



A Teaching Affiliate
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OCT Predictors for Device Oriented Clinical Endpoints

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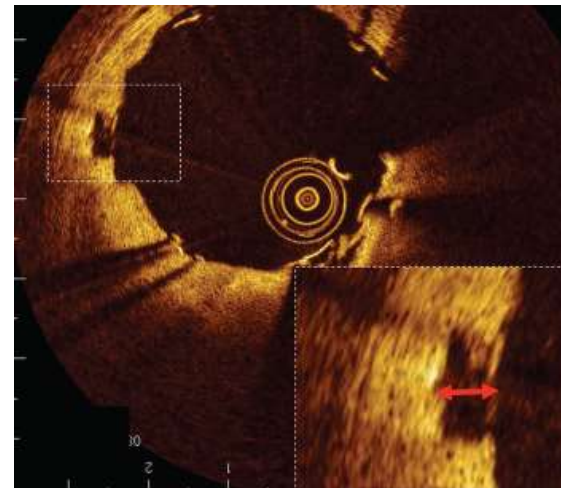
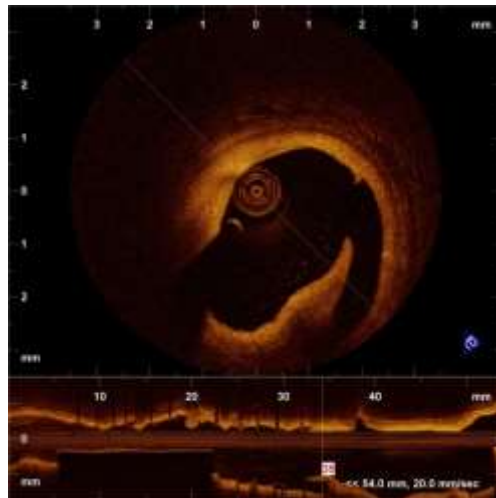
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Background

1. OCT has 10 folds higher temporal resolution compared to IVUS.
2. Post-stent abnormal findings, such as stent edge dissection, malapposition, in-stent protrusion, and thrombus are frequently found on OCT.
1. Previous studies were from single center experience with a small sample size and the definitions used in those studies were inconsistent. Moreover, no systematic long-term follow up was carried out.

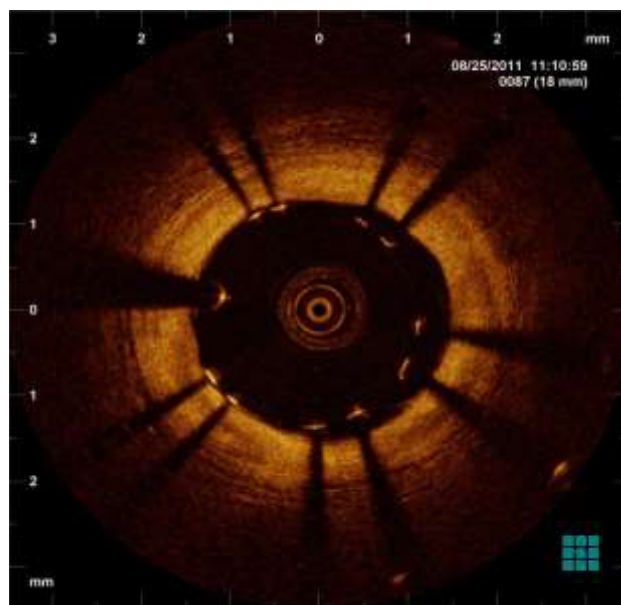
Stent Edge dissection

- In previous reports, the rate of dissection detected by OCT was 15-30%.
- In angiographic or IVUS reports, non occlusive coronary dissection was not associated with increased incidence of restenosis.



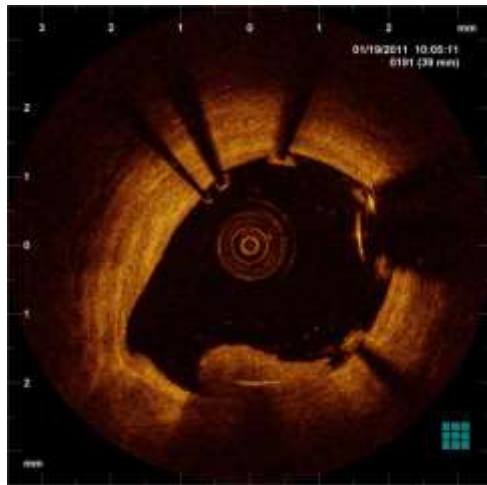
Incomplete Stent Apposition

- 30 to 40% of Incomplete stent apposition (ISA) was reported after stent implantation by OCT.
- ISA has been implicated as a potential factor for late stent thrombosis (LST) in patients treated with DES.

