IVUS: Pre-Intervention Assessment and Optimizing Final Result

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship	Company
Grant/Research Support	BostonScientific, Volcano
Consulting Fees/Honoraria	BostonScientific, Volcano, LightLab, Terumo
Major Stock Shareholder/Equity	Volcano
Royalty Income	
Ownership/Founder	
Intellectual Property Rights	
Other Financial Benefit	

Most of the concepts used in IVUS-guided intervention are no different from those used in angiography-guided intervention. However, unlike angiography, IVUS is actually able to make precise measurements and assess lesion morphology.

- Weigh potential problems (i.e. LM disease, significant proximal or distal disease)
- Assess lesion severity
- Assess unusual lesion morphology (i.e., aneurysms, calcium, thrombi, in-stent restenosis, etc.)
- Measure vessel size
- Measure lesion length
- Determine and fine-tune the final result of interventions
- Assess complications

Validation of IVUS Assessment of Ischemia Producing Stenosis (Doppler FloWire and SPECT)

	IVUS MLA $\geq 4.0mm^2$	IVUS MLA $<4.0mm^2$
CFR < 2.0	2	27
CFR ≥ 2.0	39	4

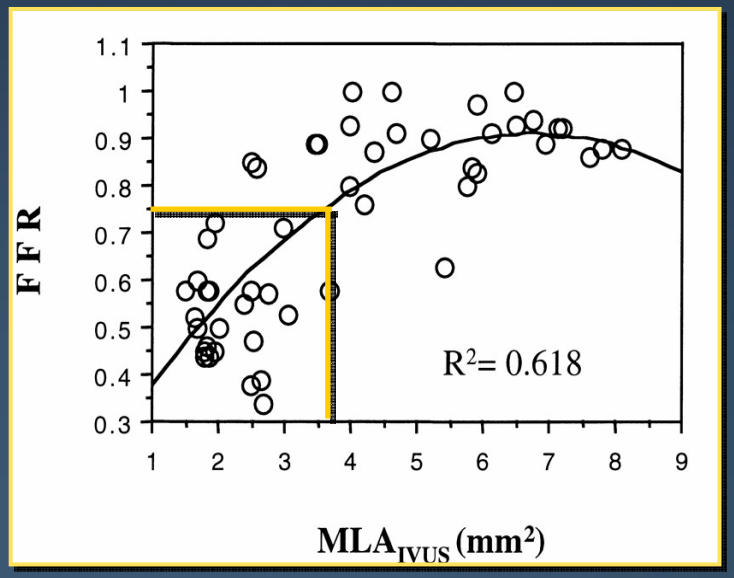
Diagnostic accuracy = 92%. *(Abizaid et al, AJC 1998;82:42-8)*

	IVUS MLA $\geq 4.0mm^2$	IVUS MLA $<4.0mm^2$
+ Spect	4	42
- Spect	20	1

Diagnostic accuracy = 93%. *(Nishioka et al, JACC 1999;33:1870-8)*

Validation of IVUS Assessment of Ischemia Producing Stenosis (Pressure Wire)

Comparison of IVUS and pressure wire (measurement of fractional flow reserve: FFR_{myo})



	Sensitivity	Specificity
AS >70%	100%	68%
MLD <1.8mm	100%	66%
MLA <4.0mm²	82%	56%
Length >10mm	41%	80%

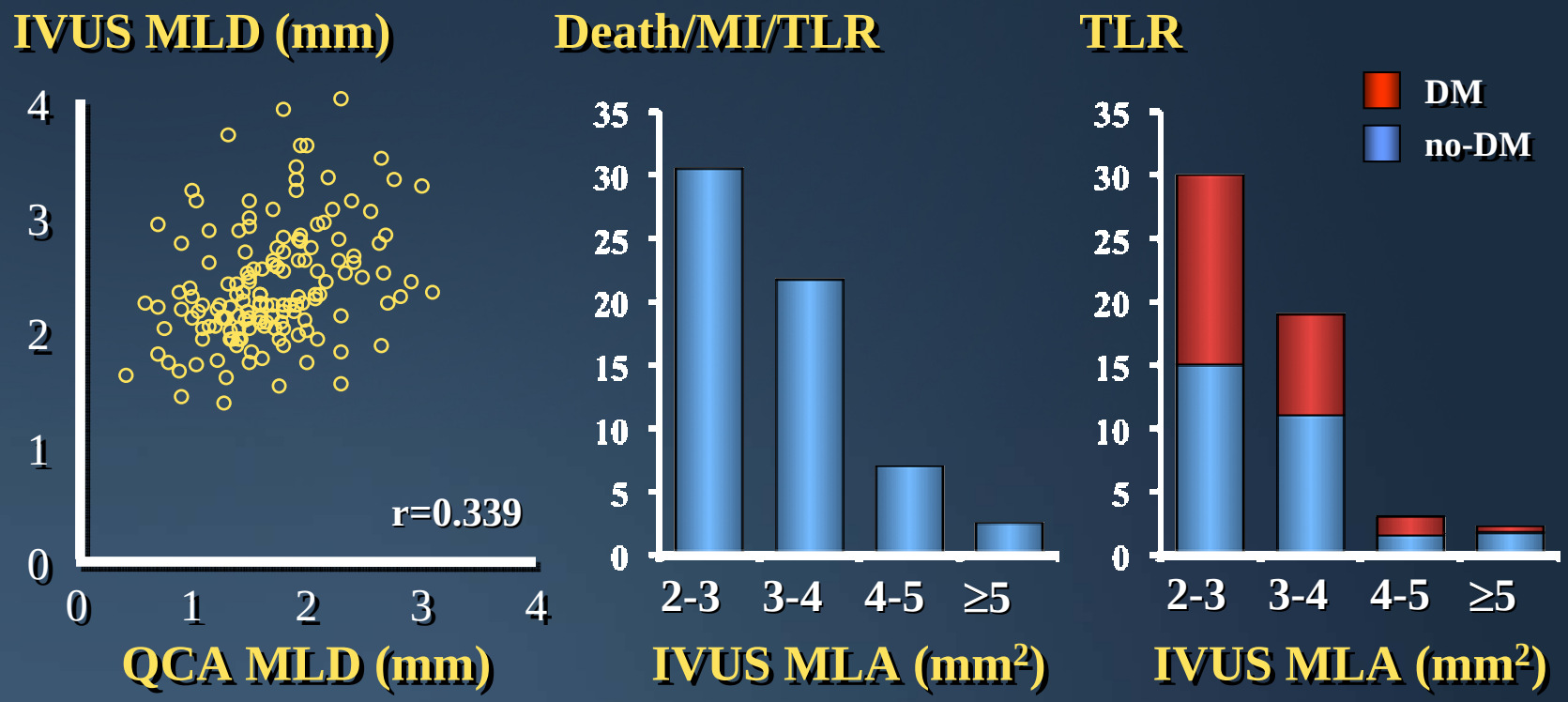
Takagi, et al. Circulation 1999;100:250-5

Briguori, et al. AJC 2001;87:136-41

IVUS Criteria for a 'Significant' Stenosis

- **Based on the studies comparing IVUS to flow wire, pressure wire, or SPECT thallium and based on studies with clinical outcome - most feel that a lumen area less than 4.0 mm^2 in a proximal epicardial artery *excluding the Left Main* (and SVGs) is a flow limiting stenosis**

Clinical Follow up in 357 Intermediate Lesions in 300 Pts Deferred Intervention After IVUS Imaging



- Death/MI/TLR @ (mean) 13 mos = 8% overall (2% death/MI and 6% TLR)
- Death/MI/TLR @ (mean) 13 mos = 4.4% in lesions with MLA >4.0mm^2
- Only independent predictor of death/MI/TLR was IVUS MLA (p=0.0041)
- Independent predictors of TLR were DM (p=0.0493) and IVUS MLA (p=0.0042)

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(Abizaid, et al. Circulation 1999;100:256-61)

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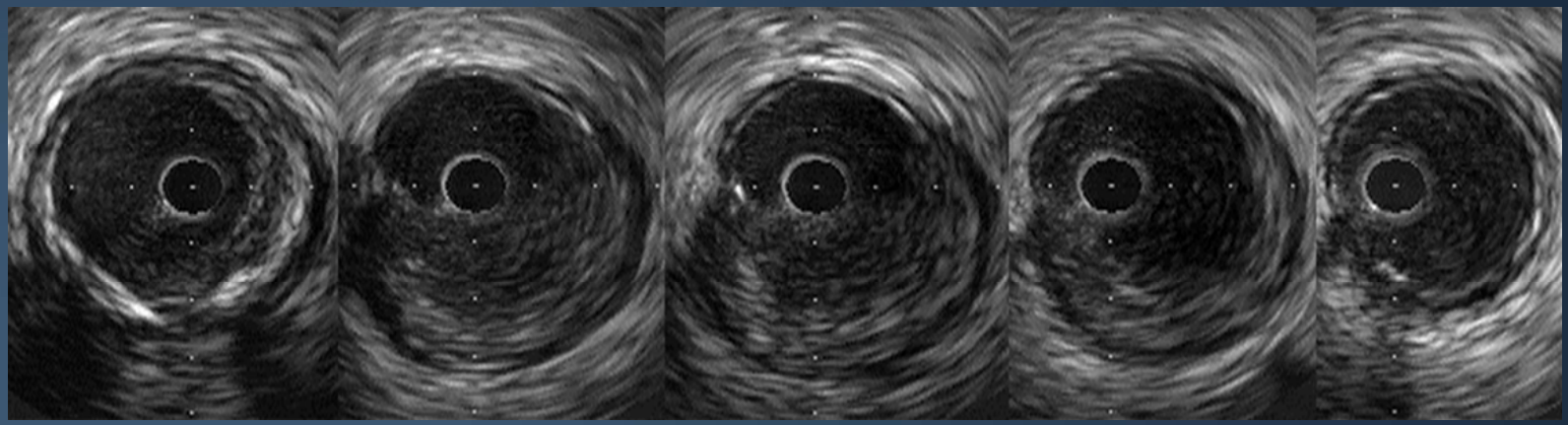
0 → 3 → 12mm



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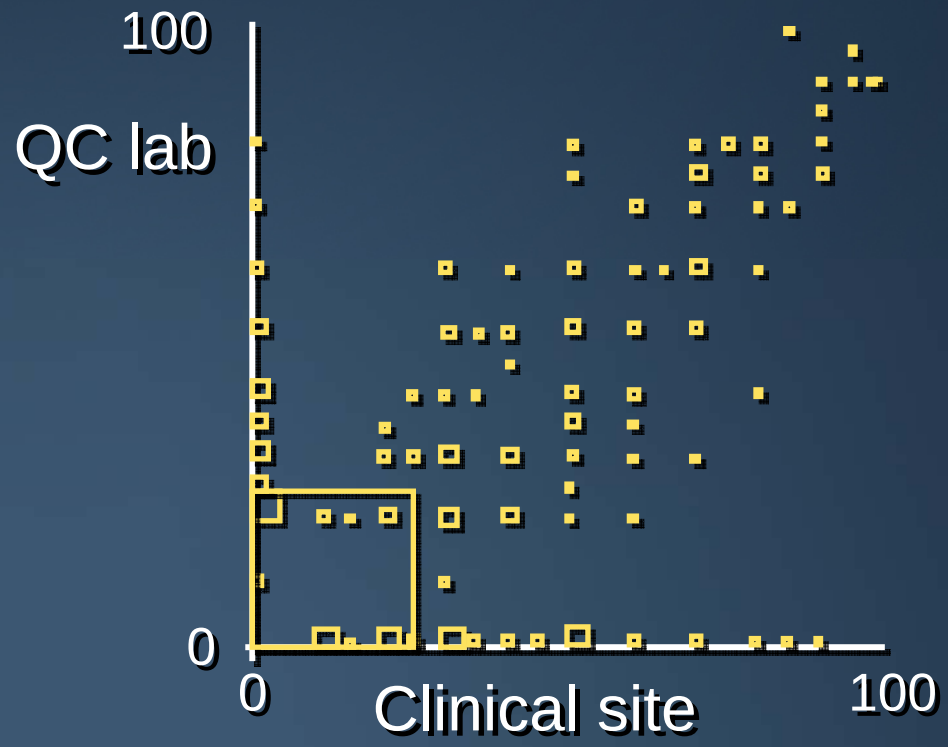
Of all the coronary segments, the LM has the greatest angiographic variability - I

