Imaging for Complex PCI

Optimize Your Stent:
A to Z of Imaging Guidance for PCI

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Wakayama Medical University

Disclosure Statement of Financial Interest

Takashi Akasaka, MD, PhD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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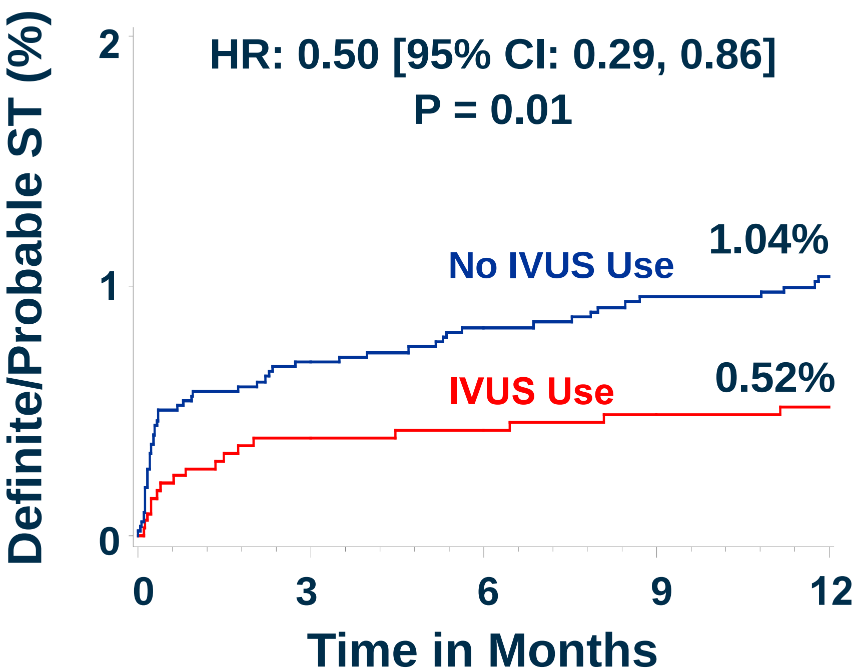
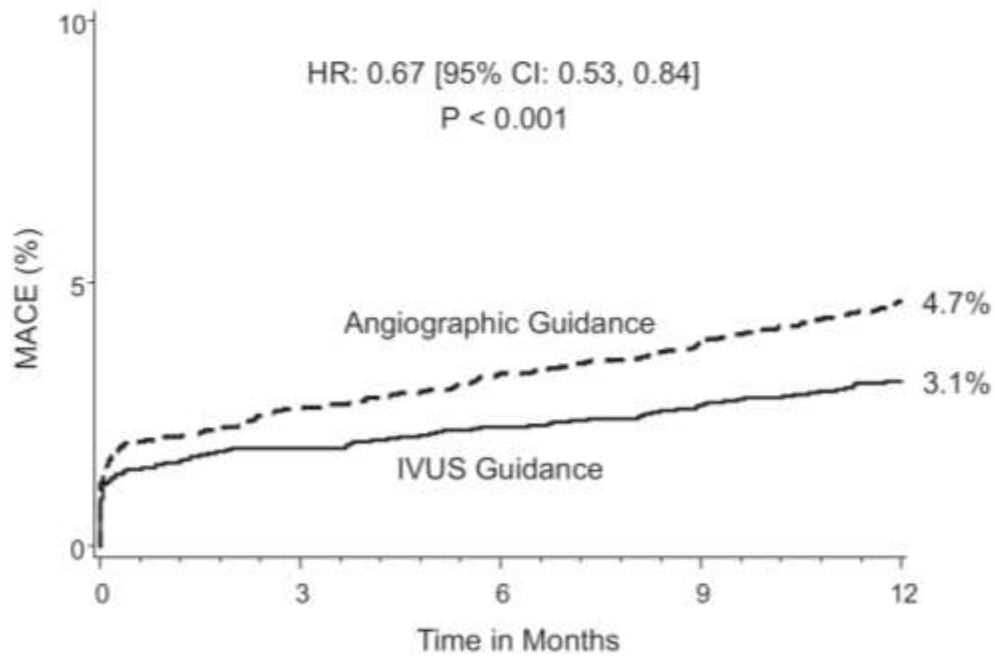
  Daiichi-Sankyo Pharmaceutical Inc.
  Nipro Inc.
  Terumo Inc.

IVUS- vs. angio-guided PCI with DES

In the assessment of dual antiplatelet therapy with drug-eluting stent (ADAPT-DES) substudy, IVUS guidance compared with angiography in 8,583 'all-comers' pts at 11 international centers.

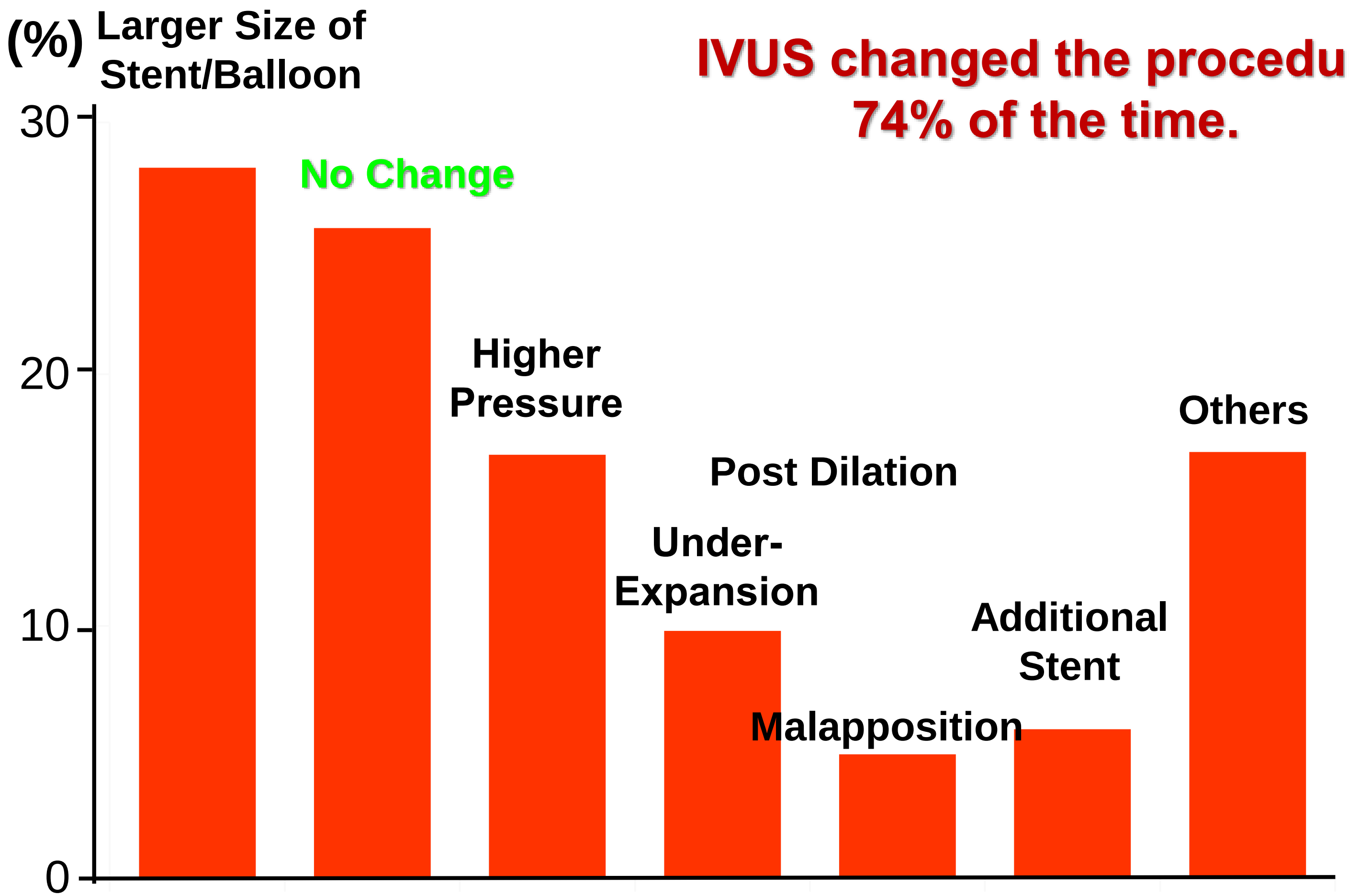




Conclusion: Compared with angiography, IVUS guidance reduces ST in addition to MI and MACE within 1 year after DES implantation.

Witzenbichler B et al. Circulation 2014;129:463-470.

How IVUS changed the procedure in ADAPT-DES substudy



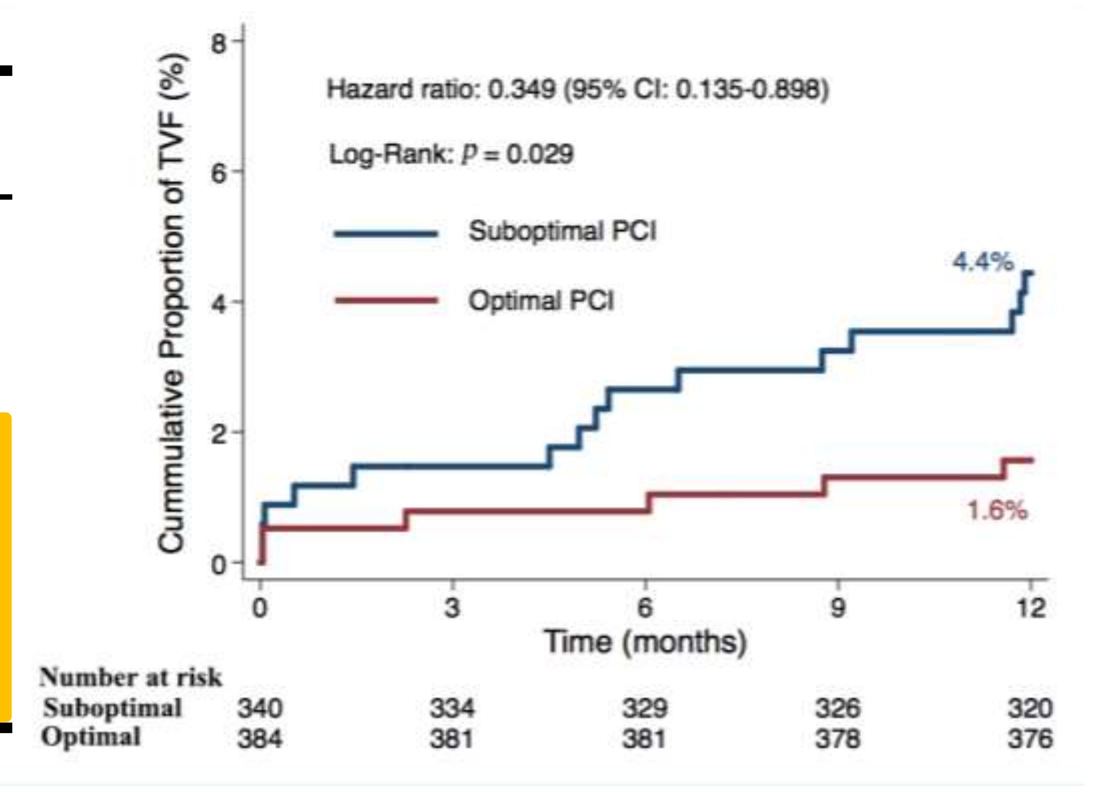
Witzenbichler B et al. Circulation 2014;129:463-470.

Optimal vs Suboptimal IVUS-guided PCI (ULTIMATE trial)

PCI results

	Optimal group	Suboptimal group	*P*
No. of patients n (%)	384 (53.0)	340 (47.0)	
No. of lesions n (%)	578 (60.1)	384 (39.9)	
MSA, mm^2	6.09	5.45	<0.001
Prox. edge plaque burden	37.2%	51.2%	<0.001
Dist. edge plaque burden	24.2%	35.1%	<0.001

TVF at 12 months



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

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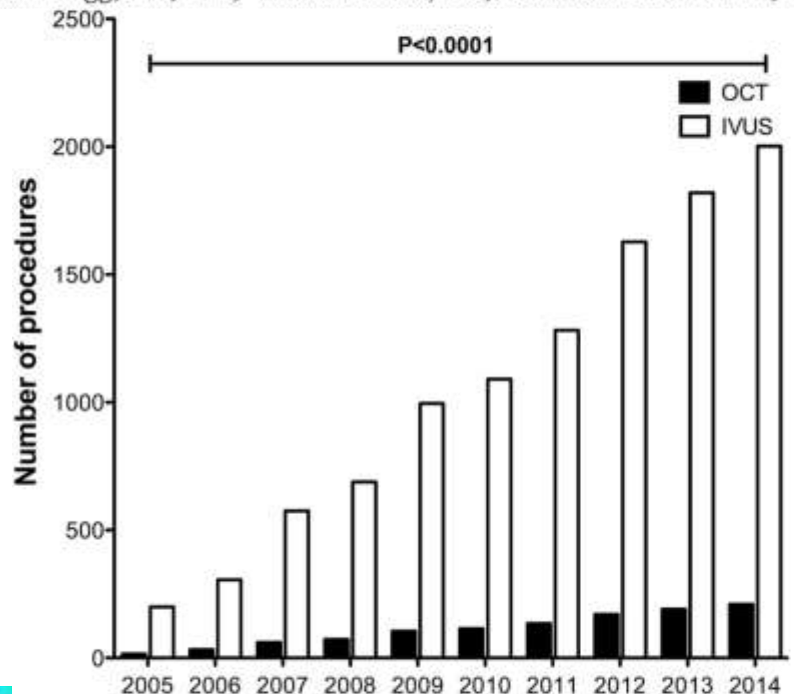
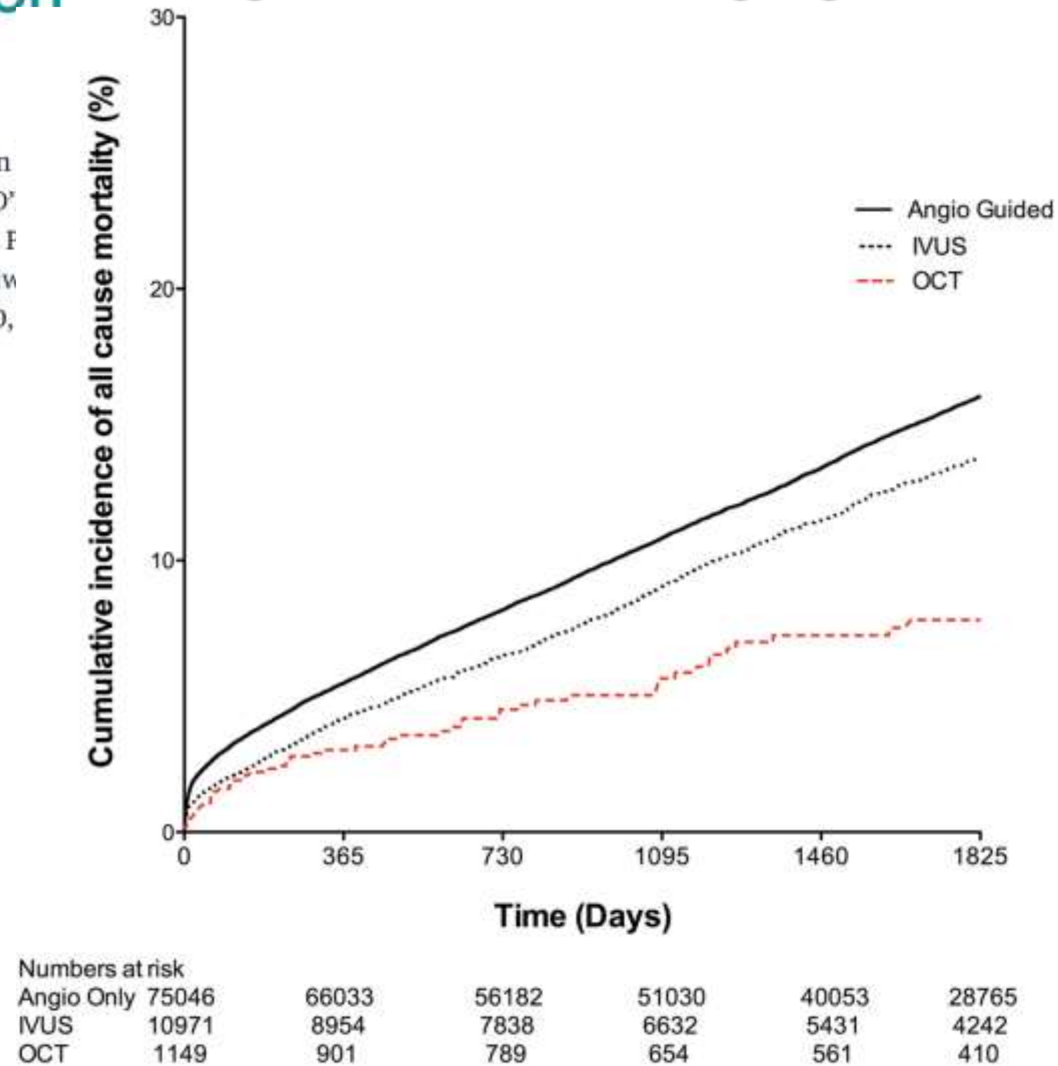
Angiography Alone Versus Angiography Plus Optical Coherence Tomography to Guide Percutaneous Coronary Intervention

