IVUS Optimization of PCI and Future Directions: A 25-Year Perspective

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<u>Prior</u> to the seminal <u>serial</u> IVUS studies, it was believed that chronic stent recoil was the cause of restenosis in stented lesions.

<u>After</u> the seminal <u>serial</u> IVUS studies, it was proved that intimal hyperplasia was the cause of restenosis in stented lesions and that underexpansion and other complications at the time of implantation were common

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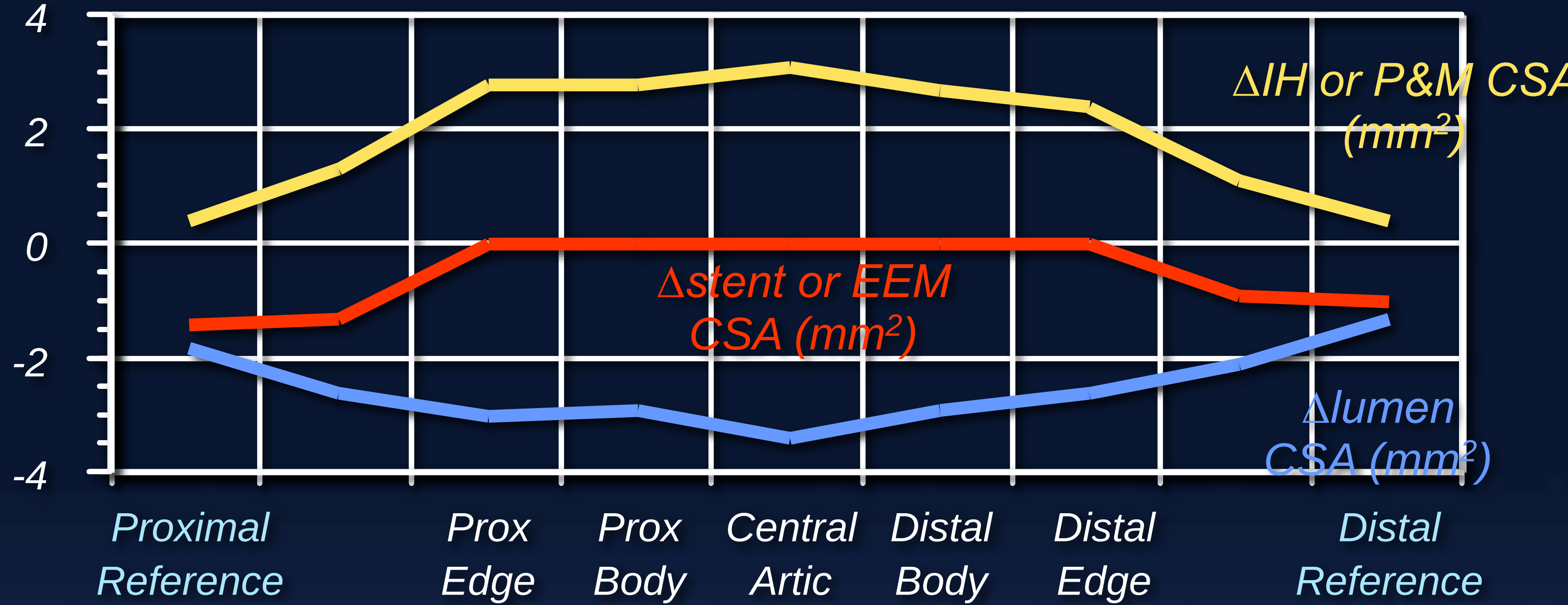
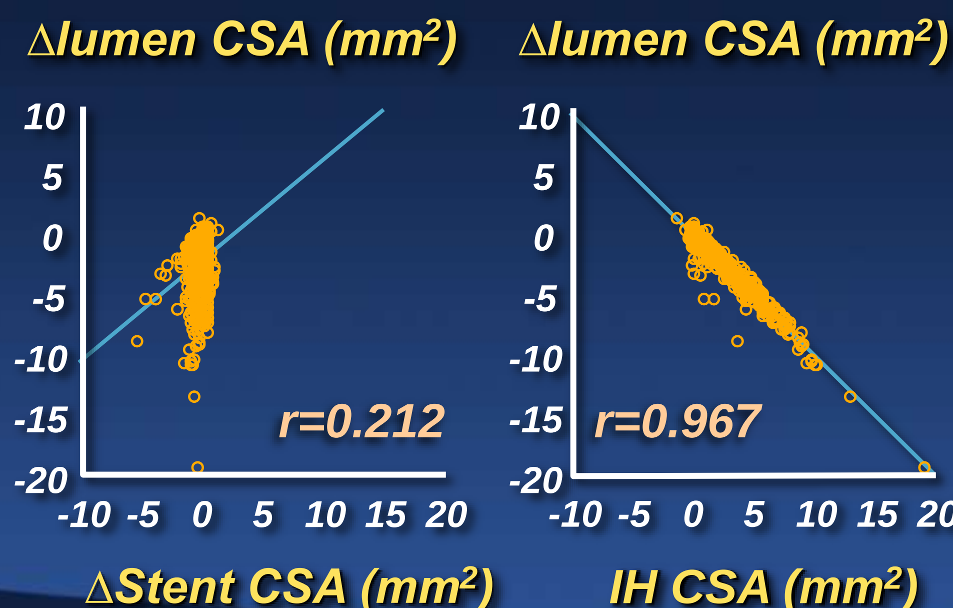
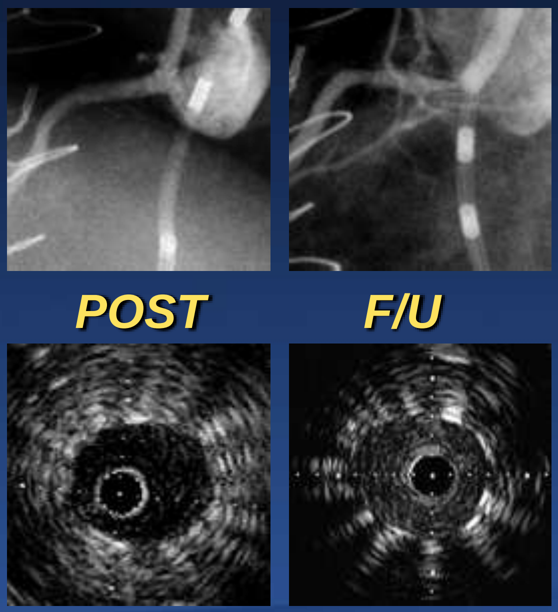


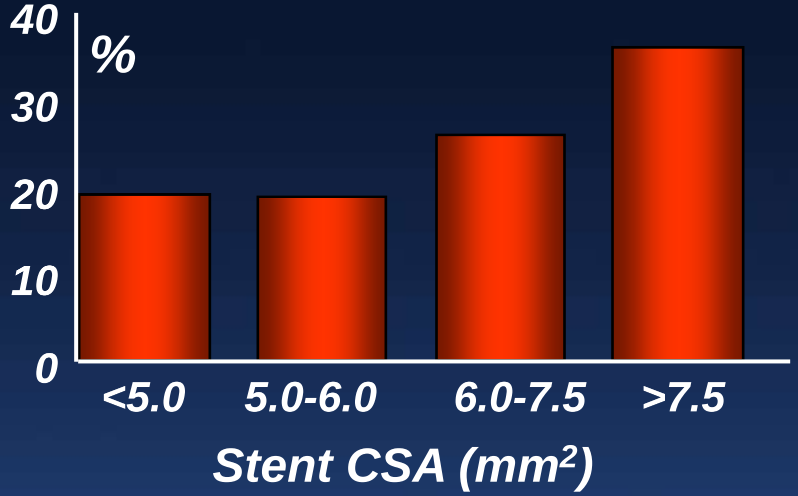


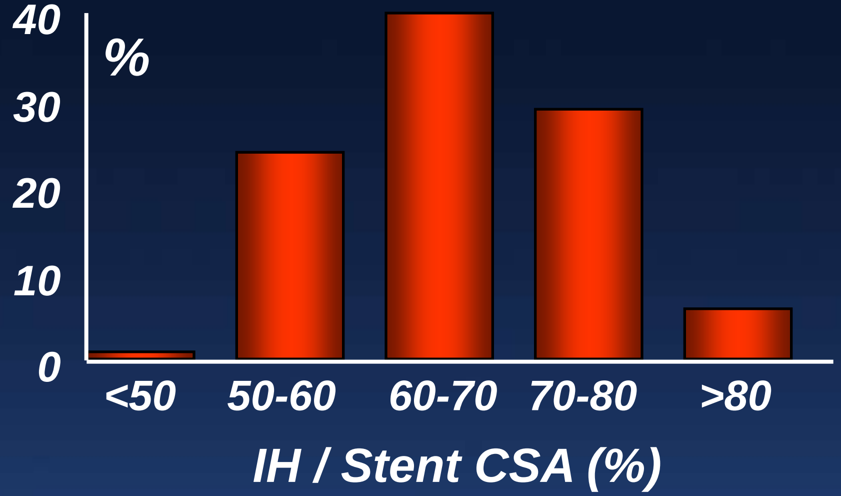


Hoffmann et al. Circulation 1996;94:1247-54

1090 pts with BMS restenosis evaluated at the Washington Hospital Center

- Twenty percent of lesions had a MSA <5.0 mm²; and an additional 18% had a MSA of 5.0-6.0 mm².





- In 49 (4.5%), there were mechanical complications: (1) missing the lesion, (2) stent "crush," and (3) stent was “missing” - stripped off the balloon during implantation.