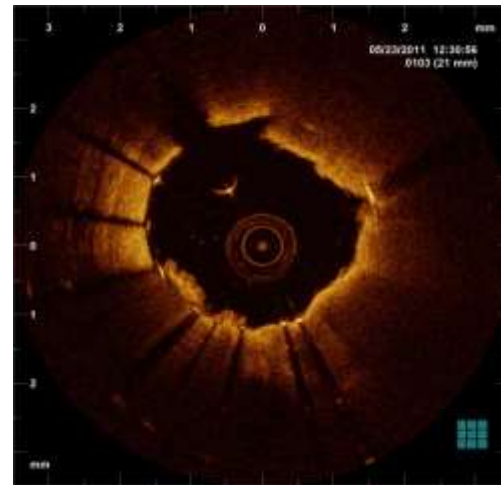


Instant prolapse / Disruption

- Tissue protrusion is detected by OCT in the majority of cases, ranging from 40% to 100%.
- However, most protrusions have healed at follow up.



Thrombus

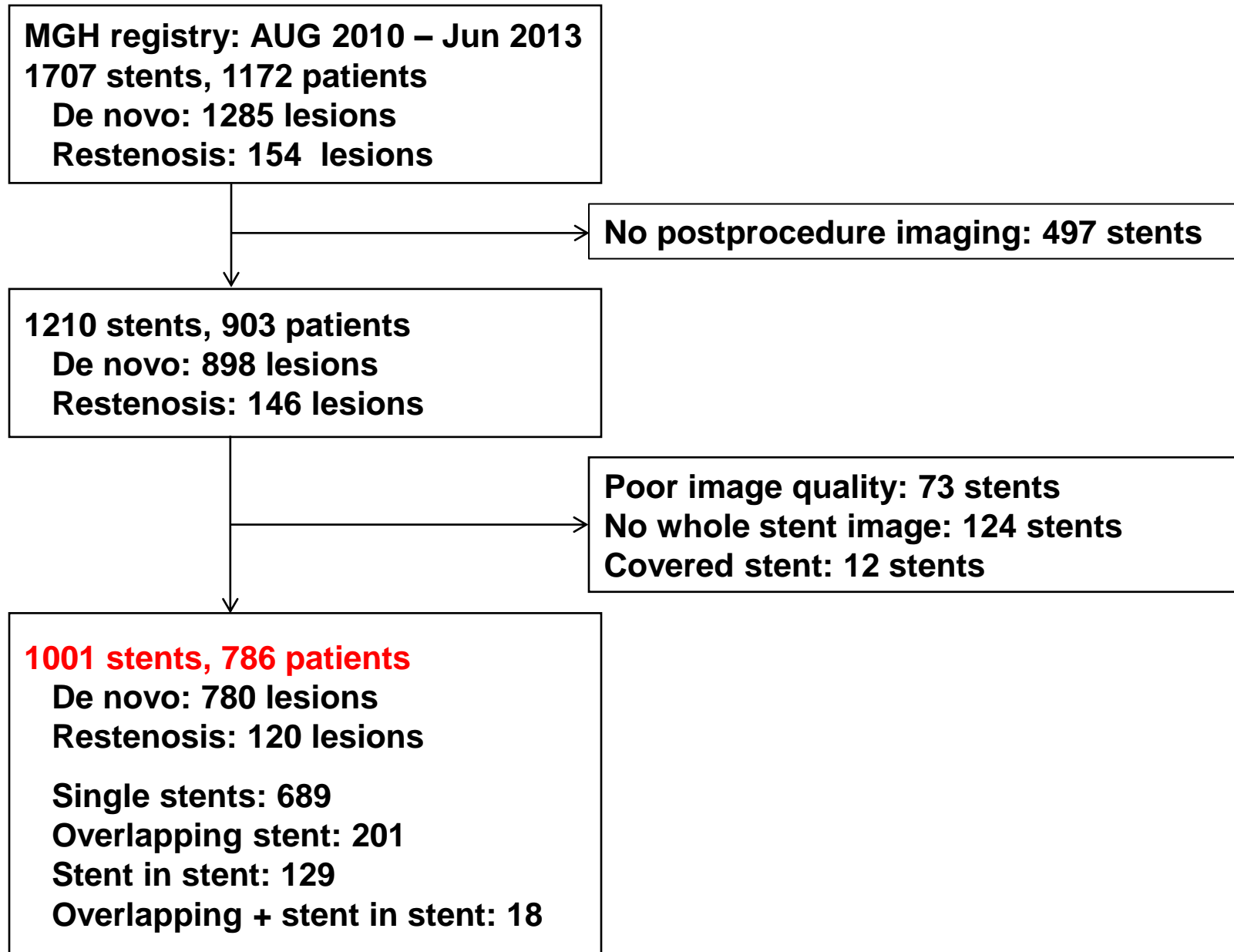


Tissue protrusion

Objectives

1. To evaluate the Incidence of post-stent abnormal OCT findings in the real world.
2. To correlate these OCT findings with clinical outcome at 1 year.
3. To identify the OCT predictors for device-oriented clinical endpoint (DoCE) including death, AMI, stent thrombosis, and TLR.

