Do Malapposition, Stent Deformation and Fracture Link to Worse Clinical Outcome?

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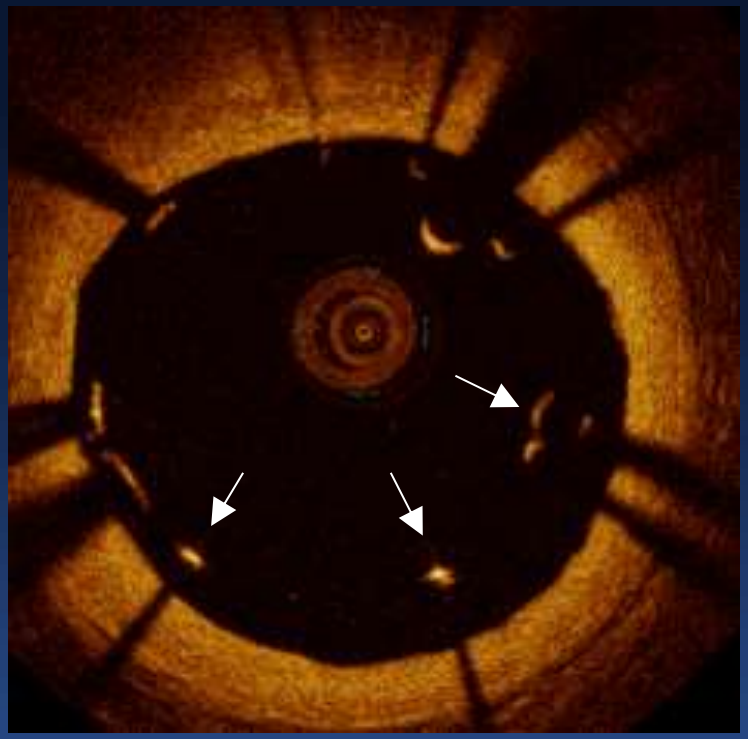
Conflict of Interest Disclosure

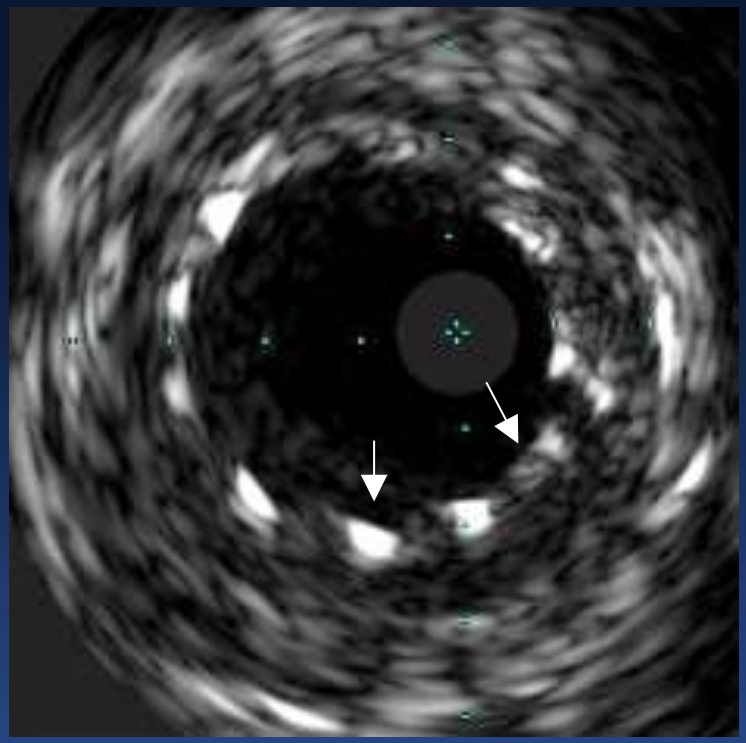
- Akiko Maehara
  - Personal: Consultant for ACIST, Boston Scientific Corporation, Speaker for St Jude Medical
  - Cardiovascular Research Foundation: Boston Scientific Corporation

Stent Strut Malapposition

OCT



IVUS



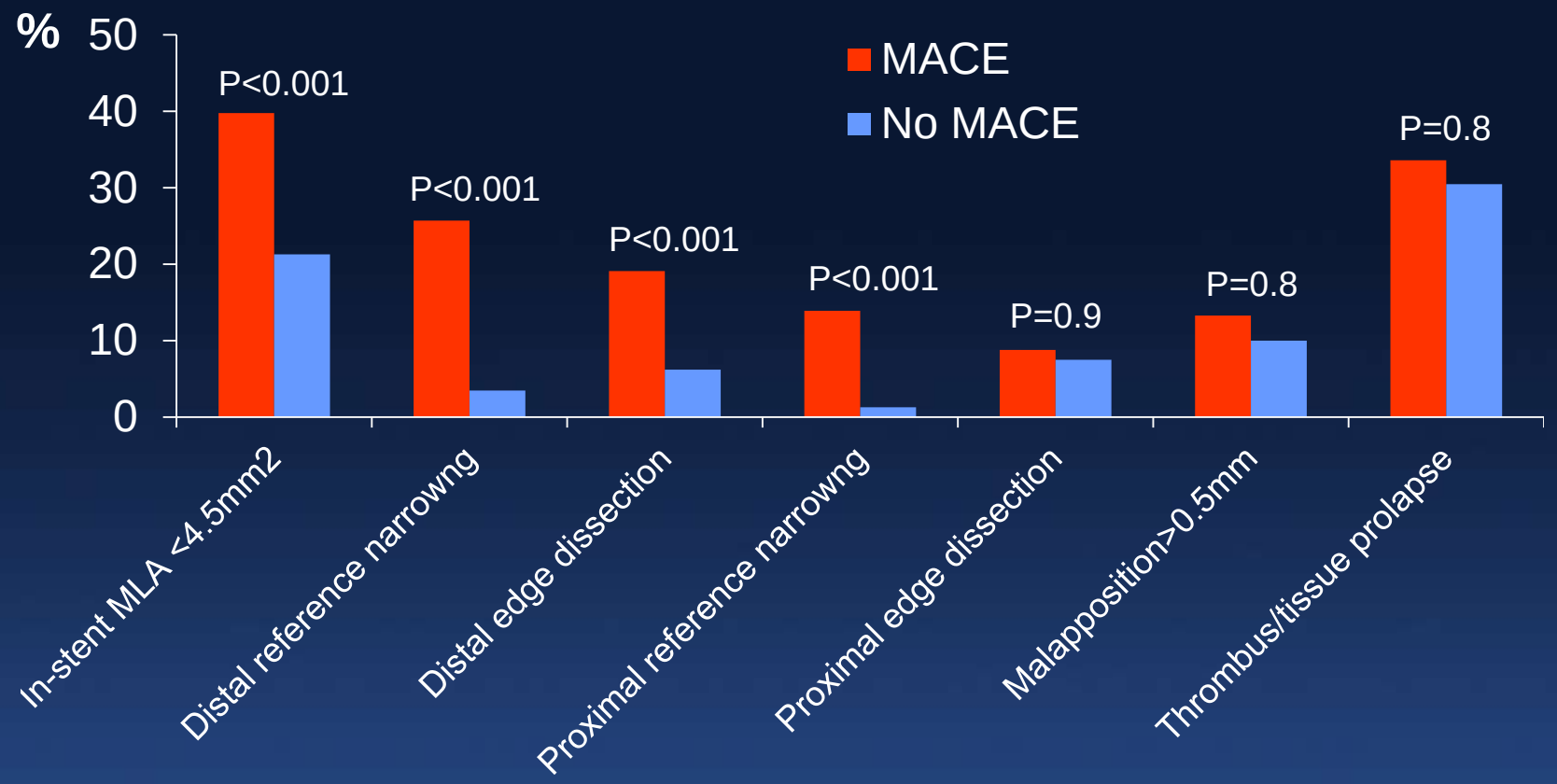
IVUS acute malapposition in ADAPT-DES

	Malapposition (N=209)*	No Malapposition (N=1773)	P-value
RCA	38.3% (118)	30.8% (658)	0.01
Total lesion length (mm)	32.0 ± 20.4	28.8 ± 19.4	0.008
Reference lumen area (mm^2)	10.6 ± 4.2	8.4 ± 3.3	<0.0001
Reference superficial calcium	52.6% (162)	44.3% (95)	0.007
Dense calcium volume, %	12.0 ± 7.2	10.3 ± 7.3	0.02
Necrotic core volume, %	24.1 ± 7.5	22.5 ± 8.0	0.05
Max superficial calcium (°)	136.5 ± 90.4	107.2 ± 82.0	0.0006
30-day MACE	0.67% (2)	0.45% (8)	0.62
30-day ST (definite/ probable)	0.67% (2)	0.23% (4)	0.19
2-year MACE	9.3% (57)	8.08% (140)	0.47
2-year ST (definite/ probable)	1.01% (3)	0.63% (11)	0.45
2-year MI	4.11% (12)	3.07% (53)	0.34
2-year TLR – Clinically driven	5.02% (15)	4.29% (76)	0.57

***The largest areas of malapposition were NOT associated with events**

Sousa et al. ACC 2014

929 pts (989 lesions) in CLI-OPI II registry
MACE (death, MI, ST, or TLR in 12.2%) @ 1 yr



Indepdent predictors of MACE were in-stent MLA <4.5mm^2, proximal or distal reference narrowing, or distal edge dissection

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Prati F et al. JACC Img 2015, 8: 1297-305.