Castagna et al. Am Heart J 2001;142:970-4

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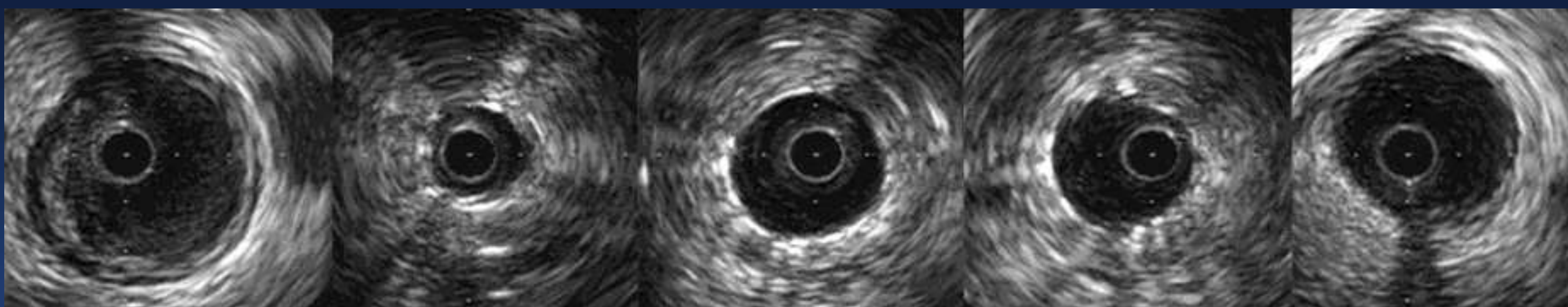

0 → 5.0 → 20.0mm

IVUS Predictors of BMS Early Thrombosis & Restenosis

	Thrombosis	Restenosis
Small MSA or underexpansion	•*Cheneau et al. Circulation 2003;108:43-7*	•*Kasaoka et al. J Am Coll Cardiol 1998;32:1630-5* •*Castagna et al. AHJ 2001;142:970-4* •*de Feyter et al. Circulation 1999;100:1777-83* •*Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* •*Morino et al. Am J Cardiol 2001;88:301-3* •*Ziada et al. Am Heart J 2001;141:823-31* •*Doi et al. JACC Cardiovasc Interv. 2009;2:1269-75*
Edge problems (geographic miss, secondary lesions, large plaque burden, dissections, etc)	•*Cheneau et al. Circulation 2003;108:43-7*	•*Sakurai et al. Am J Cardiol 2005;96:1251-3* •*Liu et al. Am J Cardiol 2009;103:501-6*
Stent length		•*Kasaoka et al. J Am Coll Cardiol 1998;32:1630-5* •*de Feyter et al. Circulation 1999;100:1777-83*

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IVUS Predictors of DES Early Thrombosis & Restenosis

	Early Thrombosis	Restenosis
Small MSA or MLA or underexpansion	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8* •*Okabe et al. Am J Cardiol. 2007;100:615-20* •*Liu et al. JACC Cardiovasc Interv. 2009;2:428-34* •*Choi et al. Circ Cardiovasc Interv 2011;4:239-47*	•*Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* •*Hong et al. Eur Heart J 2006;27:1305-10* •*Doi et al JACC Cardiovasc Interv. 2009;2:1269-75* •*Fujii et al. Circulation 2004;109:1085-1088* •*Kang et al. Circ Cardiovasc Interv 2011;4:9-14* •*Choi et al. Am J Cardiol 2012;109:455-60* •*Song et al. Catheter Cardiovasc Interv 2014;83:873-8*
Edge problems (geographic miss, secondary lesions, large plaque burden, dissections, etc)	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8* •*Okabe et al., Am J Cardiol. 2007;100:615-20* •*Liu et al. JACC Cardiovasc Interv. 2009;2:428-34* •*Choi et al. Circ Cardiovasc Interv 2011;4:239-47*	•*Sakurai et al. Am J Cardiol 2005;96:1251-3* •*Liu et al. Am J Cardiol 2009;103:501-6* •*Costa et al, Am J Cardiol, 2008;101:1704-11* •*Kang et al. Am J Cardiol 2013;111:1408-14* •*Kobayashi et al. ACC2014*

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Analysis of 298 ISR lesions (52 BMS, 73 SES, 52 PES, 16 ZES, and 105 EES) at CUMC

	BMS	1st generation DES	2nd generation DES	p-value
#	52	125	121	
Diabetes mellitus	19 (36.5%)	68 (48.9%)	57 (53.3%)	0.14
ACS presentation	28 (53.9%)	81 (58.3%)	56 (52.8%)	0.7
Total stent length (mm)	21.8±13.5	29.4±16.1	32.2±18.7	0.001
Average reference lumen area (mm^2)	**6.3±2.3**	**6.3±1.8**	**6.4±1.9**	**1.0**
Minimum stent area (MSA)	**6.4±2.2**	**4.9±1.6**	**4.7±1.6**	**<0.001**
MSA <5 mm^2	**28.8%**	**56.8%**	**69.2%**	**<0.001**
%NIH at MLA site	**60.9±12.8**	**56.1±16.0**	**52.3±16.9**	**0.006**
Diffuse ISR	28.8%	30.2%	28.0%	1.0
Neointimal calcification (%)	19.2%	13.0%	18.5%	0.41
Stent fracture, n (%)	0.0%	5.8%	6.5%	0.18
Stent malapposition, n (%)	7.7%	10.1%	10.3%	0.9

Goto, unpublished

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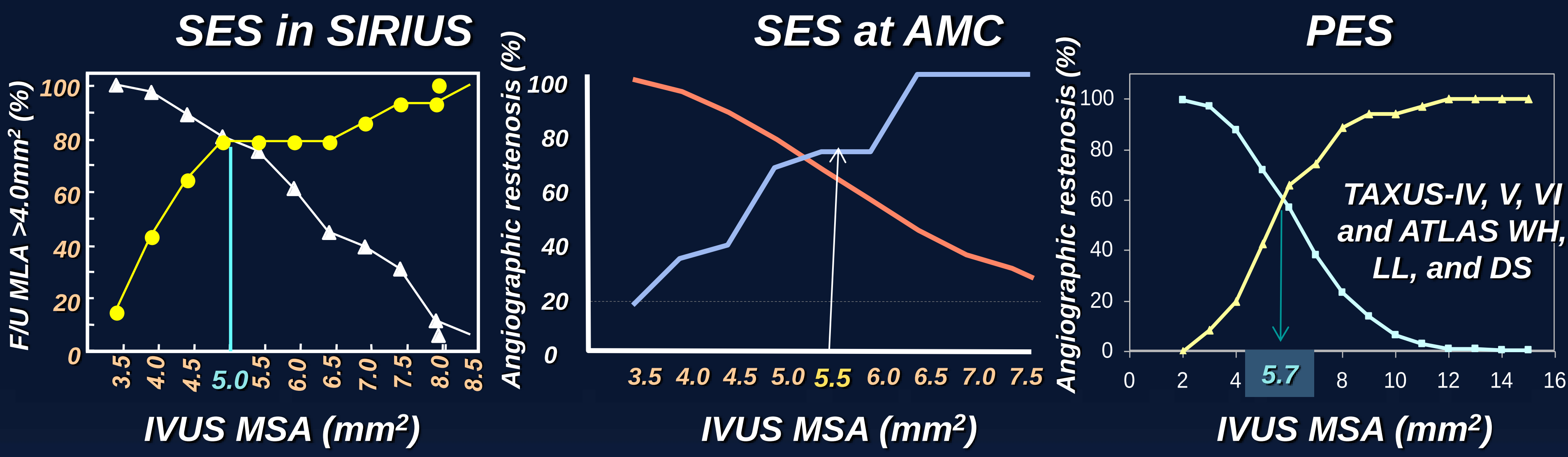
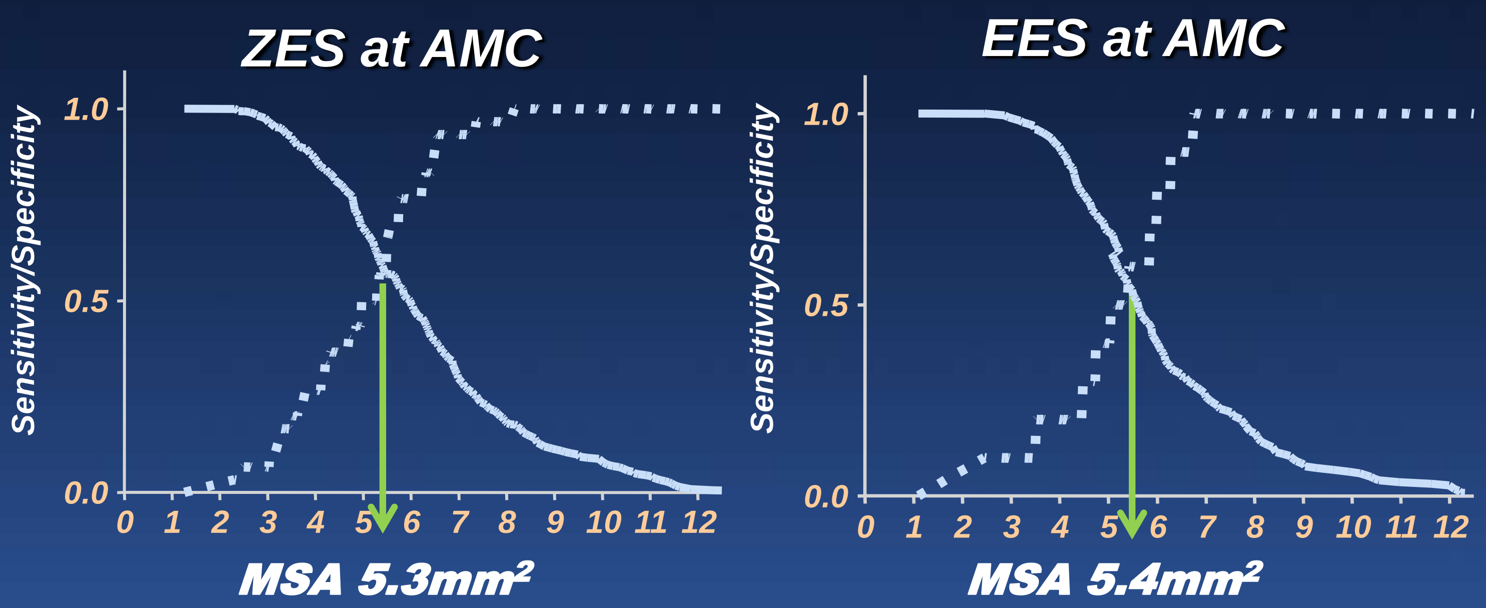




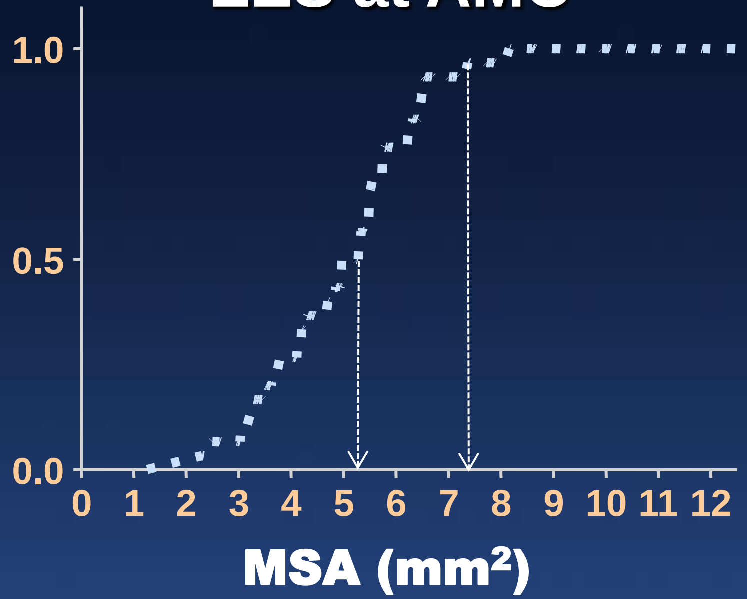
Sonoda et al. J Am Coll Cardiol 2004;43:1959-63
Hong et al. Eur Heart J 2006;27:1305-10
Doi et al. JACC Cardiovasc Interv. 2009;2:1269-75
Song et al. Cathet Cardiovasc Interv 2014;83:873-8

An ideal end point should be a clinically reasonable MSA that maximizes the probability of long-term stent patency while minimizing the risk of stent failure.