Study Flow Chart



OCT Assessment

Stent edge dissection (SED): Stent edge plaque morphology, direction (antegrade, retrograde), depth (intima, media, adventitia), flap length, angle etc

Instant dissection (ISD): dissection length

Incomplete stent apposition (ISA): stent-vessel distance, location of ISA

Instant protrusion

smooth protrusion

Disrupted fibrous plaque

Irregular protrusion

Thrombus

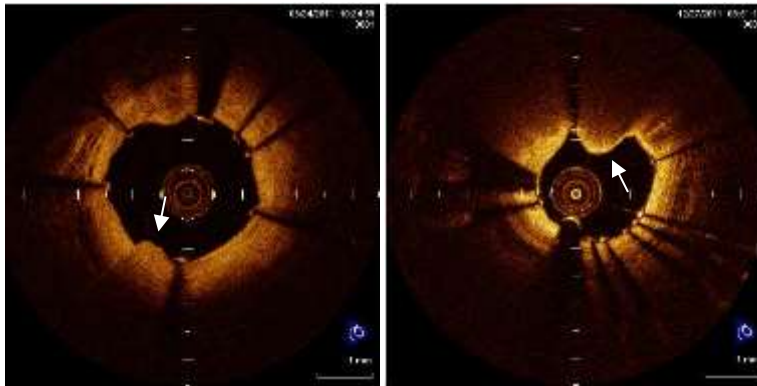
Minimal stent area (MSA)

Underexpansion

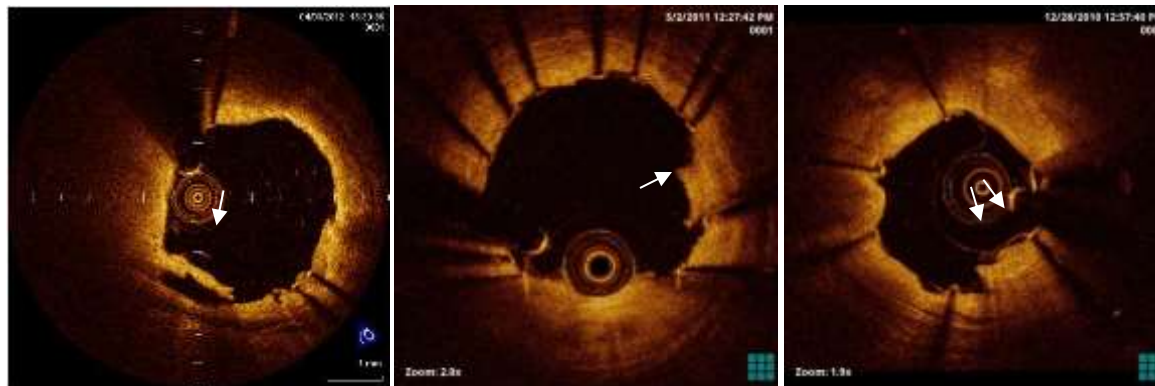
MSA /reference area < 0.8

New Definitions for Instent protrusion

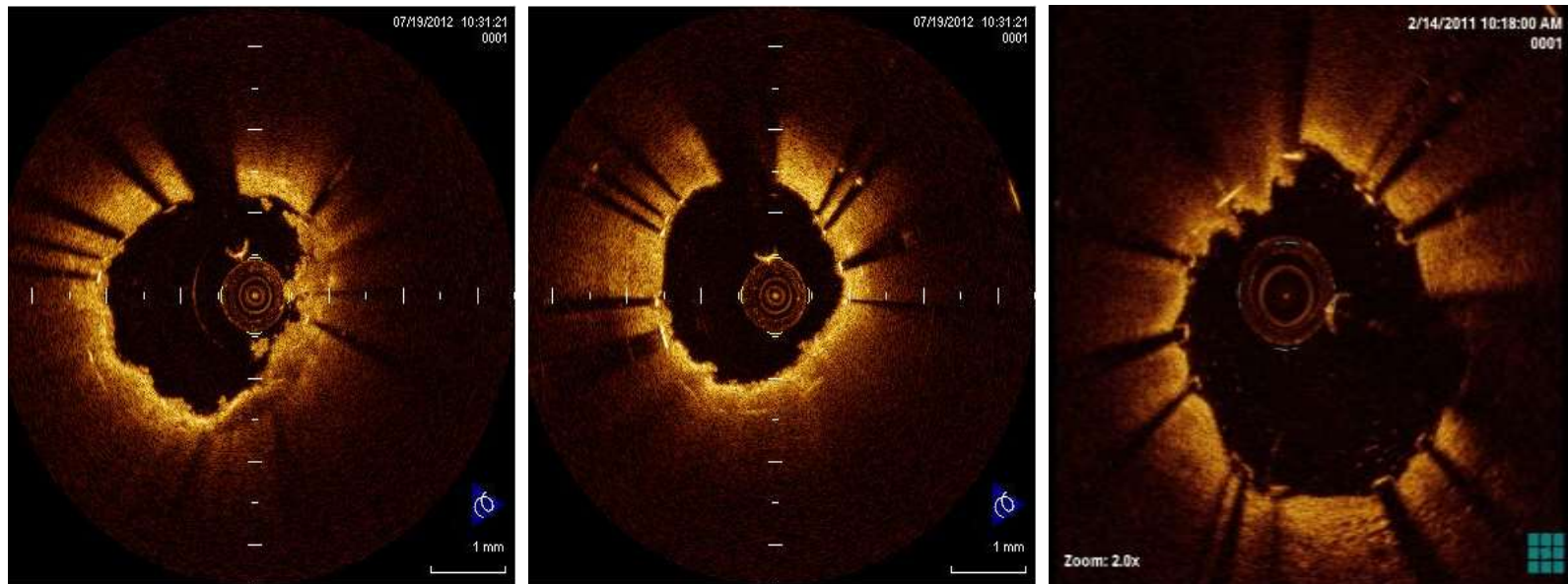
Smooth protrusion: bowing of the plaque into the lumen with smooth surface without disruption between stent struts extending inside a circular arc connecting adjacent struts probably due to compression of soft plaque by stent struts