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Frequency of acute stent malapposition

	Study	#	IVUS	OCT
Steinberg et al. JACC Cardiovasc Interv 2010;3:486-94	Combined TAXUS	1200	8%	
Guo et a. Circulation 2010;122:10-77-84	HORIZONS-AMI	263	36%	
Van der Hoven JACC Cardiovasc Interv 2008;1:192-201	MISSION-AMI	184	35%	
Sousa et al. ACC 2014	ADAPT-DES	1982	11%	
Bezerra et al. JACC Cardiovasc Interv 2013;6:228-36		26	42%	96%
Kubo et al. JACC Cardiovasc Imaging 2013;6:1095-1104	OPUS-CLASS	100	14%	39%
Im et al. Circ Cardiovasc Interv 2014;7:88-96		356		62%
Kawamori et al. EHJ Cardiovasc Imaging 2013;14:865-75		40		65%
Shimamura et al. EHJ Cardiovasc Imaging 2015;16:23-8		77		100%
Soeda et al. Circulation 2015;132:1020-9		1001		39%
Prati et al. JACC Cardiovasc Imaging, 2015; 8:1297-305	CLI-OPCI-II	1002		49%
Prati et al. unpublished	CLI-OPCI ACS	588		48%
Overall			**13%**	**49%**

Events and acute stent malapposition

	Study		Follow-up	Acute malapposition	No acute malapposition
Steinberg et al. JACC Cardiovasc Interv 2010;3:486-94	Combined TAXUS	IVUS	9 mos	8.2% MACE	10.7% MACE
Van der Hoven JACC Cardiovasc Interv 2008;1:192-201	MISSION-AMI	IVUS	9 mos	0% ST	0% ST
Guo et a. Circulation 2010;122:10-77-84	HORIZONS-AMI	IVUS	13 mos	0% ST	0% ST
Sousa et al. ACC 2014	ADAPT-DES	IVUS	2 yrs	9% MACE (1.0% ST)	8% MACE (0.6% ST)
Soeda et al. Circulation 2015;132:1020-9		OCT	1 yr	4.4% DoCE	4.8% DoCE
Prati et al. JACC Cardiovasc Imaging, in press	CLI-OPCI-II	OCT	1 yr	13% MACE	10% MACE
Prati. Unpublished	CLI-OPCI-ACS	OCT	9 mos	12.8% MACE	12.4% MACE

Study	Lesions	Follow-up	%LSM	Reference
Studies reporting a relationship between LSM & *subsequent* *VLST*				
Berne	221 (SES+PES)	5 years	18%	*Eur Heart J 2012;33:1334-43*
MISSION-AMI*	184 (SES+BMS)	5 years	38%	*Eurointervention 2012;7:1021-9*
Studies reporting NO relationship between LSM & *subsequent* *VLST*				
AMC	705 (SES+PES)	3 years	12%	*J Am Coll Cardiol 2007;50:1515-6*
RAVEL, SIRIUS, E-SIRIUS	180 (SES)	4 years	25%	*Heart 2008;94:322-8*
TAXUS IV, V, VI, Atlas Workhorse, LL, Direct Stent	548 (PES)	3 years	6%	*J Am Coll Cardiol Intv 2010;3:486-94*
HORIZONS-AMI*	286 (PES+BMS)	4 years	45%	*J Am Coll Cardiol 2012;59:A74-A75*
Yonsei	356 (SES, EES, ZES, BES)	2 years	28%	*Circ Cardiovasc Interv 2014;7:88-96*
Hur	205 (EES, SES)	1 year	11%	*Eurointervention, in press*

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***combined DES and BMS in the analysis**

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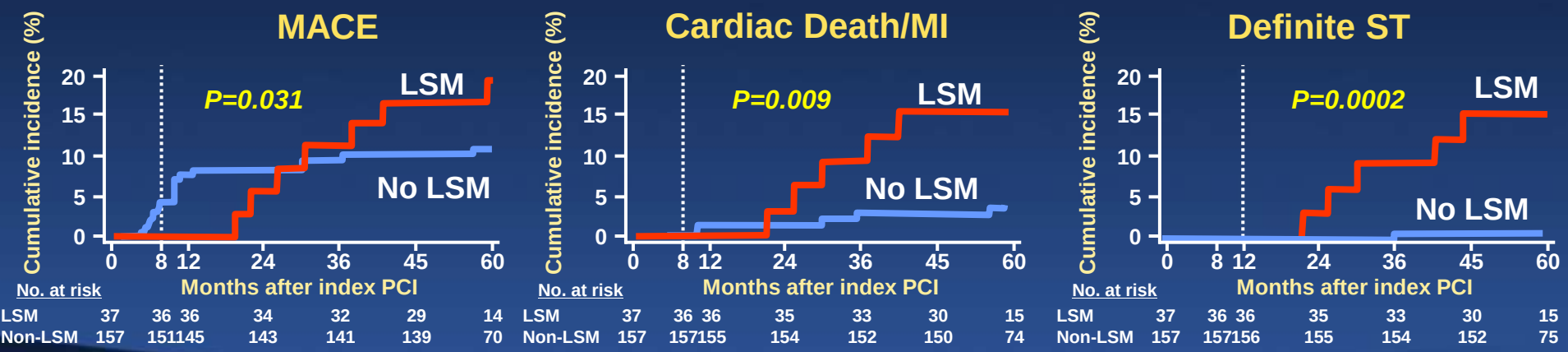
Frequency of late stent malapposition in pts presenting with late/very late ST

	Study	LST/VLST (#)	LSM (#)	
			IVUS	OCT
Cook et al. Circulation 2007;115:2426-34		13	10 (77%)	
Cook et al. Circulation 2009;120:391-9		11	8 (73%)	
Guagliumi et al. JACC Cardiovasc Intervent 2012;5:12-20		18	14 (78%)	
Kosonen et al. Int J Cardiol 2013;168:1010-6	NORDIC-IVUS	91	36 (40%)	
Kang et al. JACC Cardiovasc Imaging 2013;6:695-703		33		14 (42%)
Lee et al. J Am Coll Cardiol. 2010;55:1936-42		30	17 (57%)	
Ko et al. Int J Cardiovasc Imaging 2012;28:715-23		18		7 (39%)
Amabile. ESC 2015	PESTO	97		31 (32%)
Overall		**311**	**137 (44%)**	

Events 5 years after LSM is detected at 8 months post-DES implantation

	LSM at 8 mos*	No LSM at 8 mos	HR	P-value
Pts	37	157		
Cardiac death	0	1.3%	0.83	1.0
MI	13.5%	1.9%	7.53	0.001
Cardiac death/MI	13.5%	3.8%	3.75	0.019
TLR	16.2%	4.5%	3.6	0.013
MACE	18.9%	7.0%	2.71	0.031
Definite/probable ST	13.5%	1.3%	11.6	0.0002

*LSM measured 4.6±5.0mm^2



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Cook et al. Eur Heart J 2012;33:1334-43

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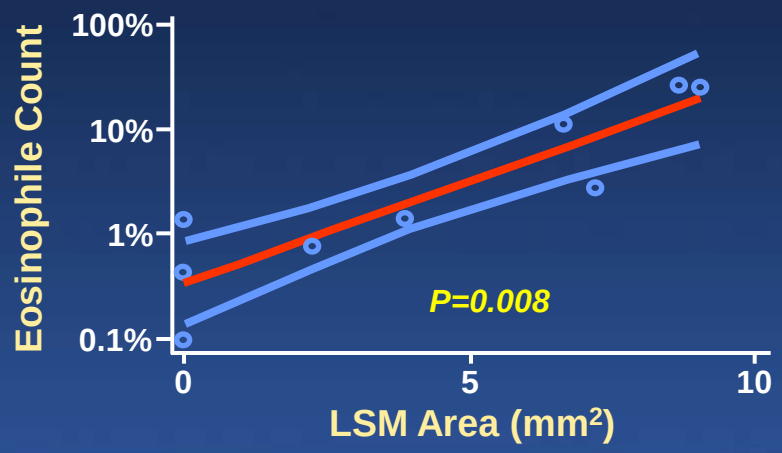
Correlation of IVUS Findings With Aspirates in 28 Pts with Very Late DES Thrombosis

