Baseline Features & Plaque Characteristics from the PROSPECT Trial

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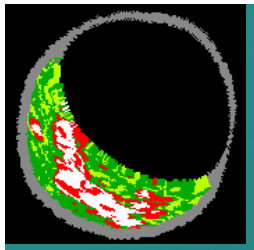
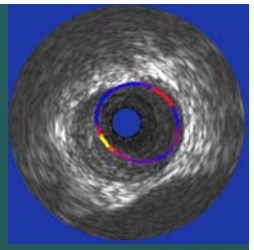
Columbia University Medical Center
Cardiovascular Research Foundation



The PROSPECT Trial



700 pts with ACS

UA (with ECGΔ) or NSTEMI or STEMI >24º

1-2 vessel CAD undergoing PCI

at up to 40 sites in U.S., Europe

Metabolic S.
-Waist circum
-Fast lipids
-Fast glu
-HgbA1C
-Fast insulin
-Creatinine

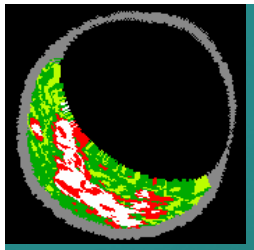
PCI of culprit lesion(s)

Successful and uncomplicated

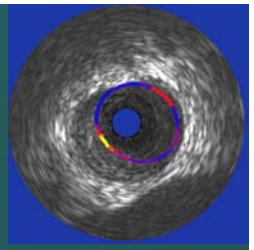
Formally enrolled

Biomarkers
-Hs CRP
-IL-6
-sCD40L
-MPO
-TNFα
-MMP9
-Lp-PLA2
-others

PI: Gregg W. Stone
Sponsor: Abbott Vascular; Partner: Volcano



3-vessel imaging post PCI



Culprit artery, followed by non-culprit arteries

Angiography (QCA of entire coronary tree)

IVUS

Virtual histology

Palpography (n=~350)

Proximal 6-8 cm of each coronary artery

Meds rec
Aspirin
Plavix 1yr
Statin
Repeat biomarkers
@ 30 days, 6 months

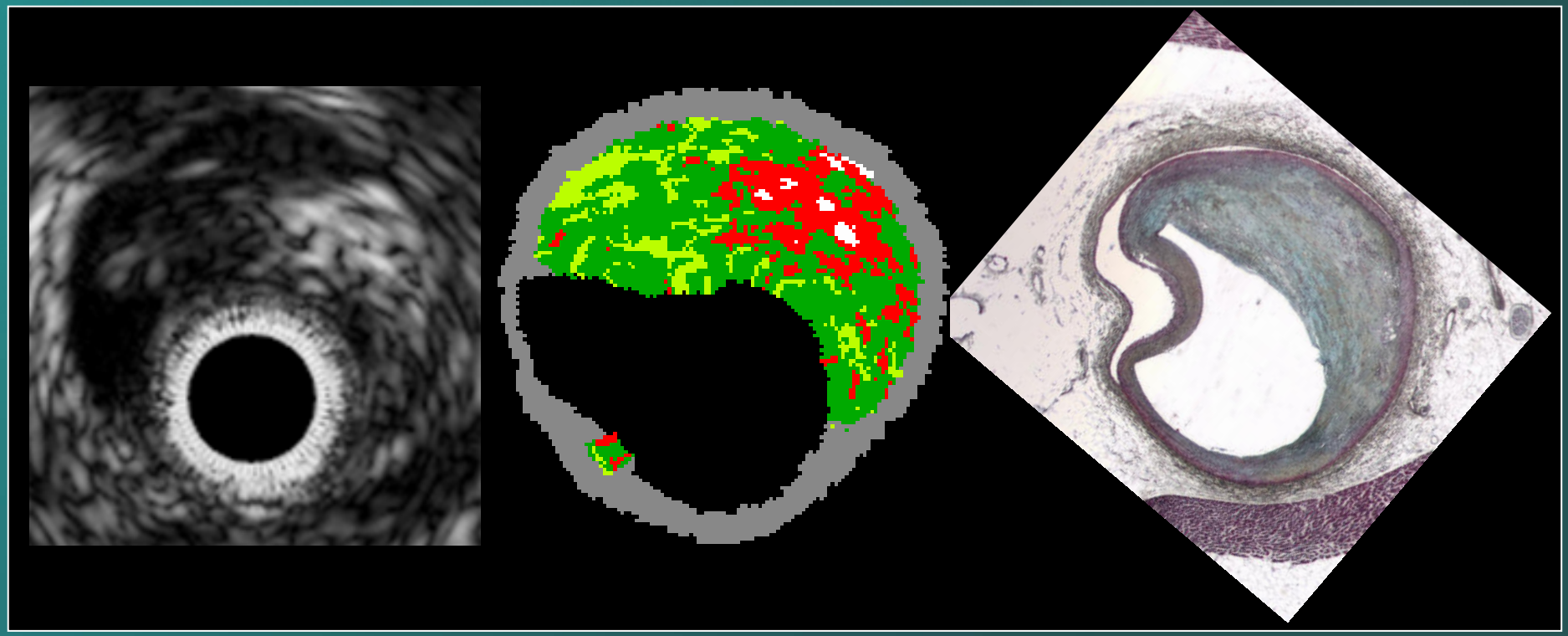
F/U: 1 mo, 6 mo, 1 yr, 2 yr, ±3-5 yr
(event driven)