Outcomes From the Pan-London PCI Cohort

Daniel A. Jones, MD, PhD,[a] Krishnaraj S. Rathod, MD,[a] Sudheer Koganti, MD,[a] Stephen
Zoe Astroulakis, MD, PhD,[c] Pitt Lim, MD,[c] Alexander Sirker, MD, PhD,[a] Constantinos O'
Ajay K. Jain, MD,[a] Charles J. Knight, MD,[a] Miles C. Dalby, MD,[d] Iqbal S. Malik, MBBS, F
Anthony Mathur, MD, PhD,[a] Roby Rakhit, MD,[e] Tim Lockie, MBChB, PhD,[e] Simon Redw
Philip A. MacCarthy, MBChB, PhD,[g] Ranil Desilva, MD, PhD,[d] Roshan Weerackody, MD,
Andrew Wragg, MD, PhD,[a] Elliot J. Smith, MD,[a] Christos V. Bourantas, MD, PhD[a]



Kaplan-Meier Curve Comparing All-Cause Mortality Among OCT-, IVUS- and Angio-guided PCI



Jones DA, et al., J Am Coll Cardiol Intv 201811:1313-1321

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European Heart Journal (2017) **0**, 1–9
doi:10.1093/eurheartj/ehx351

CLINICAL RESEARCH
Interventional cardiology

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

Takashi Kubo[1], Toshiro Shinke[2], Takayuki Okamura[3], Kiyoshi Hibi[4], Gaku Nakazawa[5], Yoshihiro Morino[6], Junya Shite[7], Tetsuya Fusazaki[6], Hiromasa Otake[2], Ken Kozuma[8], Tetsuya Ioji[9], Hideaki Kaneda[9], Takeshi Serikawa[10], Toru Kataoka[11], Hisayuki Okada[12], and Takashi Akasaka[1]*; on behalf of the OPINION Investigators†

ased, high-resolution intravascular imaging
l imaging technique for guiding percutane-
riority 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; $P_{\text{non-inferiority}} = 0.042$). 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.

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Optical coherence tomography compared with intravascular ultrasound and with angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised controlled trial

Ziad A Ali, Akiko Maehara, Philippe Généreux, Richard A Shlofmi
Fernando Alfonso, Habib Samady, Takashi Akasaka, Eric B Carlso
Ori Ben-Yehuda, Gregg W Stone, for the ILUMIEN III: OPTIMIZE P

Summary

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 that it might lead to smaller luminal diameters after stent implantation. We sought to establish whether or not a novel 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.

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 procedural MACE. We tested non-inferiority of OCT guidance to IVUS guidance (with a non-inferiority margin of 1·0 mm^2), superiority of OCT guidance to angiography guidance, and superiority of OCT guidance to IVUS guidance, in a hierarchical manner. This trial is registered with ClinicalTrials.gov, number NCT02471586.

Findings Between May 13, 2015, and April 5, 2016, we randomly allocated 450 patients (158 [35%] to OCT, 146 [32%] to IVUS, and 146 [32%] to angiography), with 415 final OCT acquisitions analysed for the primary endpoint (140 [34%] in the OCT group, 135 [33%] in the IVUS group, and 140 [34%] in the angiography group). The final median minimum stent area was 5·79 mm^2 (IQR 4·54–7·34) with OCT guidance, 5·89 mm^2 (4·67–7·80) with IVUS guidance, and

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 large-scale randomised trial to establish whether or not OCT guidance results in superior clinical outcomes to angiography guidance.

scale randomised trial to establish whether or not OCT guidance results in superior clinical outcomes to angiography guidance.

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See Online/Comment
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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, USA (R A Shlofmitz MD); Centro Cardiologico Monzino Istituto di Ricovero e Cura a Carattere Scientifico, Milan, Italy (F Fabbiocchi MD); Ospedale Papa Giovanni XXIII, Bergamo, Italy (G Guagliumi MD); Northwell Health, Manhasset, New York, NY, USA (P M Meraj MD); Hospital
(Prof M A Leesar MD)

ESC European Society of Cardiology
European Heart Journal (2018) **00**, 1–96
doi:10.1093/eurheartj/ehy394

2018 ESC/EACTS Guidelines on myocardial revascularization

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

Developed with the special contribution of the I Association for Percutaneous Cardiovascular In

Authors/Task Force Members: Franz-Josef Neumann* (ESC (Germany), Miguel Sousa-Uva*[1] (EACTS Chairperson) (Po (Sweden), Fernando Alfonso (Spain), Adrian P. Banning (UI (UK), Robert A. Byrne (Germany), Jean-Philippe Collet (Fr (Gerr Adna Josef Dirk (Swit

Docum Co-or (Norw (Canad

Recommendations on intravascular imaging for procedural optimization

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

Restenosis		
DES are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	IIa	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	IIa	C

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Stent sizing

ESC European Society of Cardiology

European Heart Journal (2018) 00, 1–20
doi:10.1093/eurheartj/ehy285

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 Räber[1], Gary S. Mintz[2], Konstantinos C. Koskinas[1], Thomas W. Johnson[3], Niels R. Holm[4], Yoshinubo Onuma[5], Maria D. Radu[6], Michael Joner[7,8], Bo Yu[9], Haibo Jia[9], Nicolas Meneveau[10,11], Jose M. de la Torre Hernandez[12], Javier Escaned[13], Jonathan Hill[14], Francesco Prati[15], Antonio Colombo[16], Carlo di Mario[17], Evelyn Regar[18], Davide Capodanno[19], William Wijns[20], Robert A. Byrne[21], and Giulio Guagliumi[22]*

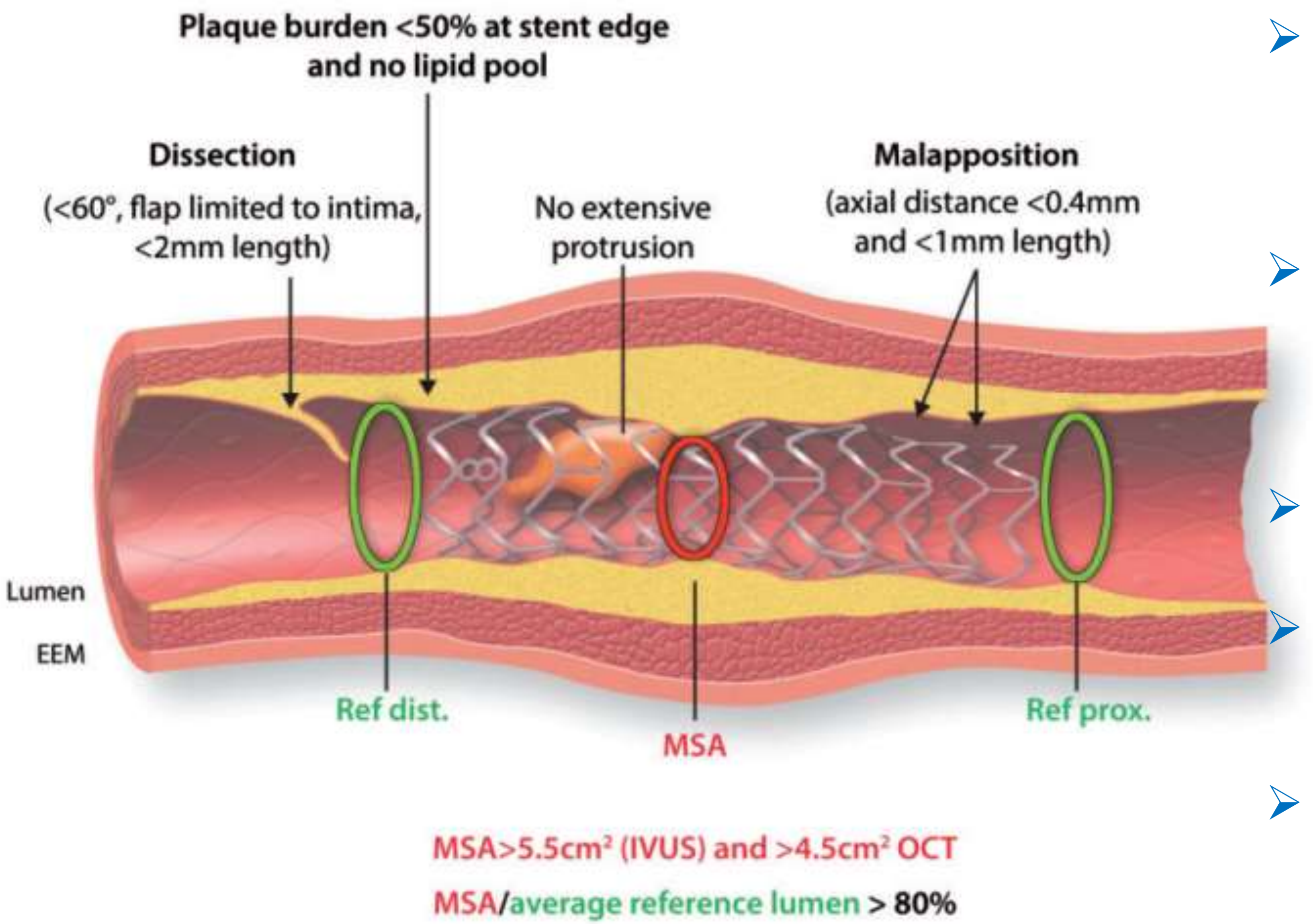
Coordinating editor: Prof Patrick W. Serruys, MD, PhD, Imperial College, London, UK

Document Reviewers: Fernando Alfonso[23], Ravinay Bhindi[24], Ziad Ali[25], Rickey Carter[26]

- 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 → 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 → 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.

Räber L, et al. Eur Heart J 2018:39;3281-3300

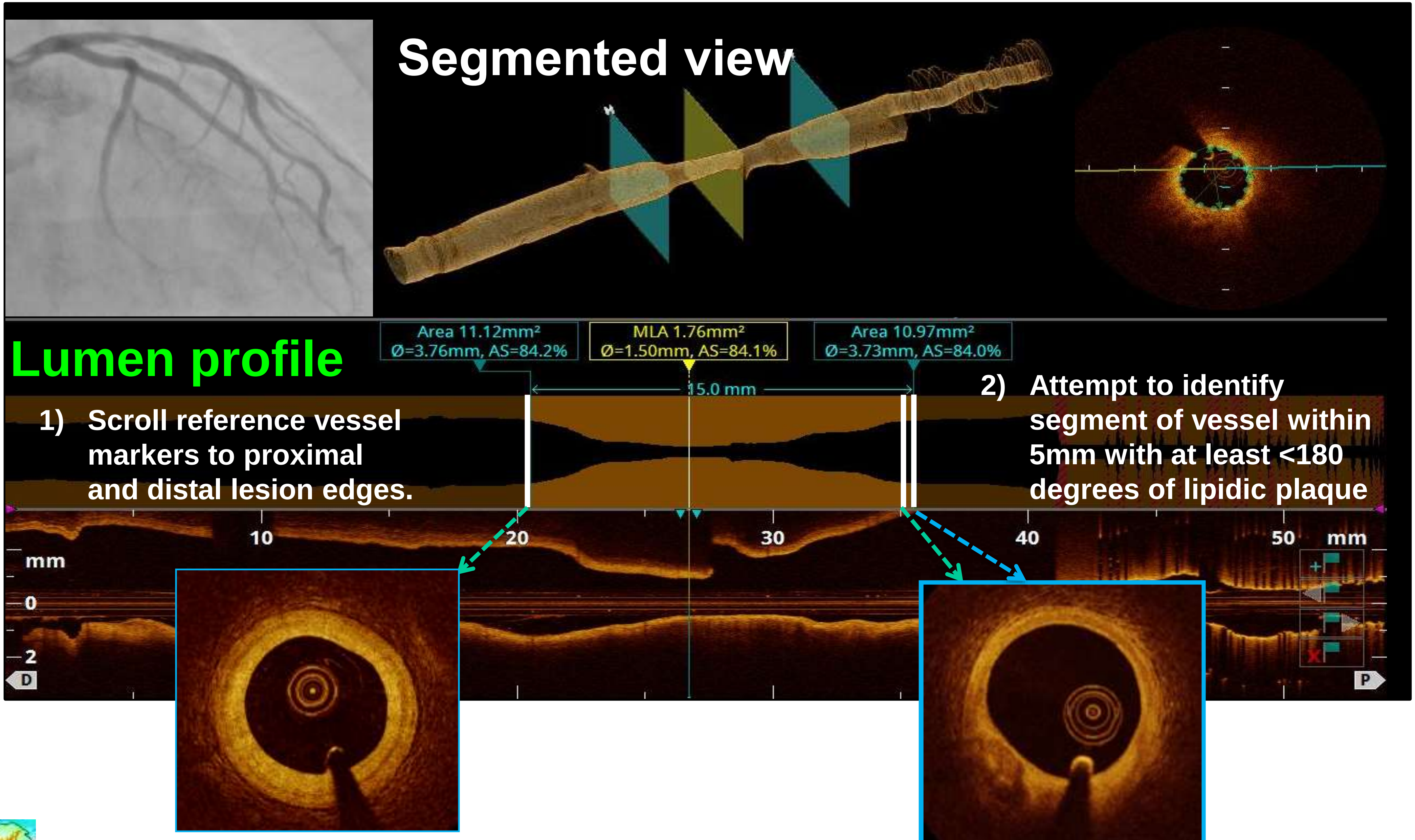
Post PCI optimization



- **MSA**
  >4.5 mm2, or
  > 80% of RA.
- **Mal-apposition**
  distance < 400μm
  length <1mm
- **No extensive protrusion.**
- **Distal landing: PB < 50%**
  No lipid pool
- **Distal edge dissection:**
  angle: <60°
  flap: limited to intima
  length: < 2 mm

Räber L, et al. Eur Heart J 2018:39;3281-3300

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



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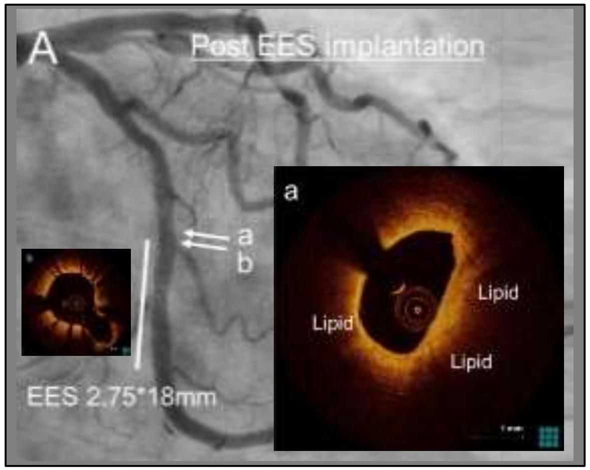
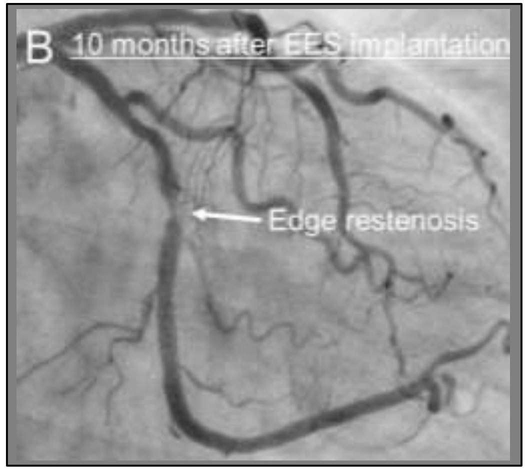
Precursor lesion of stent edge restenosis

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

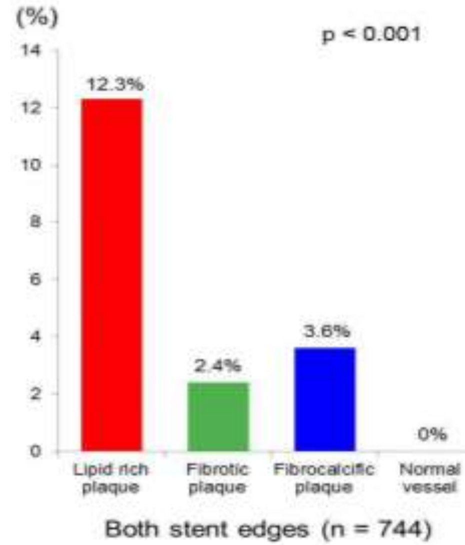
Post-stenting



10 months follow-up



Stent edge restenosis



(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.