Disrupted fibrous plaque protrusion: a separation of fibrous cap or disrupted fibrous tissue protruding into the lumen. Underlying plaque is fibrous or thick cap fibroatheroma.

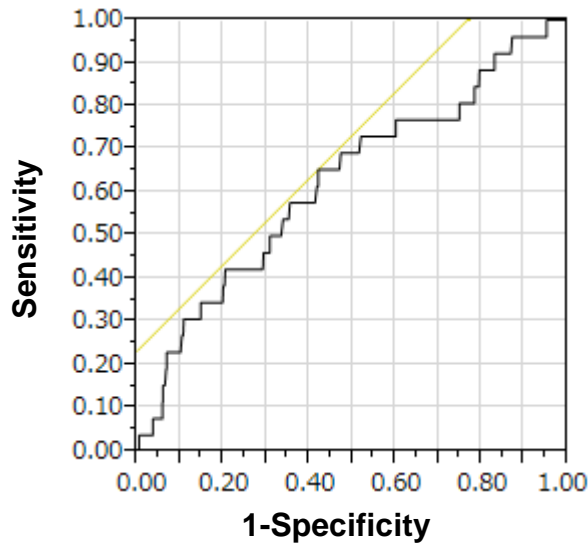


Irregular protrusion : disruption of tissue with irregular surface. Sometimes struts are buried inside the disrupted tissue. **Most of underlying plaque are lipid plaque.**



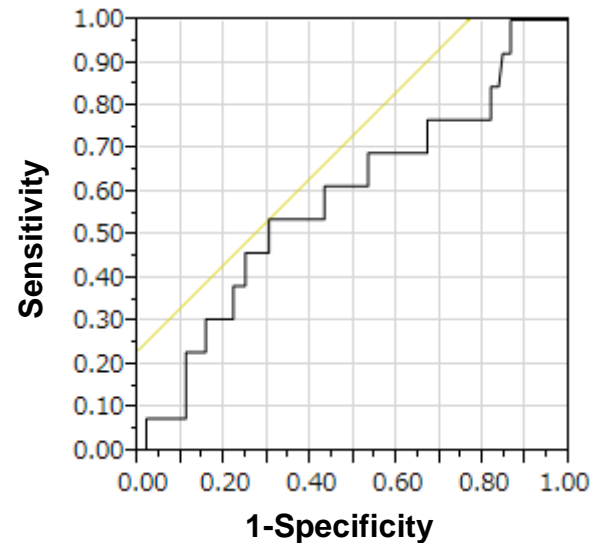
Definition of small MSA

A. Drug eluting stent (DES)



MSA Best cut off 5.0 mm²
AUC 0.626
Sensitivity 65.4
Specificity 58.0
PPV 5.6
NPV 97.8

B. Bare metal stent (BMS)



MSA Best cut off 5.6 mm²
AUC 0.591
Sensitivity 53.8
Specificity 69.7
PPV 17.5
NPV 92.7

Incidences of Clinical Event at 1-year

	Overall	Early (Up to 30 days)	Long-term (30 d to 1 yr)
DoCE	33 (4.5)	2 (2.8)	31 (4.3)
Cardiac death	1 (0.1)	0 (0)	1 (0.1)
Target vessel related MI	10 (1.4)	2 (2.8)	8 (1.1)
TLR	31 (4.3)	2 (2.8)	29 (4.0)
Stent thrombosis	3 (0.4)	2 (2.8)	1 (0.1)
Definite	3 (0.4)	2 (2.8)	1 (0.1)
Acute		1 (0.1)	–
Subacute		1 (0.1)	–
Late		–	1 (0.1)