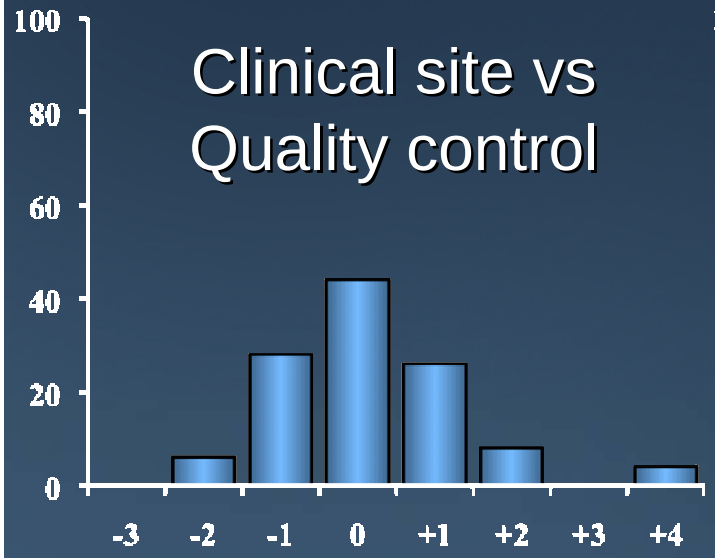
Comparison between percent stenosis assessment from the quality control (QC) lab vs the clinical site in the CASS Study

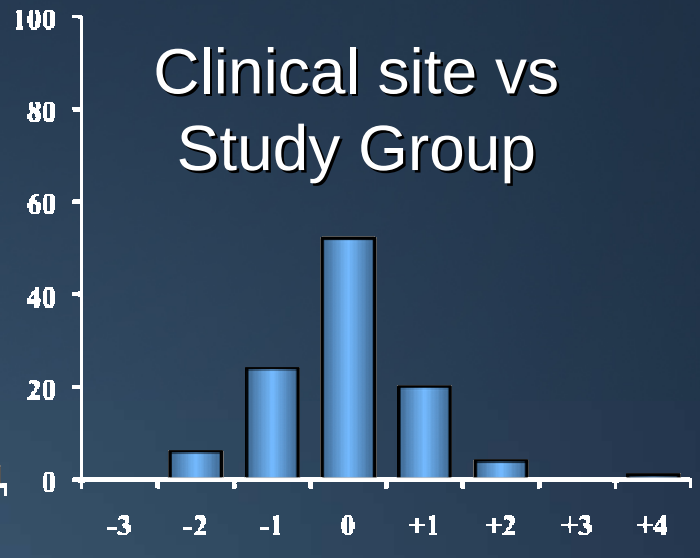


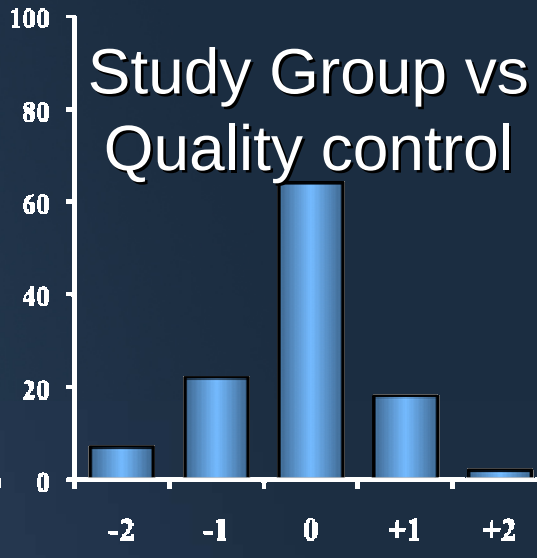
*area of the square is proportional to the number of cases

Fisher et al. Cathet Cardiovasc Diagn 1982;8:565-75

Of all the coronary segments, the LM has the greatest angiographic variability - II







Five grades of LM severity		# of grades of difference in assessment of LM severity	
1:	0-24% DS	0:	no difference
2:	25-49% DS	+1 or -1:	1 grade difference
3:	50-74% DS	+2 or -2:	2 grades of difference
4:	75-89% DS	+3 or -3:	3 grades of difference
5:	90-100%DS	+4 or -4:	4 grades of difference

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Cameron et al. Circulation 1983;68:484-489

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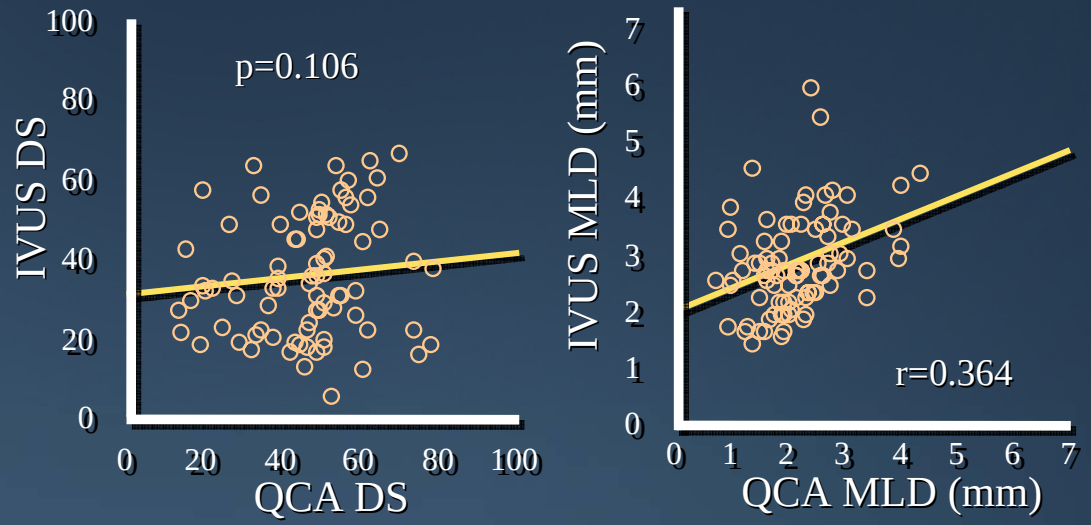
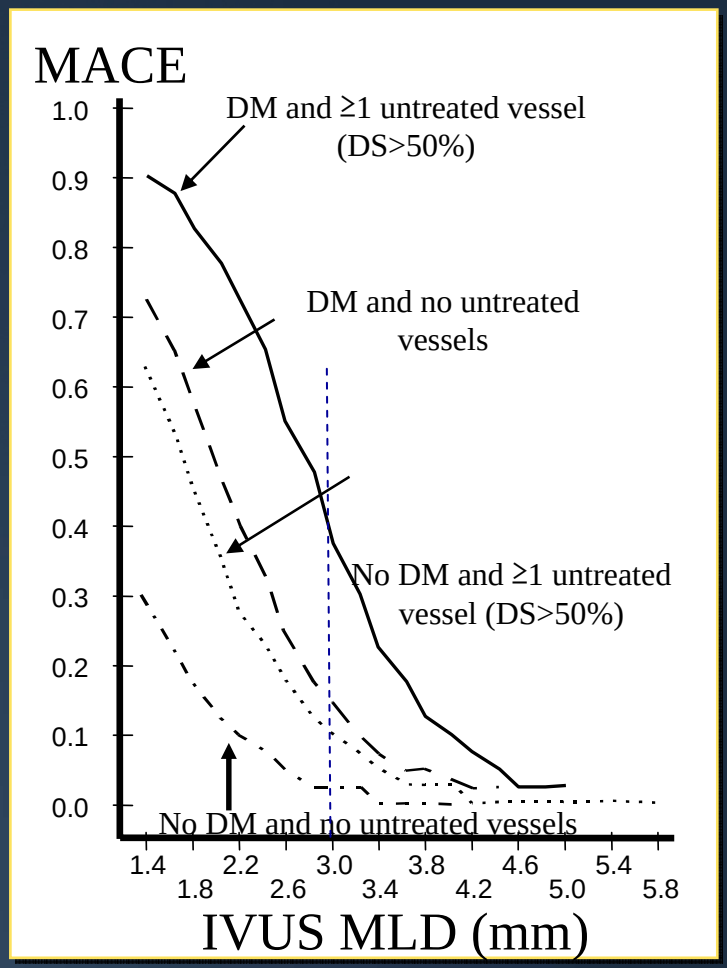
But surely we are better today!

- 51 intermediate or equivocal LM lesions were evaluated by FFR and angiography. Four experienced interventional cardiologists visually classified lesions as ‘significant’, ‘not significant’, or ‘unsure.’
- The 4 experienced interventional cardiologists achieved correct lesion classification in no more than ~50% of each case regardless of the FFR threshold (≤0.75 or ≤0.80).
- Interobserver variability was large, resulting in unanimous correct lesion classification in only 29%!