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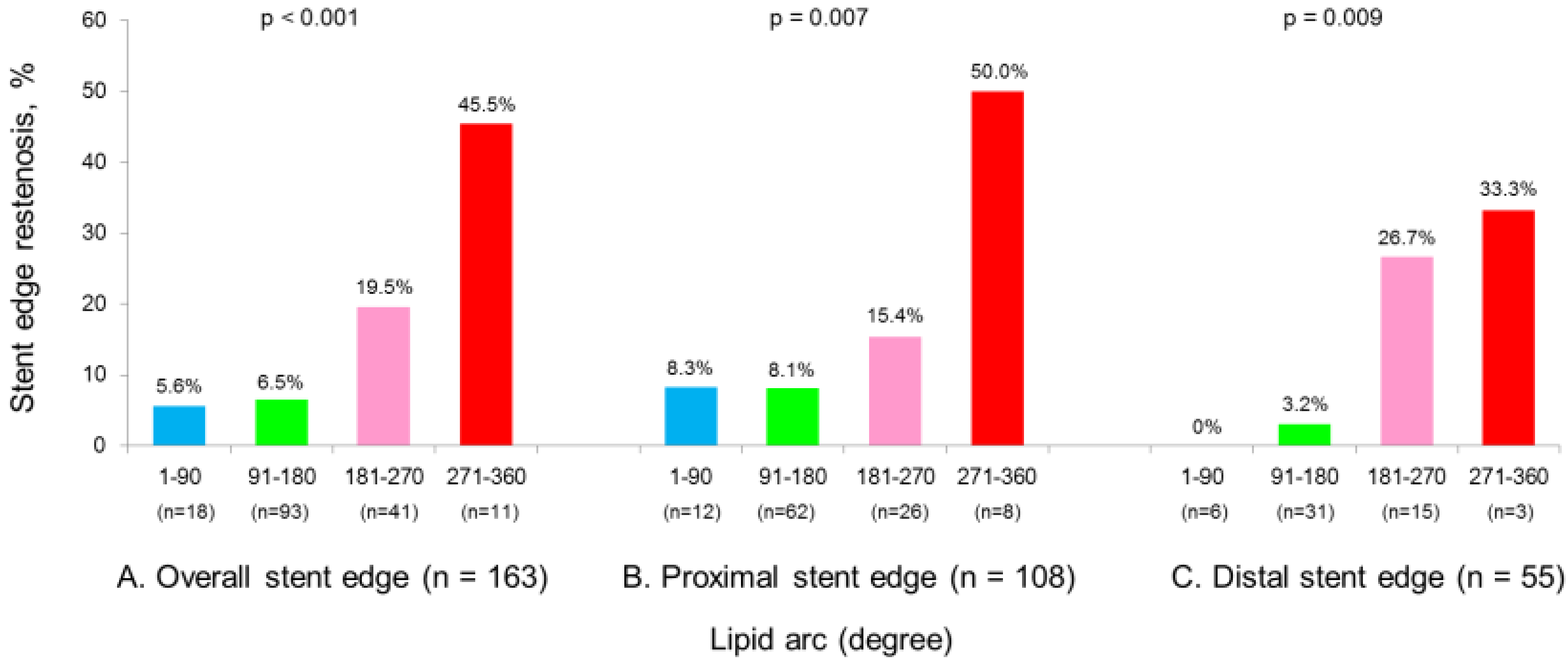
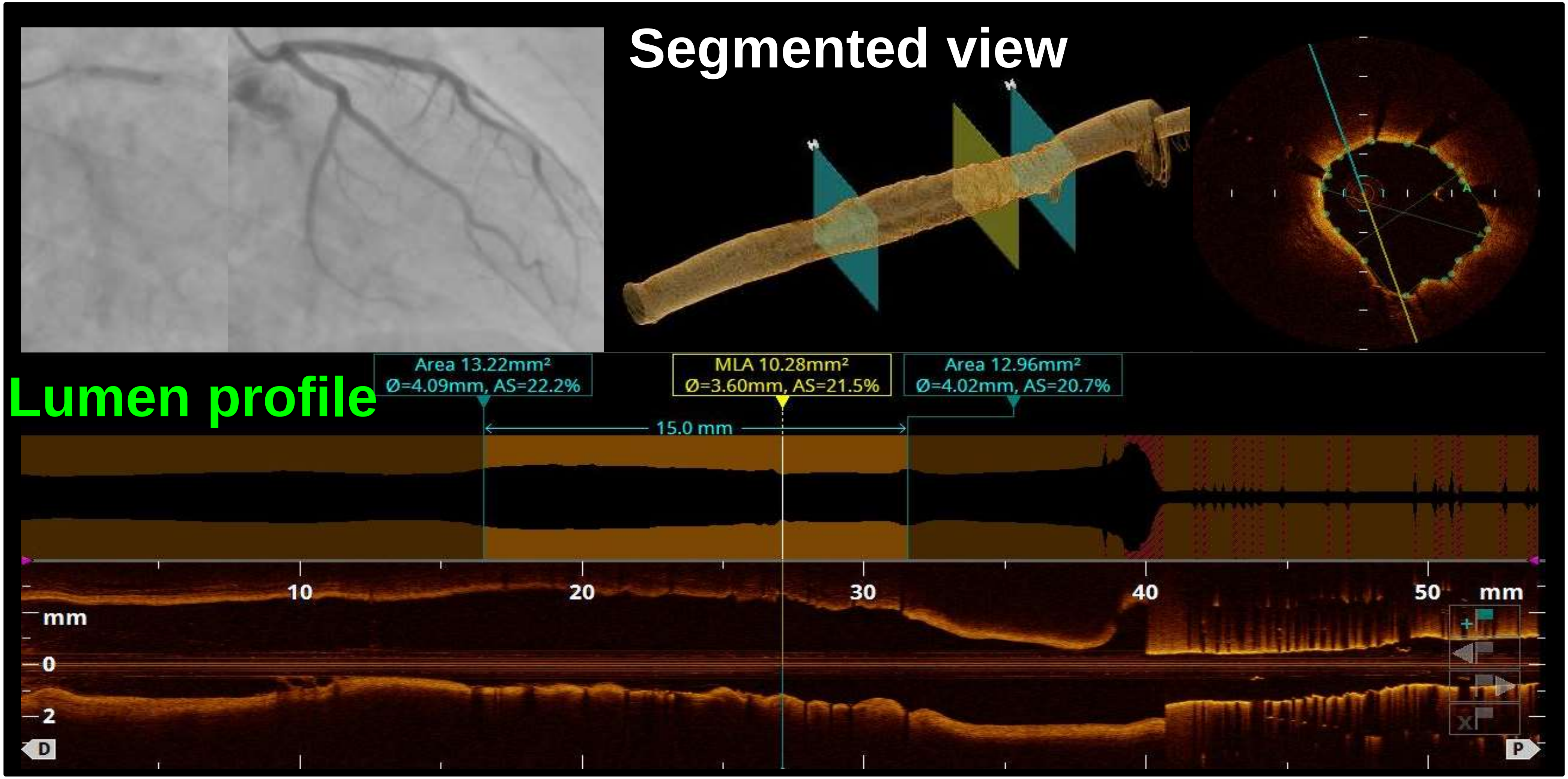
Relation between lipid arc in stent edge at the time of PCI & frequency of SER at 9-12 months follow-up



Within lepidic plaques, stent edge restenosis could be identified more frequently in cases with grater lipid arc at the stent edge.

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

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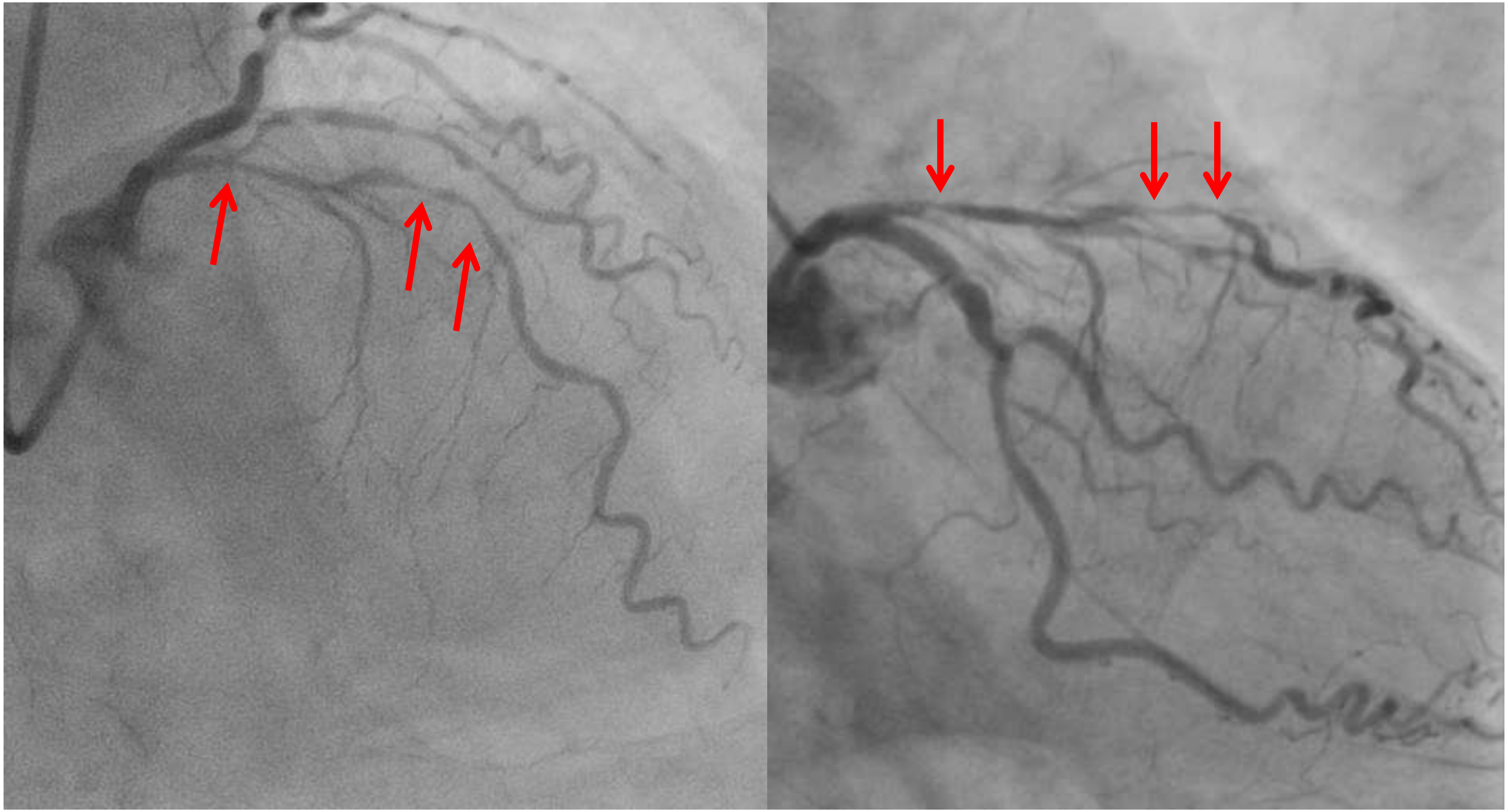
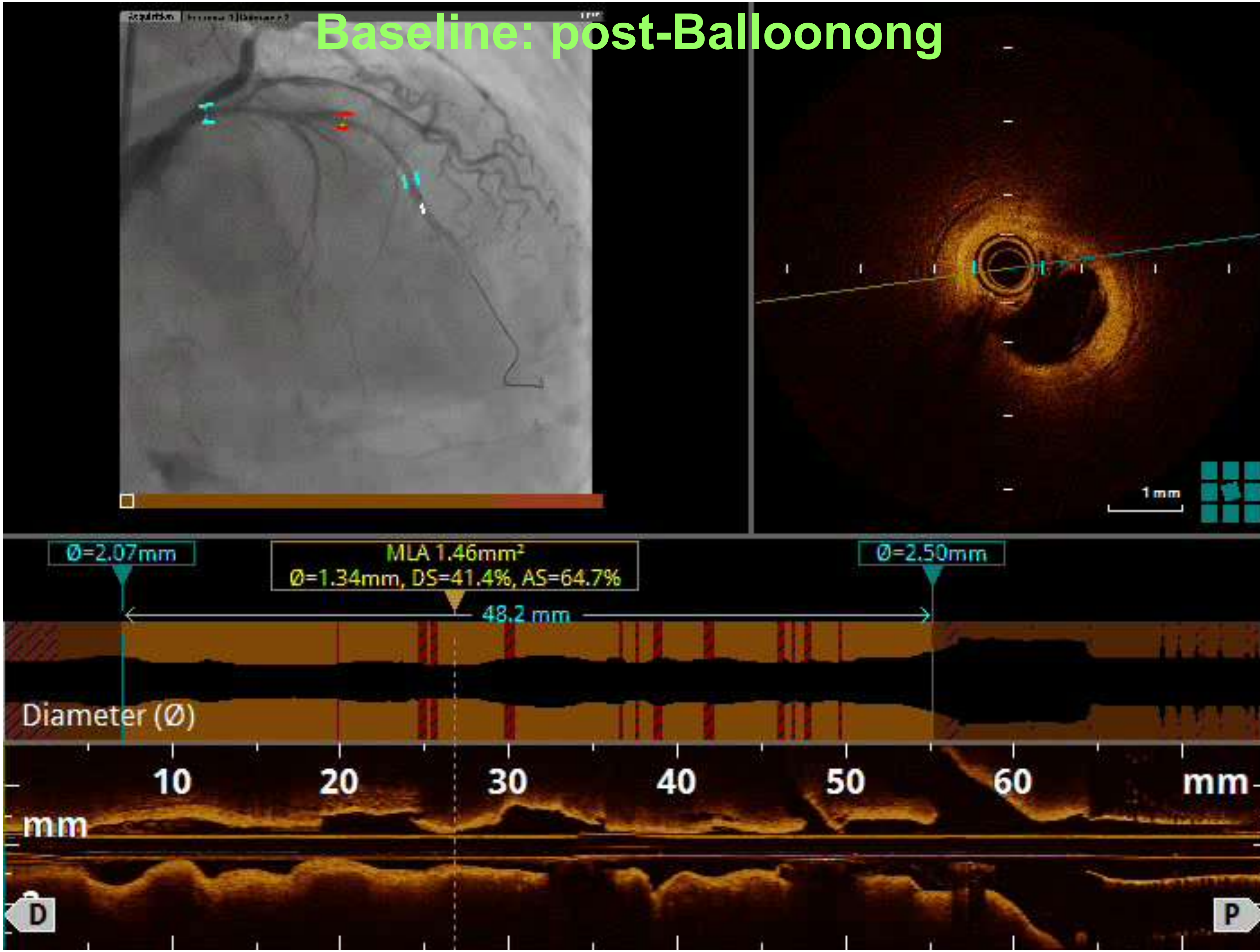
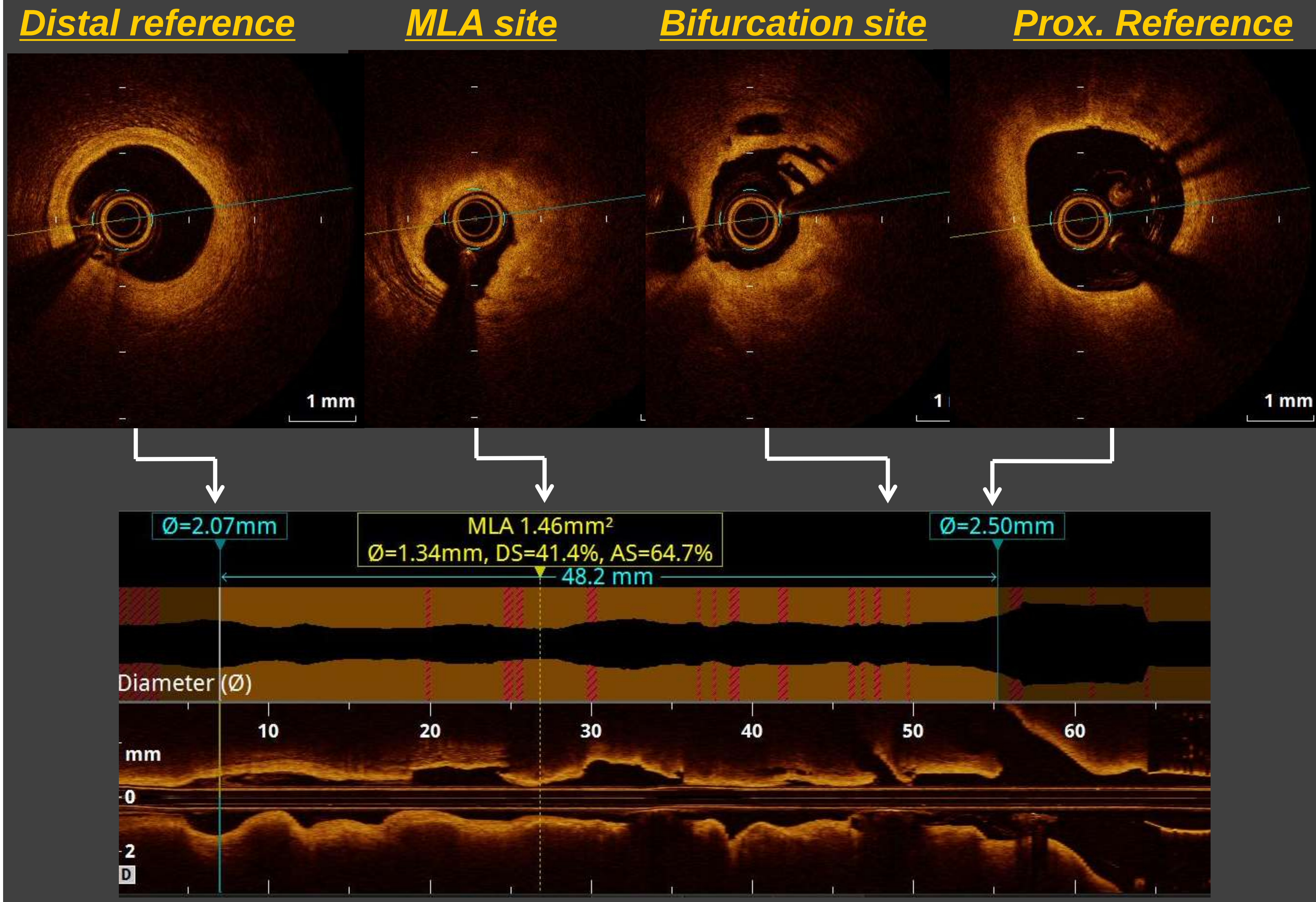
Coronary angio. (Pre PCI)



