoto
 Congress Chairperson

Takeshi Kimura, M.D., Ph.D. Professor, Department of Cardiovascular Medicine, Kyoto University Graduate School of Medicine, Kyoto Read School of Medicine, Store

Evolution & Collaboration APSC2020 Asian Pacific Society of Cardiology Congress 2020 March 12(Thu)-14(Sat),2020 Venue

 Kyoto International Conference Center
 Grand Prince Hotel Kyoto Congress Chairperson
 Takashi Akasaka, M.D., Ph.D.
 Professor, Department of Cardiovascular Medicine, Wakayama Medical University, Wakayama

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Thank you for your kind attention !!

Welcome to APSC 2020 in Kyoto, Japan!!

COCOA

Comparison between Optical Coherence tomography guidance and Angiography Guidance in percutaneous coronary intervention

ILUMIEN IV: OPITIMAL PCI

Optical Coherence Tomography guided Coronary Stent Implantation Compared to Angiography: a Multicenter Randamized Trial in PCI

Comparison of HD-IVUS system with OCT

Feature	ACIST HDi / Kodama	BostonVolcanoScientificFACT		Nipro InfraReDx	Abbott Vascular OCT	
Frequency or Wavelength	60 MHz	55 MHz NA		50 MHz	1.3 µm	
Nature of the Energy		Ultrasoun	Optical			
Axial Resolution	ial Resolution $40 \mu m$ $22 \mu m$ $<50 \mu m$		20 µm	15 µm		
Lateral Resolution	90 µm	50-140 μm 100-200 μm		<200 µm	40 µm	
Soft Tissue Penetration	> 2.5 mm	>3.5 mm			0.8-1.2 mm*	
Blood Penetration	> 3.4 mm	>4.0 mm	≤ 1.2 mm			
Pullback Speed (mm/s)	0.5, 1.0, 2.5, 5.0, 10	0.5,1.0 0.5			20	
Pullback Length (mm)	130	100 150		150	75	

***** Soft Tissue Penetration with contrast injection to achieve blood clearing.

FD-OCT and HD-IVUS (Pre PCI)

HD-IVUS with negative contrast

HD-IVUS images with & without negative contrast (Pre PCI)

Negative contrast (+)

Negative contrast (-)

FD-OCT and HD-IVUS (Post PCI)

ontrast (100%)

HD-IVUS with negative contrast

HD-IVUS images with & without negative contrast (Post PCI)