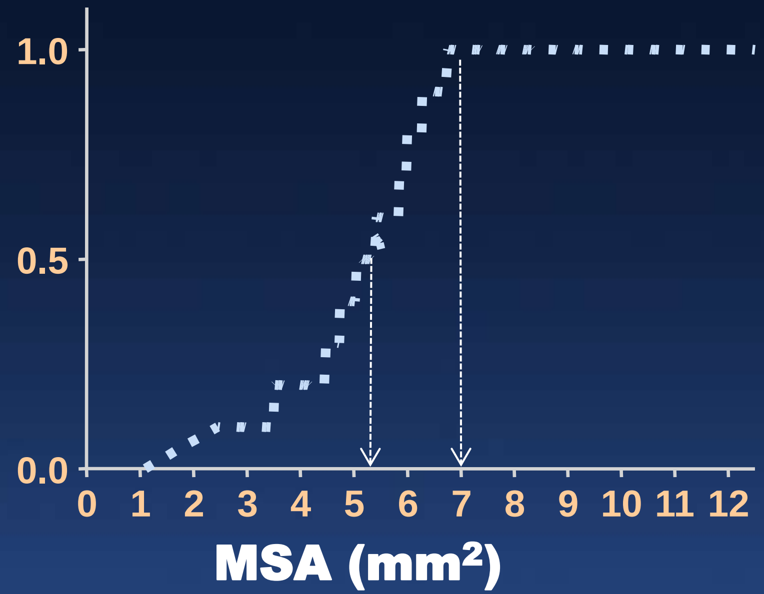
- By definition, sensitivity/specificity curve analysis "must" identify a single MSA that "best" separates restenosis from no restenosis. However, sensitivity and specificity are not of similar importance when predicting events.
- Is an MSA of $5.5mm^2$ enough in big arteries? "No." Can it be achieved in small arteries? Also "No
- If only one MSA was always sufficient in all situations, we would only need one size stent :
  - 100% expansion of a 2.75mm DES = $5.9mm^2$
- Finally, can it be predicted angiographically? "No."

Predicting Freedom From Angiographic Restenosis with Second Generation DES

ZES at AMC



EES at AMC



Song et al. Cathet Cardiovasc Interv 2014;83:873-8

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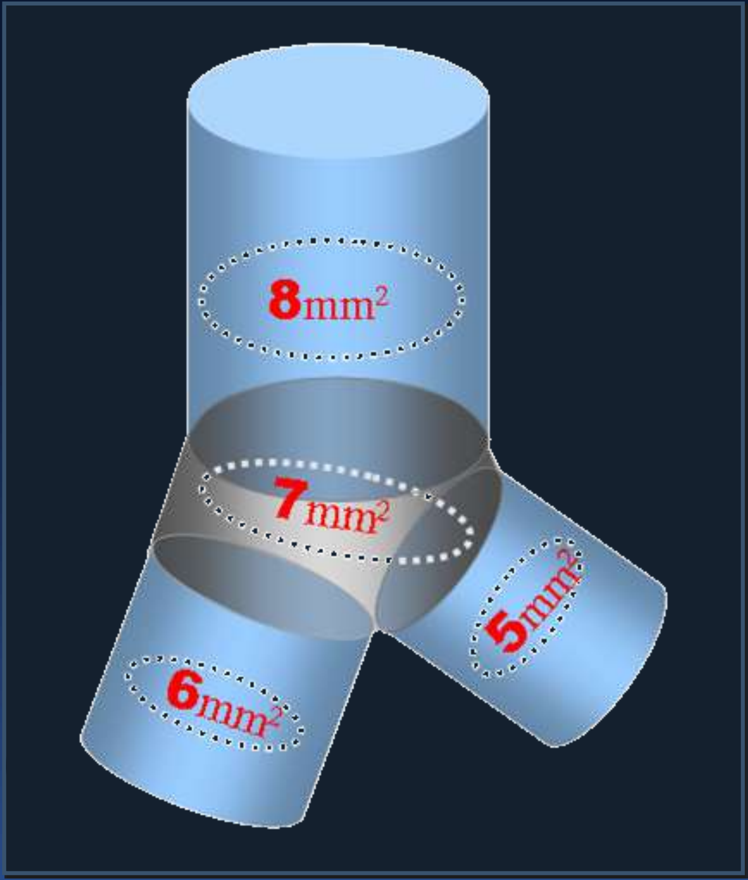
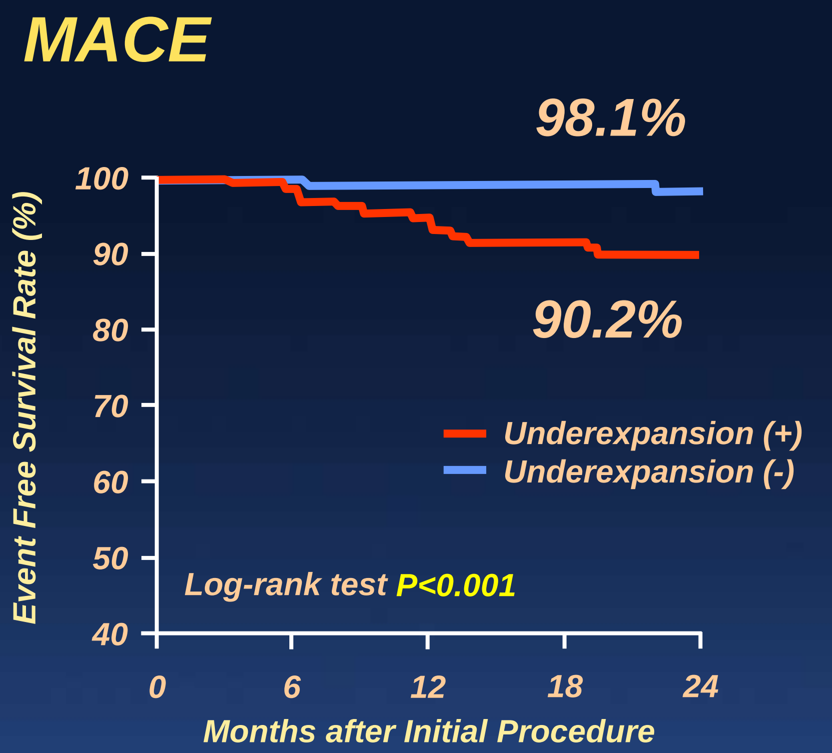
Criteria for Stent Underexpansion at the Distal LMCA Bifurcation (n=403)



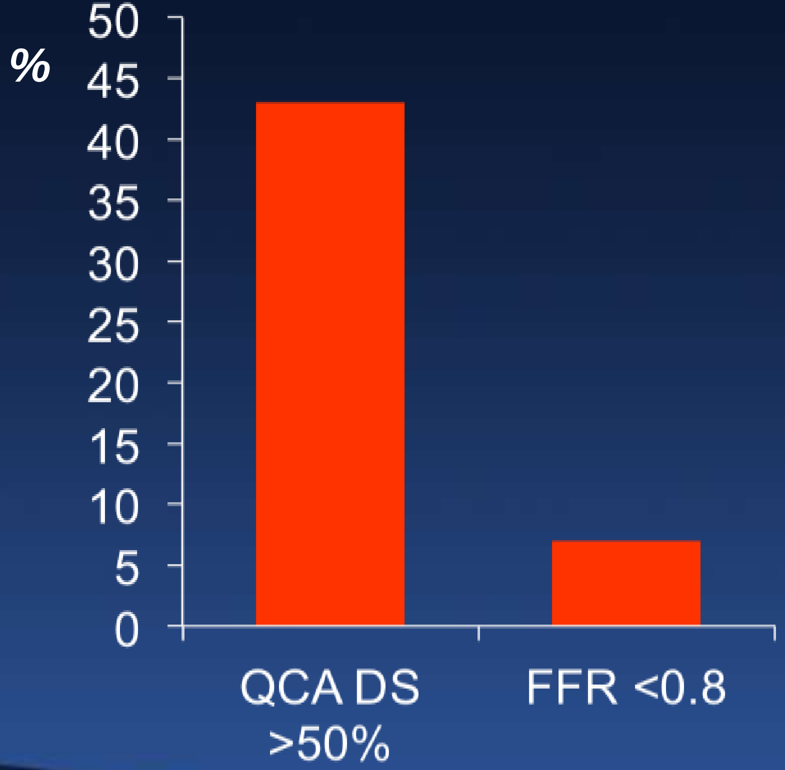


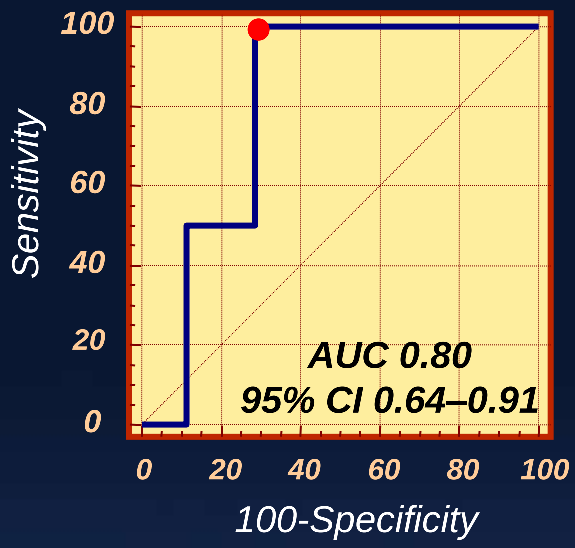
No. at risk

	0	6	12	18	24
Underexpansion (+)	133	131	126	121	75
Underexpansion (-)	260	260	255	246	129