MSCT Substudy
N=50-100

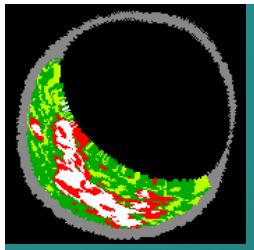
Repeat imaging in pts with events

Volcano IVUS RF (Virtual Histology™)

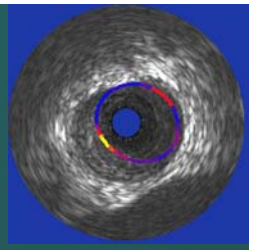
Ex-vivo validation



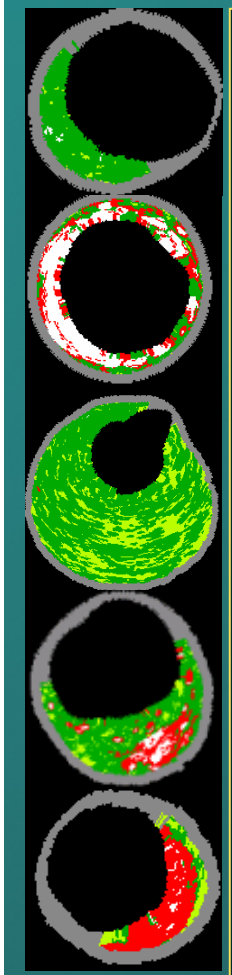
Fibrous; Fibrofatty; Necrotic core; Dense calcium



PROSPECT Methodology
IVUS/VH Core Lab Analysis



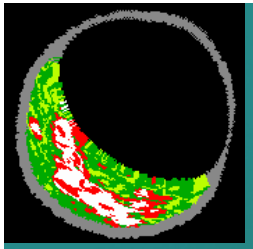
Lesions are classified into 11 sub-types based on VH composition



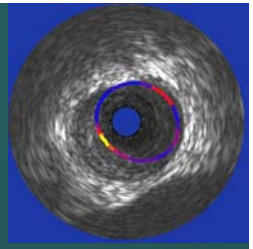
1. Fibrotic
2. Fibrocalcific
3. Pathological intimal thickening
4-7. Thick cap fibroatheroma
8-11. VH thin cap fibroatheroma
(presumed high risk)

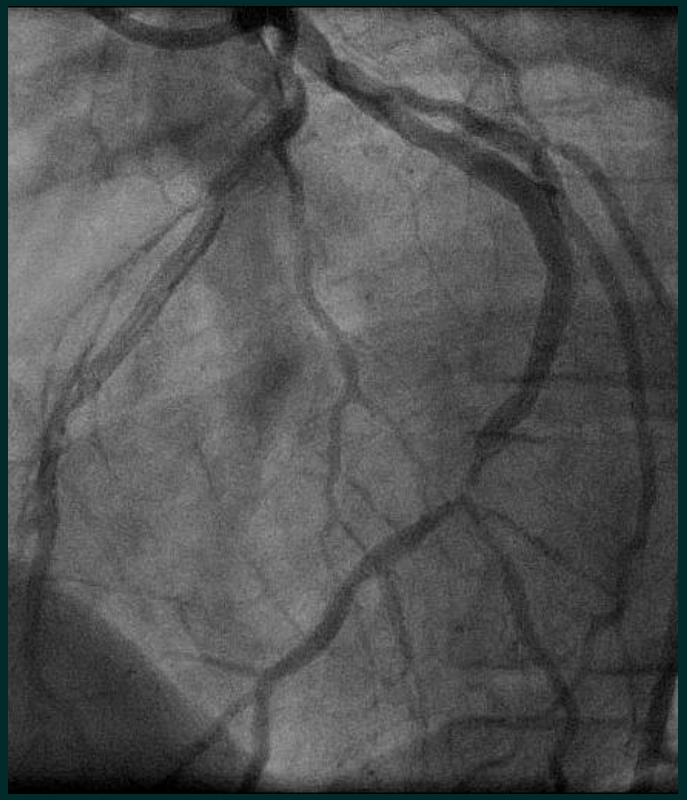
Single layer, no DC
Single layer, +DC
Multiple layers, no DC
Multiple layers, +DC