Baseline Clinical Characteristics

	Overall (786Pts)	No-DoCE (694Pts)	DoCE (33Pts)	P-value
Age, y	62.2 ± 10.9	62.2 ± 10.8	59.4 ± 12.6	0.141
Male	630 (80.2)	539 (77.8)	31 (91.2)	0.085
BMI, kg/m ²	26.0 ± 4.6	25.8 ± 4.4	27.3 ± 4.6	0.051
Hypertension	518 (65.9)	444 (64.0)	21 (63.6)	1.000
Dyslipidemia	567 (72.1)	481 (69.3)	27 (81.8)	0.173
Diabetes mellitus	289 (36.8)	250 (36.0)	16 (48.5)	0.194
Current smoker	204 (26.0)	177 (25.5)	9 (27.3)	0.839
Family History	113 (14.4)	95 (13.7)	7 (21.2)	0.207
Prior MI	176 (22.4)	152 (21.9)	9 (27.3)	0.519
Prior stent	257 (32.7)	226 (32.6)	12 (36.4)	0.705
PCI indication				0.433
Stable angina	394 (50.1)	352 (50.7)	15 (45.5)	
Unstable angina	205 (26.1)	183 (26.4)	10 (30.3)	
non-STEMI	103 (13.1)	90 (13.0)	3 (9.1)	
STEMI	84 (10.7)	69 (9.9)	5 (15.2)	

Baseline Medications and Laboratory Findings

	Overall (786Pts)	No-DoCE (694Pts)	DoCE (33Pts)	P-value
Laboratory data				
TC, mg/dl	175.0±43.1	173.8±42.5	191.4±54.8	0.046
LDL-C, mg/dl	101.3±36.4	100.1±36.0	119.1±46.5	0.013
HDL-C, mg/dl	45.5±14.9	45.6±15.0	43.6±15.0	0.514
TG, mg/dl	150.8±112.9	113.2±79.4	134.2±94.7	0.207
HbA1c, %	6.5±1.5	6.5±1.5	6.7±1.2	0.687
Scr, mg/dl	1.2±1.5	1.1±1.4	1.1±0.7	0.518
LVEF, %	60.0±11.2	60.0±11.4	58.4±8.6	0.491
Medication at discharge				
Aspirin	888 (98.7)	687 (99.0)	32 (97.0)	0.312
ADP receptor antagonist	846 (94.0)	657 (94.7)	33 (100)	0.404
DAPT	844 (93.8)	657 (94.7)	33 (100)	0.404
Statin	812 (90.2)	631 (90.9)	30 (90.9)	1.000
ACE-I/ARB	506 (56.2)	384 (55.3)	23 (69.7)	0.110
Beta blocker	556 (61.8)	435 (62.7)	25 (75.8)	0.143

Baseline Angiographic Characteristics

	Overall (n=900)	No-DoCE (n=795)	DoCE (n=39)	P-value
Lesion location				0.950
RCA	265 (29.4)	230 (28.9)	12 (30.8)	
LAD	476 (52.9)	421 (53.0)	21 (53.8)	
LCX	155 (17.2)	140 (17.6)	6 (15.4)	
LMT	4 (0.4)	4 (0.5)	0 (0)	
ACC/AHA lesion class				0.539
A/B1	510 (56.7)	448 (56.4)	24 (61.5)	
B2/C	390 (43.3)	347 (43.6)	15 (38.5)	
Baseline TIMI grade 3	768 (85.3)	681 (85.7)	34 (87.2)	0.790
Baseline QCA analysis				
Minimal lumen diameter, mm	0.9±0.5	0.9±0.5	1.0±0.6	0.795
% diameter stenosis, %	67.1±17.0	66.9±16.7	64.0±19.7	0.375
Proximal reference diameter, mm	2.9±0.5	3.0±0.5	2.9±0.6	0.511
Distal reference diameter, mm	2.7±0.5	2.7±0.5	2.5±0.6	0.056
Lesion length, mm	15.7±9.3	15.7±9.3	14.2±7.5	0.271

Procedural Characteristics

	Overall (n=900)	No-DoCE (n=795)	DoCE (n=39)	P-value
Number of stent	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.241
Multiple stent	246 (31.3)	220 (31.4)	12 (35.3)	0.730
Stent type				
BMS	138 (13.8)	122 (13.0)	14 (33.3)	0.003
DES	863 (86.2)	819 (87.0)	28 (66.7)	
SES	186 (18.6)	179 (19.0)	7 (16.7)	
PES	42 (4.2)	41 (4.4)	1 (2.4)	
ZES	131 (13.1)	124 (13.2)	2 (4.8)	
EES	343 (34.3)	319 (33.9)	13 (31.0)	
BES	161 (16.1)	156 (16.6)	5 (11.9)	
Stent diameter, mm	3.0 ± 0.4	3.0 ± 0.4	2.9 ± 0.5	
Stent length, mm	21.7 ± 7.3	21.8 ± 7.3	20.3 ± 6.5	0.145
Thrombectomy	32 (3.6)	28 (3.5)	2 (5.1)	0.605
Predilation	590 (65.6)	526 (66.2)	22 (56.4)	0.271
Stent overlapping	211 (23.4)	193 (24.3)	6 (15.4)	0.274
Final TIMI grade 3	887(98.6)	783 (98.5)	39 (100)	1.000
Angiographic SED	12 (1.3)	11 (1.4)	0 (0)	1.000
Instant haziness	14 (1.6)	12 (1.5)	1 (2.6)	0.609
Postprocedure QCA analysis				
Minimal lumen diameter, mm	2.7 ± 0.4	2.7 ± 0.4	2.6 ± 0.5	0.241
% diameter stenosis, %	8.2 ± 7.6	8.1 ± 6.9	8.2 ± 7.2	0.909
Proximal reference diameter, mm	3.1 ± 0.6	3.1 ± 0.6	3.0 ± 0.7	0.286
Distal reference diameter, mm	2.8 ± 0.6	2.8 ± 0.6	2.7 ± 0.6	0.350