Kang et al. *Circulation Cardiovasc Interv.* 2011;4:562-9

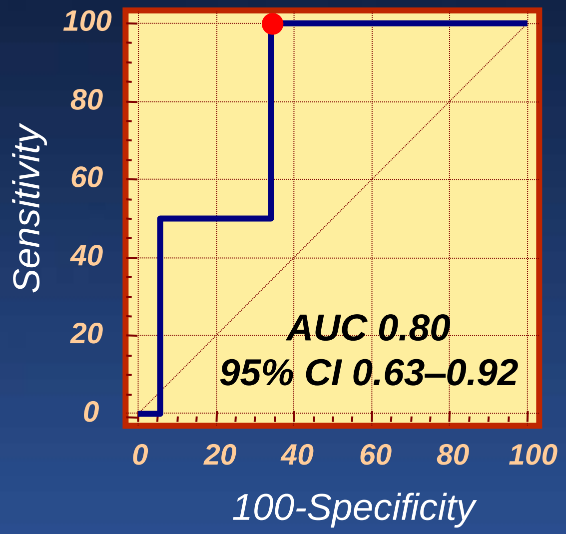
43 LMCA bifurcation lesions with a pre-PCI LCX ostial DS<50% were treated by single-stent cross-over





MLA <3.7mm²

- *Sensitivity 100%*
- *Specificity 71%*
- *PPV 16%*
- *NPV 100%*



Plaque Burden >56%

- *Sensitivity 100%*
- *Specificity 65%*
- *PPV 14%*
- *NPV 100%*

Kang et al. Catheter Cardiovasc Interv 2014;83:545-52

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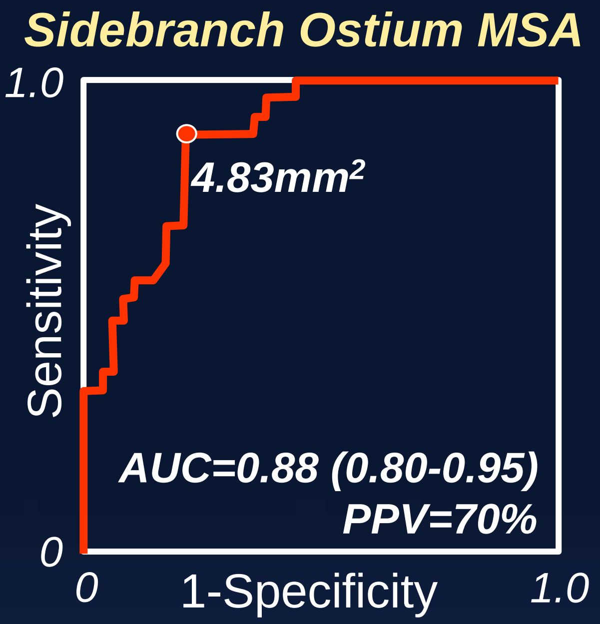
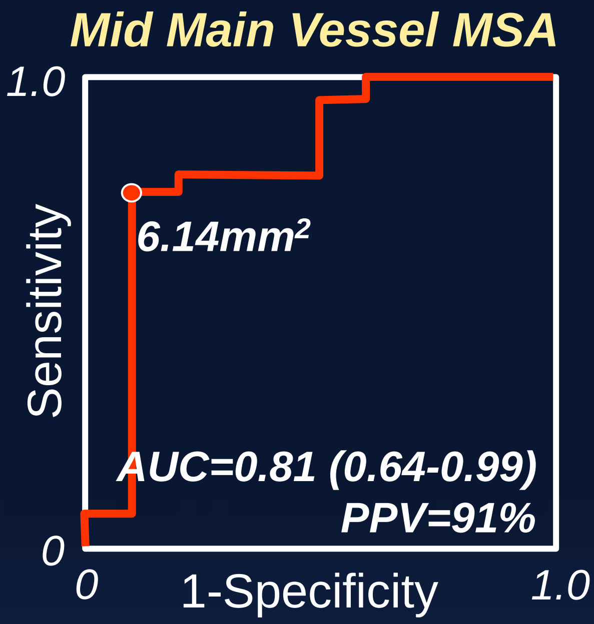
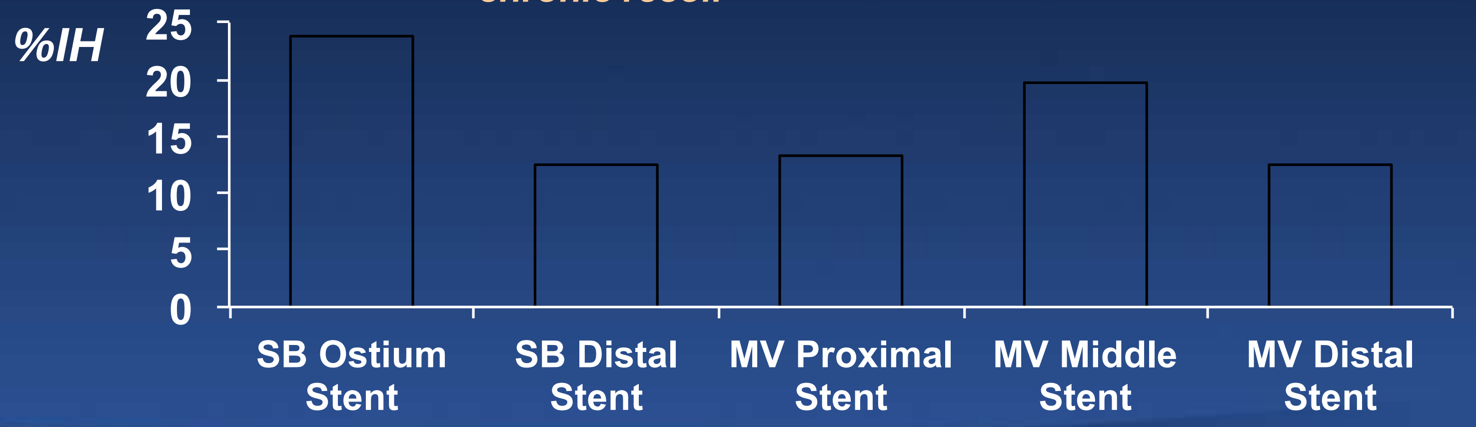
Optimal Cutoff Value of Post-Procedural MSA to Predict a F/U MLA ≥4mm² After Bifurcation T-Stenting





Distal reference lumen = 5.5mm²
Stent expansion = 87%
Follow-up MLA correlated with final MSA (r=0.81) with no chronic recoil

Distal reference lumen = 6.5mm²
Stent expansion = 97%
Follow-up MLA correlated with final MSA (r=0.75)



Hahn et al. J Am Coll Cardiol 2009;54:110-7

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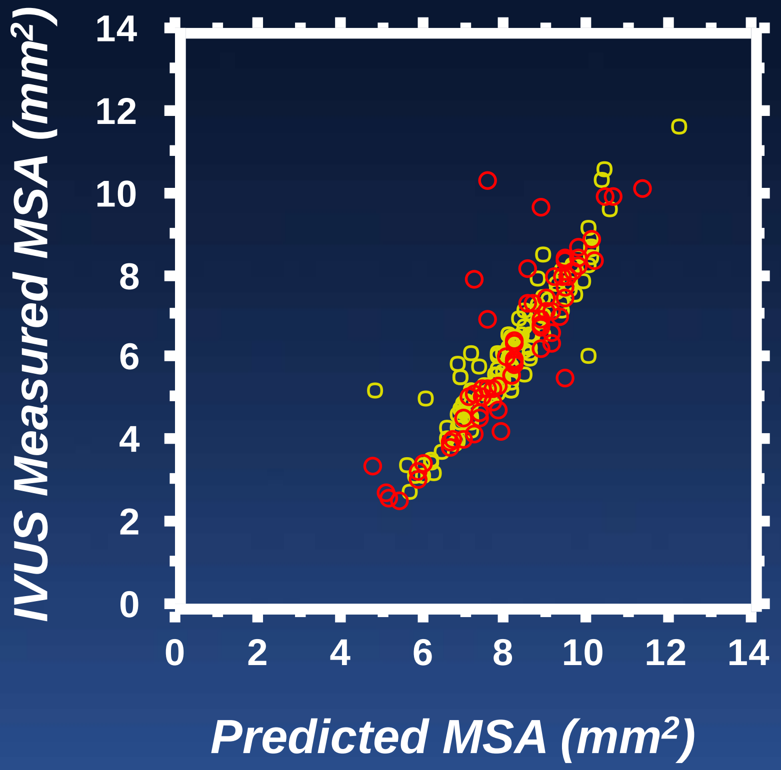
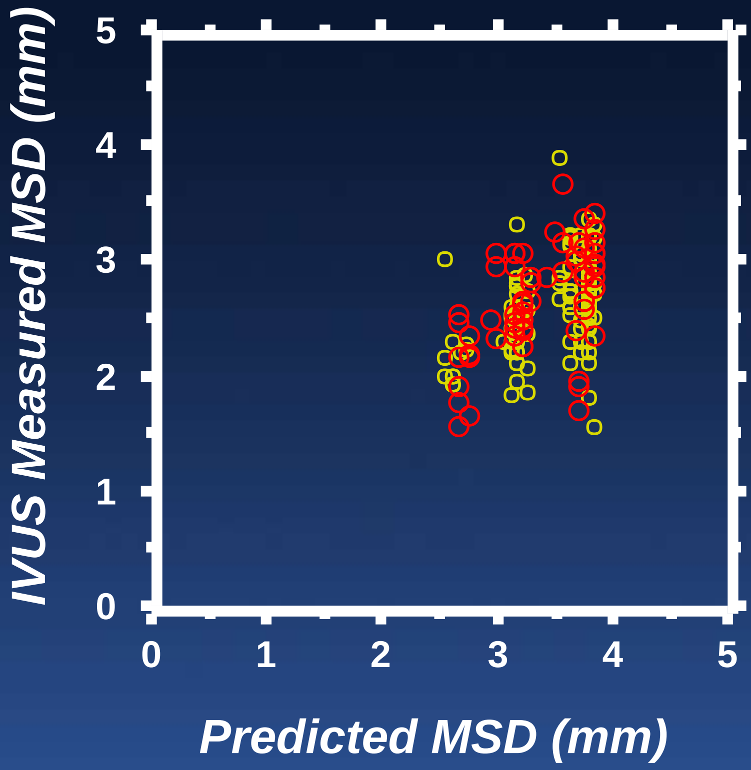
Manufacturer's Compliance Charts Cannot Be Used to Guarantee Adequate Stent Expansion