Lindstaedt et al. Int J Cardiol 2007;120:254-61

Follow-up of 122 patients with moderate LM disease

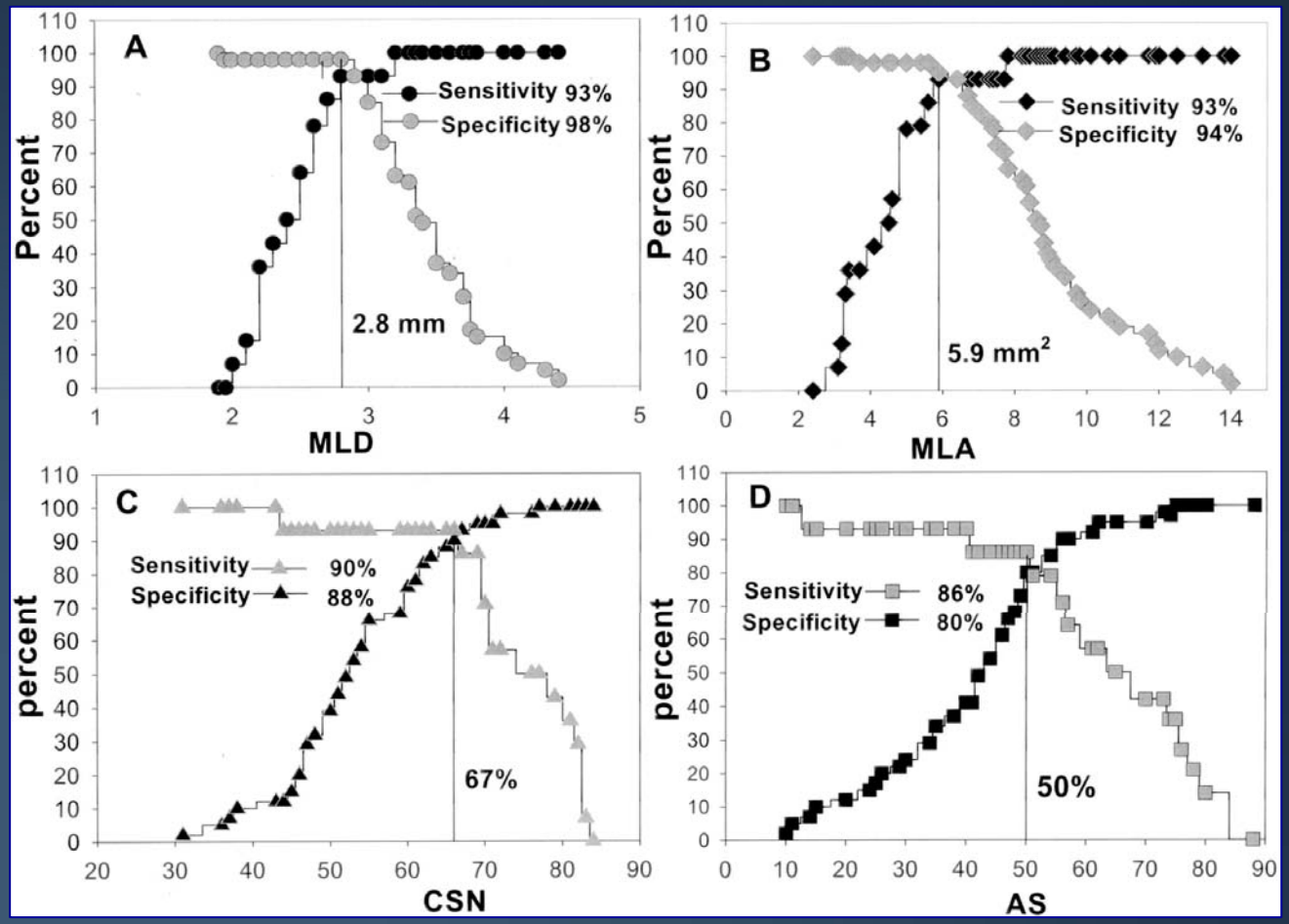




Independent predictors of MACE @11.7 months: DM (p=0.004), untreated lesion >50% (p=0.037), and IVUS MLD (p=0.005) – but NOT the plaque burden.

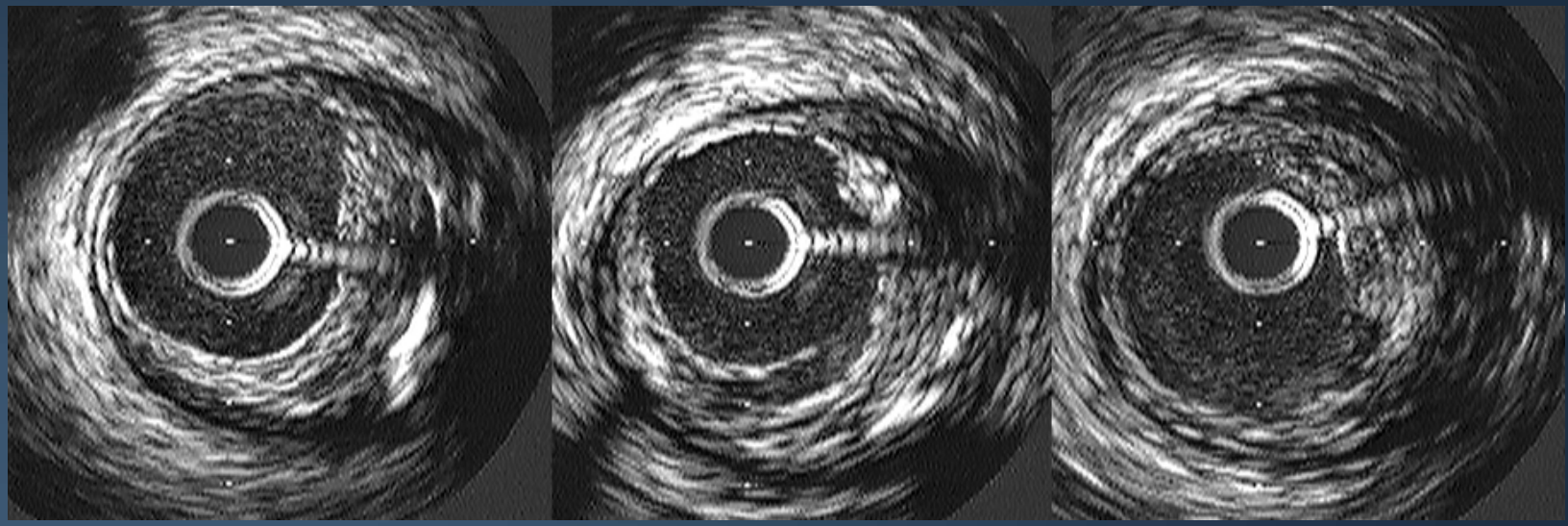
Abizaid et al. J Am Coll Cardiol 1999;34:707-15

IVUS determinants of LMCA FFR <0.75



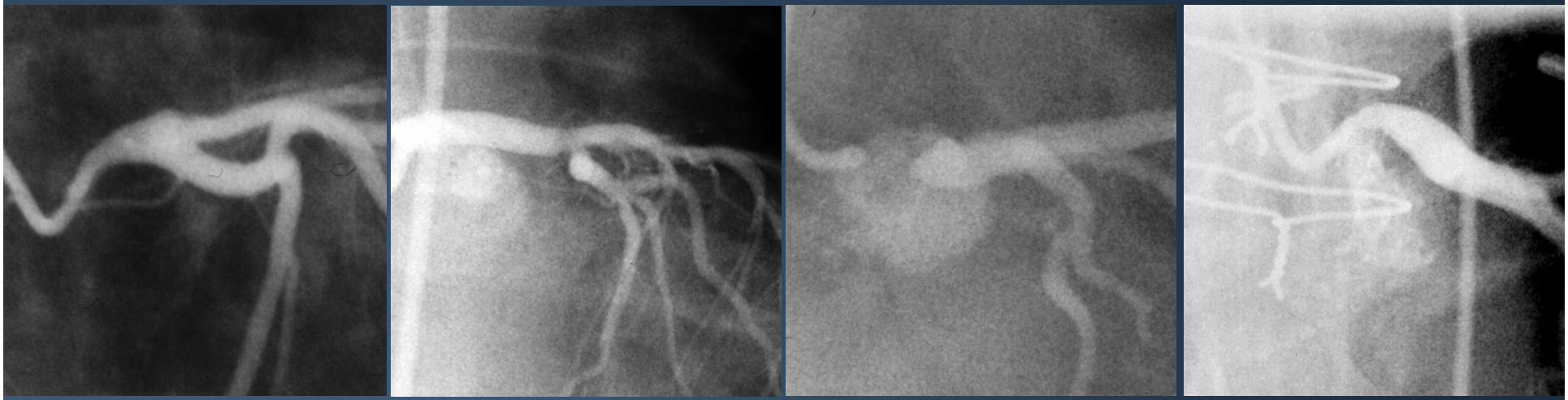
Jasti et al. Circulation 2004;110:2831-6

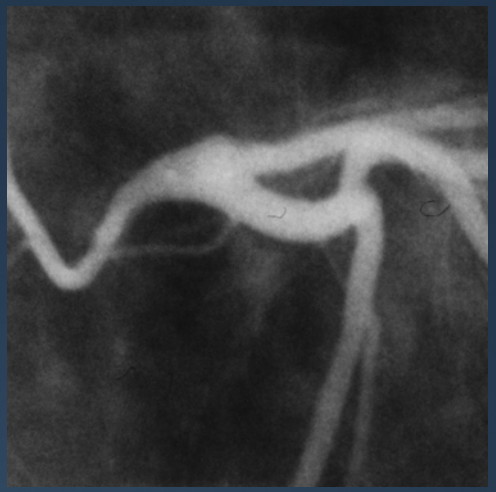
IVUS assessment of LM disease significance is based on lumen dimensions, not plaque burden

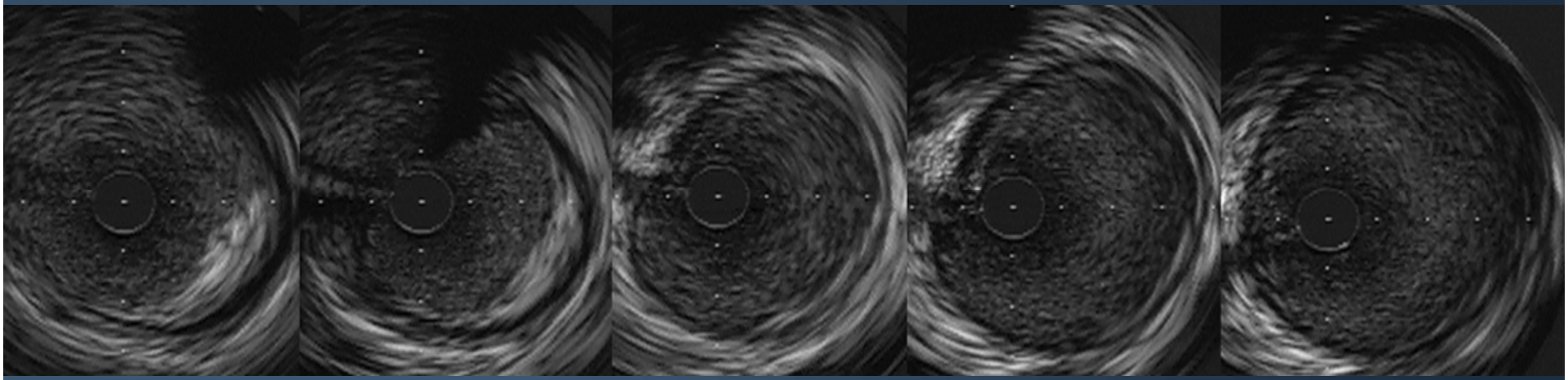


Plaque burden (P&M/EEM) = 68%
MLA=7.2mm^2

Which of these LMCA lesions is significant and, therefore, should be treated? And which is not??