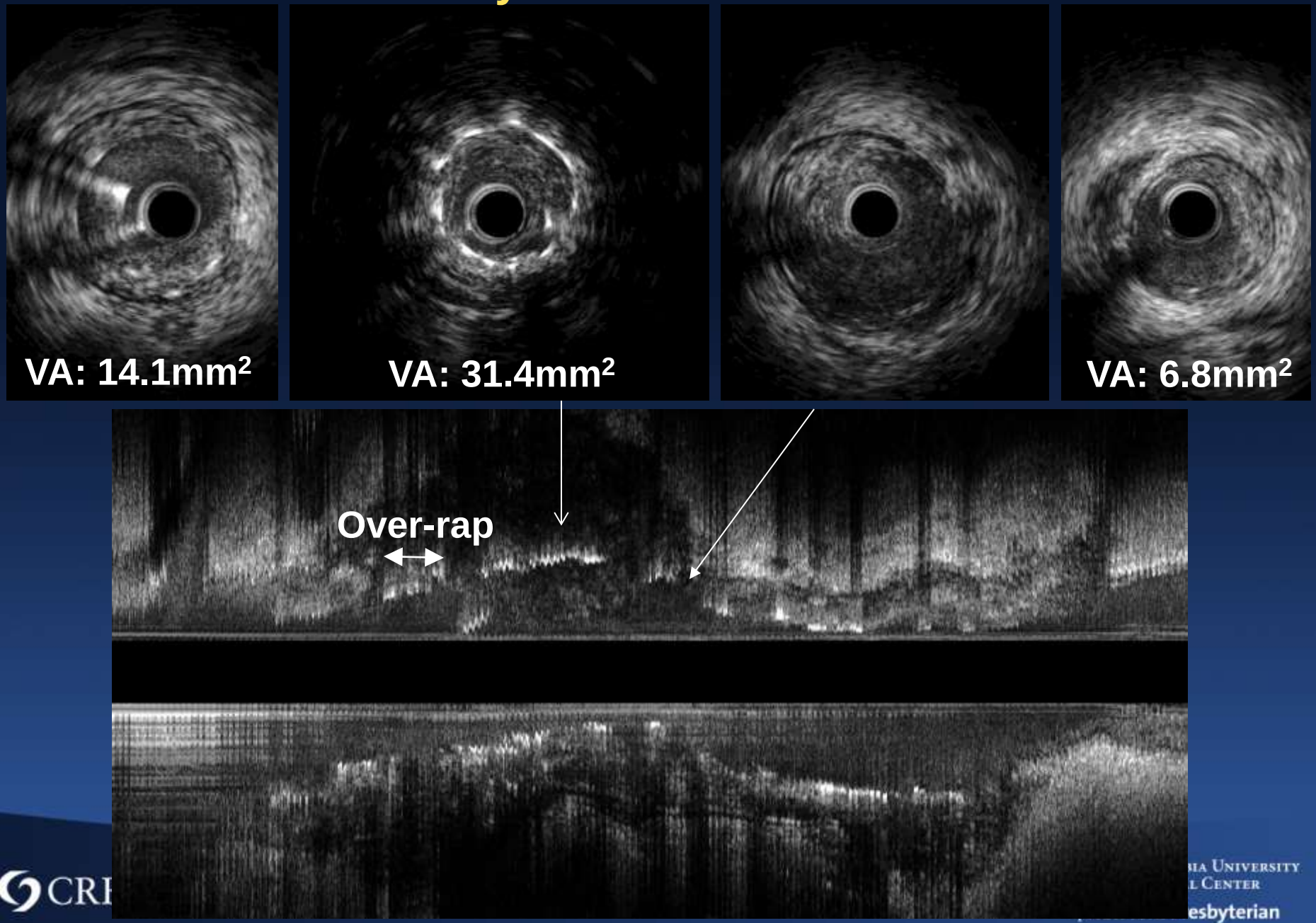
- **LSM was present in 73% of very late DES ST. Maximal LSM area measured 6.2±2.4mm² (>5mm² in 5/8) and length measured 9.4±9.5mm.**

	#	WBCs	p-ANOVA	Eosinophils	P-ANOVA
Controls	26		0.0001		0.038
Spontaneous MI	7	291±94		7±10	
Early ST-BMS	4	146±117		1±1	
Early ST-DES	10	73±117		1±2	
Very late ST-BMS	5	84±50		2±3	
Very late ST-DES	**28**	**283±149**		**20±24**	



Cook et al. Circulation 2009;120:391-9

Prox ref | Aneurysm | Stent fracture | Distal ref



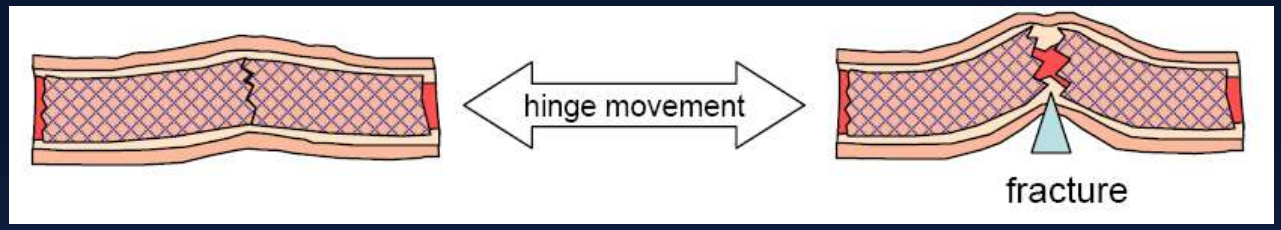
Nordic IVUS Study (NIDUS): A registry of 124 stent thrombosis cases (87 DES, 37 BMS)

	#	Stent fracture	Stent malapposition
DES thrombosis			
Acute/Early	20	2 (15%)	6 (30%)
Late	6	0 (0%)	1 (17%)
Very Late	61	10 (16%)	32 (52%)
BMS thrombosis			
Acute/Early	13	4 (20%)	7 (54%)
Late	5	0	0
Very Late	19	7 (37%)	3 (16%)

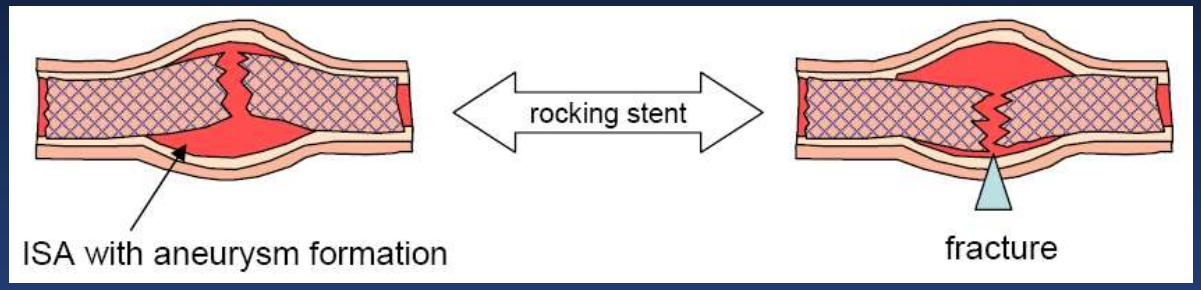
Kosonen et al. Int J Cardiol 2013;168:1010-6

Three Mechanisms of Stent Fracture

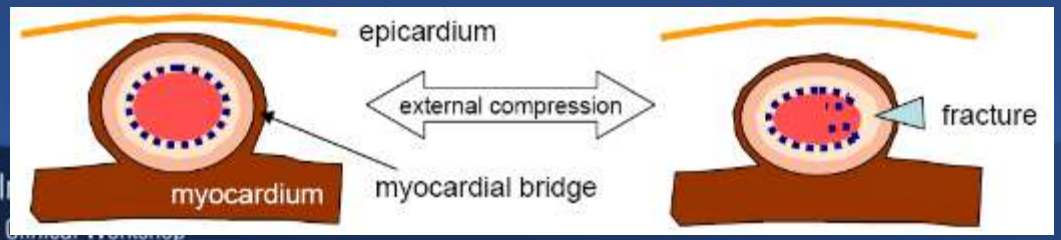
Type I: Stent Fracture in the Lesion With Neither Aneurysm Nor Myocardial Bridge (n=14).



Type II: Stent Fracture in An Aneurysm with Incomplete Apposition (n=5).



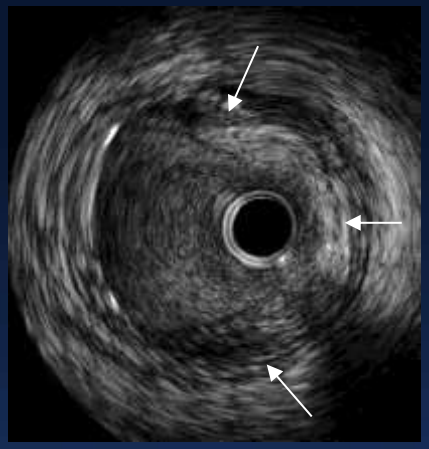
Type III: Stent Fracture in a Myocardial Bridge (n=1).