Incidence of Post-stent OCT findings

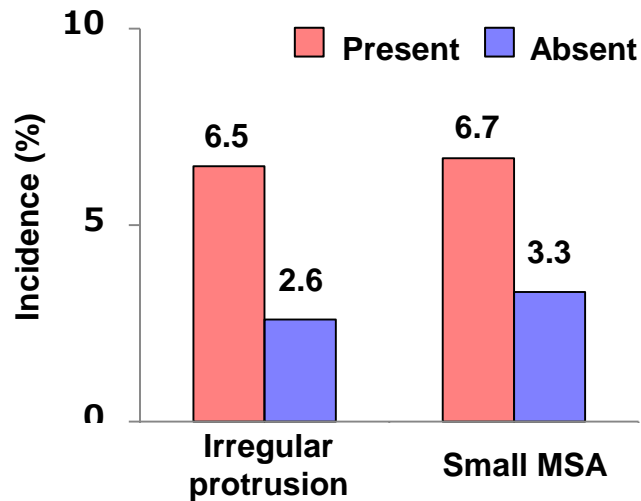
	Overall (n=900)	No-DoCE (n=795)	DoCE (n=39)	P-value
Stent edge dissection	258 (28.7)	230 (28.9)	12 (30.8)	0.789
Proximal stent edge dissection	142 (15.8)	125 (15.7)	9 (23.1)	0.202
Distal stent edge dissection	146 (16.2)	126 (15.8)	8 (20.5)	0.430
Instent dissection	603 (67.0)	535 (67.3)	24 (61.5)	0.488
Incomplete stent apposition	352 (39.1)	305 (38.4)	14 (35.9)	0.765
Instent tissue protrusion	870 (96.7)	767 (96.5)	39 (100)	0.636
Smooth protrusion	836 (92.9)	735 (92.5)	37 (94.9)	0.688
Disrupted fibrous tissue	549 (61.0)	490 (61.6)	21 (53.8)	0.330
Irregular protrusion	484 (53.8)	416 (52.3)	29 (74.4)	0.003
Thrombus	352 (39.1)	302 (38.0)	20 (51.3)	0.132
Severe stent underexpansion	337 (37.4)	296 (37.2)	13 (33.3)	0.656
Small MSA	364 (40.4)	321 (40.4)	23 (59.0)	0.039
Minimal stent area, mm ²	5.8±2.0	5.8±2.0	5.4±2.0	0.264
Minimal lumen area, mm ²	5.9±2.0	5.9±2.0	5.4±2.0	0.224
Proximal reference area, mm ²	7.8±3.1	7.8±3.0	7.2±3.2	0.392
Distal reference area, mm ²	6.3±2.7	6.3±2.7	5.9±2.9	0.429

Predictors of DoCE and TLR at 1-year Follow-up

Predictor	DoCE			TLR		
	HR	95% CI	P-value	HR	95% CI	P-value
LDL-cholesterol at baseline	1.02	1.00 – 1.03	0.018	1.01	0.998 – 1.02	0.130
BMS	1.35	0.81 – 2.26	0.250	1.64	1.02 – 2.62	0.040
Irregular protrusion	4.12	1.73 – 9.85	0.001	5.03	1.82 – 13.86	0.002
Small MSA	2.84	1.17 – 6.92	0.021	2.57	1.05 – 6.27	0.038