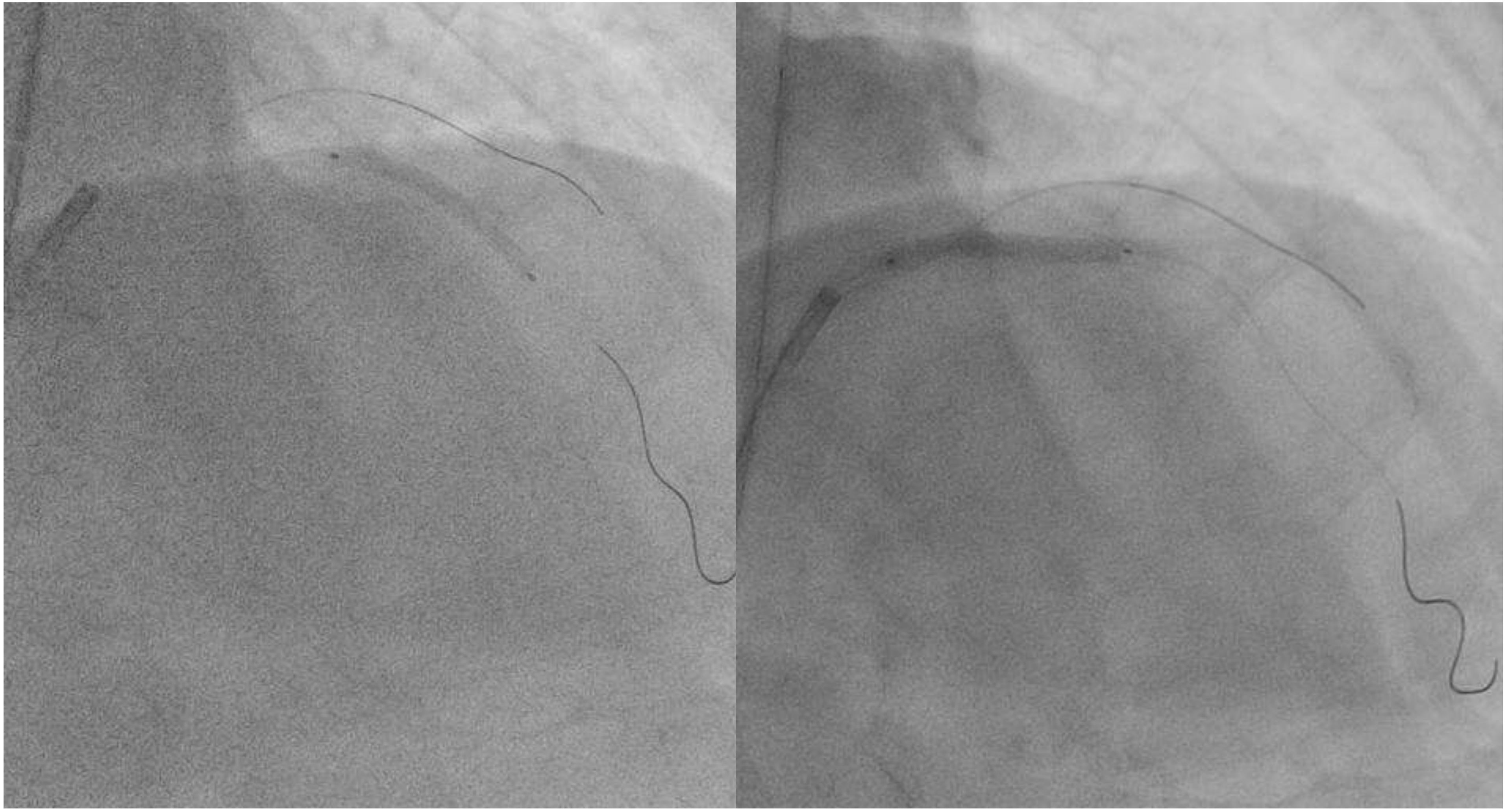
Baseline: post-Balloonong



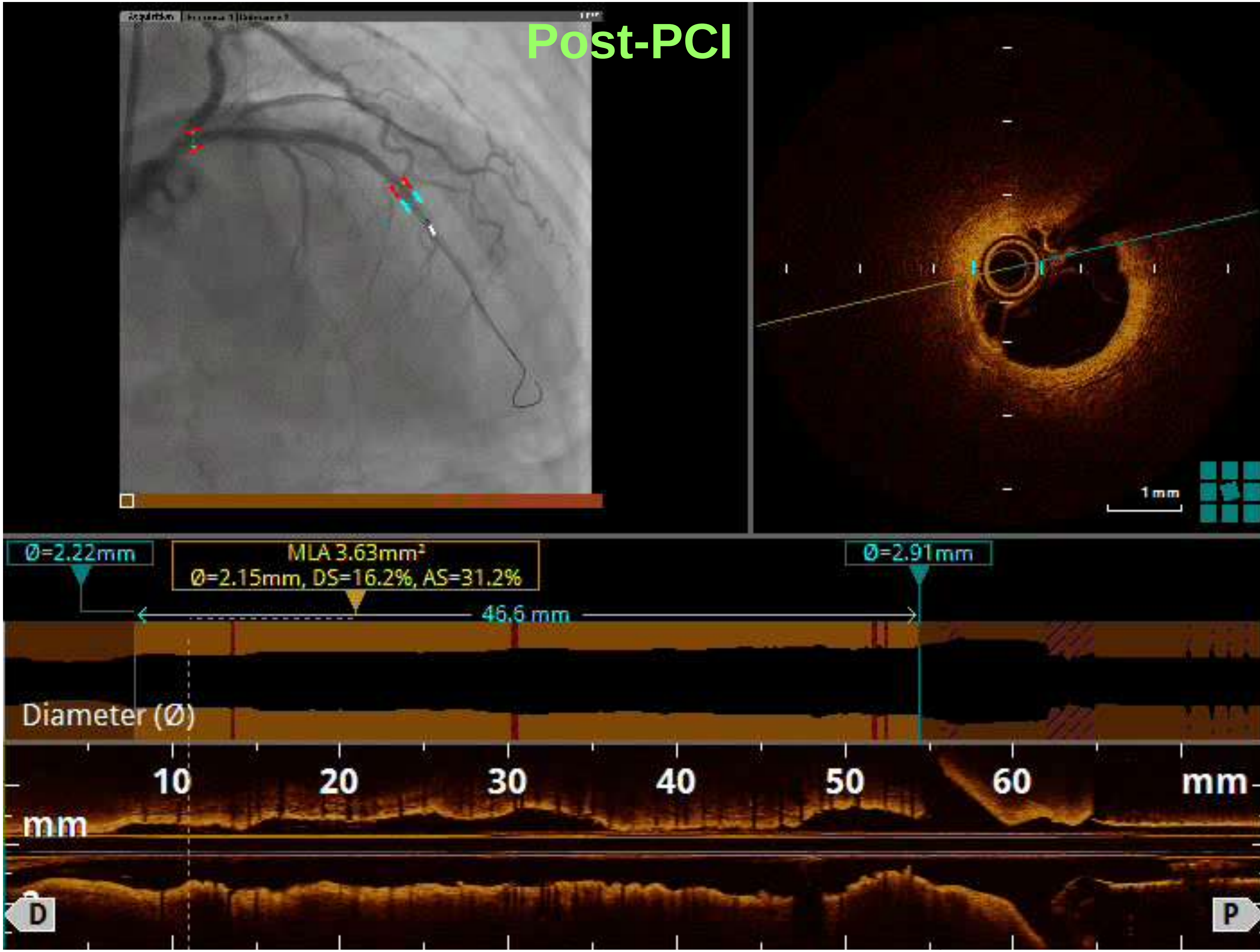
Baseline: post-Balloonong



PCI for #6-7



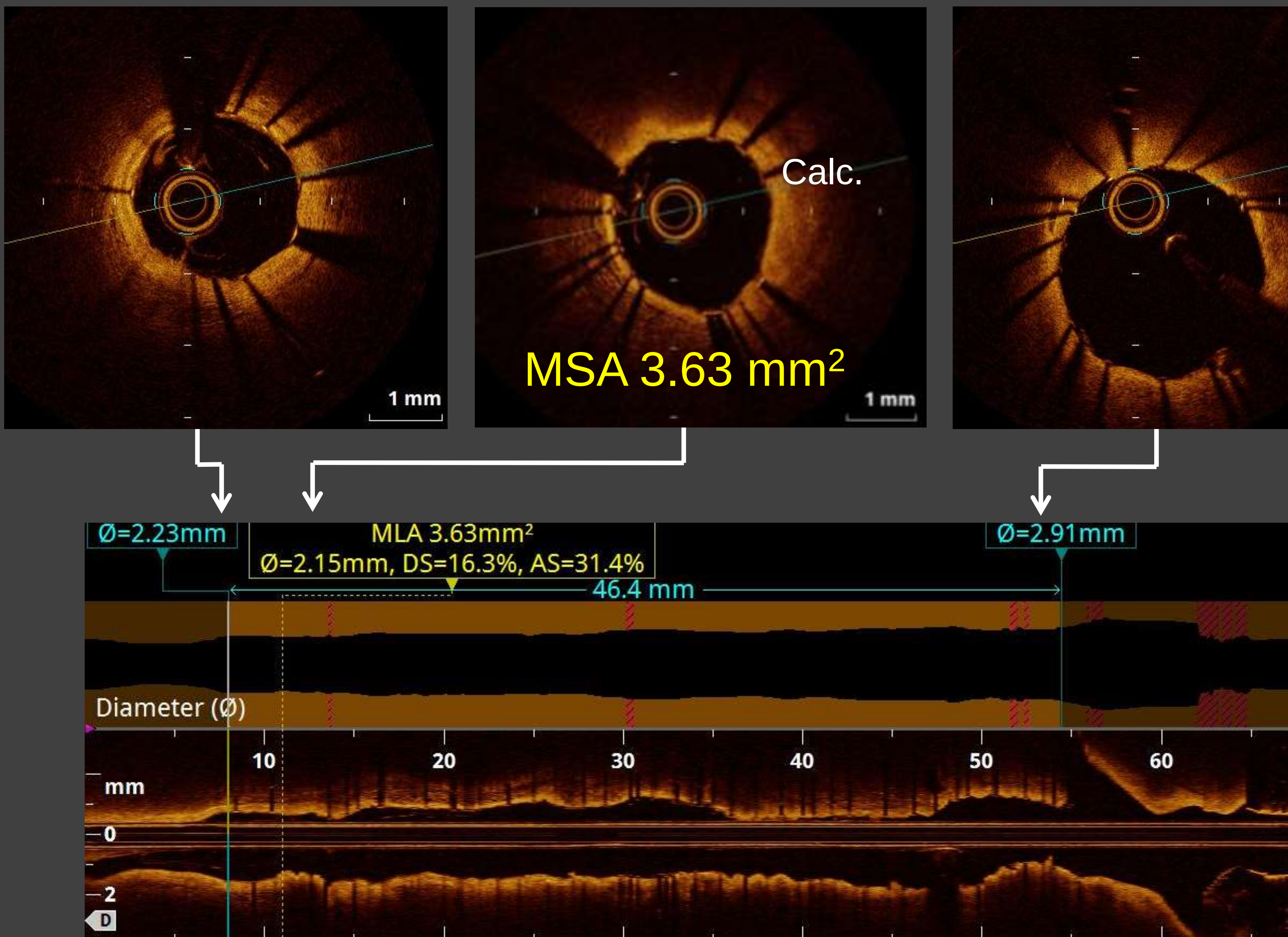
EES : 2.5*26mm / 2.75*26mm (14atm.)