Comparison of IVUS-measured minimum stent diameter (MSD) and minimum stent area (MSA) with the predicted measurements from Cypher in yellow, n=133) and Taxus in red, n=67). DES achieve an average of only 75% of the predicted MSD (66% of MSA)





de Rebamar Costa et al. Am J Cardiol 2005;96:74-8

de Rebamar Costa et al. Am Heart J 2007;153:297-303

He et al. Am J Cardiol 2010;105:1272-5

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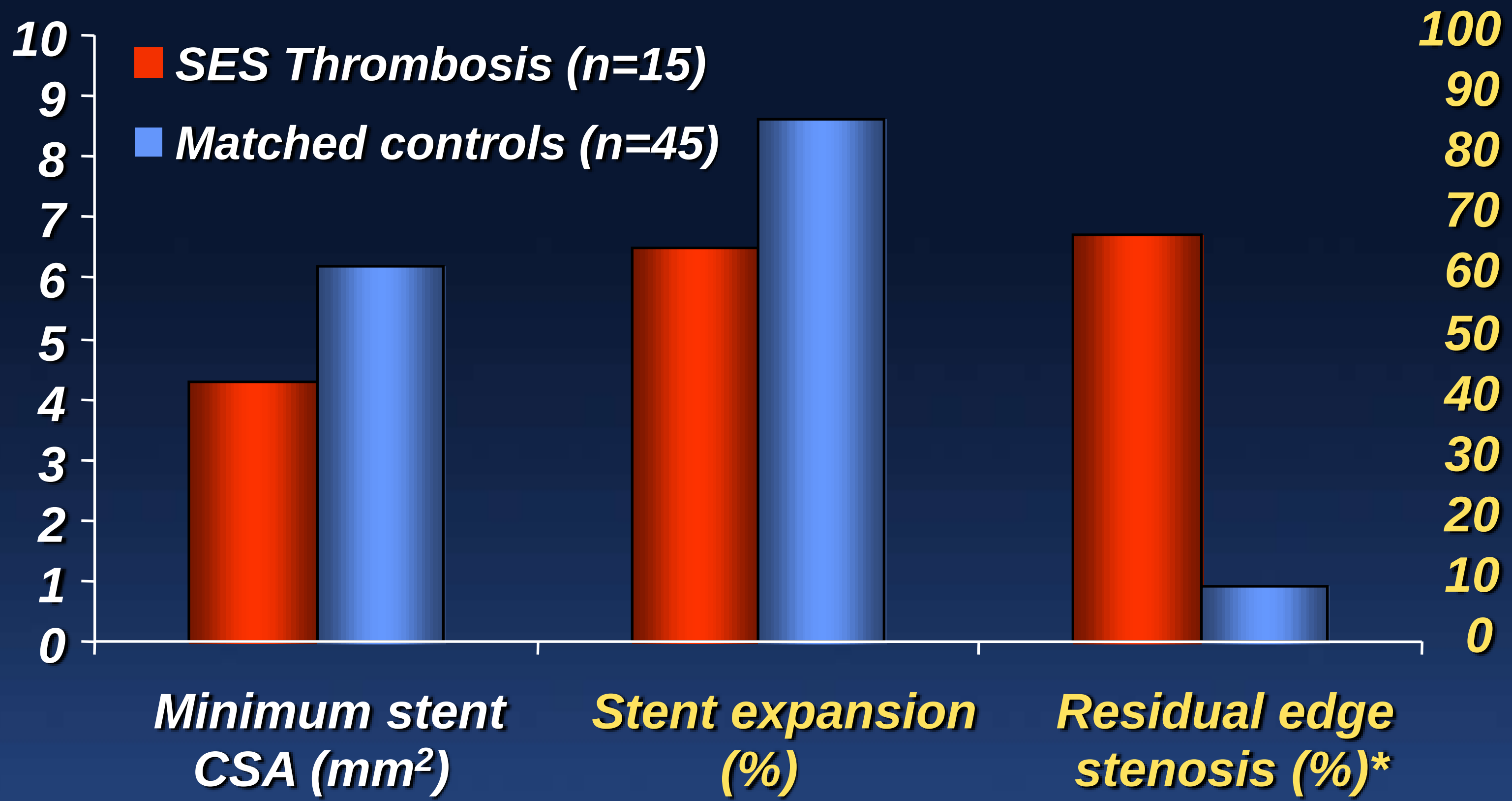
IVUS Predictors of Early SES Thrombosis



*Residual edge stenosis = edge lumen CSA <4.0mm² & plaque burden >70%.

Fujii et al. J Am Coll Cardiol 2005;45:995-8

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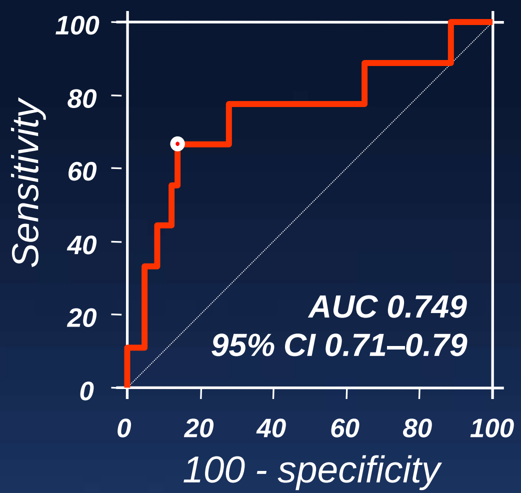
IVUS Predictors of Edge Restenosis after Second Generation DES

433 E-ZES

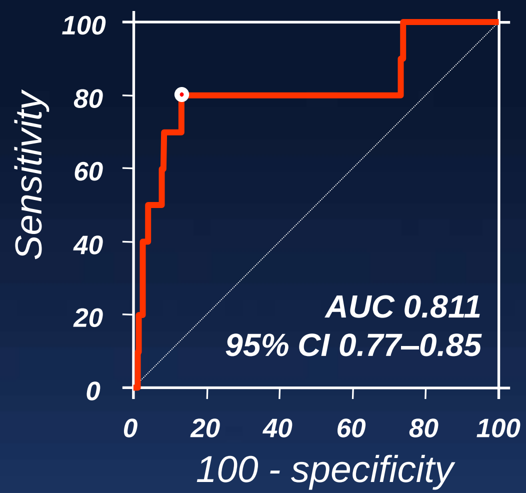


Plaque burden=56.3%

Sensitivity 67%

Specificity 86%

422 R-ZES

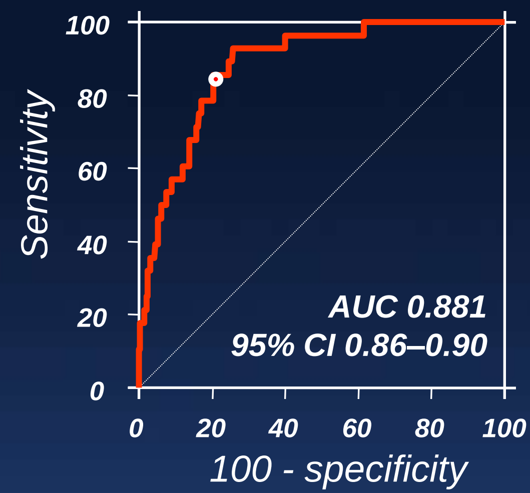


Plaque burden=57.3%

Sensitivity 80%

Specificity 87%

813 EES



Plaque Burden=54.2%

Sensitivity 86%

Specificity 80%

Kang et al. Am J Cardiol 2013;111:1408-14

Edge Dissection in ADAPT-DES

	Dissection (159 pts)	No dissection (1903 pts)	P Value
MACE	11.48% (18)	7.97% (148)	0.097
Cardiac death	1.91% (3)	1.44% (26)	0.6
Peri-procedural MI	2.52% (4)	1.16% (22)	0.14
Clinically driven TLR	5.8% (9)	3.1% (68)	0.067
Stent Thrombosis	1.28% (2)	0.53% (10)	0.2

In 159 pts with dissection, the predictors of TLR were dissection length of 2.3 mm (AUC 0.72, p=0.04), dissection angle of 70.0° (AUC 0.66, p=0.16), and effective lumen CSA of 6.0mm² (AUC 0.66, p=0.13).

(Kobayashi et al. ACC 2014)

Although it was one of the original Colombo criteria, there is little or no data linking *isolated* acute stent malapposition to adverse clinical events including ST and restenosis.

- **Stent malapposition is associated with *less* intimal hyperplasia – the drug can cross small stent vessel-wall gaps**
  - *Hong et al, Circulation. 2006;113:414-9*
  - *Kimura et al, Am J Cardiol . 2006;98:436-42*
  - *Steinberg et al, JACC Cardiovasc Intervent 2010;3:486-94*
  - *Balakrishnan et al., Circulation 2005;111:2958-65*
- **In the integrated analysis of slow release formulation PES in TAXUS IV, V, & VI & TAXUS ATLAS Workhorse, Long Lesion, and Direct Stent Trial, there was no effect of acute stent malapposition on MACE or ST within the first 9 mos – whether BMS or DES**
  - *Steinberg et al, JACC Cardiovasc Intervent 2010;3:486-94*
- **In HORIZONS-AMI, acute stent malapposition was detected in 33.8% of 68 lesions treated with PES and 38.7% of 24 lesions treated with BMS (p=0.7). There was no difference in MACE between pts with versus without acute stent malapposition in either BMS or PES cohorts; and acute malapposition was not a predictor of early ST**
  - *Guo et al. Circulation 2010;122:1077-84*
  - *Choi et al. Circ Cardiovasc Interv 2011;4:239-47*
- **Although acute malapposition was observed in 28/403 pts with LMCA lesions treated with DES implantation, malapposition was not related to MACE at follow-up.**
  - *Kang et al. Circ Cardiovasc Interv 2011;4:562-9*
- Although acute malapposition was detected in 10.5% of 1982 pts in ADAPT-DES, it was not associated with advere events at either 30 days or 2 years.
  - *Sousa et al. ACC2014*

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

(Sousa et al. ACC 2014)