0 → 1.5 → 6.0mm

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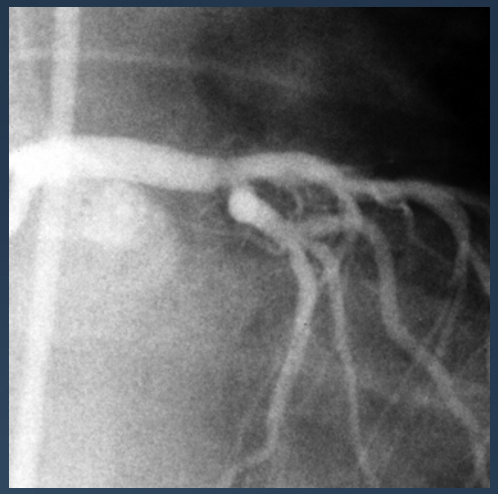

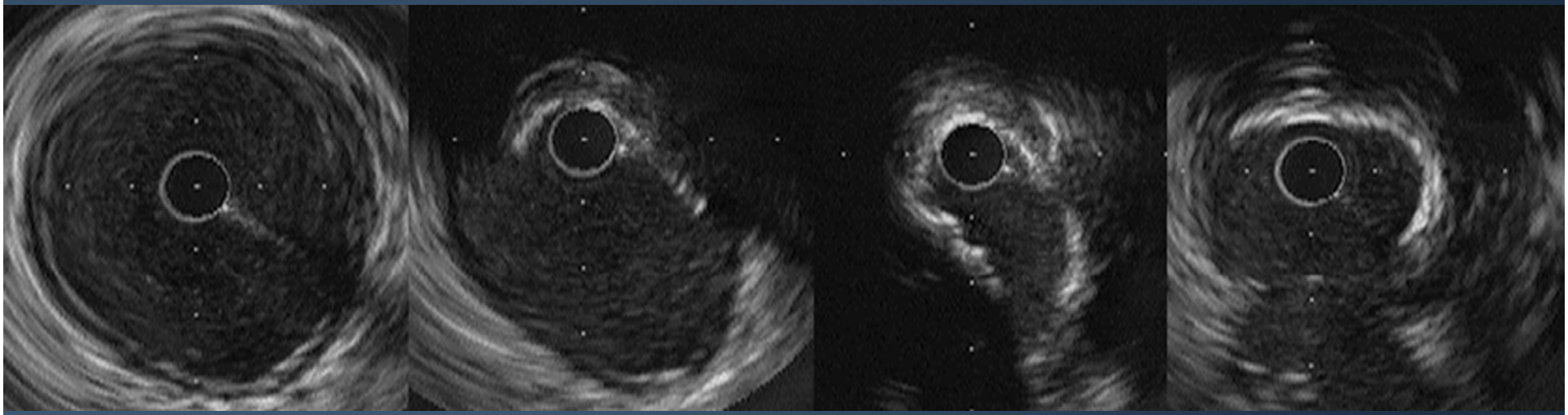

0 → 3.0 → 9.0mm

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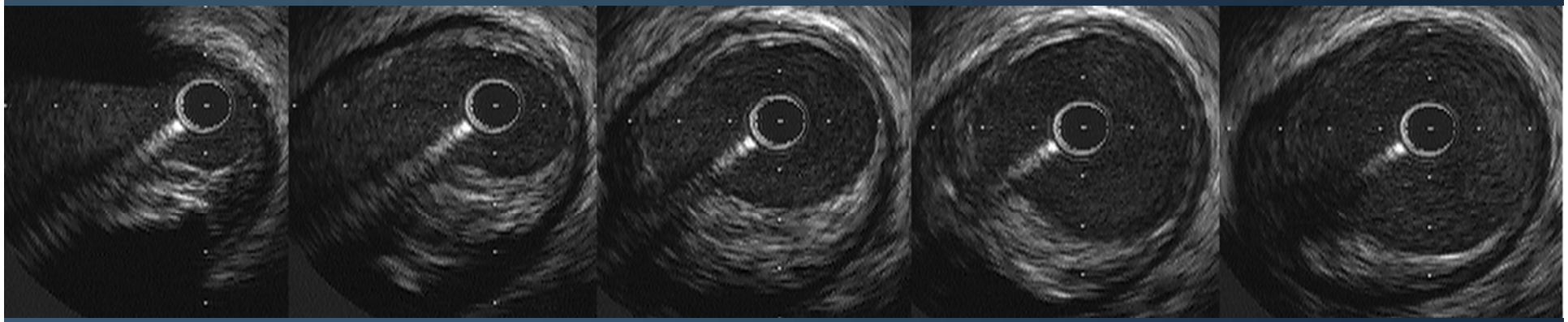

0 → 2.0 → 8.0mm

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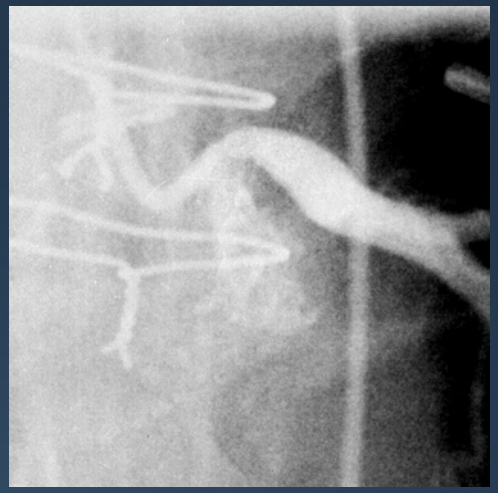

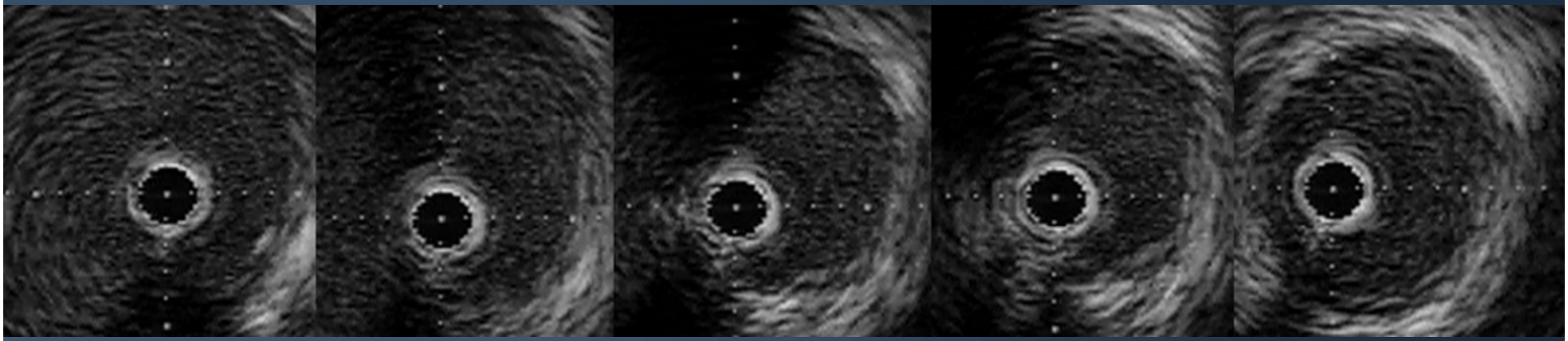

0 → 1.0 → 4.0mm

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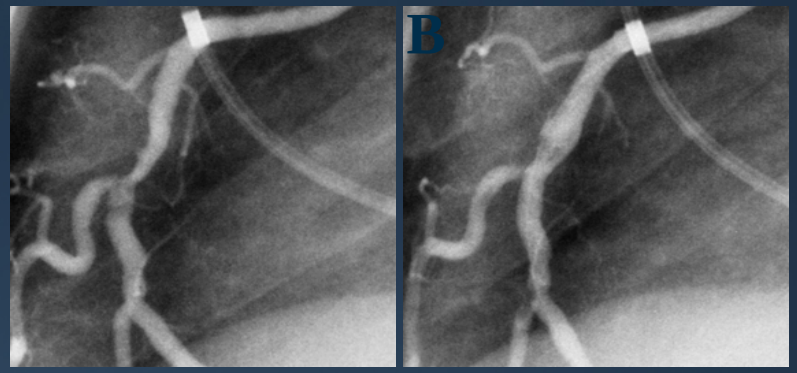
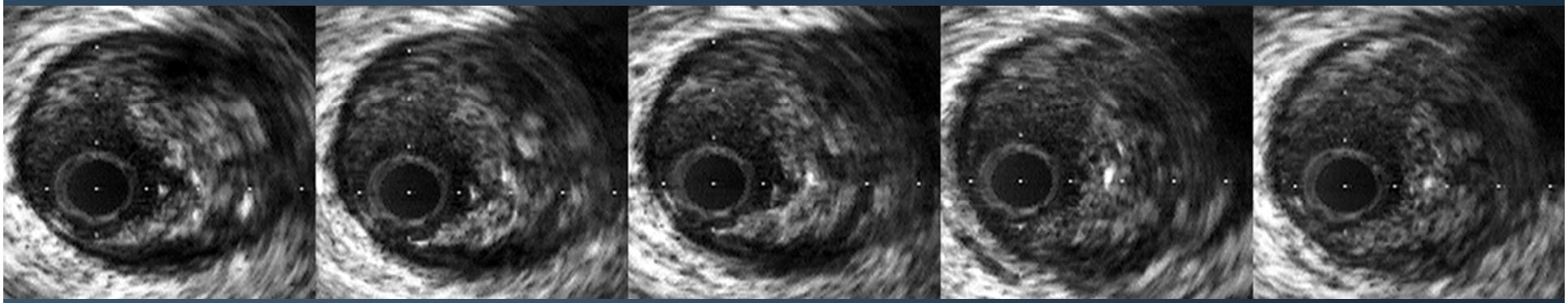
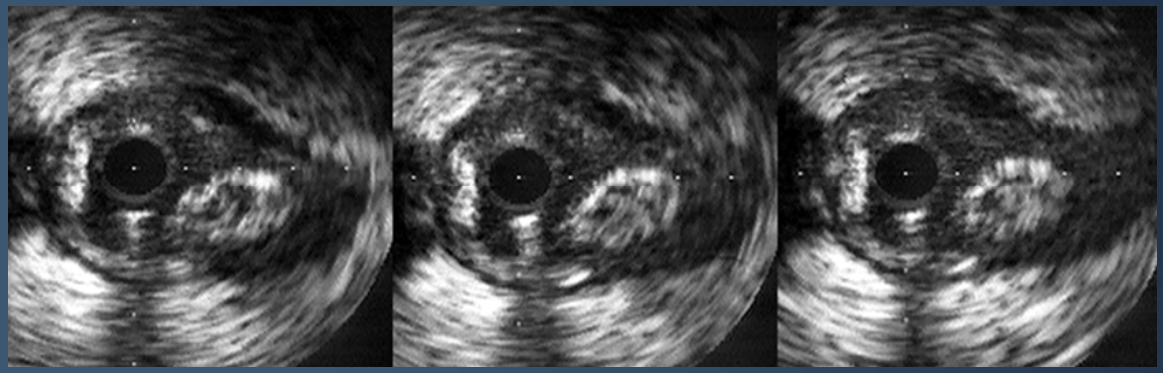
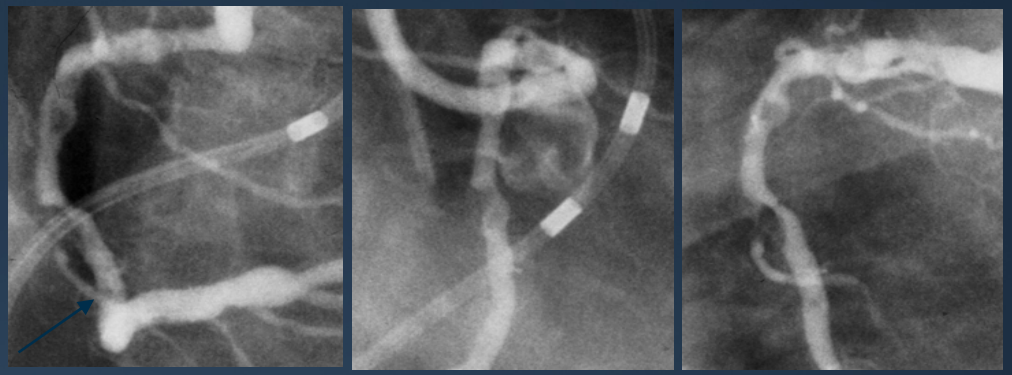
Unusual Lesions