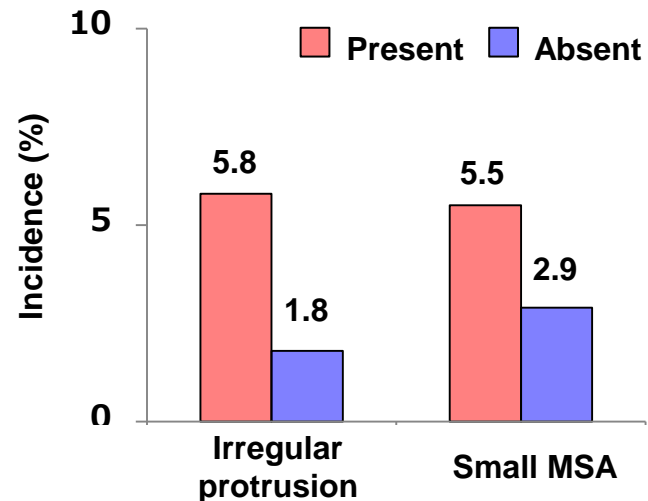
Incidence of DoCE and TLR

A. Device-oriented clinical endpoint



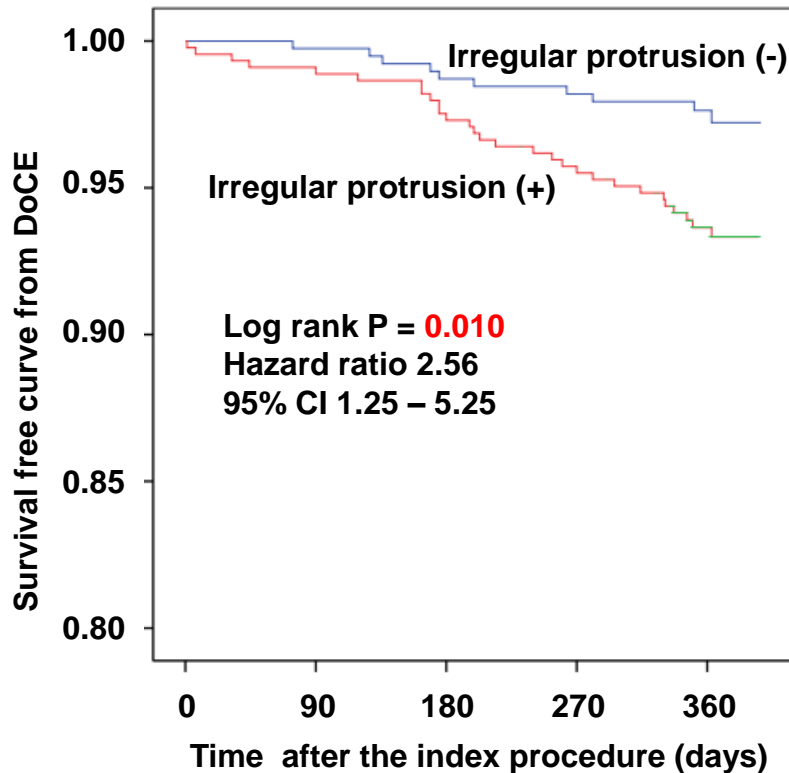
HR	4.12	2.84
(95%CI)	(1.73 – 9.85)	(1.17– 6.92)
P-value	0.001	0.021
Sensitivity	74.4	59.0
Specificity	47.7	59.6
PPV	6.5	6.7
NPV	97.4	96.7

B. Target lesion revascularization

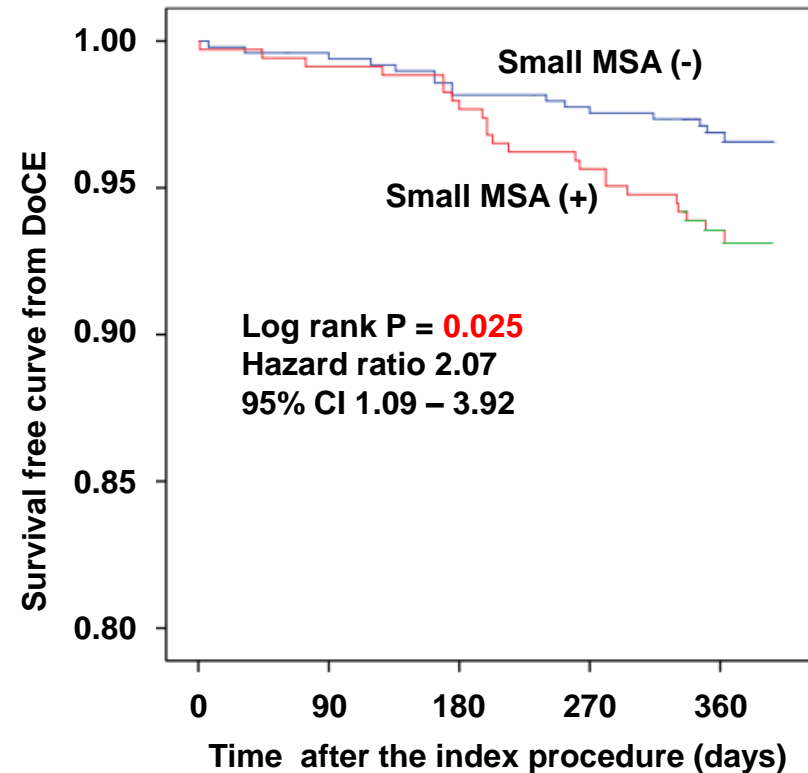


HR	5.03	2.57
(95%CI)	(1.82 – 13.86)	(1.05 – 6.27)
P-value	0.002	0.038
Sensitivity	78.8	57.6
Specificity	47.7	59.4
PPV	5.8	5.5
NPV	98.2	97.1