Post-PCI
1 mm
Ø=2.22mm
MLA 3.63mm²
Ø=2.15mm, DS=16.2%, AS=31.2%
Ø=2.91mm
46.6 mm
Diameter (Ø)
10
20
30
40
50
60
mm
mm
D
P

rsity

Post-PCI

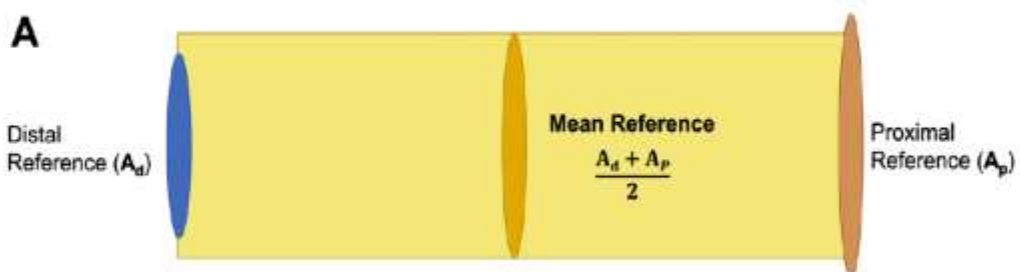
Distal reference ***MSA site*** ***Prox. Reference***



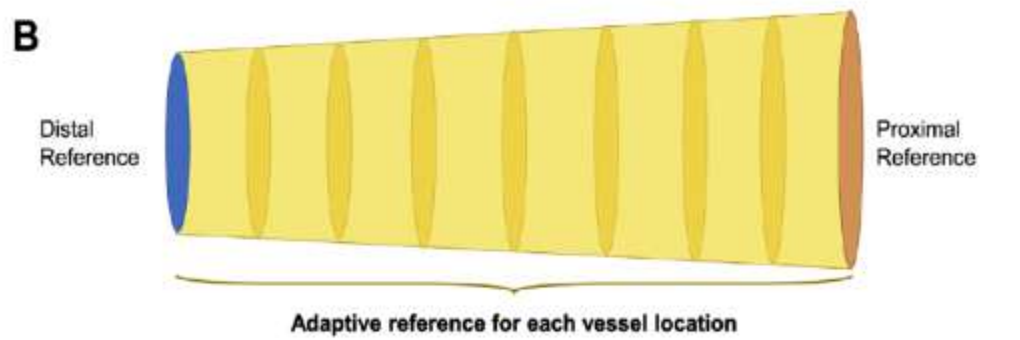
Volumetric Stent Expansion Assessment

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

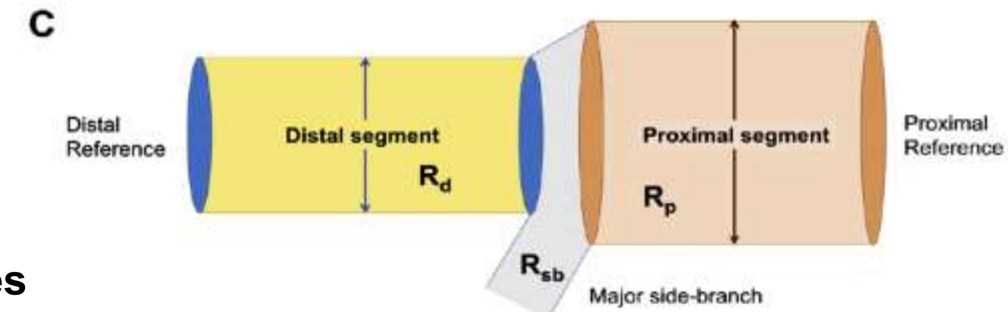
Conventional Method



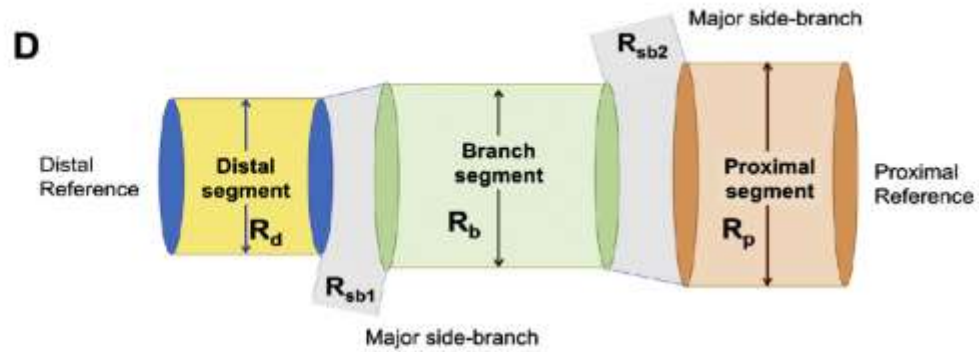
New method for vessels with no major side -branches

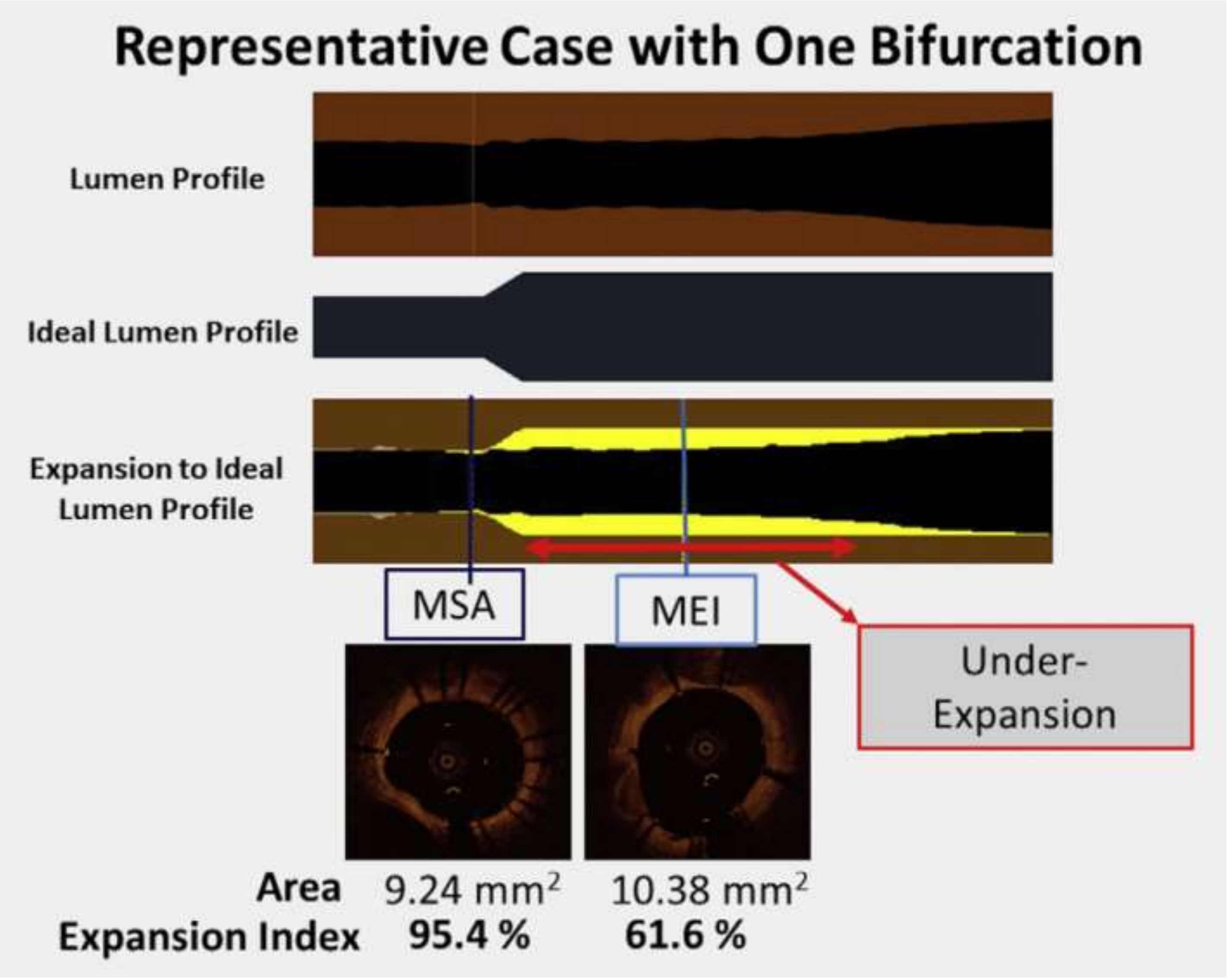


Method for vessels with 1 major side -branches



Method for vessels with 2 major side -branches





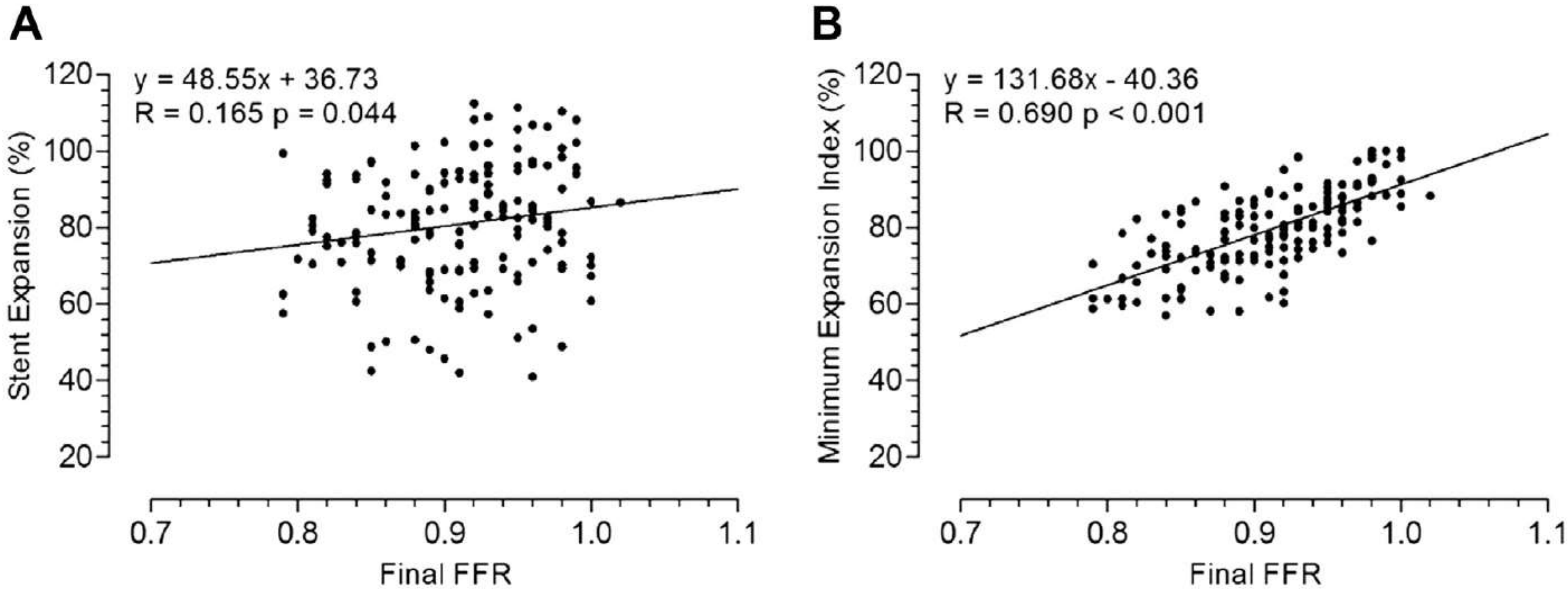
Normalized Expansion Index Value = actual lumen area / ideal lumen area x 100

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

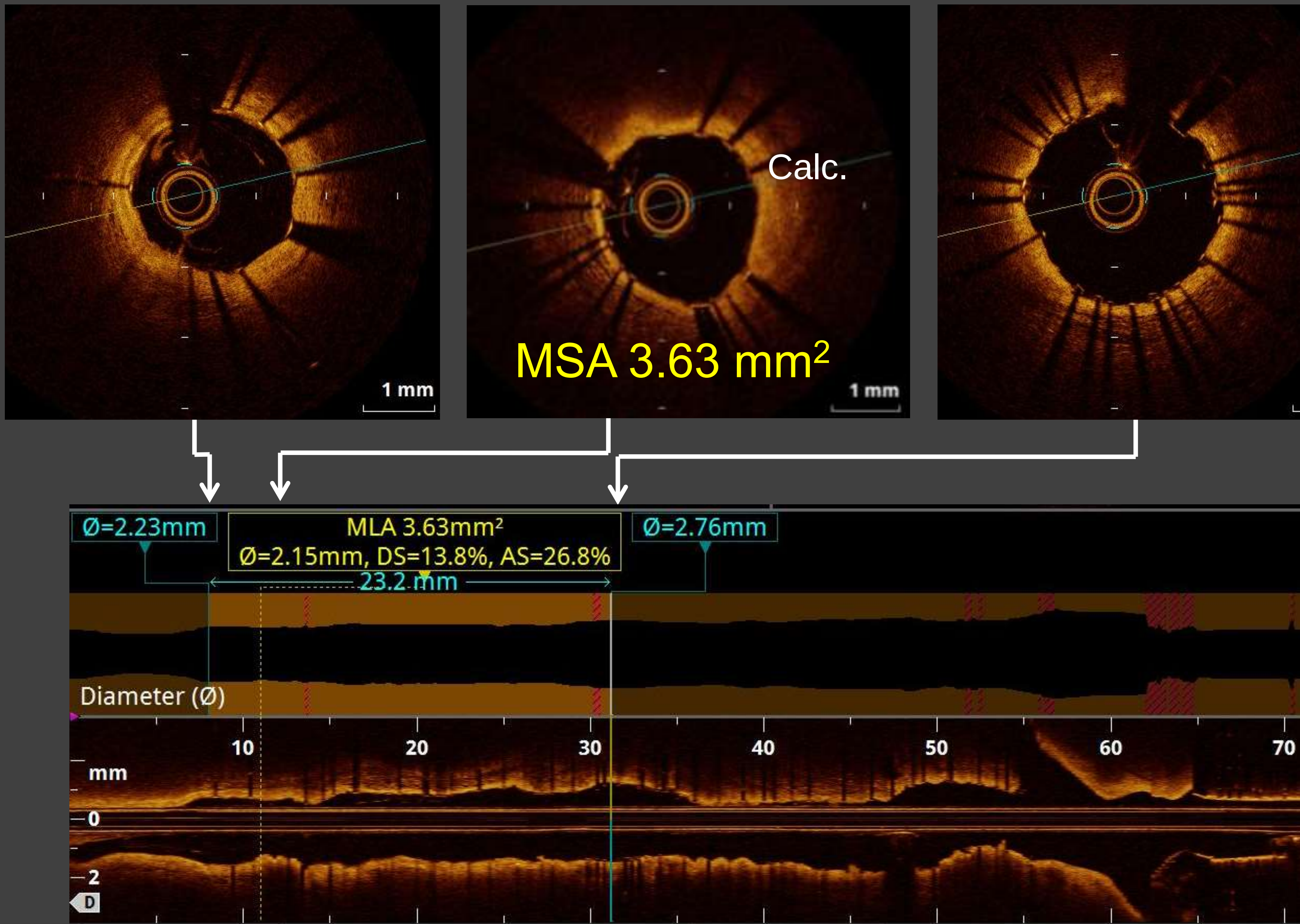
Correlation of %AS with Final FFR Value for Conventional Method and New Volumetric Method