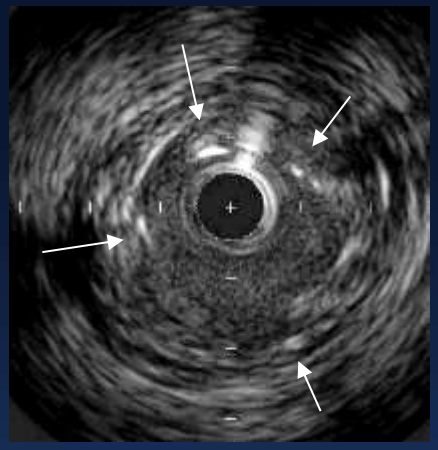
IVUS Classification of Fracture/Deformation

Complete

Partial

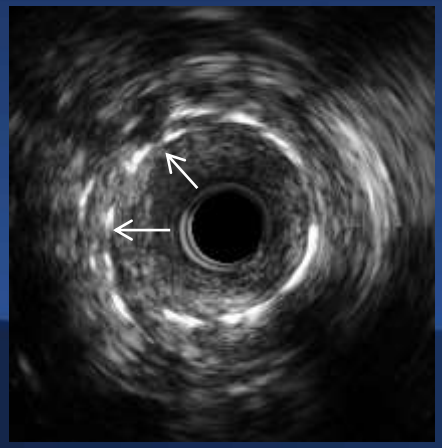


Mal-alignment



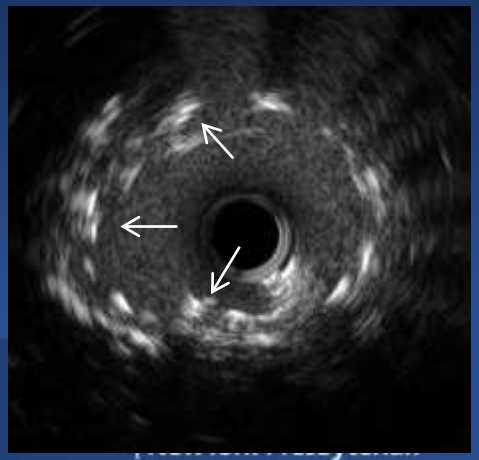
Fracture with Overlap

65% of EES Mechanical Complication



Deformation

12% of EES Mechanical Complication

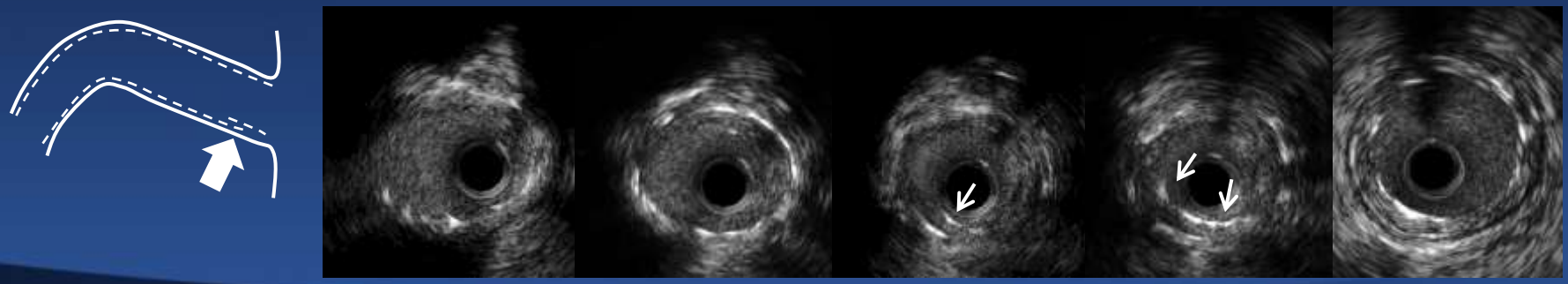


Fracture/Deformation of EES Relates to Restenosis

- 177 EES in 136 patients with follow-up IVUS (1.3 yrs)
- 17 pts (9.6%) with 15 TLR, angio visible fracture (29%)
- Fracture site: 36% smaller stent area than adjacent site

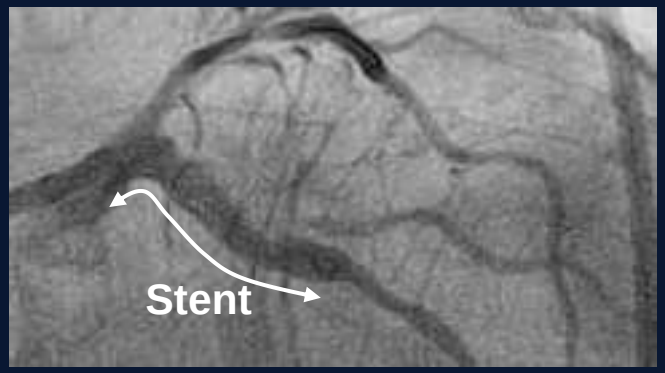
Baseline

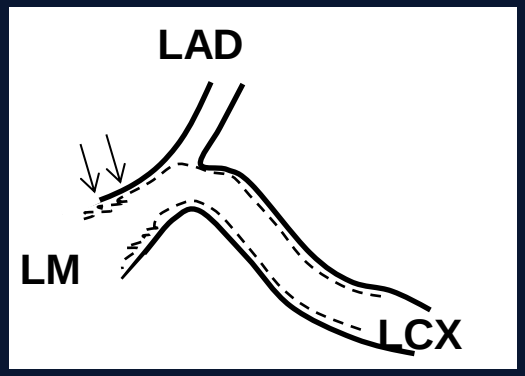
Follow-up

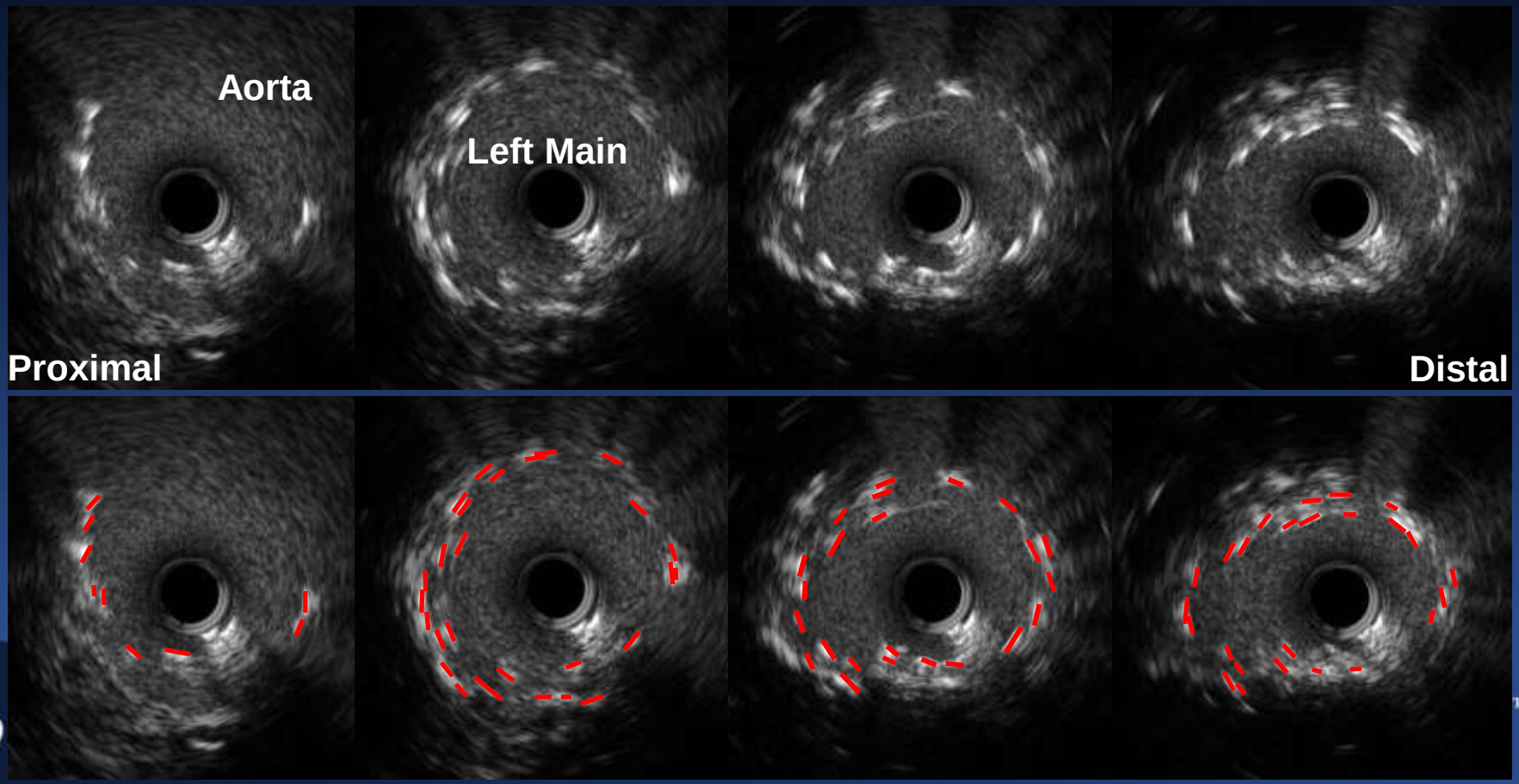


Inaba et al. EuroIntervention. 2014;9:1301-8.