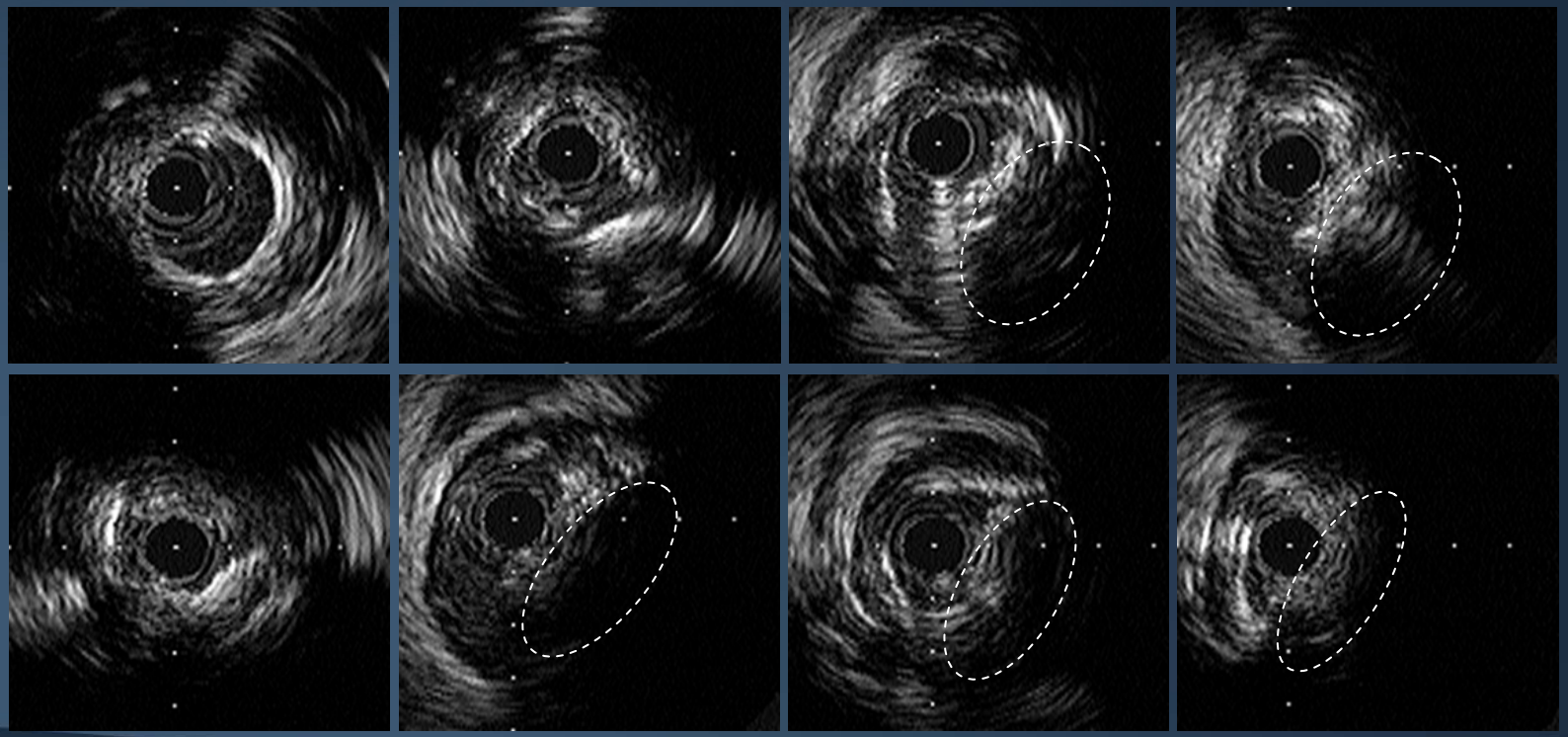
- Filling Defects
- Aneurysms
- Acute Coronary Syndromes
- Spontaneous Dissections
- Hazy Lesions


B









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IVUS Classification of Angiographic Aneurysms

- **Of 77 angiographic aneurysms**
  - **21 (27%) true aneurysm**
  - **3 (4%) pseudoaneurysm**
  - **12 (16%) complex plaques or unhealed dissections**
  - **41 (53%) normal segment adjacent to one or more stenoses**

	True Aneurysm	PSA	Complex Plaque	Normal Site with Adjacent Stenoses
No prior PCI	10	0	6	26
Prior PCI	11	3	6	15

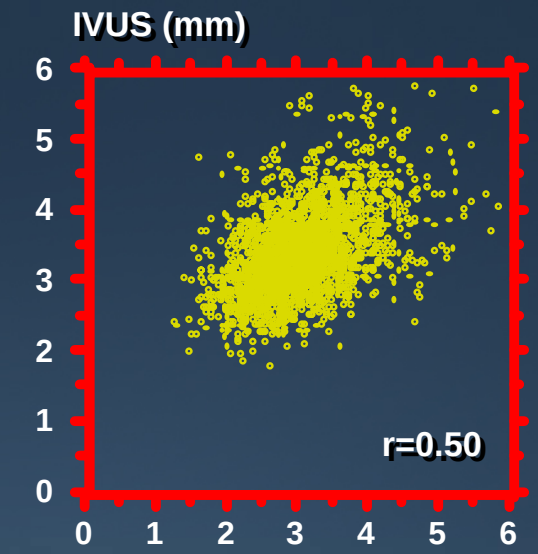
(Maehara et al Am J Cardiol 2001;88:365-70)

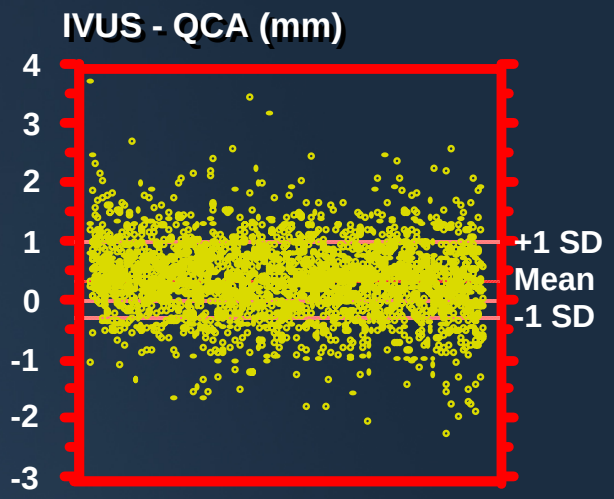
Pre-, Inter-, and Post-Procedure IVUS

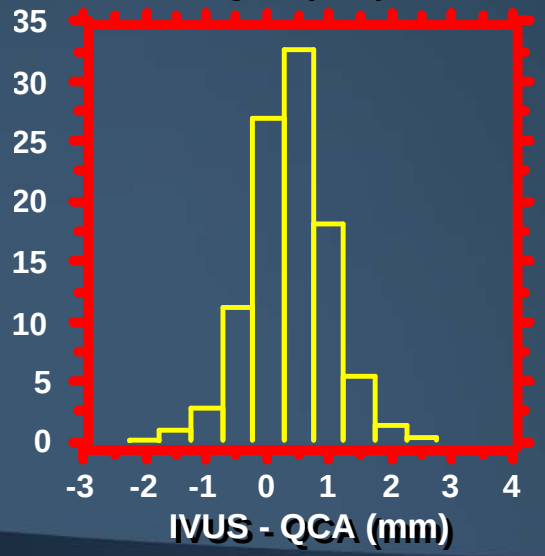
- Pre-intervention
  - Measure vessel size and lesion length to select DES size and length
  - Assess unusual lesion morphology
- Post-intervention
  - Expansion*: Absolute stent CSA or stent CSA relative to a pre-defined reference or target area/diameter
  - Apposition*: Contact between stent and vessel wall
  - Full lesion coverage
  - Complications

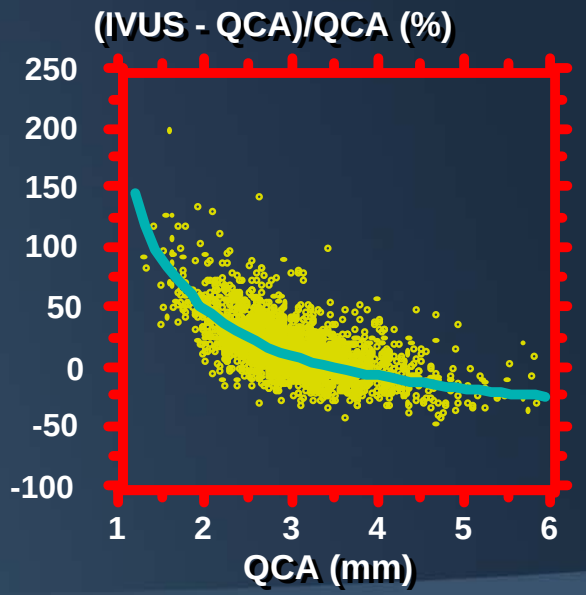
*While expansion and apposition can co-exist, they not the same. The prognostic implications are different, and the solutions are different. These terms should NOT be used interchangeably

IVUS vs QCA measurements of reference lumen dimensions (3311 nonostial lesions)