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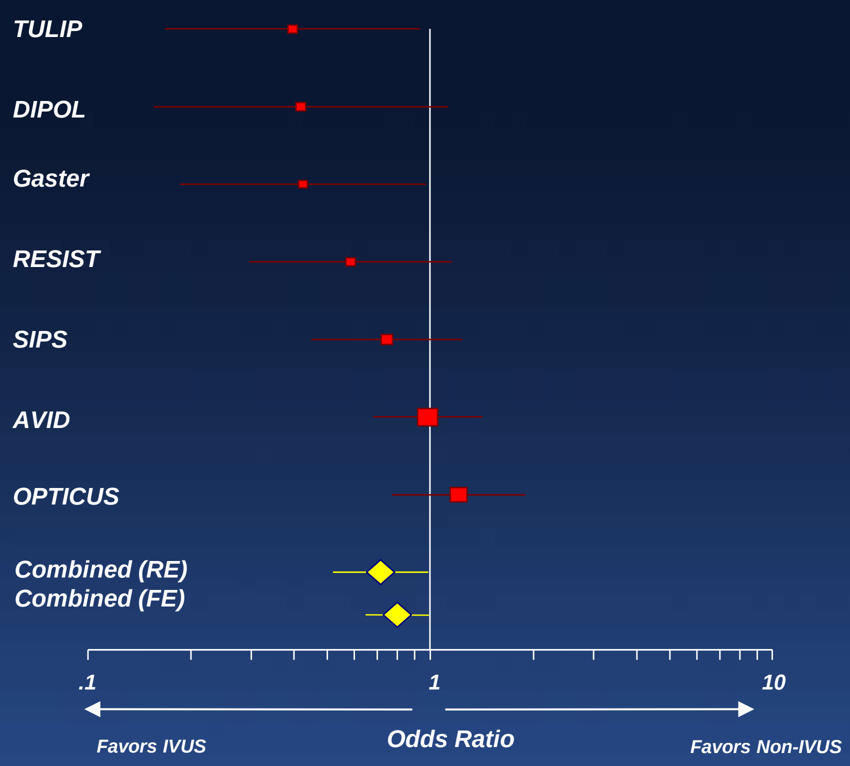
Meta-analysis of Randomized Trials of IVUS vs Angiographic Guided BMS implantation (n=2193 pts)

IVUS guidance was associated with significantly lower rate of

- *Angiographic restenosis (22.2% vs. 28.9%; OR 0.64, p=0.02)*
- *Repeat revascularization (12.6% vs. 18.4%; OR 0.66, p=0.004)*
- *Overall MACE (19.1% vs. 23.1%; OR 0.69, p=0.03)*
- *But no significant effect on MI (p=0.51) or mortality (p=0.18).*
- *ST was not reported*

MACE



Parise et al. Am J Cardiol. 2011;107:374-82

Four meta-analyses have assessed IVUS vs angiography-guided DES implantation

					HR (p-values)					
Reference	**Yr**	**RCT**	**Non-RCT**	**Pts**	**MACE**	**Death**	**MI**	**ST**	**TLR**	**TVR**
Zhang et al Eurointervention	2012	1	10	19,619	0.87 (p=0.008)	0.59 (p<0.001)	0.82 (p=0.13)	0.58 (p<0.001)	0.90 (p=0.3)	0.90 (p=0.2)
Propensity score matched sub-analysis			6	5,300	0.86 (p=0.06)	0.73 (p=0.04)	0.63 (p=0.01)	0.57 (p=0.004)	0.85 (p=0.3)	0.94 (p=0.6)
Klersy et al Int J Cardiol	2013	3	9	18,707	0.80 (p<0.001)	0.60 (p<0.001)	0.59 (p=0.001)	0.58 (p=0.007)	0.95 (p=0.8)	
Jang et al. JACC Cardiovasc Interv	2014	3	12	24,869	0.79 (p=0.001)	0.64 (p<0.001)	0.57 (p<0.001)	0.59 (p=0.002)	0.76 (p=0.01)	0.81 (p=0.01)
Propensity score matched sub-analysis			9	13,545	0.79 (p=0.01)	0.58 (p=0.01)	0.56 (p=0.04)	0.52 (p=0.004)	0.85 (p=0.3)	0.93 (p=0.3)
Ahn et al. Am J Cardiol	2014	3	14	26,503	0.74 (p<0.001)	0.61 (p<0.001)	0.57 (p<0.001)	0.59 (p<0.001)	0.81 (p=0.046)	0.82 (p=0.022)

Recently Published Studies Assessing the Benefit of IVUS

Reference	Lesion subset	Stats	# Pts	Endpoint
Patel et al. Cath Cardiovasc Interv, in press	Ostial	Propensity score matched	225	MACE (HR=0.54, p=0.04)
De la Torre Hernandez et al. JACC Cardiovasc Interv 2014;7:244-54	LM	Propensity score matched	505 pairs	ST (0.6% vs 2.2%, p=0.04) MACE (11.7% vs 16.0%, p=0.04, especially distal lesions treated with 2 stents: 16.7% vs 41.0%, p=0.02)
Gao et al. Patient Pref Adherence 2014;8:1-11	LM	Propensity score matched	291 pairs	MACE (16.2% vs 24.4%, p=0.014)
Hong et al. Am J Cardiol 2014;114:534	CTO	Propensity score matched	201 pairs	ST (0% vs 3%, p=0.014)
Singh et al. Am J Cardiol 2015, in press			377,096 angio vs 24,475 IVUS	In-hospital mortality (0.4% vs. 0.8%, P<0.001)

Studies showing NO benefit of IVUS

Reference	Lesion subset	Stats	# Pts	Endpoint
Fröhlich et al. JAMA Intern Med. 2014;174:1360-1366	All	Propensity score	803 pairs	also no benefit for FFR-guidance

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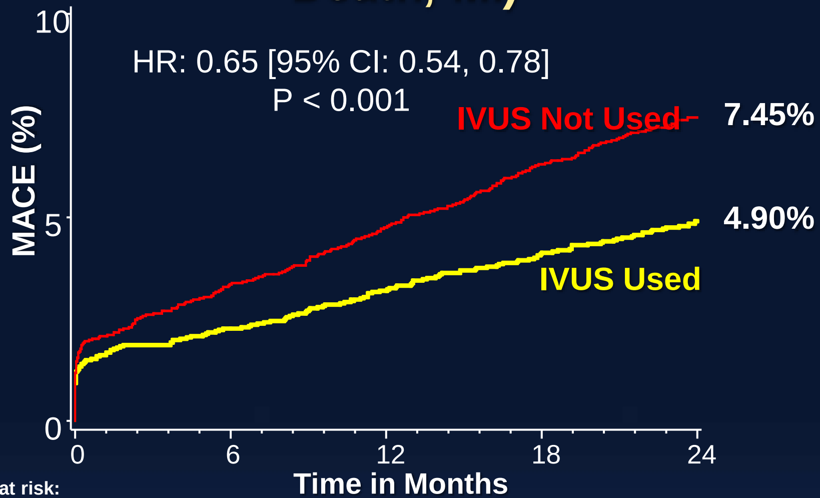
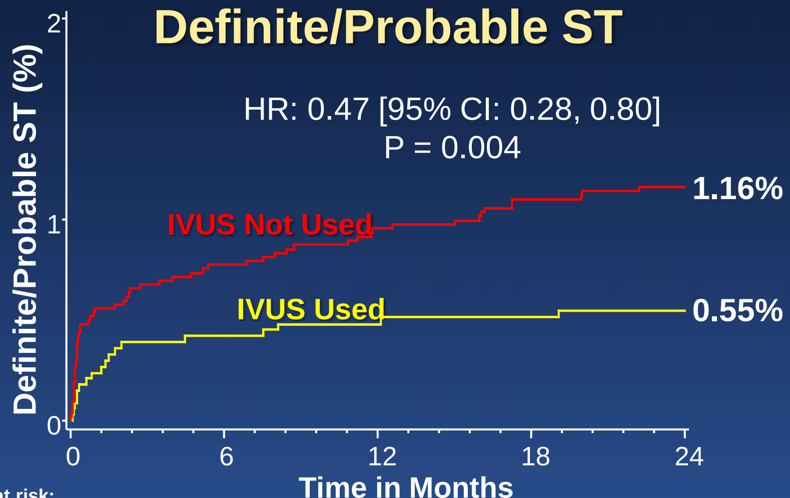
MACE (Definite/Probable ST, Cardiac Death, MI)



Number at risk:					
IVUS Used	3361	3206	3117	2988	1739
IVUS Not Used	5221	4912	4740	4537	2177

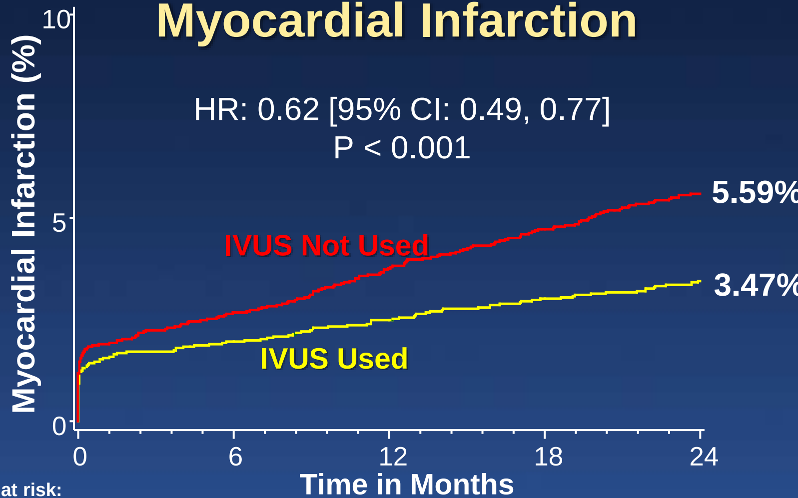
Two year follow-up data from ADAPT-DES (3361 pts treated with IVUS-guidance vs 5221 pts treated with angiographic guidance)

Definite/Probable ST



Number at risk:					
IVUS Used	3361	3260	3182	3065	1791
IVUS Not Used	5221	5019	4886	4713	2279

Myocardial Infarction



Number at risk:					
IVUS Used	3361	3209	3120	2991	1739
IVUS Not Used	5221	4916	4744	4541	2179