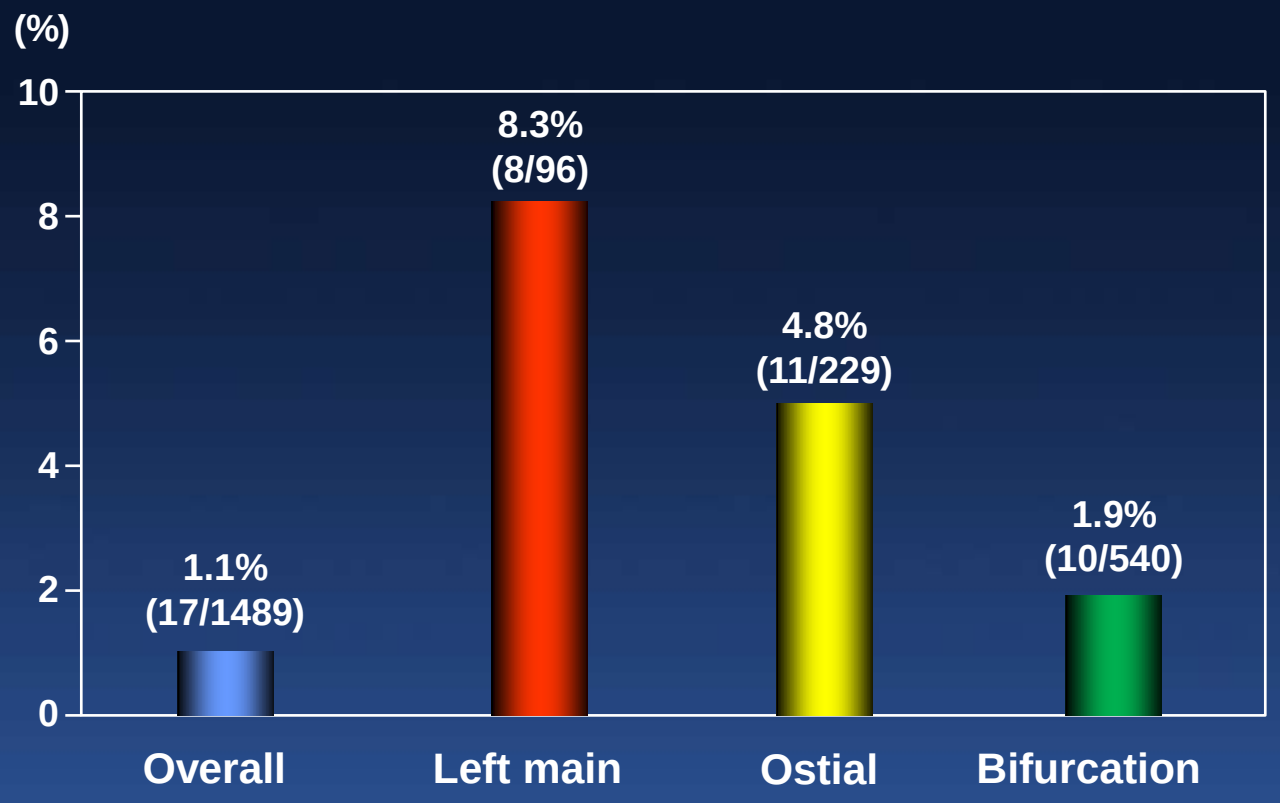
Stent Deformation







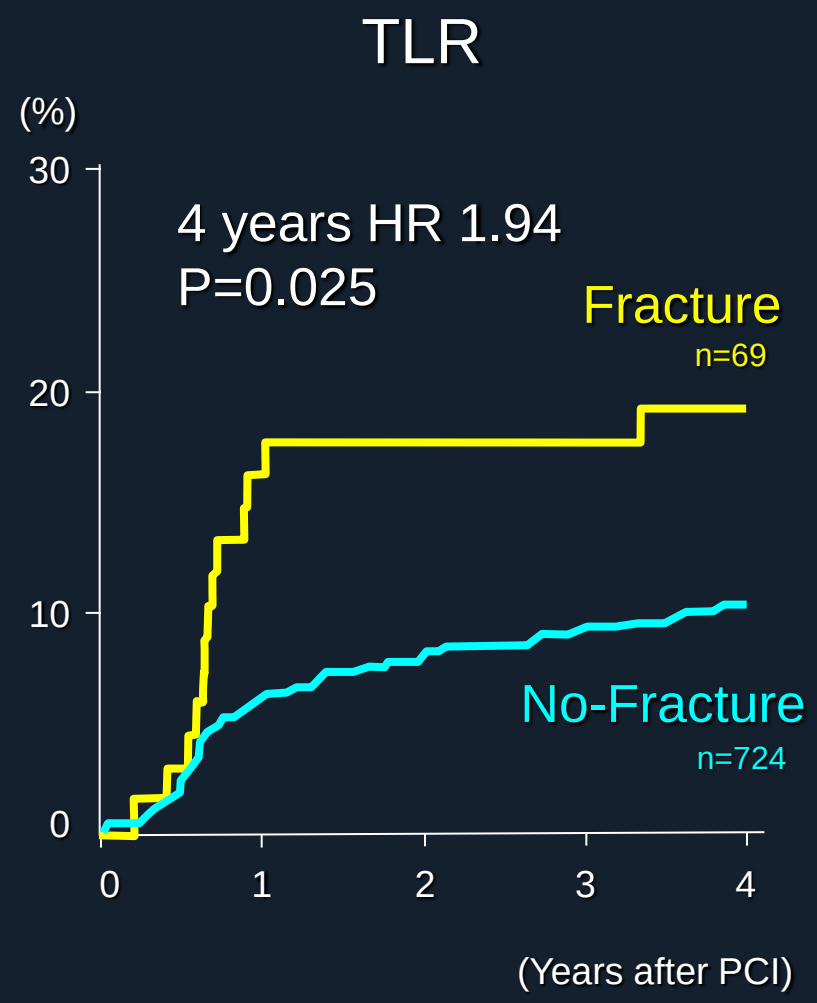
Incidence of Stent Deformation

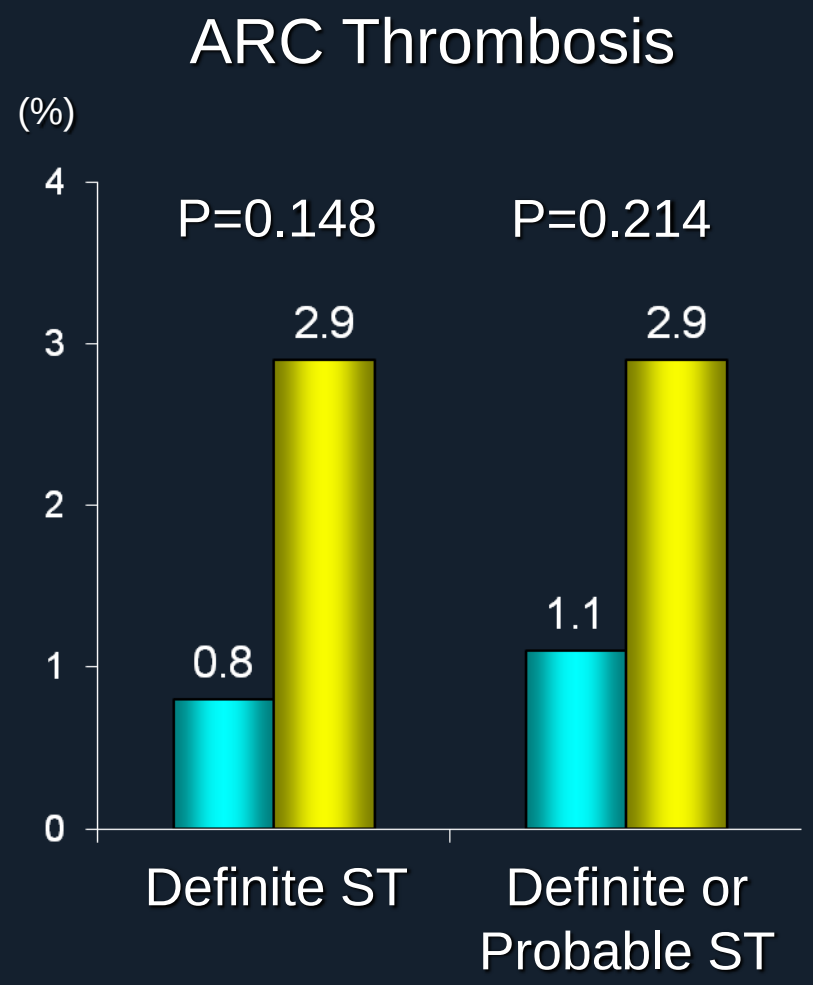


Inaba et al. *Catheter Cardiovasc Interv.* 2014;84:388-396

4-Year Outcomes of SES Strut Fracture

Stent fracture was observed in 8.0% of lesions (8.7% of pts) in 793 pts (874 lesions) undergoing SES implantation with 6-9 months angio follow-up.