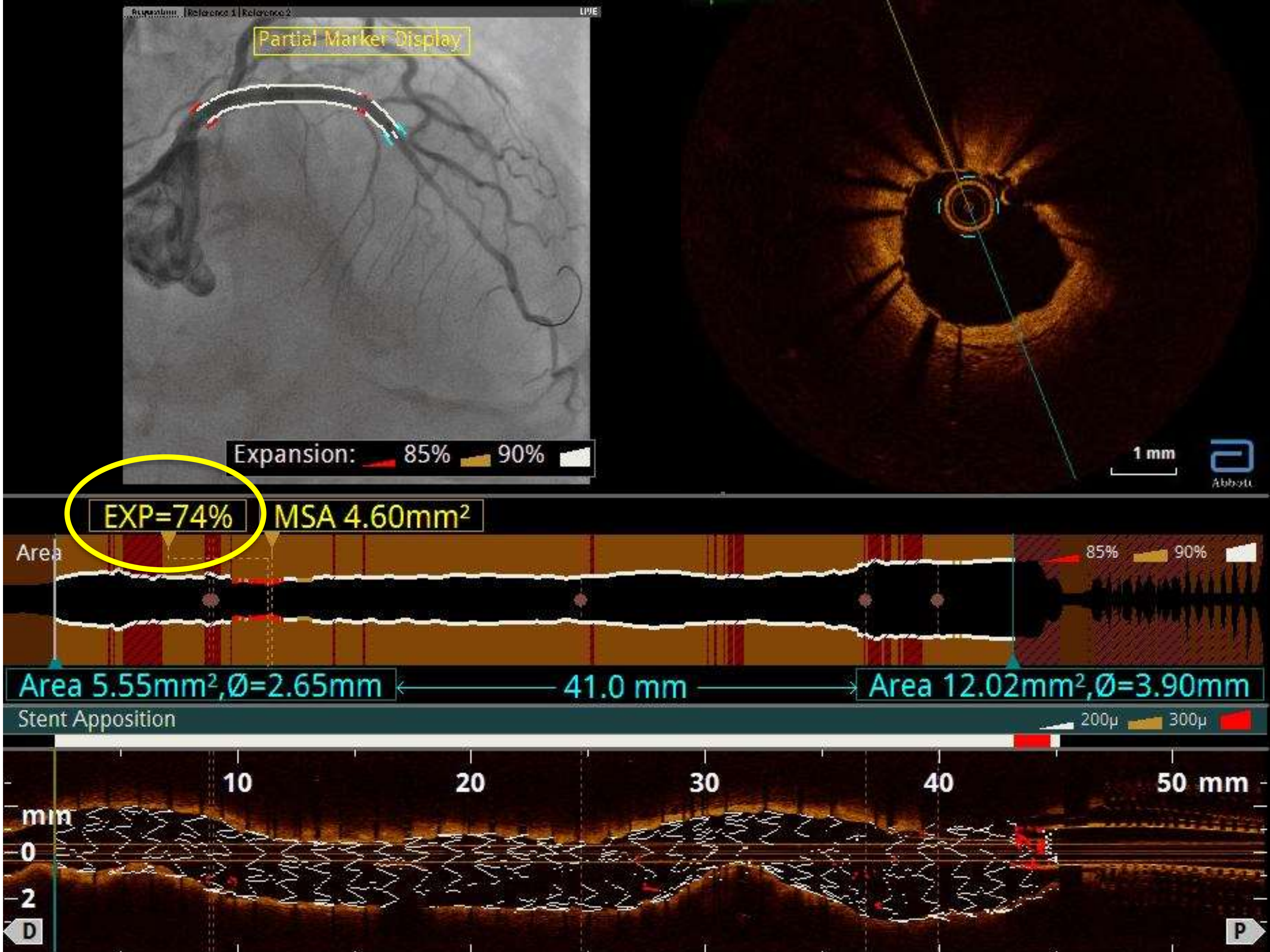
Nakamura D, et al. J Am Coll Cardiol Intv 2018;11:1467-1478



Post-PCI

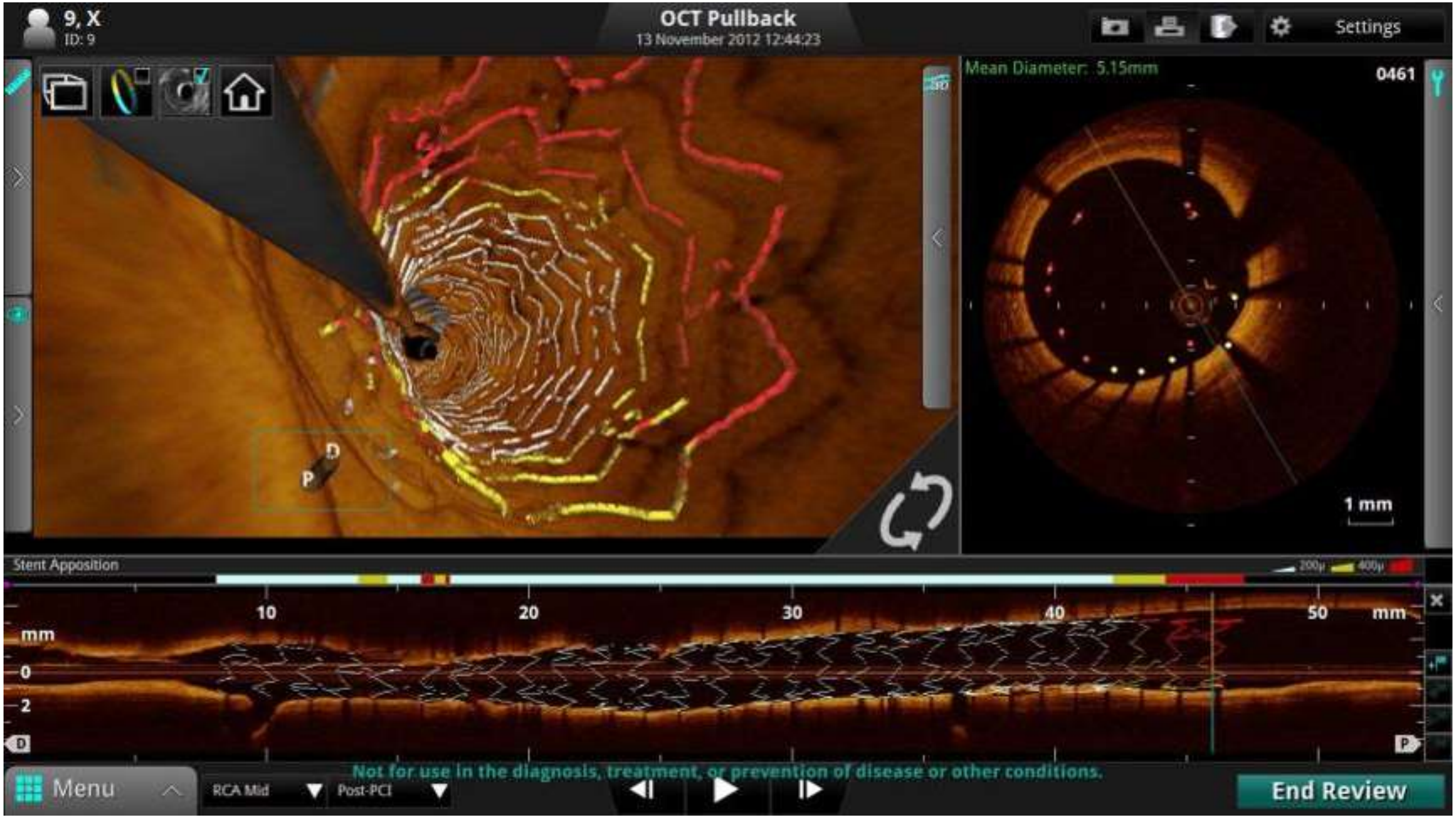
Distal reference | ***MSA site*** | ***Prox. Reference***




Partial Marker Display
Expansion: 85% 90%
1 mm
EXP=74%
MSA 4.60mm²
Area
85% 90%
Area 5.55mm²,Ø=2.65mm
41.0 mm
Area 12.02mm²,Ø=3.90mm
Stent Apposition
200μ 300μ
10
20
30
40
50 mm
mm
0
2
D
P

sity

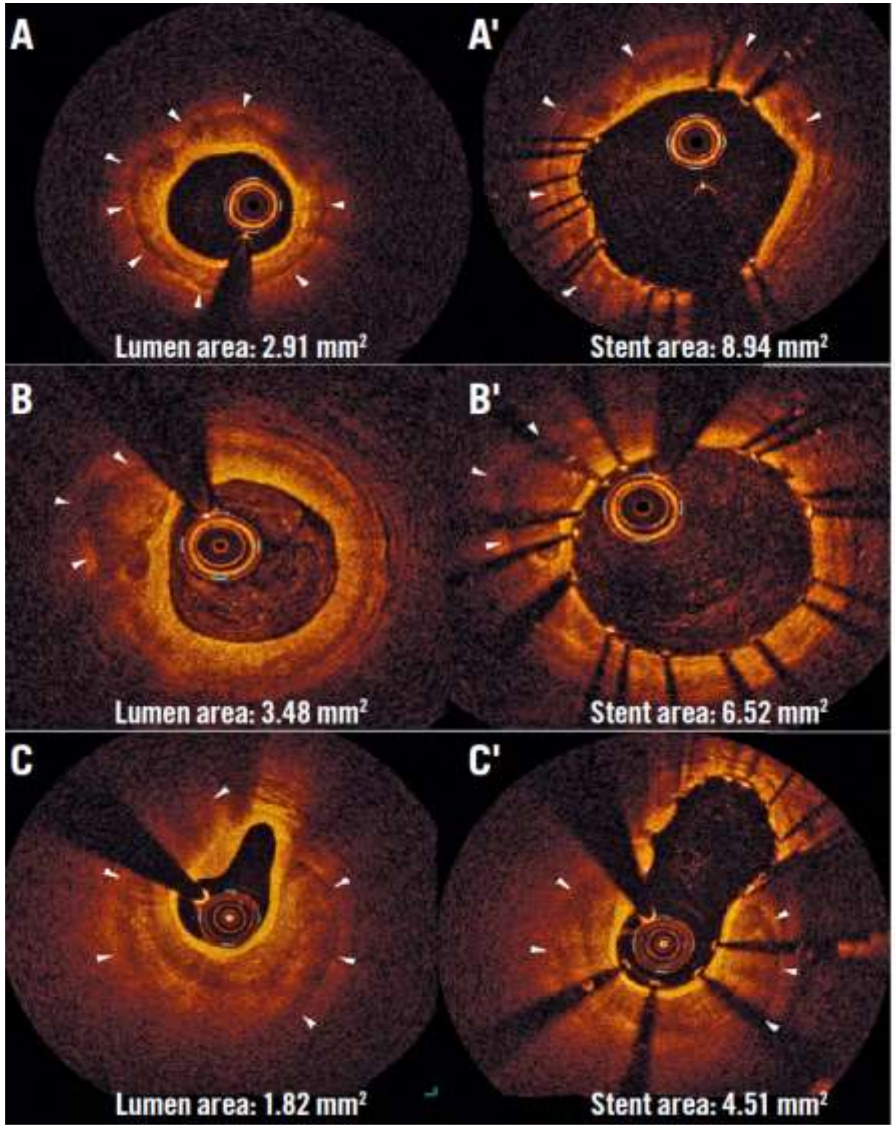
New Development in OCT



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

Calcium eccentricity, thickness & length and stent expansion

Baseline **Final**



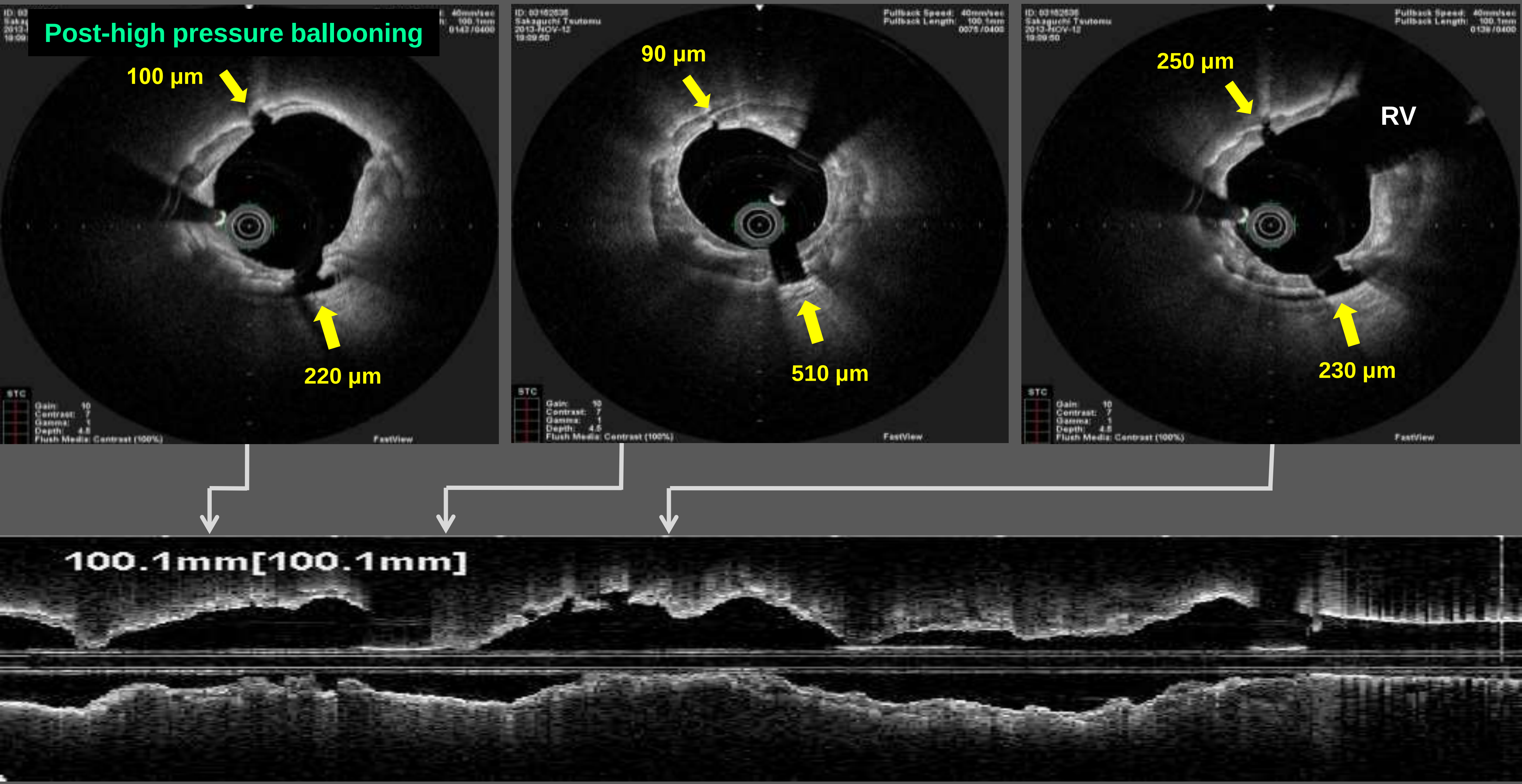
Angle: 360°
Thickness: 0.48 mm
Length: 3.8 mm
Calcium score: 2 points
Expansion: 99%

Angle: 75°
Thickness: 1.1 mm
Length: 4.3 mm
Calcium score: 1 point
Expansion: 97%