Maehara et al. J Am Coll Cardiol 2013;62:B21-B22

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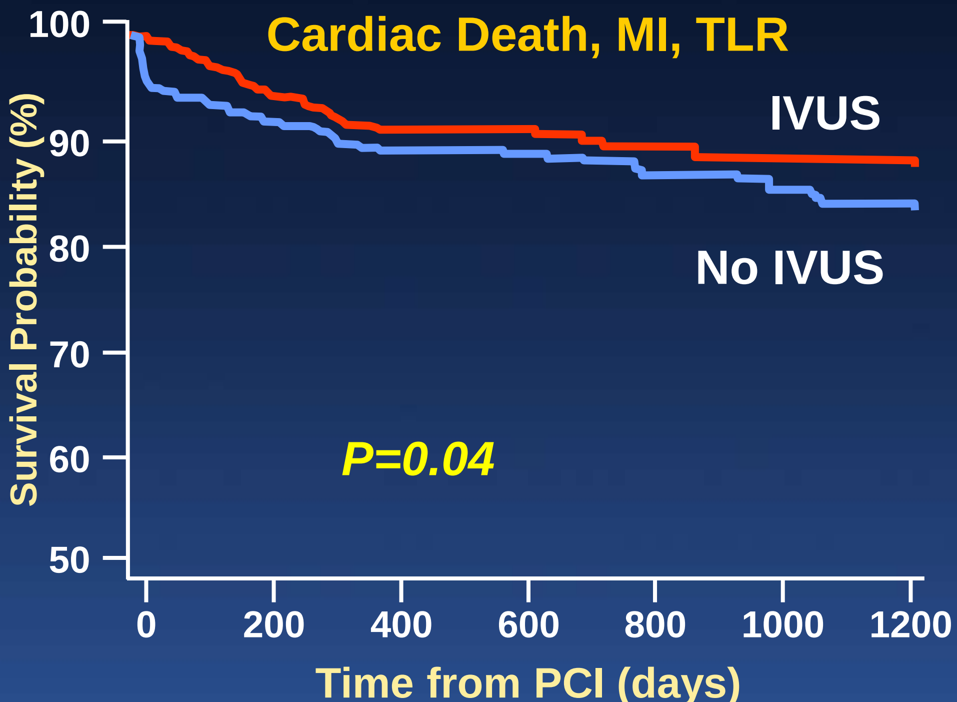
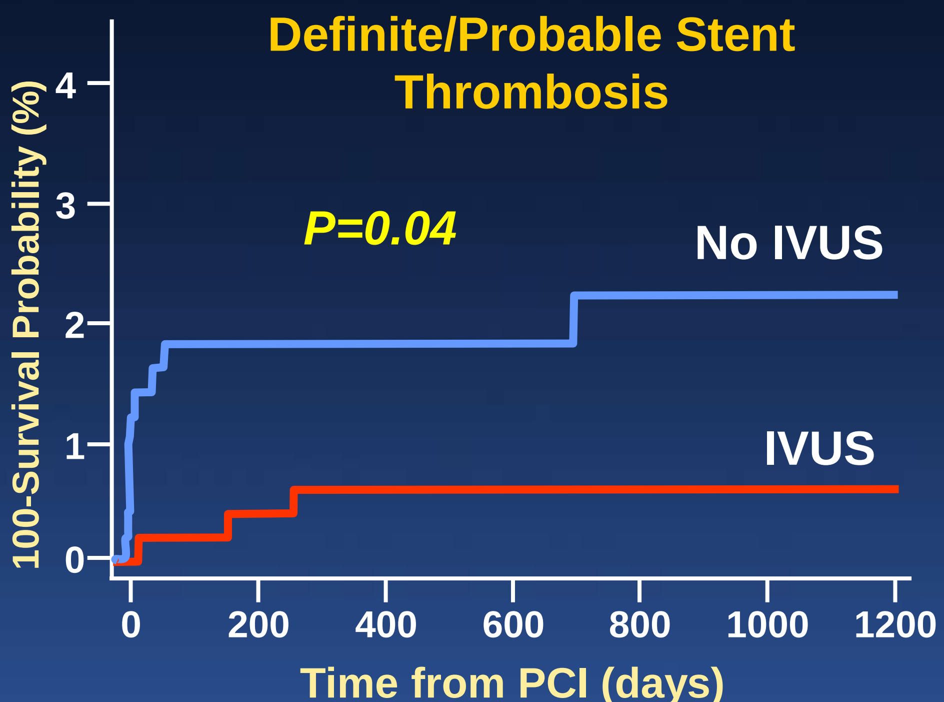
Impact of IVUS Guidance of Unprotected LM Propensity Matched 1010 pts from 4 Registries

- *Distal LM lesion ~60%, 2 stent technique ~13%*
- *IVUS guidance was an independent predictor of MACE*





De la Torre Hernandez et al. *JACC* 2014:244-54

Comparison of 1-year clinical outcomes between IVUS-guided versus angiography-guided implantation of DES for LMCA lesions: A single-center analysis of a 1,016 pt cohort

	IVUS	No IVUS	P
Overall	**337**	**679**	
Cardiac death	1.8%	6.2%	0.002
STEMI	1.2%	3.4%	0.004
TLR	2.4%	9.4%	<0.001
Stent thrombosis	0.6%	2.7%	0.026
MACE	14.8%	27.2%	<0.001
Propensity Score Matched	**291**	**291**	
Cardiac death	12.4%	15.1%	0.023
STEMI	1.0%	3.4%	0.05
TLR	2.7%	8.2%	0.004
Stent thrombosis	0.3%	2.4%	0.075
MACE	16.2%	24.4%	0.014

Gao et al. Patient Pref Adherence 2014;8:1-11

Randomized IVUS vs Angiographic Guided CTO Intervention

467 patients with CTO were initially screened

Exclusions
- Wiring failure - 61 patients
- Refusal of study enrollment - 4 patients

A total of 402 pts were finally enrolled after successful guidewire-crossing

1:1 randomization

IVUS-guided group (n=201)

1:1 randomization
R-ZES vs. N-BES

Angiography-guided group (n=201)

IVUS-guided group (n=231)

Angiography-guided group (n=171)

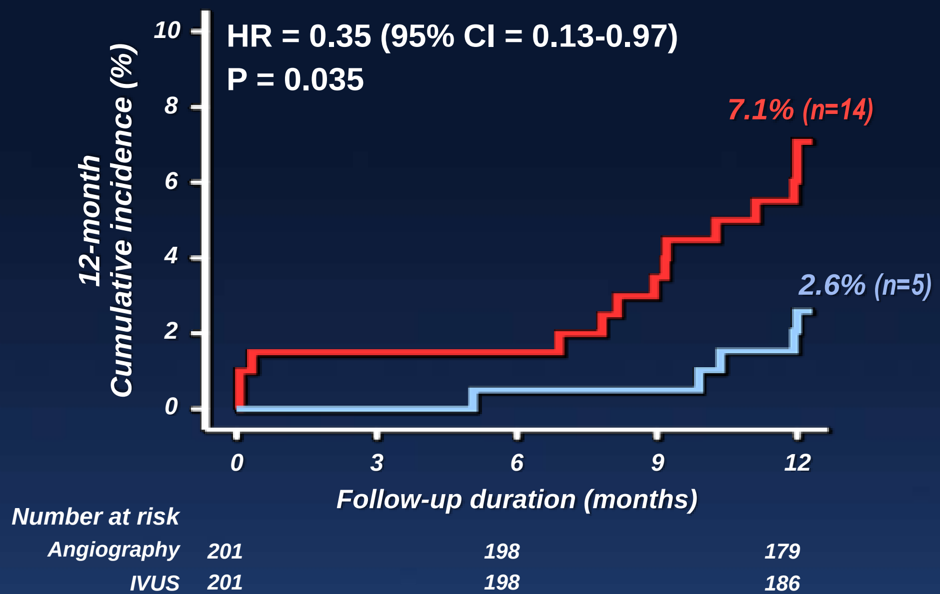
Primary endpoint was a composite of cardiac death, MI, or TVR at 12 months

Jang et al. TCT2014

Primary endpoint (Cardiac death, MI, TVR)

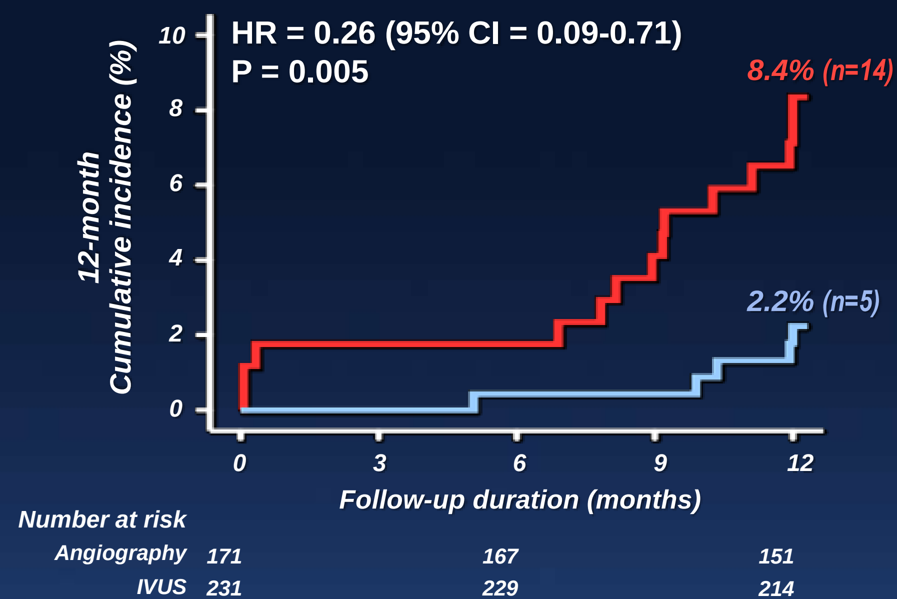
Angiography-guided group
IVUS-guided group

Intention to Treat



	IVUS	Angio	P-value
Cardiac death/MI	0%	2%	0.045
TVR	2.6%	5.2%	0.186

Per Protocol



	IVUS	Angio	P-value
Cardiac death/MI	0%	2.3%	0.019
TVR	2.2%	6.1%	0.049

Jang et al. TCT2014

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IVUS Guidance to Minimize the Use of Iodine Contrast in PCI

- 83 pts randomized to IVUS vs angiographic guidance
- Pts treated with a pre-specified PCI strategy designed to reduce contrast usage in both groups
- IVUS-guided pts were treated with a pre-specified strategy to minimize contrast usage even further by avoiding angiography and using IVUS for pre-intervention assessment, stent sizing, stent positioning, and final assessment
- **<u>Reduction in contrast use (primary endpoint) from 64.5ml (IQR 42.8-97ml, range 19-170ml) to 20.0ml (IQR 12.5-30.0ml, range 3-54ml): p<0.0001</u>**
- Increased procedure time (34.0 (18.5-54.5) to 48.0 (34.0-61.0) min: p=0.06
- No difference in 4-month outcomes although there was a trend toward a less common increase in serum Cr >0.5mg/dl (7.3% vs 19.0%, p=0.2)

Mariani et al. JACC Cardiovasc Interv 2014;7:1287-93

IVUS in the EXCELLENT Trial

- 619 “IVUS-guided” vs 802 angiography-guided PCI-treated patients
- Overall, IVUS “guidance” was associated with a significantly higher

However, this negative effect of IVUS guidance has not been seen in any other BMS or DES study. In fact, in the most recent meta-analysis the risk of peri-procedural MI did not significantly differ between IVUS-guided and angiography-guided DES implantation (OR 1.01, 95% CI 0.73 to 1.67, P=0.65)

were no significant advantages of IVUS “guidance,” but rather a significant increase in periprocedural enzyme elevation, reflecting more aggressive procedures performed with IVUS “guidance.”