Umeda H, et al. Circ Cardiovasc Interv 2011

Incidence and Clinical Impact of Stent Fracture After Cobalt Chromium (CoCr) EES Implantation

Retrospective analysis of 1,035 patients (1,339 lesions) with stable angina who underwent EES implantation at 2 Japanese centers with 6-9 months follow-up angio irrespective of clinical symptom.

9-Month Follow-up	Stent Fracture (n = 39)	No Fracture (n = 996)	*P* Value
MACE	25.6%	2.3%	< 0.001
TLR	25.6%	2.0%	< 0.001
Late Definite ST	5.1%	0.1%	0.004

Overall rate of stent fracture with EES was 3.8% of patients, 2.9% of lesions.

Conclusion: **The rate stent fracture after EES implantation, though low, is associated with increased MACE, TLR, and stent thrombosis.**

Kuramitsu S, et al. *Circ Cardiovasc Interv*.2012; 5: 663-671.

Incidence and Clinical Impact of Stent Fracture After Platinum Chromium (PtCr) EES Implantation

Retrospective analysis of 700 patients (898 lesions) with stable angina (85% of pts) who underwent EES implantation at Japanese center with 6-9 months follow-up angio irrespective of clinical symptom.

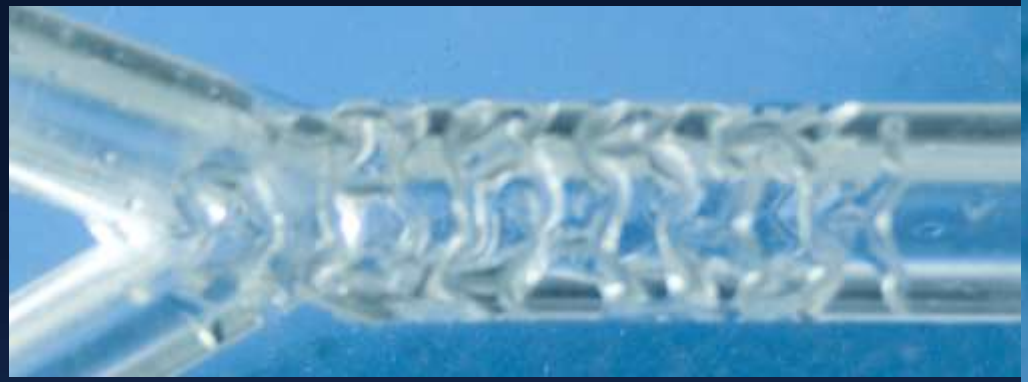
9-Month Follow-up	Stent Fracture (n = 16)	No Fracture (n = 684)	*P* Value
In-stent binary restenosis	56.2%	9.8%	< 0.001
Clinically driven TLR	18.7% (3)	2.3% (21)	NA
Definite ST	0% (0)	0.2% (2)	NA

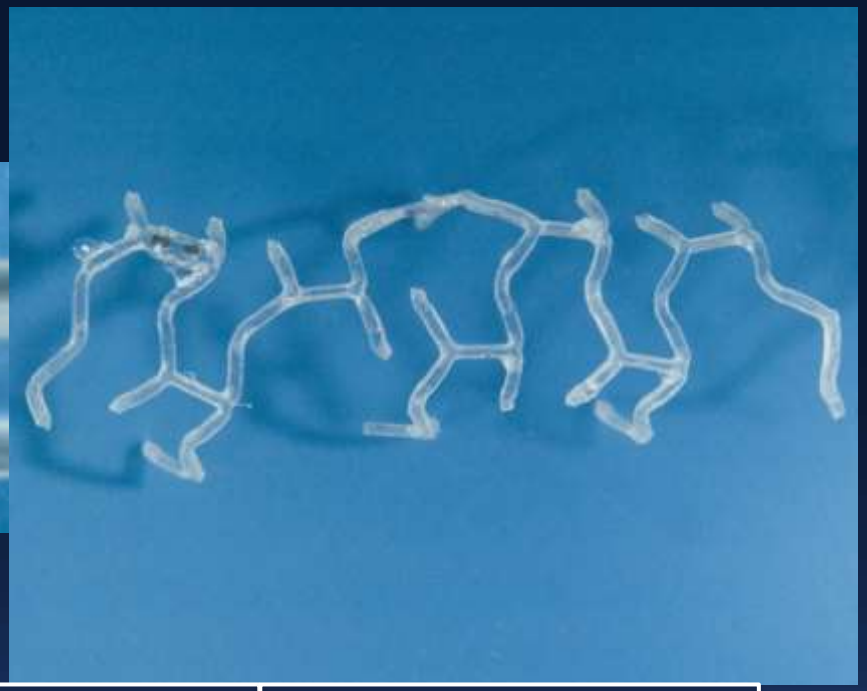
Overall rate of stent fracture with EES was 2.2% of patients, 1.7% of lesions.

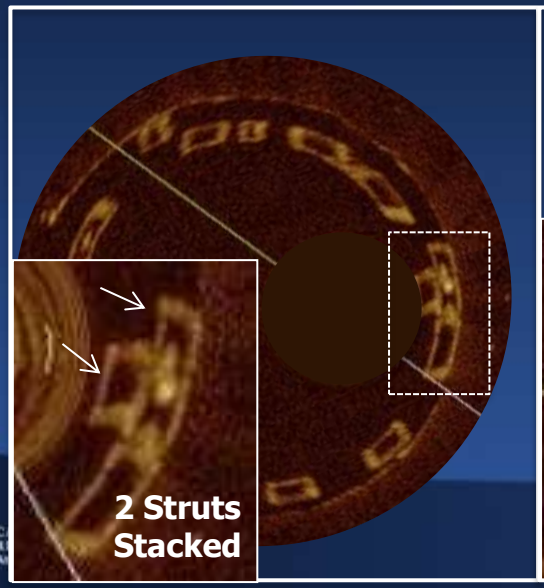
Conclusion: The rate stent fracture after EES implantation, though low, is associated with increased TLR.

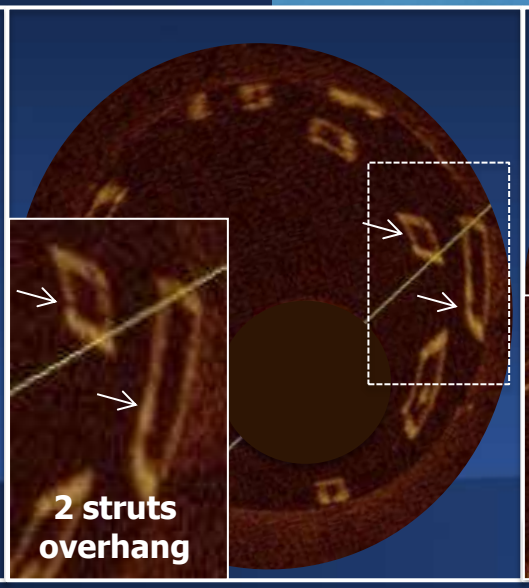
Kuramitsu S, et al. *JACC Interv* 2015: 8; 1180-8