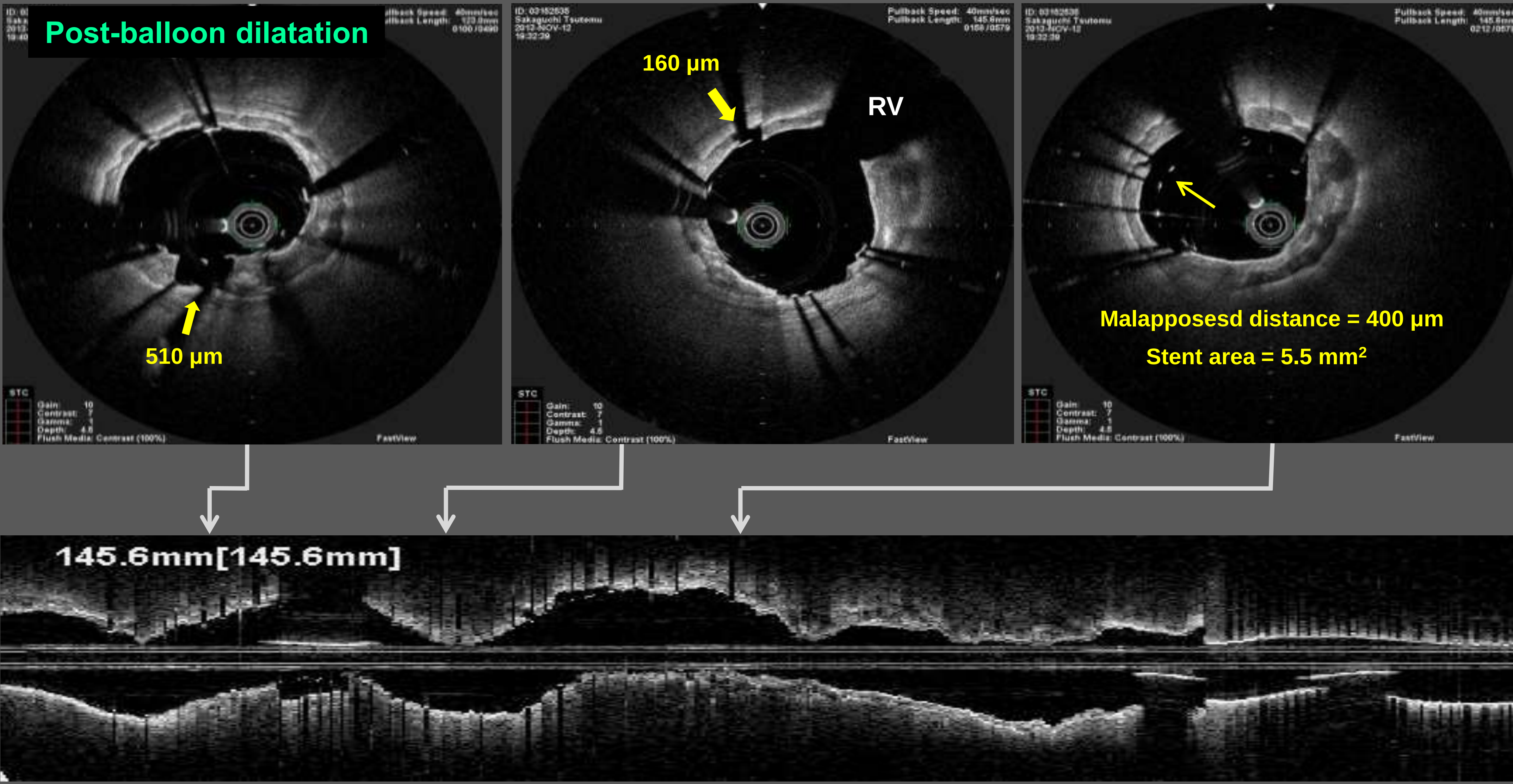
Angle: 312°
Thickness: 1.4 mm
Length: 11.0 mm
Calcium score: 4 points
Expansion: 68%

Fusiono A, et al. EuroInterv 2018;13:e2182-e2189

Broken calcium plate | Broken calcium plate | Broken calcium plate



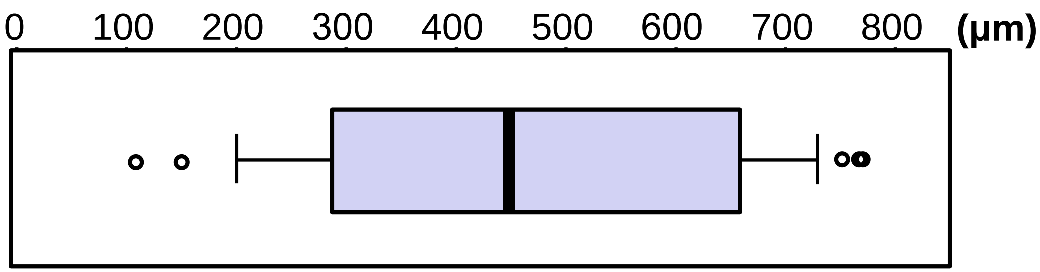
Broken calcium plate | *Broken calcium plate* | *Stent malappsoition*



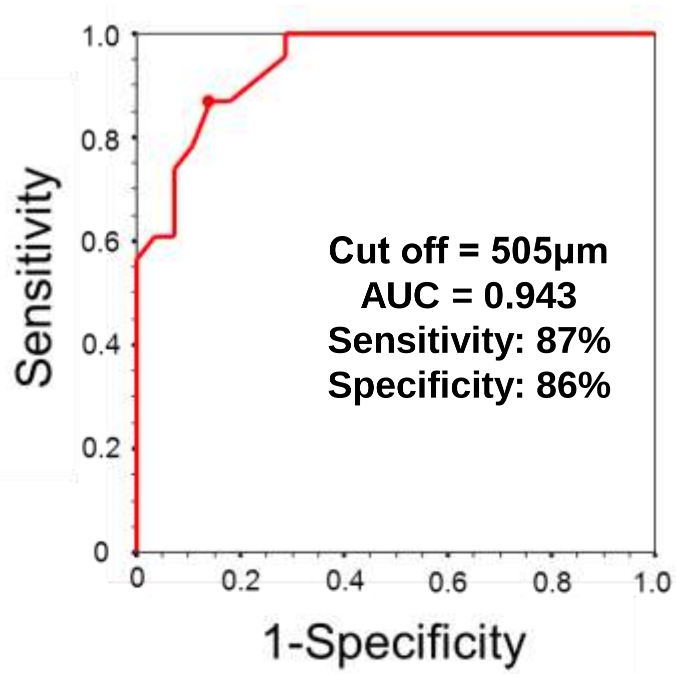
Prediction of calcium plate fracture by ballooning

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

Thickness distribution of calcium fracture



Median = 450µm; Lower quartile = 300µm; Upper quartile = 660µm; Minimum = 110µm; and Maximum = 770µm.

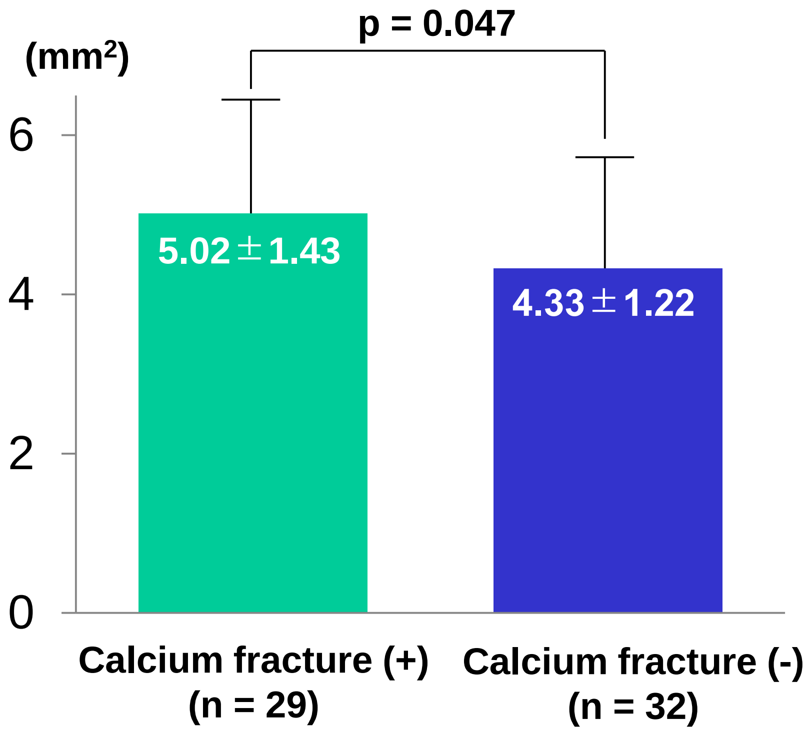


Conclusion: A calcium plate thickness < 505 µm was the corresponding cut-off value for predicting calcium plate fracture by high pressure ballooning.

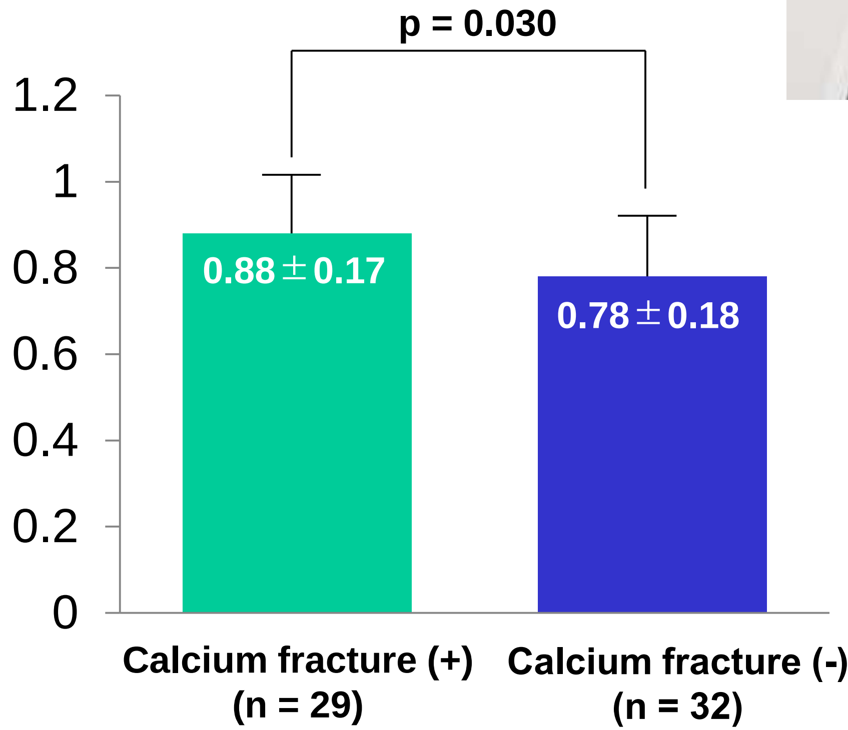
Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Stent expansion at post-PCI

Minimum stent area



Stent expansion index

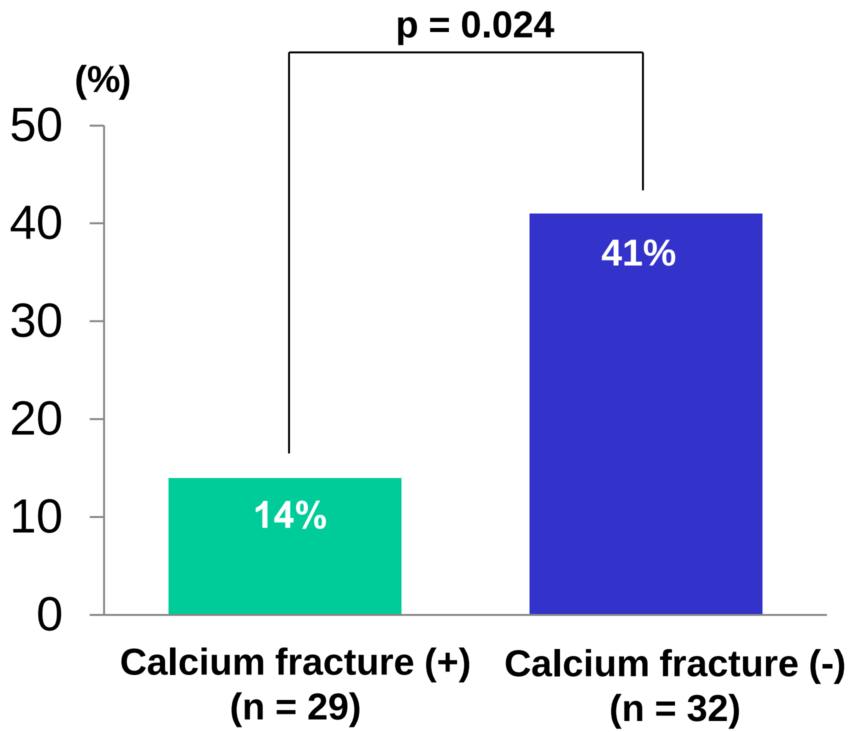


Minimum stent area and stent expansion index were significantly greater in the group with calcium fracture compared with the group without calcium fracture.

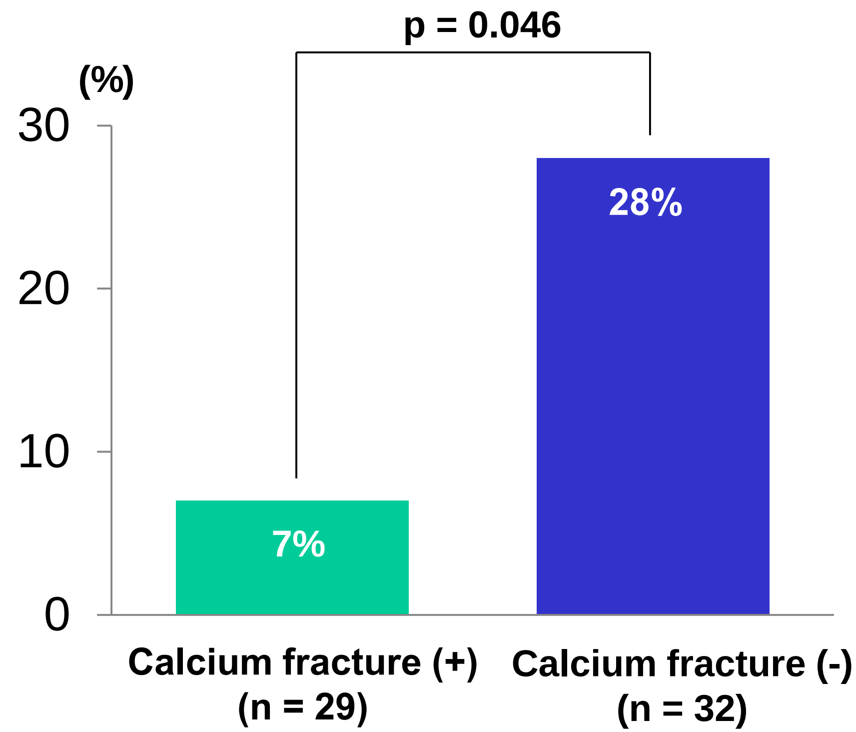
Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Restenosis and TLR at 10 months follow-up

Binary restenosis



Target lesion revascularization



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.