Survival Free Curve from DoCE

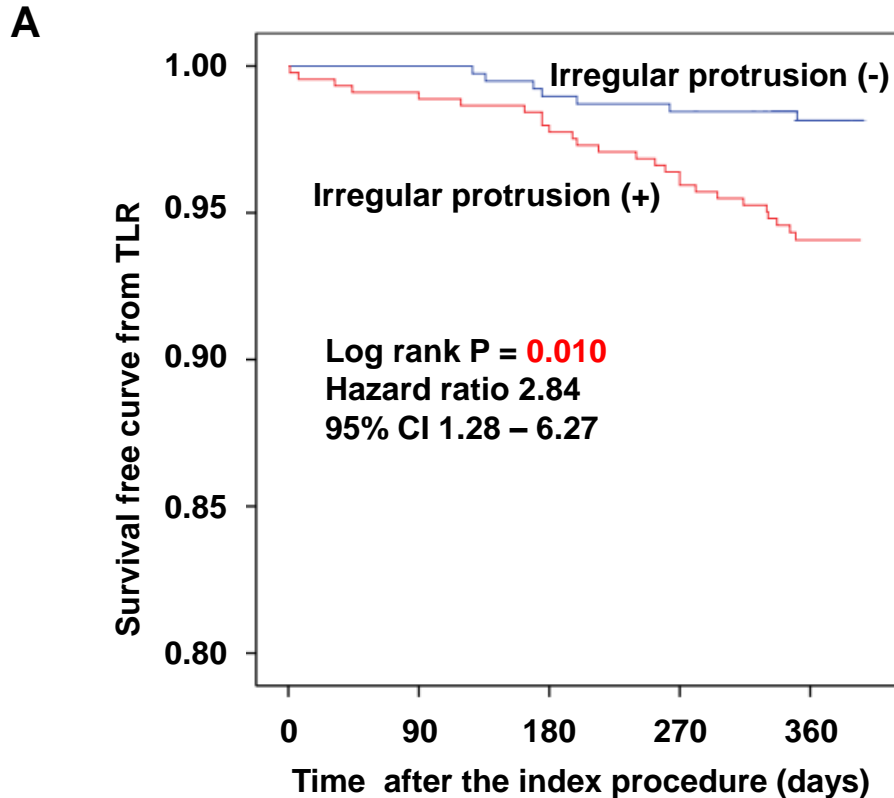


Number at risk			
	0	90	180
Irregular Protrusion (-)	389	383	273
Irregular Protrusion (+)	445	434	323

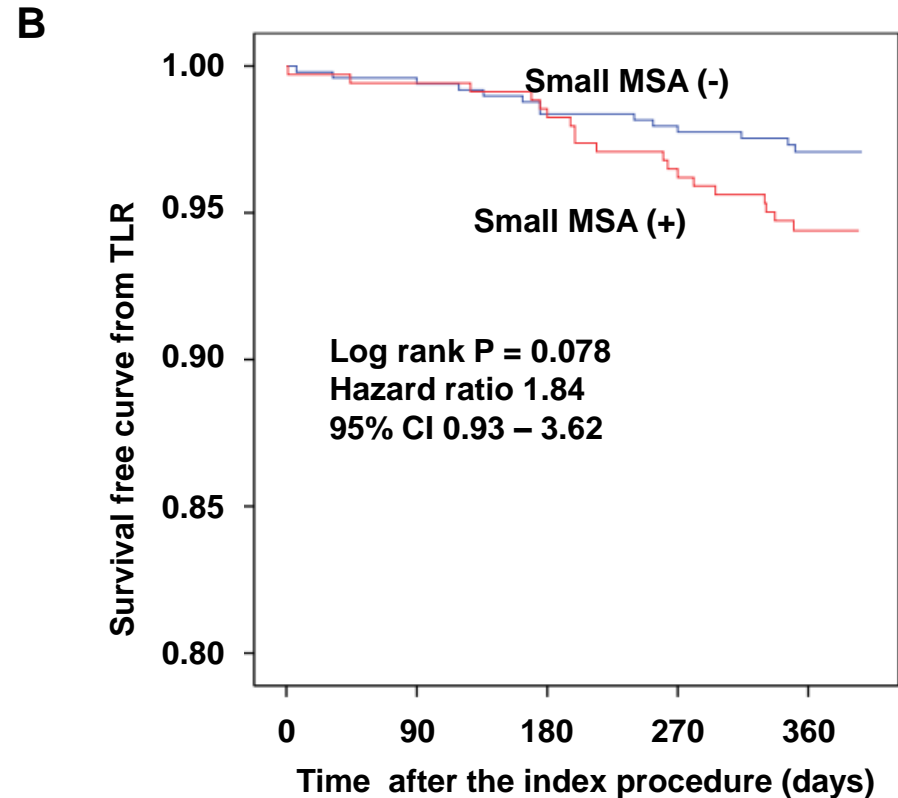


Number at risk			
	0	90	180
Small MSA (+)	490	480	360
Small MSA (-)	344	337	236

Survival Free Curve from TLR



Number at risk	0	90	180	270	360
Irregular Protrusion (-)	389	383	273		
Irregular Protrusion (+)	445	434	323		



Number at risk	0	90	180	270	360
Small MSA (+)	490	480	360		
Small MSA (-)	344	337	236		

Limitation

1. Retrospective analysis
2. Several different types of DES were included.
3. The classification of in-stent tissue protrusion was not validated by pathology. .
4. Low event rate at 1-year follow-up.

Conclusions

1. The incidence of abnormal OCT findings is high.
2. Irregular protrusion and small MSA assessed by OCT are independent predictors of DoCE at 1-year.

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Thank You