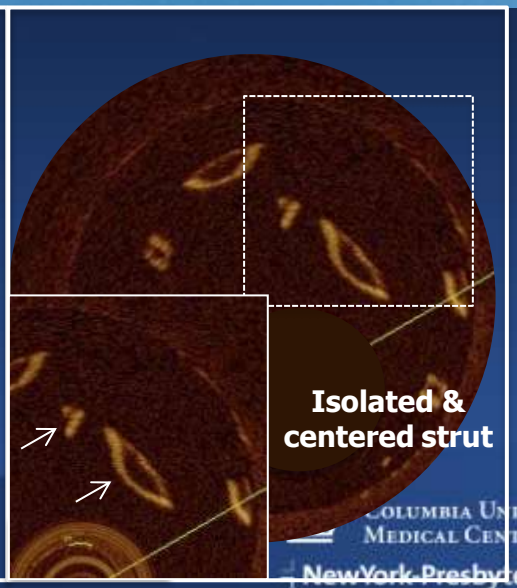
Induced Acute Fracture in a Phantom











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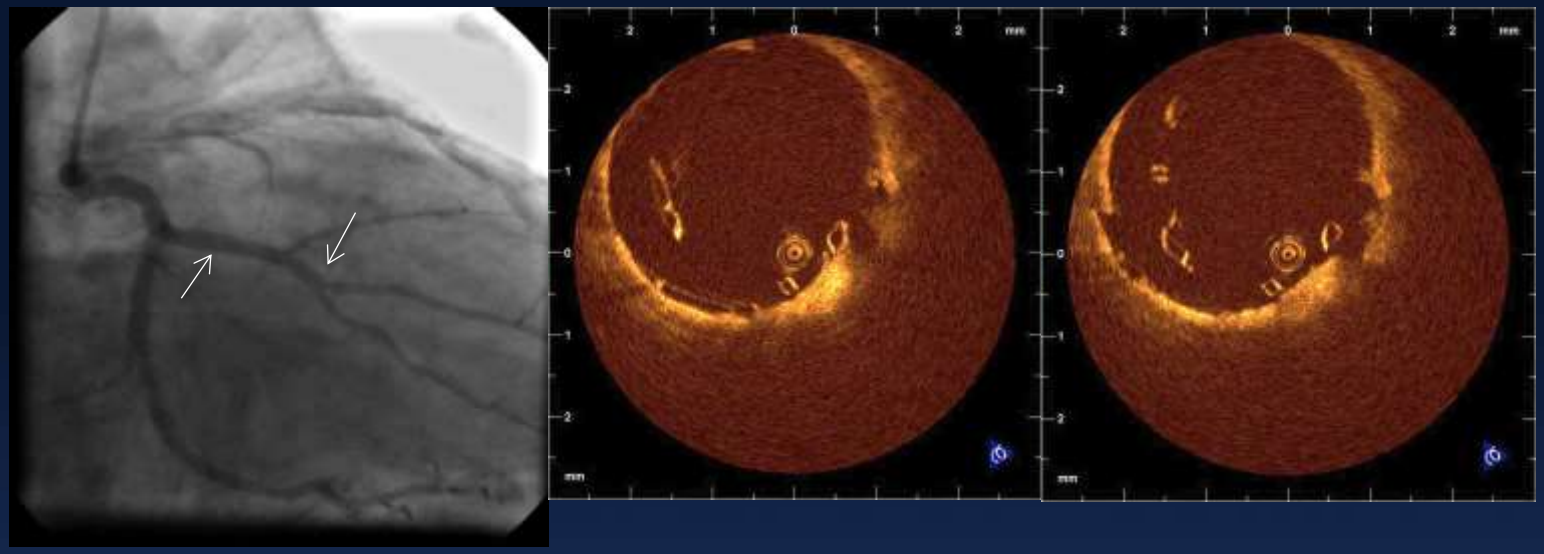
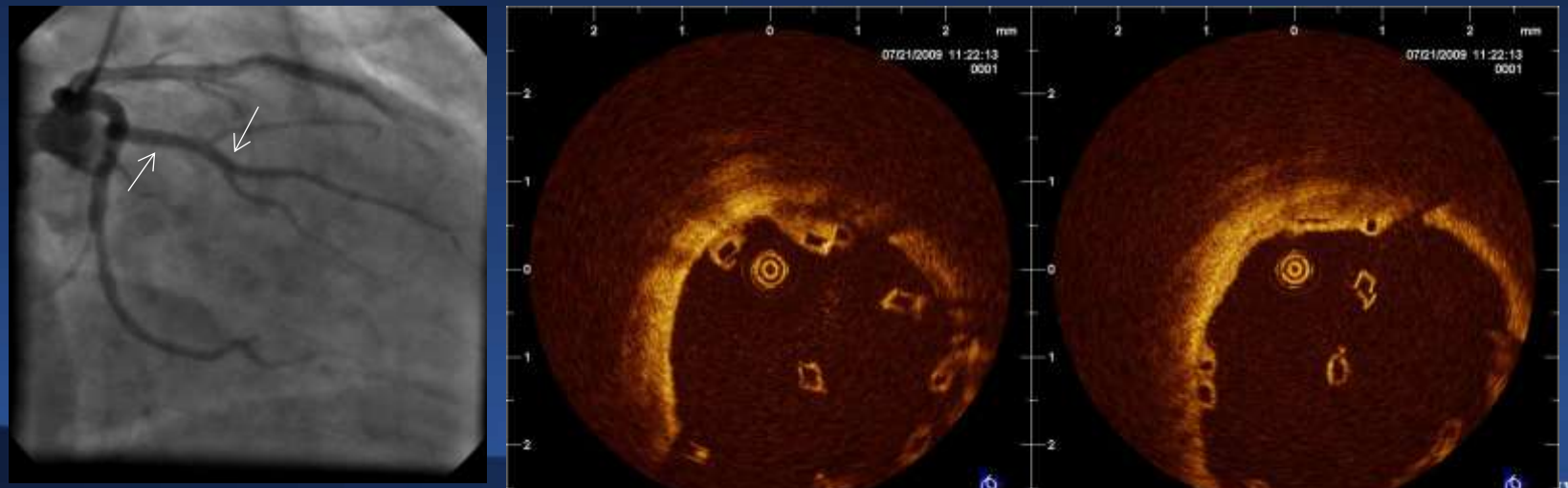
Acute Disruption 3.9% (2/51) in ABSORB Cohort B

Overexpansion of a 3.0 mm ABSORB by 3.5mm balloon with 16 atm (>3.96mm)

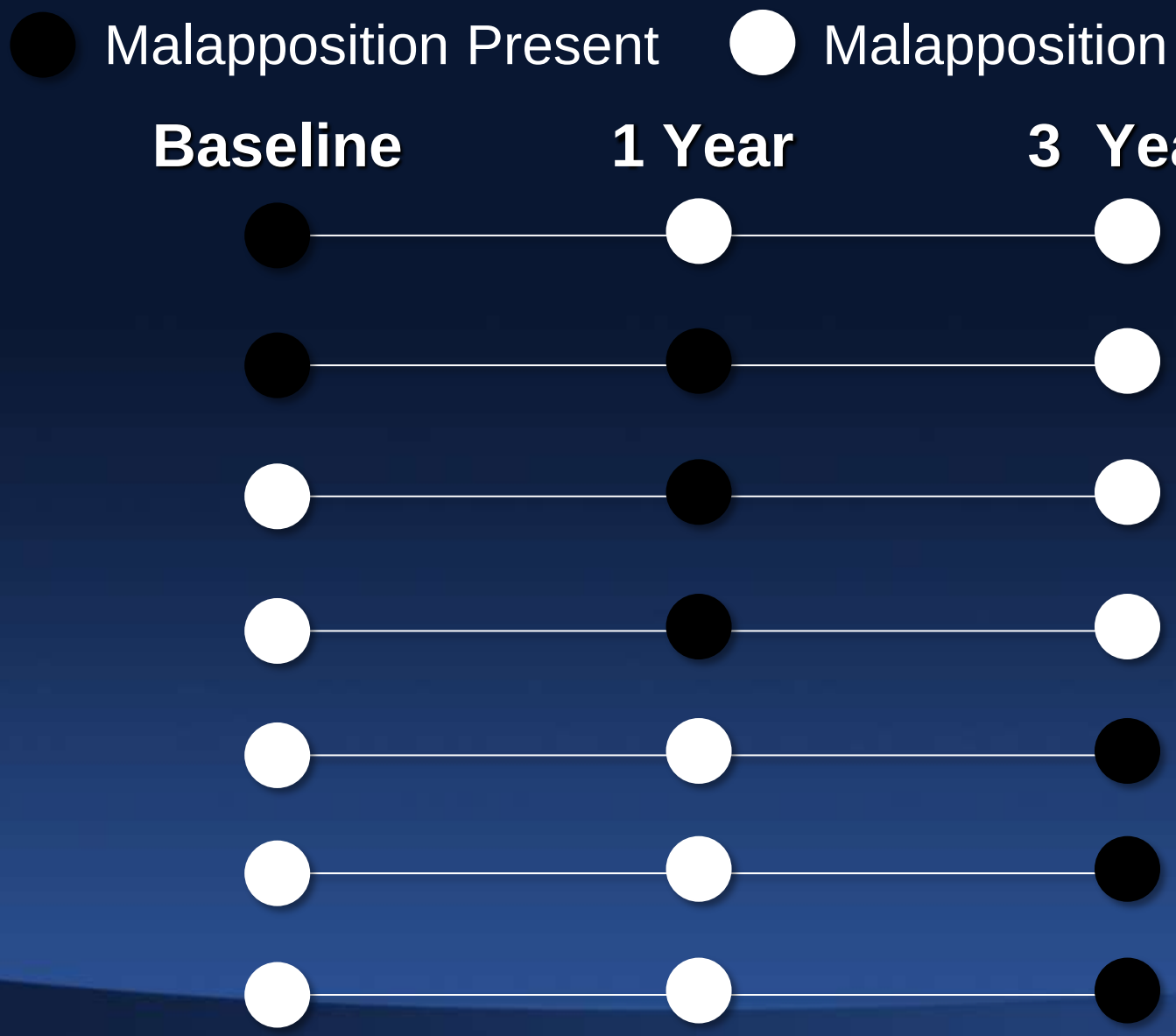


1M later the patient presented with recurrent angina at rest.