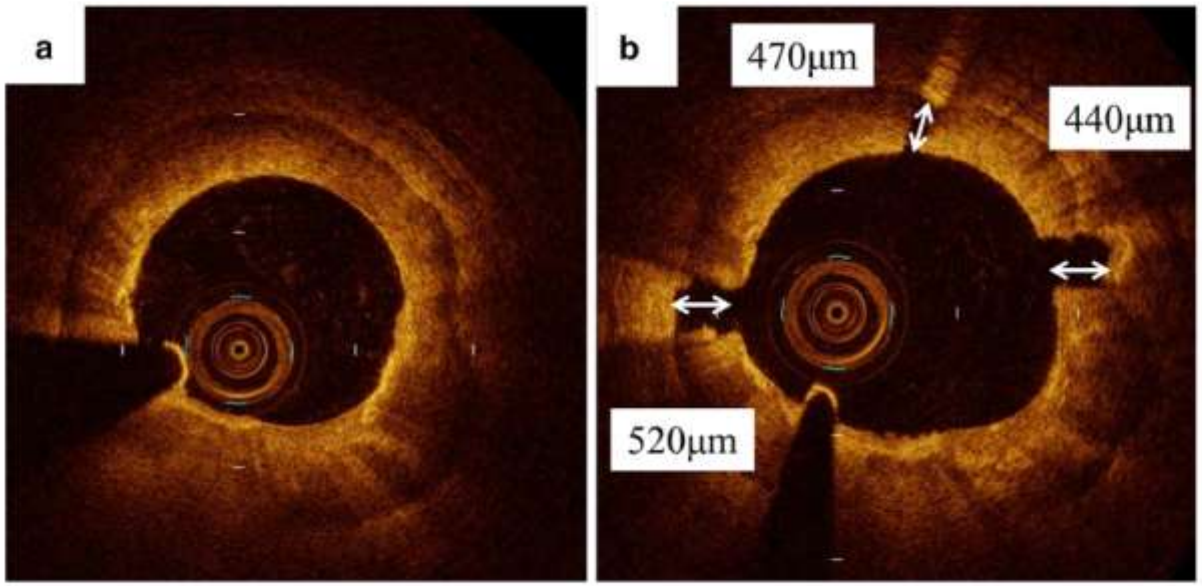
Kubo, Akasaka et al. JACC Imag 2015;8:1228-9

Cardiovascular Intervention and Therapeutics (2019) 34:242–248
https://doi.org/10.1007/s12928-018-0553-6

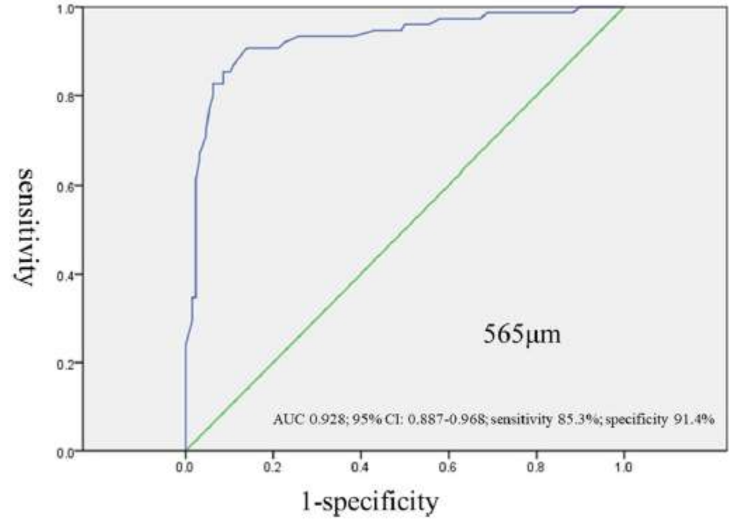
ORIGINAL ARTICLE

Plaque modification of severely calcified coronary lesions by scoring balloon angioplasty using Lacrosse non-slip element: insights from an optical coherence tomography evaluation

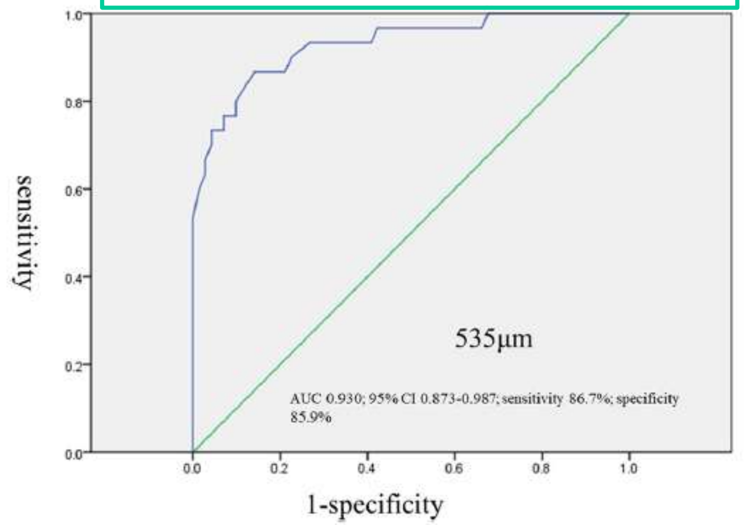
Yu Sugawara[1] · Tomoya Ueda[1] · Tsunenari Soeda[1] · Makoto Watanabe[1] · Hiroyuki Okura[1] · Yoshihiko Saito[1]



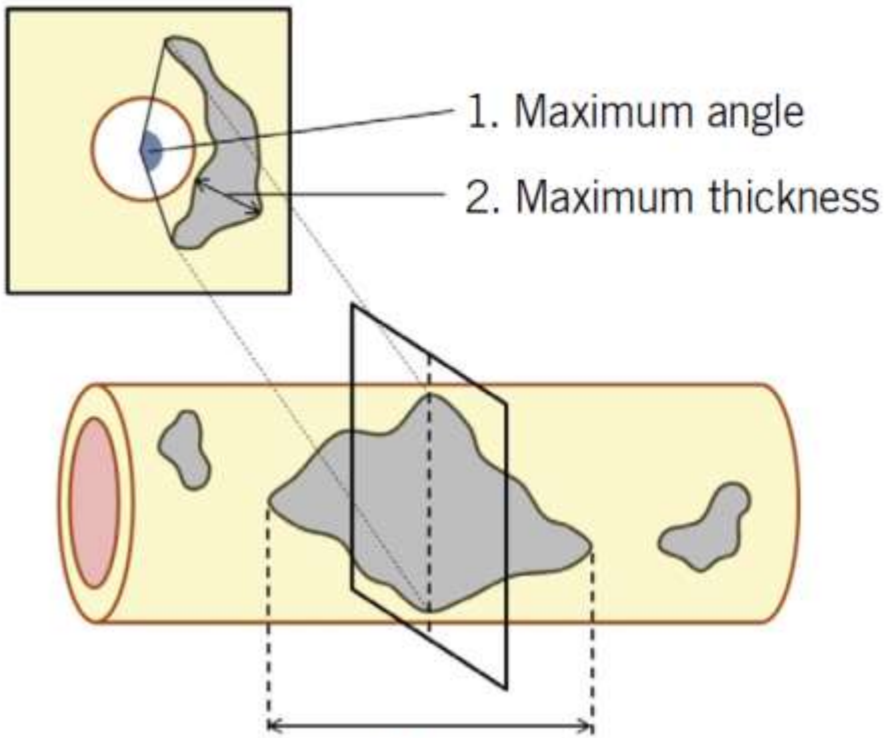
All cross sectional OCT images



Calcium angle >270°



OCT based calcium scoring system

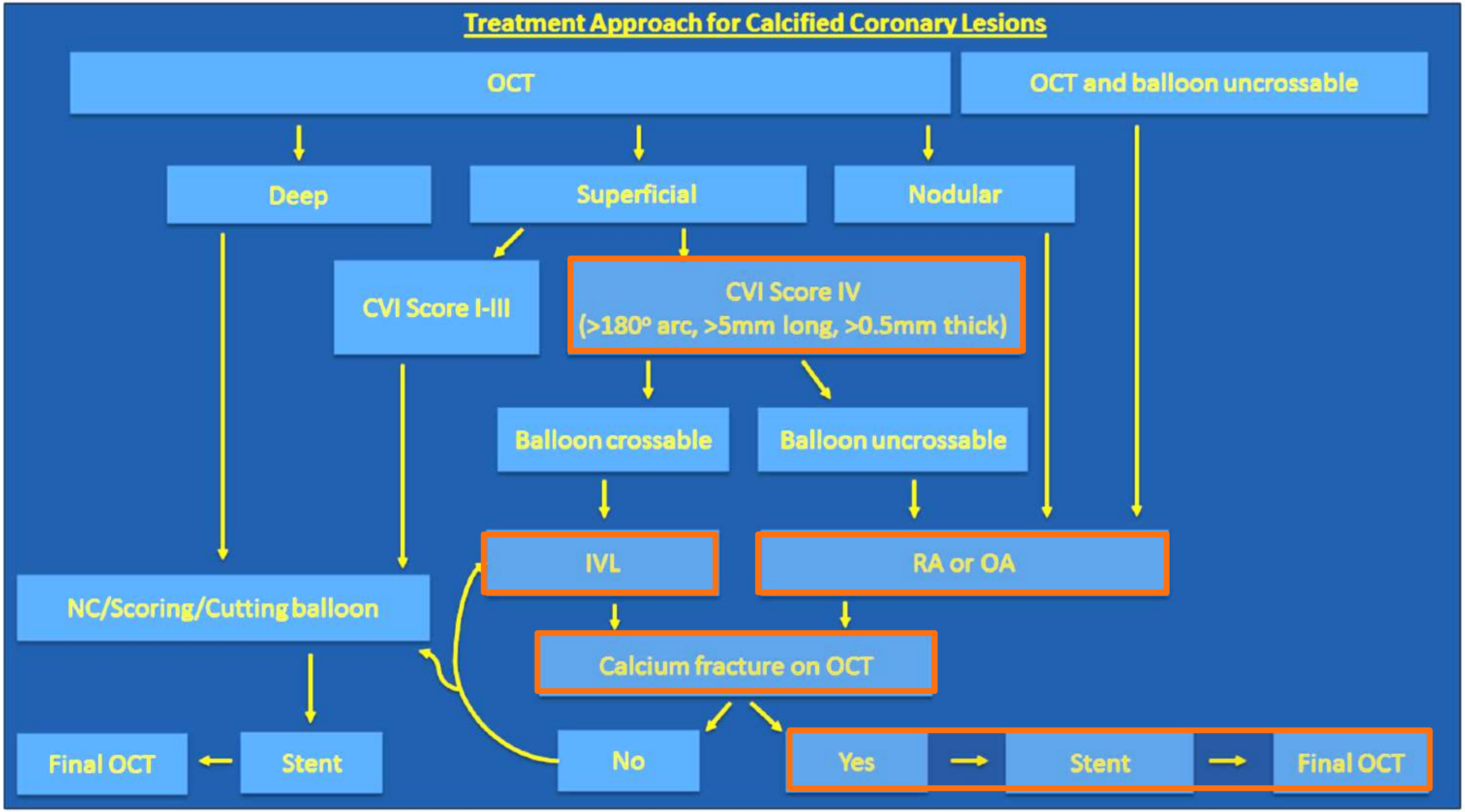


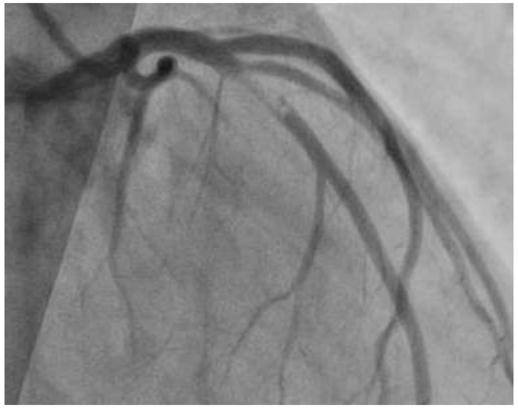
OCT-based calcium score	
1. Maximum calcium angle (°)	≤180° ➡ 0 point >180° ➡ 2 points
2. Maximum calcium thickness (mm)	≤0.5 mm ➡ 0 point >0.5 mm ➡ 1 point
3. Calcium length (mm)	≤5.0 mm ➡ 0 point >5.0 mm ➡ 1 point
Total score	**0 to 4 points**

Fusiono A, et al. EuroInterv 2018;13:e2182-e2189

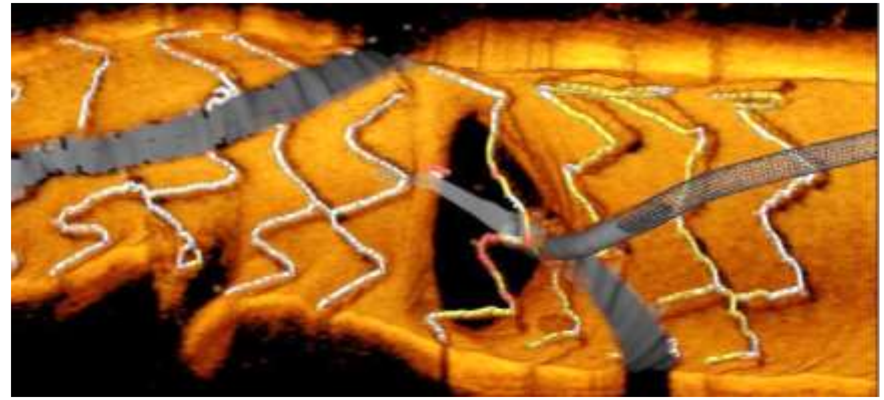
OCT-guided PCI for severe calcified lesions

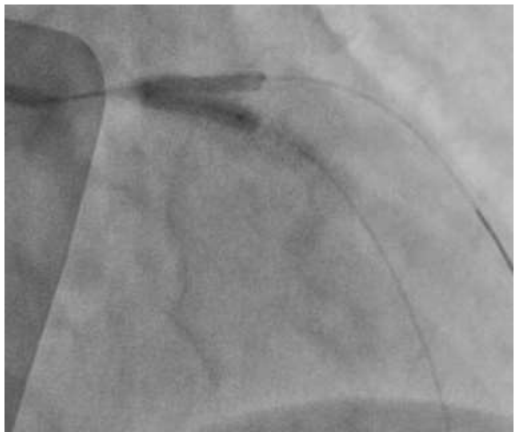
Shlofmitz E, et al. Curr Cardiovasc Imaging Rep 2019;12;32



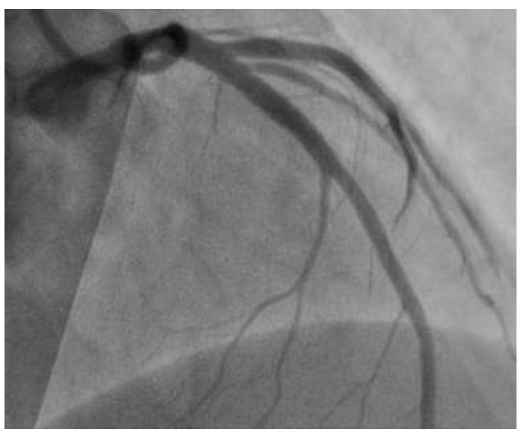


3D-OCT image before KBT

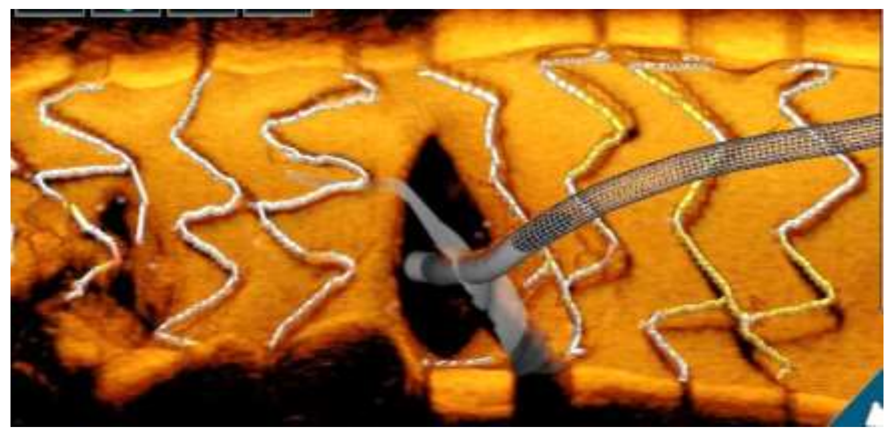




3D-OCT image after re-wiring before KBT



3D-OCT image after KBT



Take home message
Imaging guidance for PCI

- Pre- & post-PCI lesion morphology can be assessed easily, precisely and accurately by imaging because of higher resolution, auto-pullback & auto-measurement systems, angio-co-registration, and/or 3D reconstruction, etc., compared with coronary angiography alone.
- Imaging-guided PCI is becoming more popular in daily clinical practice based on the guideline recommendation as class IIa, and expert consensus document of imaging-guided PCI optimization has described recently.
- Much more precise PCI could be expected by OCT compared with IVUS-guidance in specific lesions such as severe calcification, left main bifurcation, and so on, and OCT may allow us to change our daily clinical practice in PCI and to expect further improvement in the result of PCI.
- Although clinical evidences of superiority to angio-guided PCI has been demonstrated not in OCT-guided but in IVUS-guided at the moment, randomized prospective studies of OCT-guided PCI compared with angio-guided could demonstrate the advantages of OCT especially for specific pathological condition including diffuse, calcified, or bifurcation lesion.