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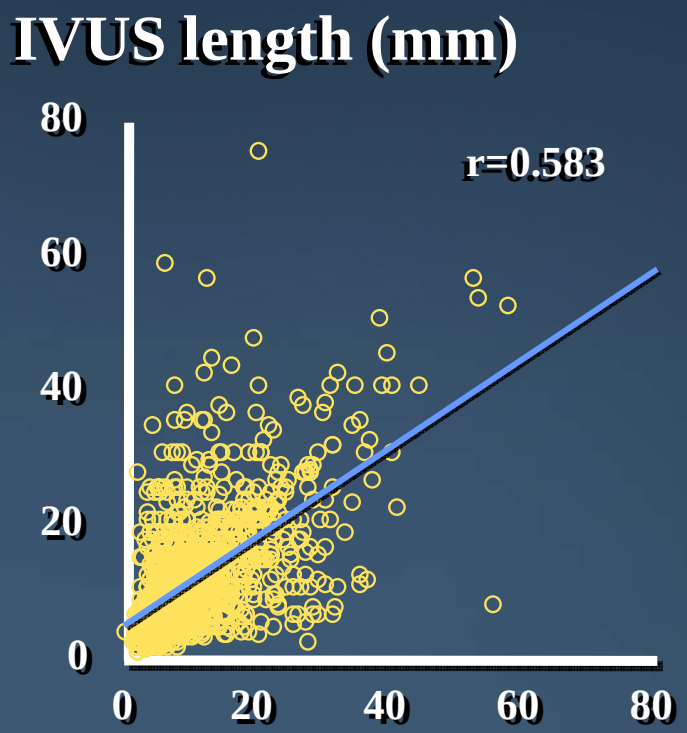
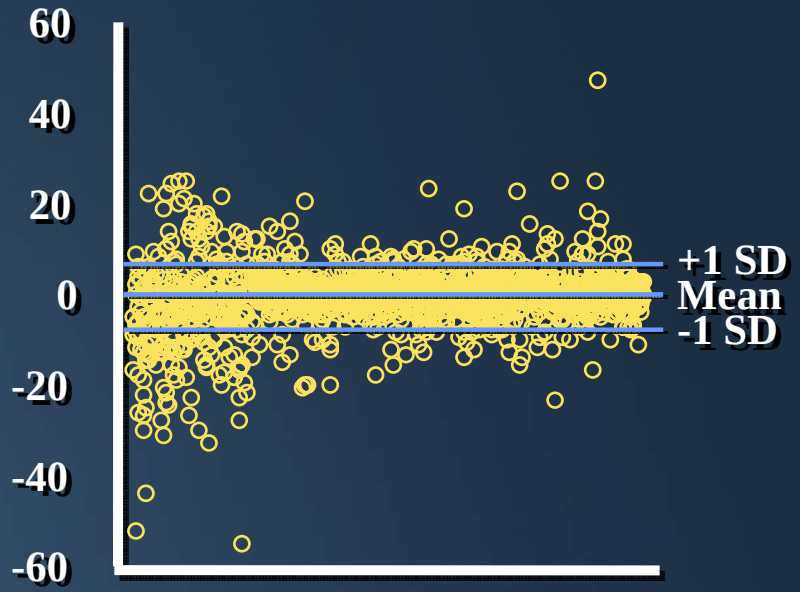
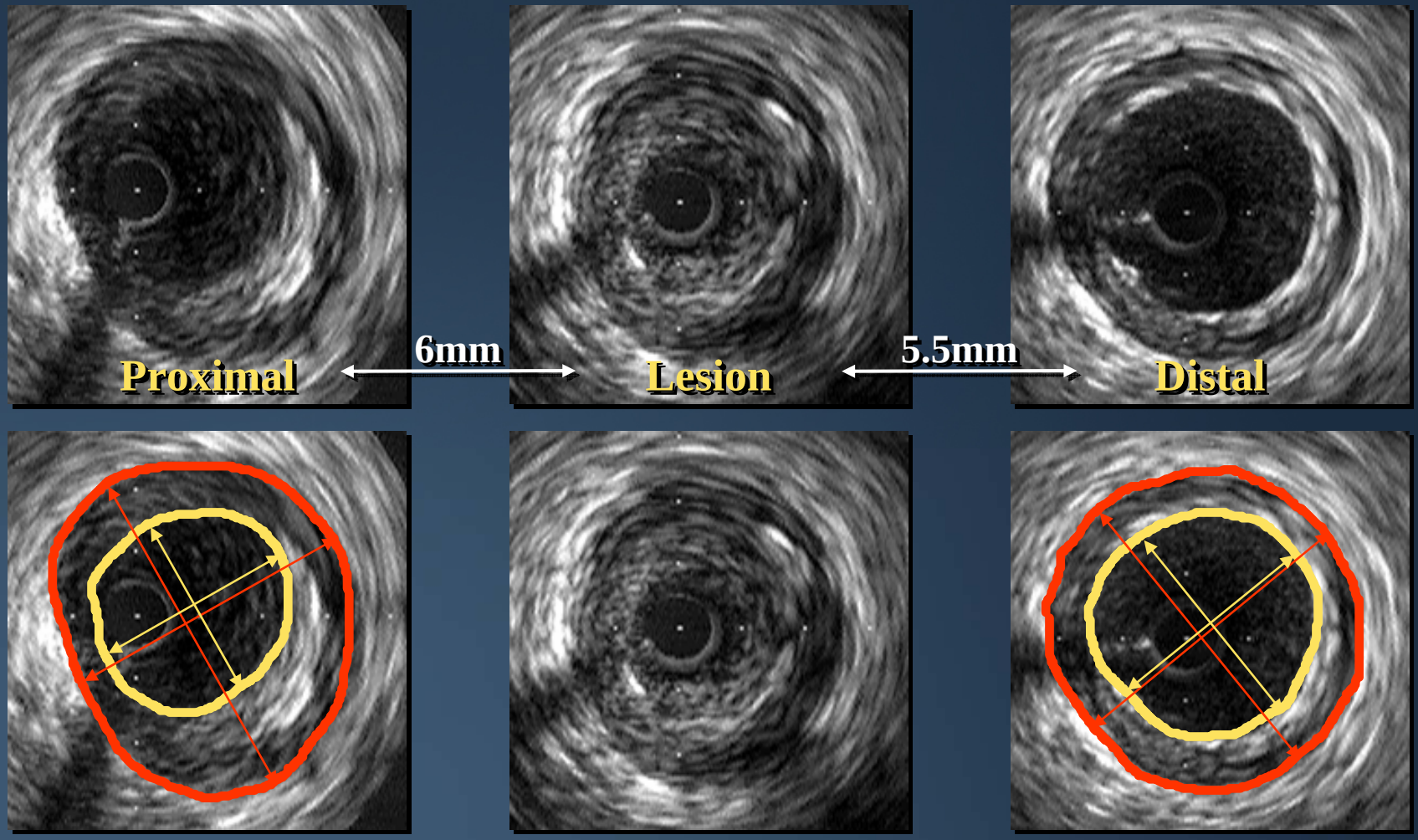
IVUS vs QCA measurement of lesion length

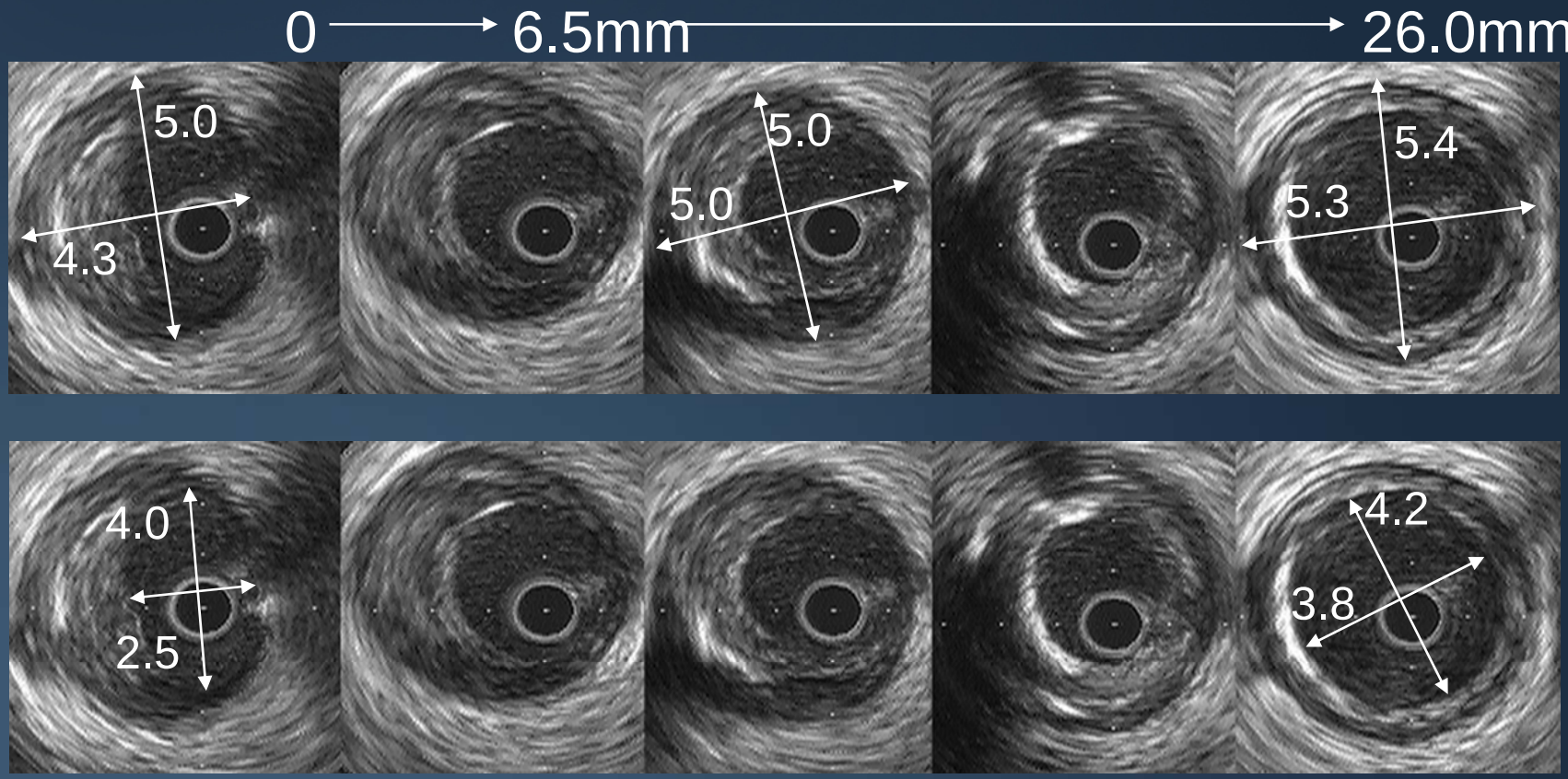




IVUS-QCA length=
0.6±7.2mm

Stent sizing using IVUS





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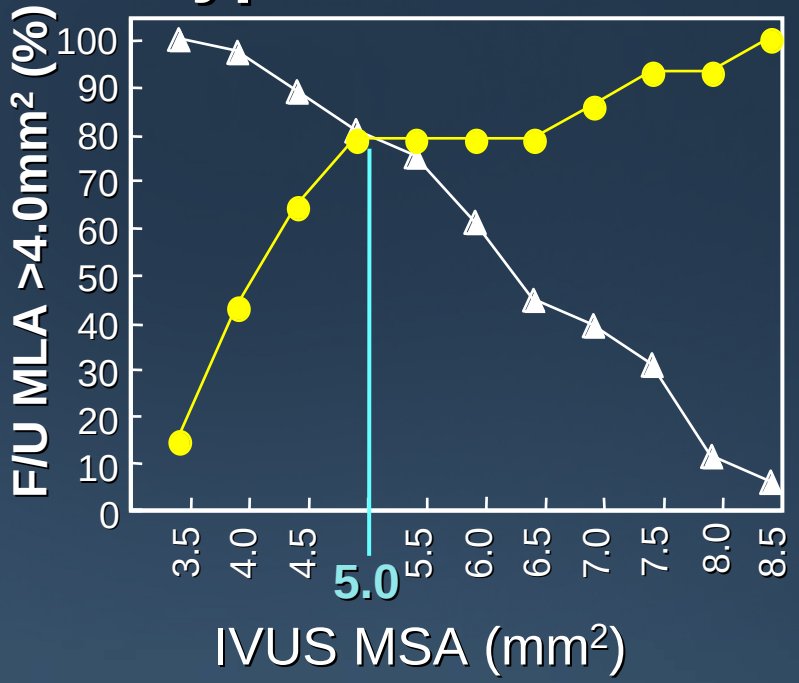
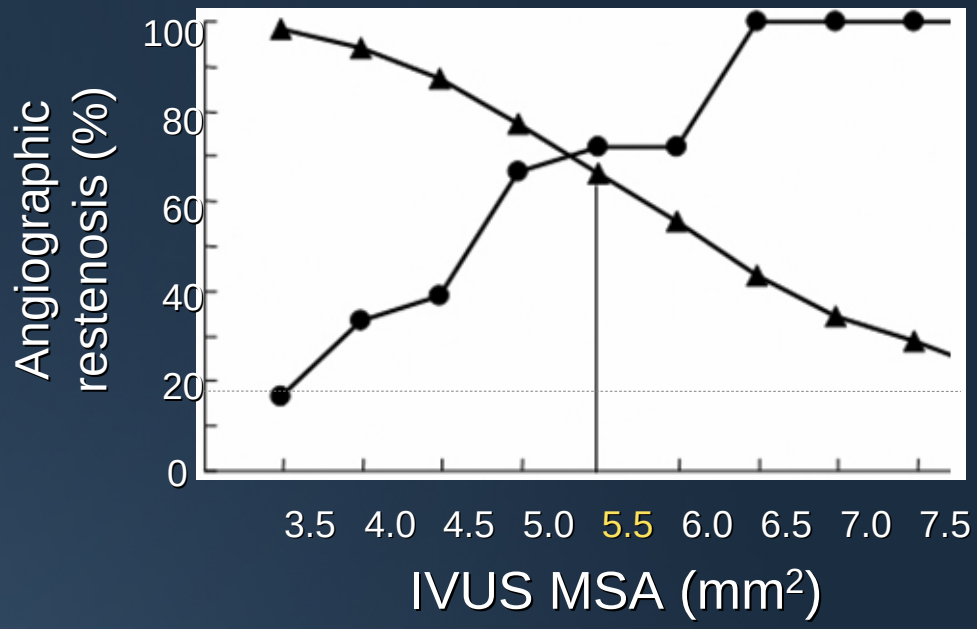
Predictors of DES Thrombosis & Restenosis