Ormiston et al. Circ interv 2012

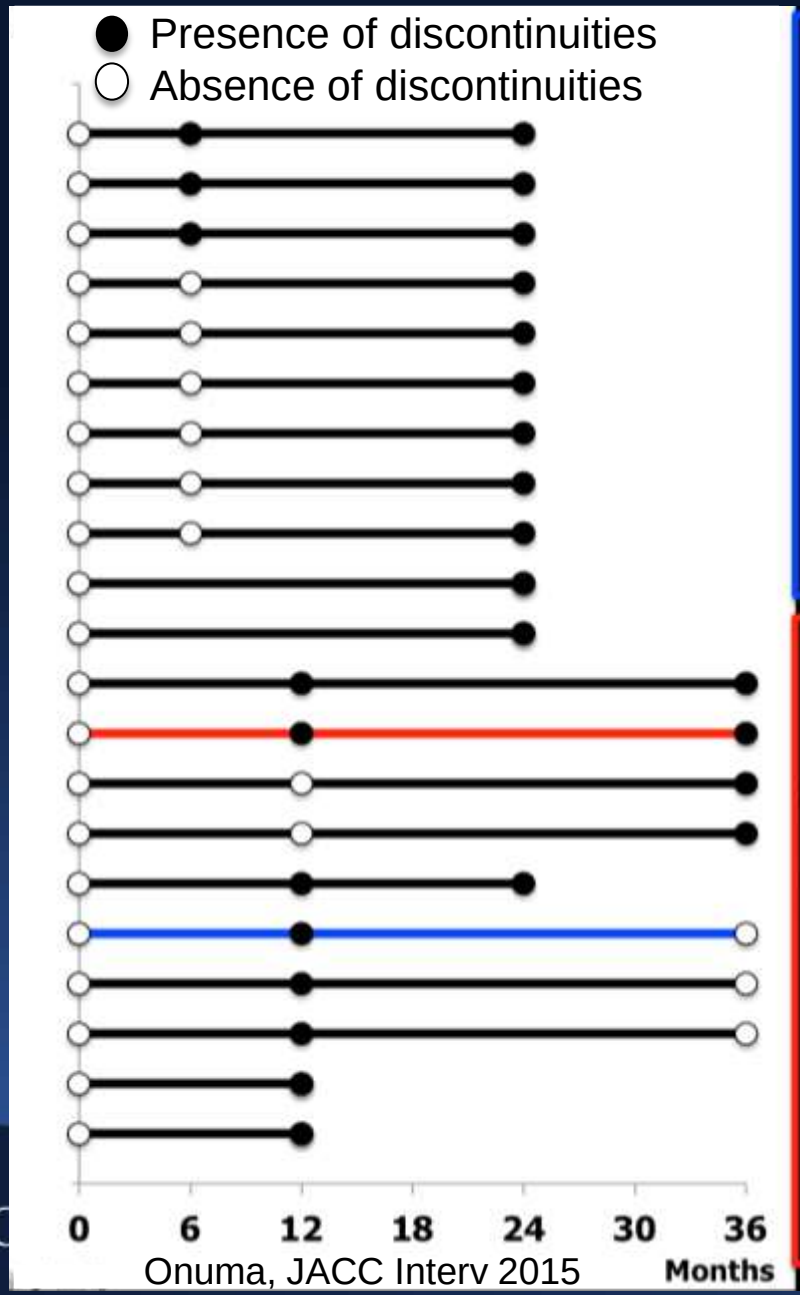
Malapposition in ABSORB B (7/43 patients)



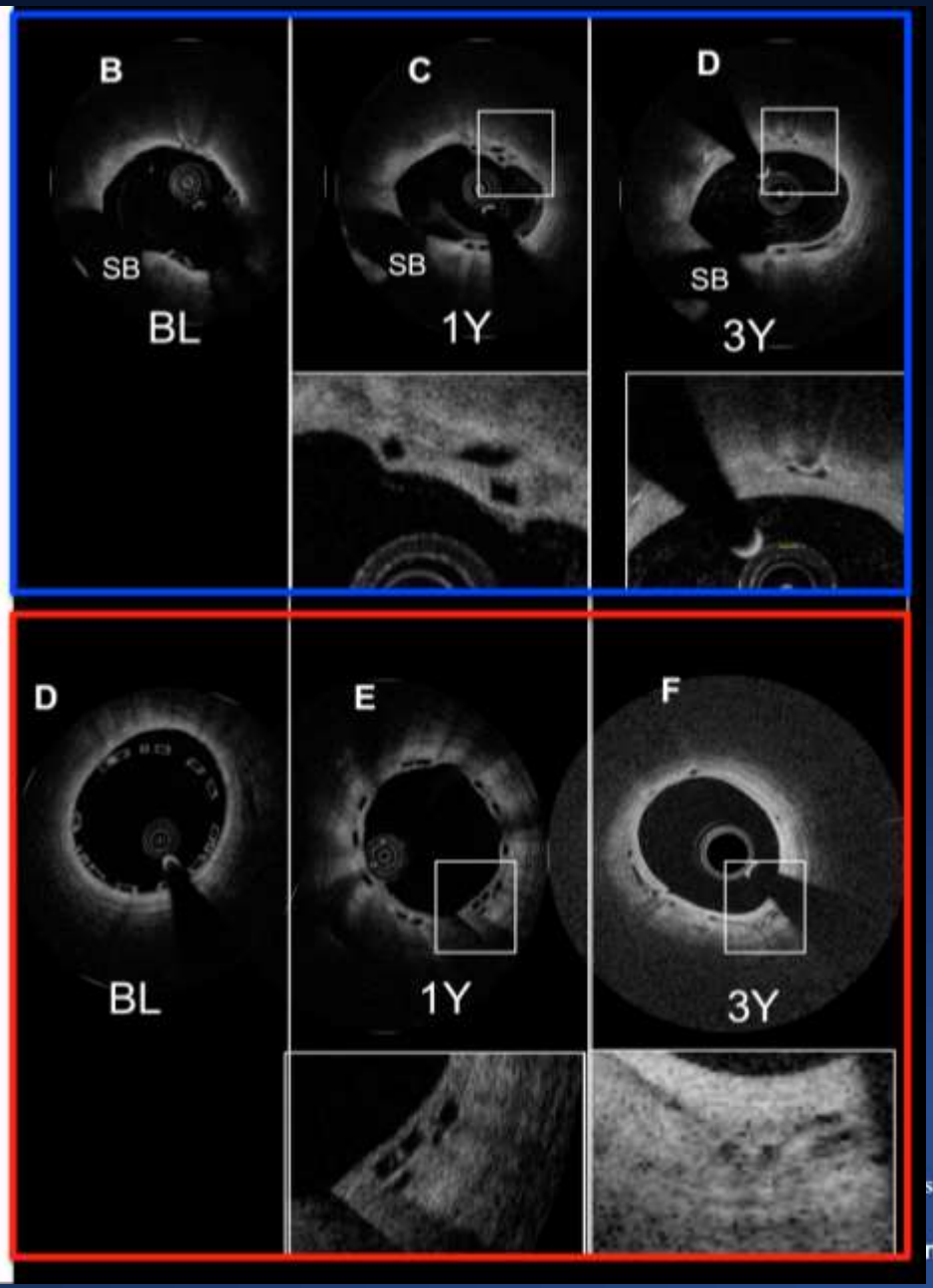
Max Malapposition Area=1.05±0.97mm^2

Serruys PW, et al. Eurointerv 2014

Summary of late discontinuities: Late discontinuities are observed in 21 out of 51 cases at different time points



Onuma, JACC Interv 2015



Take Home Message

1. As long as stent area is large enough, acute stent malapposition were NOT associated with the clinical outcome.
2. Large late acquired malapposition related to the adverse vessel reaction may be associated to the subsequent worse clinical outcome.
3. Though the rate stent fracture after EES implantation decreased (4%) from the rate of SES fracture (9%), fracture is still associated with increased TLR.
4. The outcome related to the malapposition and fracture in BVS needs further evaluation.