Park et al. Int J Cardiol 2013;167:721-6

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CENIC Registry - Stent Implantation in Brazil

IVUS Guidance vs no IVUS guidance (1997-2001)

In-Hospital Outcomes

	IVUS Guidance (n = 3,375 Pts)	No IVUS Guidance (n = 15,151 Pts)	P-value
Cardiac death	0.4%	1.1%	<0.001
Q-MI	0.6%	0.9%	0.054
Death or MI	0.8%	1.7%	<0.001
CABG	0.2%	0.2%	0.8

IVUS guidance was the only independent predictor of freedom from in-hospital death/MI (OR=0.47, 95% CI 0.31 - 0.70)

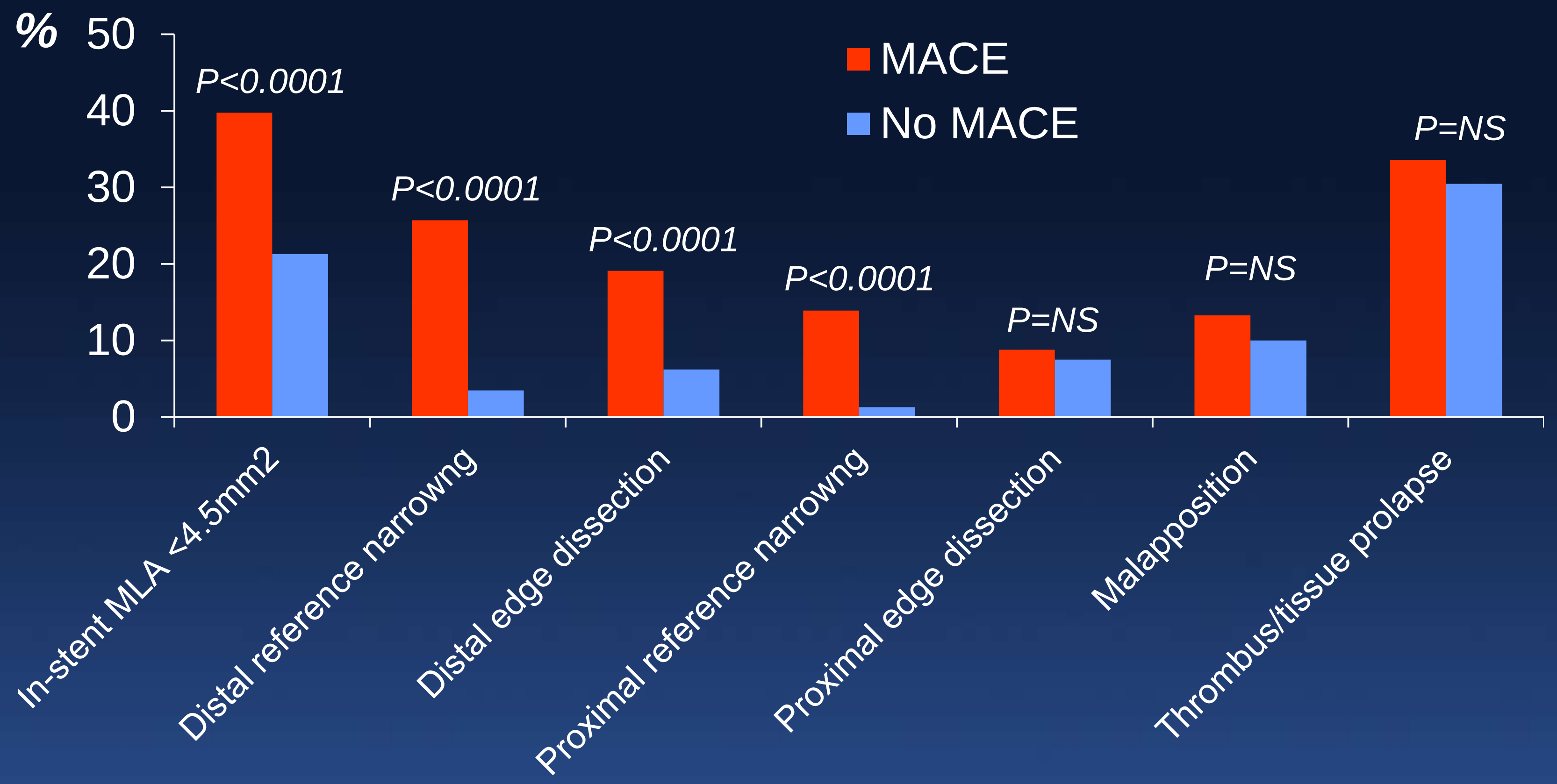
Sousa et al. ACC 2002

Peri-procedural MI in ADAPT-DES

	IVUS n = 3361	No IVUS n = 5221	P Value
Definite/probable ST	0.55% (18)	1.16% (59)	0.004
All death	3.32% (106)	4.23% (210)	0.034
Cardiac death	1.71% (54)	2.42% (119)	0.028
All MI	**3.47% (112)**	**5.59% (279)**	**<0.0001**
- Peri-procedural MI	1.31% (44)	1.62% (84)	0.26
- ST-related MI	0.52% (17)	0.92% (46)	0.045
- Non-ST related MI	1.66% (52)	3.11% (151)	<0.0001
- Q wave MI	0.34% (11)	0.85% (42)	0.006
- Non Q wave MI	3.13% (101)	4.85% (242)	0.0001
Clinically driven TLR	4.79% (161)	6.01% (314)	0.02
Clinically driven TVR	8.30% (279)	9.77% (510)	0.02

Witzenbichler et al. Circulation 2014;129:463-70

929 pts (989 lesions) in CLIO-PCI III registry
MACE (death, MI, ST, or TLR in 113 pts,12.2%) @ 1 yr



Prati, TCT2014

Four Companies Are Working on Next Generation IVUS Systems

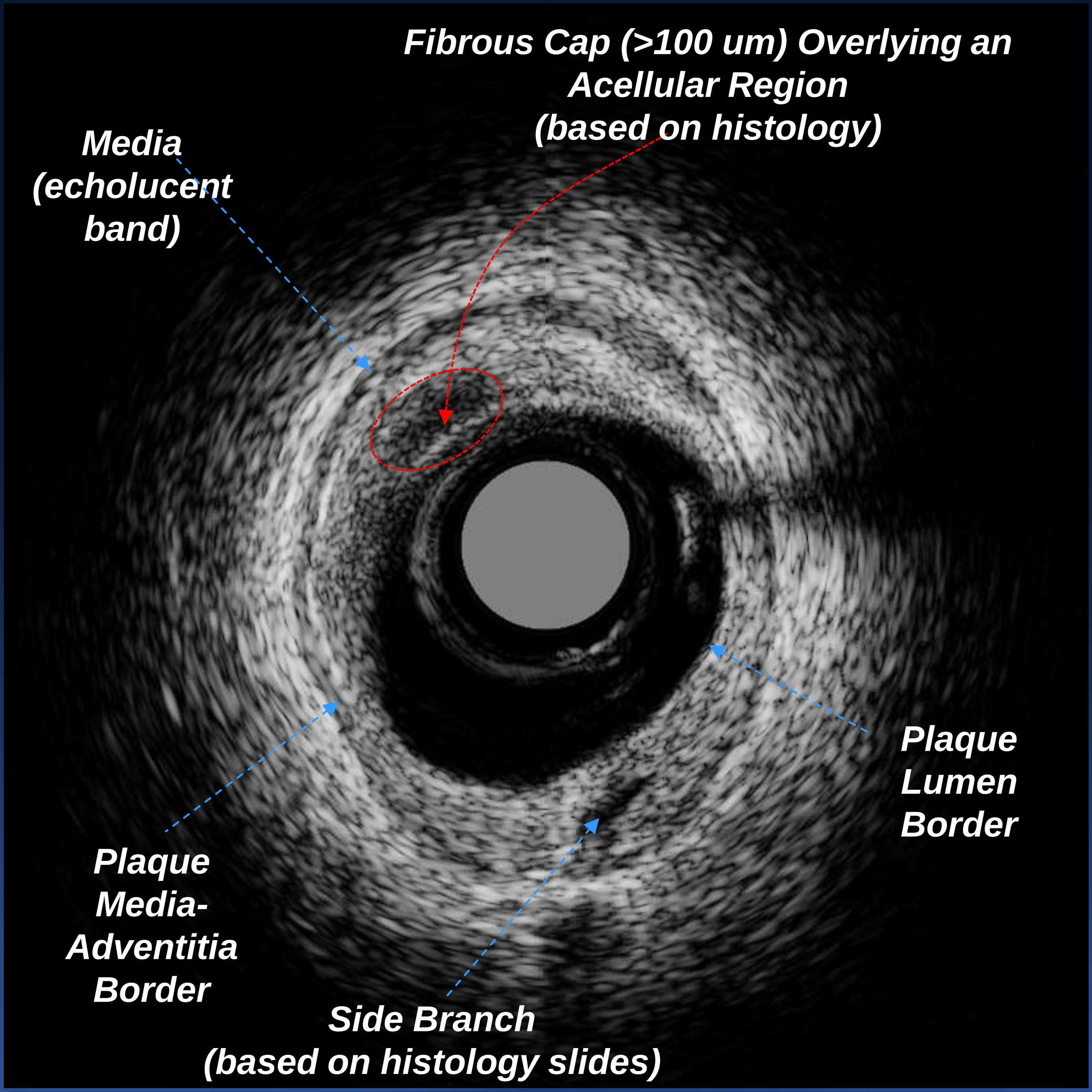
- ACIST (purchased SVMI - has been working on next generation IVUS since 2007) — *Available*
- InfraReDx — *Limited market release*
- BostonScientific
- Volcano

Under development (BostonScientific, Volcano)

Each is taking a very different approach

ACIST: HD-IVUS

Measured Axial Resolution	<50 μm
Lateral Resolution	~200 μm
Max. Frame Rate	60 fps
Max. Pullback Speed	10 mm/sec
Frame Spacing	5-167 μm
Pullback length	120 mm
Tissue Penetration	~3 mm @ 60 Mhz
Imaging in Blood	Yes



Conclusions

- The only reason that we know as much as we do about how stents do or do not work is because of intravascular imaging – in particular many many studies utilizing intravascular ultrasound.
- Today, IVUS remains the gold standard for optimal stent implantation