	DES Thrombosis	DES Restenosis
Underexpansion	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8)* •*Okabe et al., Am J Cardiol. 2007;100:615-20*	•*Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* •*Hong et al. Eur Heart J 2006;27:1305-10* •*TAXUS IV, V, VI meta-analysis* •*Fujii et al. Circulation 2004;109:1085-1088*
Edge problems (geographic miss, secondary lesions, large plaque burden, etc)	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8)* •*Okabe et al., Am J Cardiol. 2007;100:615-20*	•*Sakurai et al. Am J Cardiol 2005;96:1251-3* •*Liu et al, Am J Cardiol, in press* •*Costa et al, Am J Cardiol, 2008;101:1704-11*

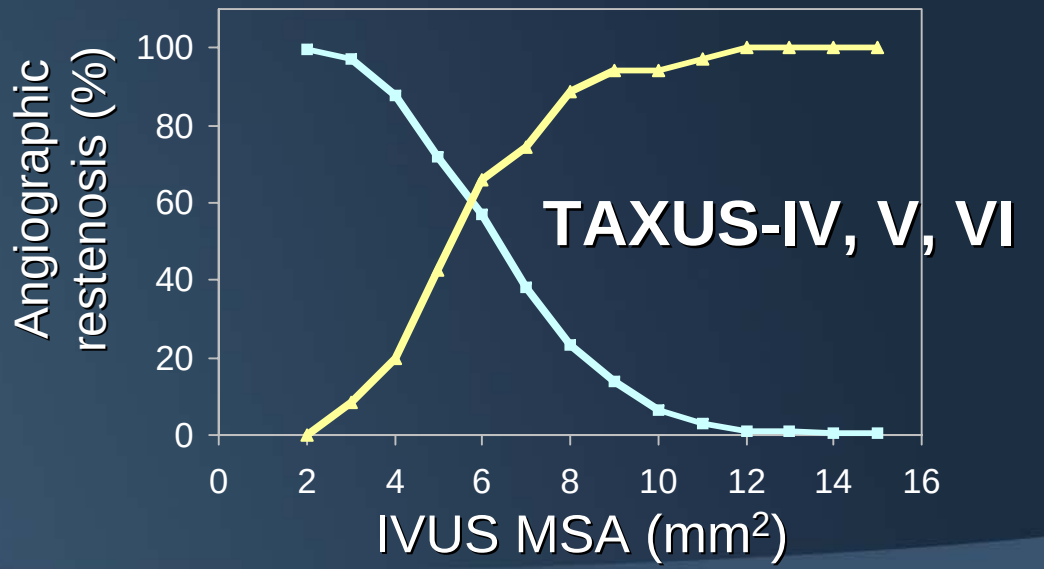
Cypher in SIRIUS*



Cypher at AMC**



By definition, sensitivity/specificity curve analysis "must" identify a single MSA that best separates restenosis from no restenosis



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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)*

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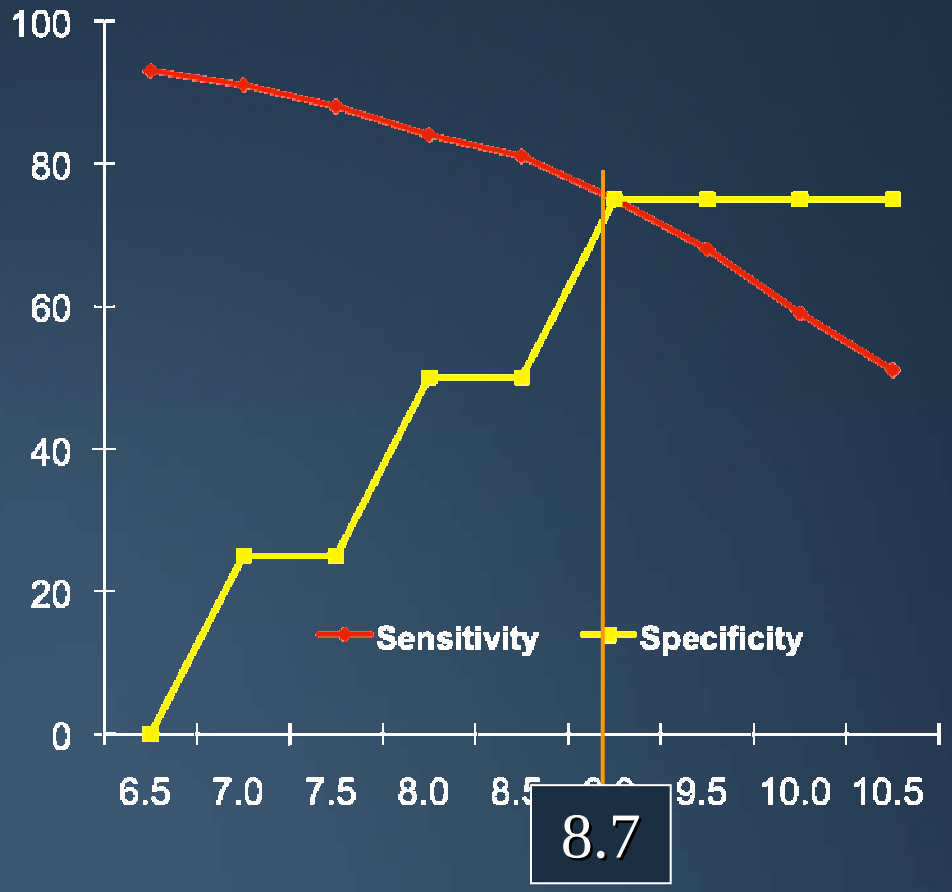
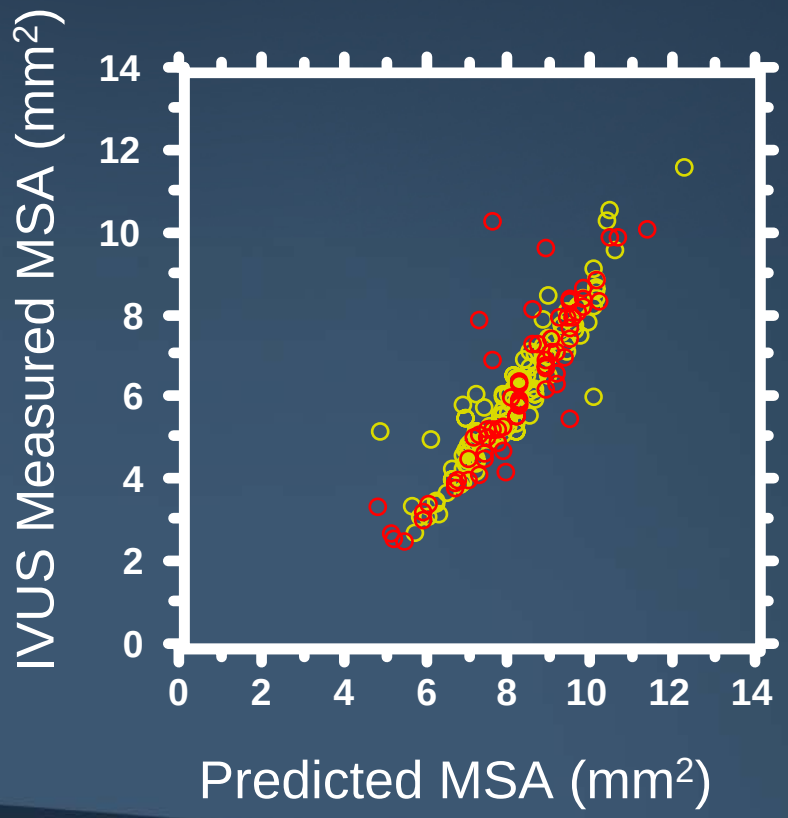
“Optimal” MSA and TLR after LMCA DES Implantation (n=595)

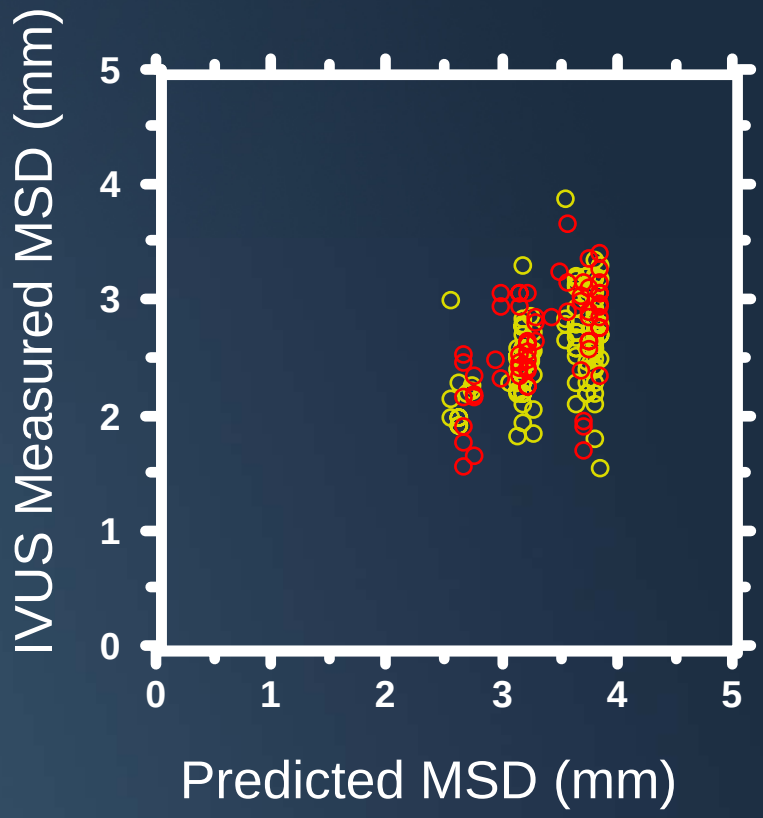


(SJ Park et al. TCT 2007)

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 Cordis (Cypher in yellow, n=133) and BSC (Taxus in red, n=67). DES achieve an average of only 75% of the predicted MSD (66% of MSA)





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(de Rebamar Costa et al, Am Heart J 2007;153:297-303)

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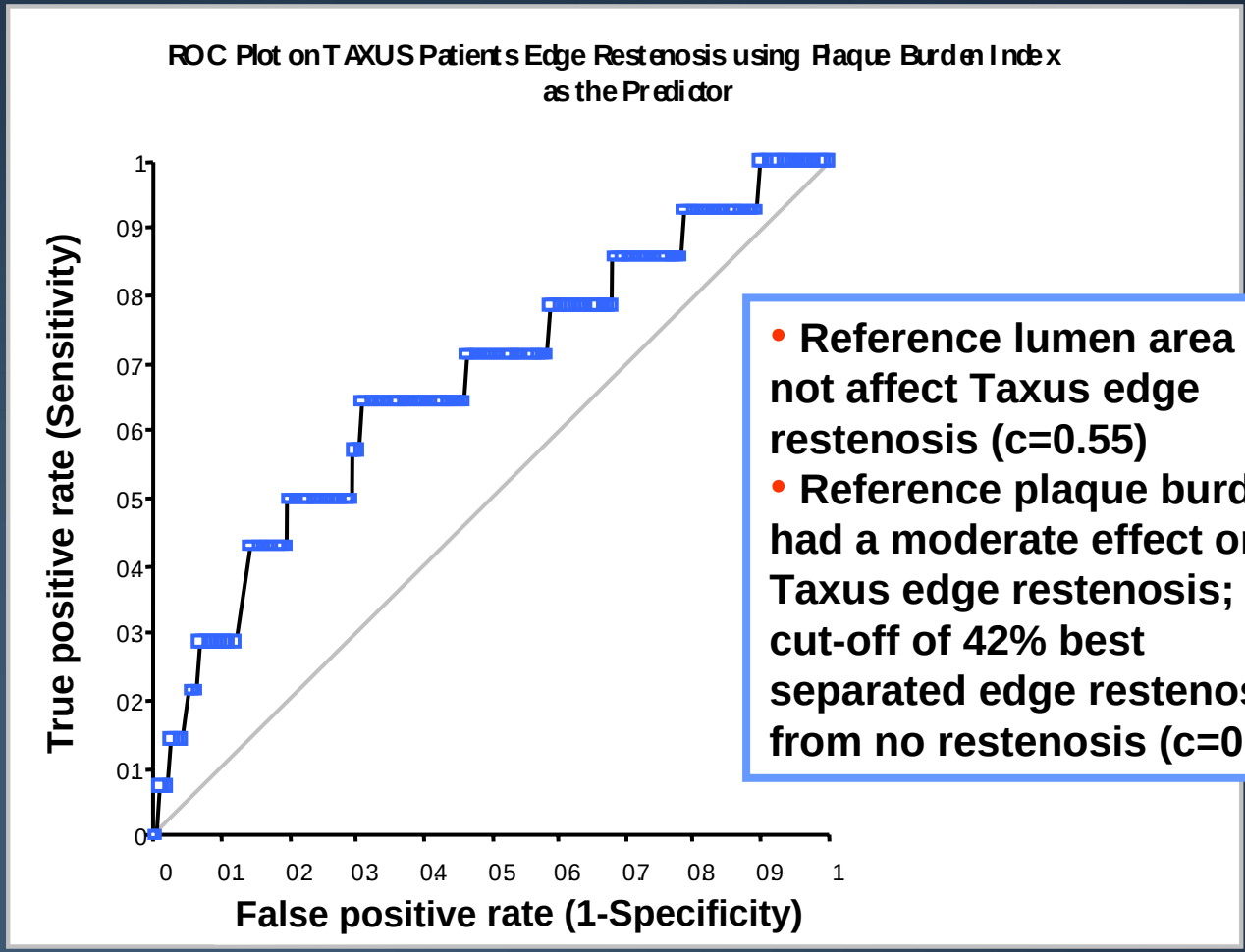
Comparison of 9-month QCA edge restenosis vs reference lumen area and plaque burden in TAXUS-IV, V, and VI (n=810)



- Reference lumen area did not affect Taxus edge restenosis (c=0.55)
- Reference plaque burden had a moderate effect on Taxus edge restenosis; a cut-off of 42% best separated edge restenosis from no restenosis (c=0.67)

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(Liu et al, Am J Cardiol, in press)

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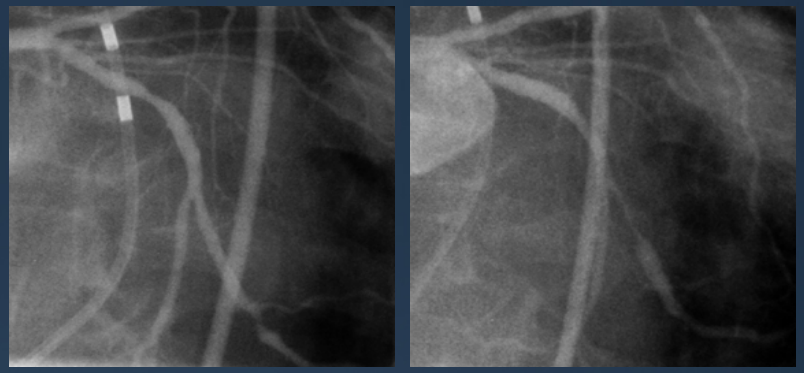
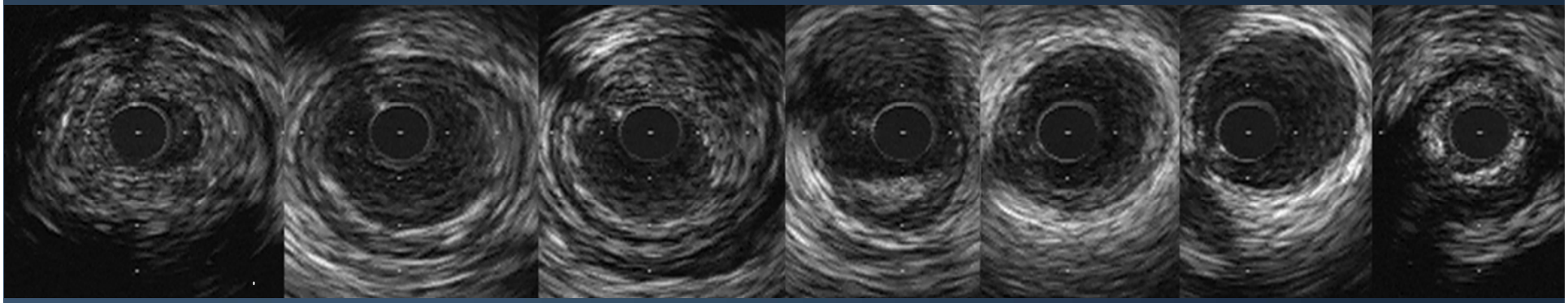
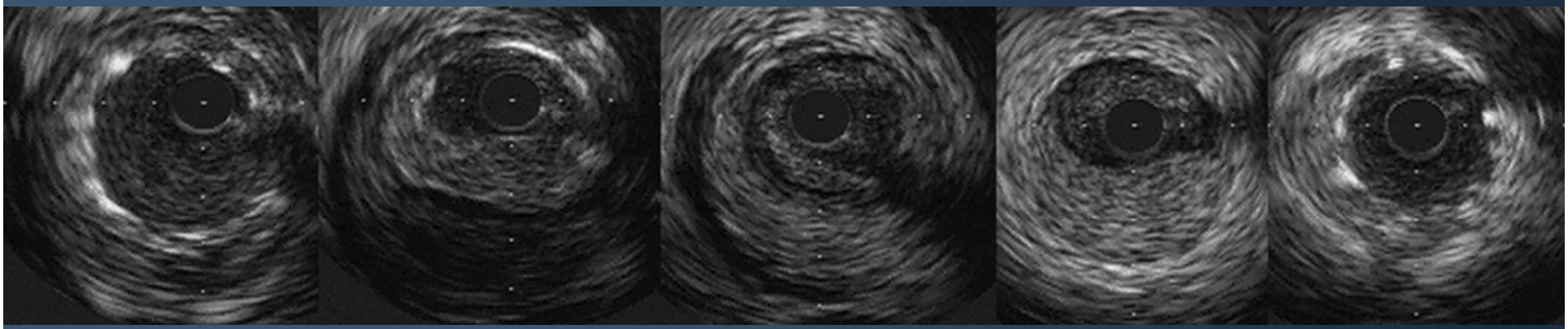




0 → 7.5mm → 45.0mm



0 → 8.0mm → 32.0mm

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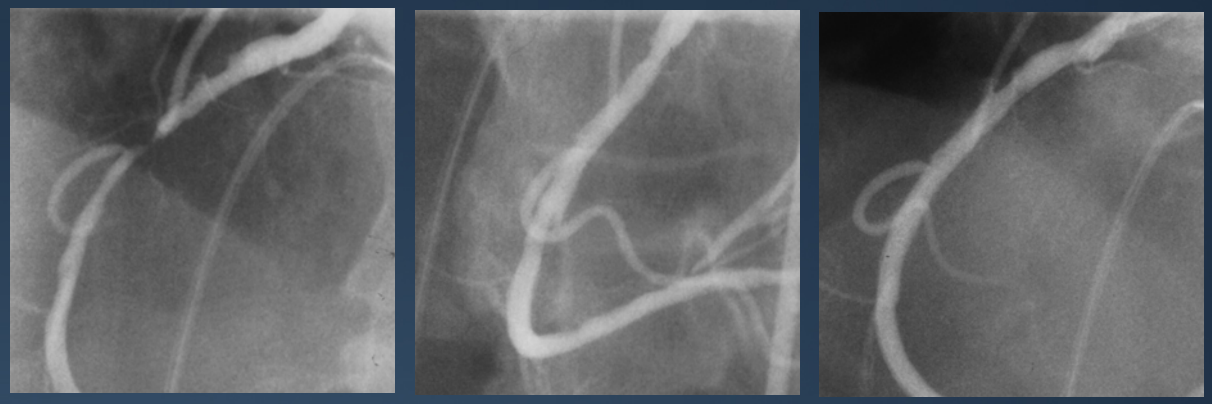

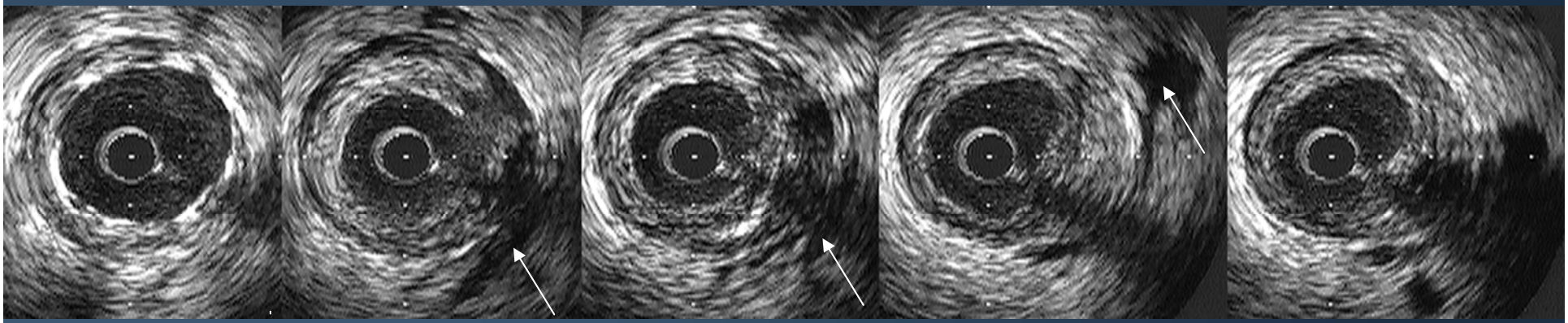

0 → 1.5mm → 6.0mm

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