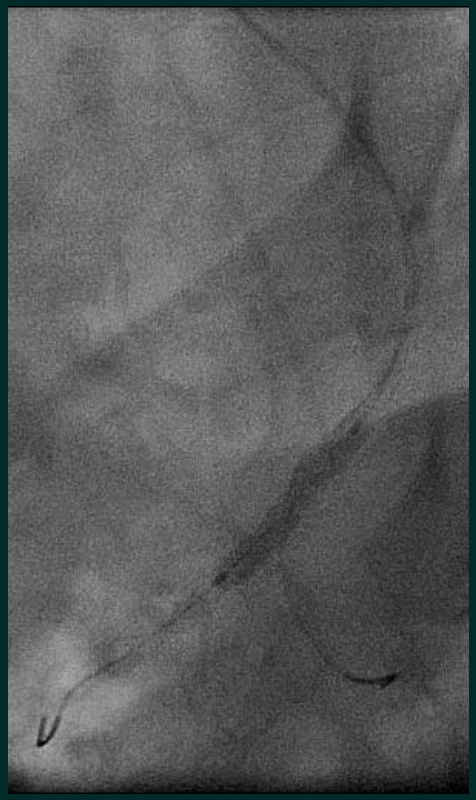
Single layer, no DC
Single layer, +DC
Multiple layers, no DC
Multiple layers, +DC

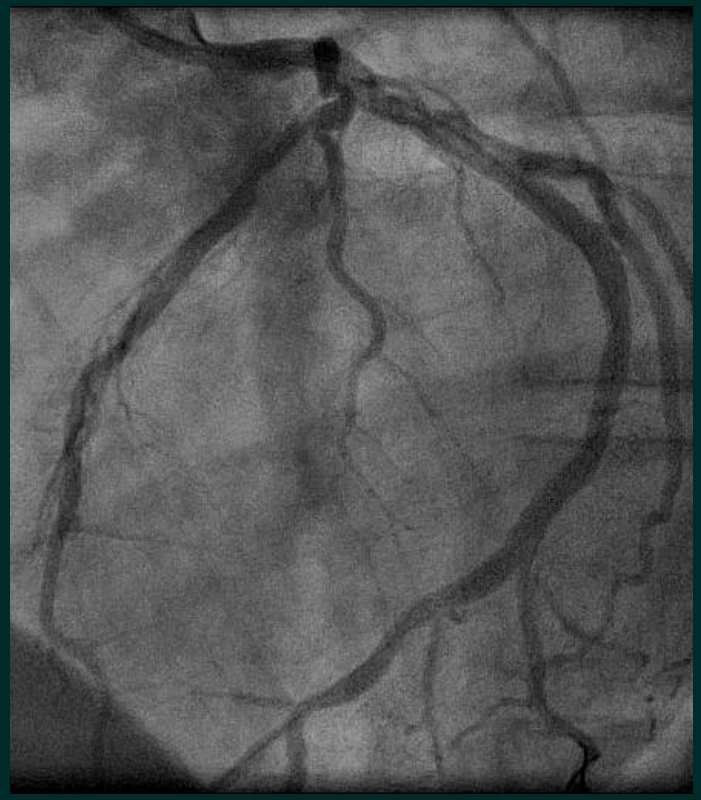


PROSPECT: Case example
74. y.o. ♂ with NSTEMI

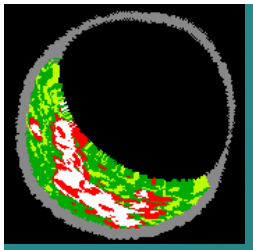








Pre PCI **Stent** **Post PCI**



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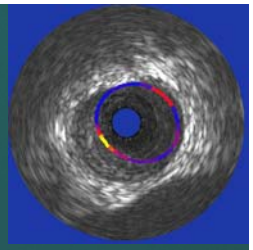
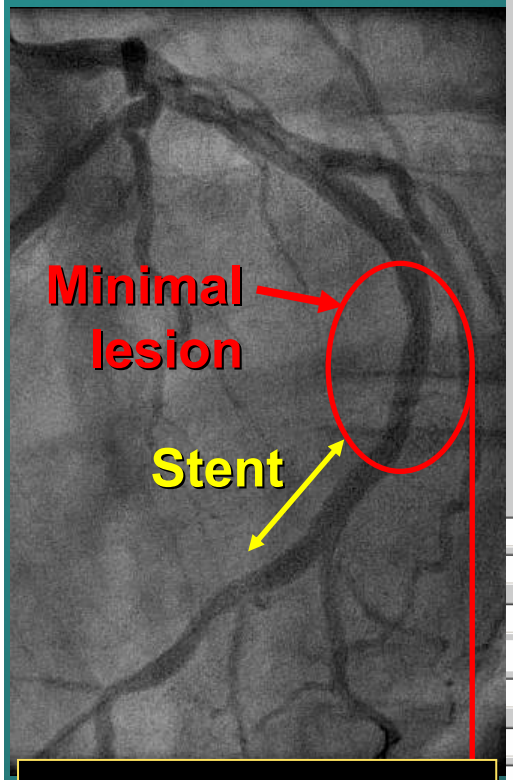
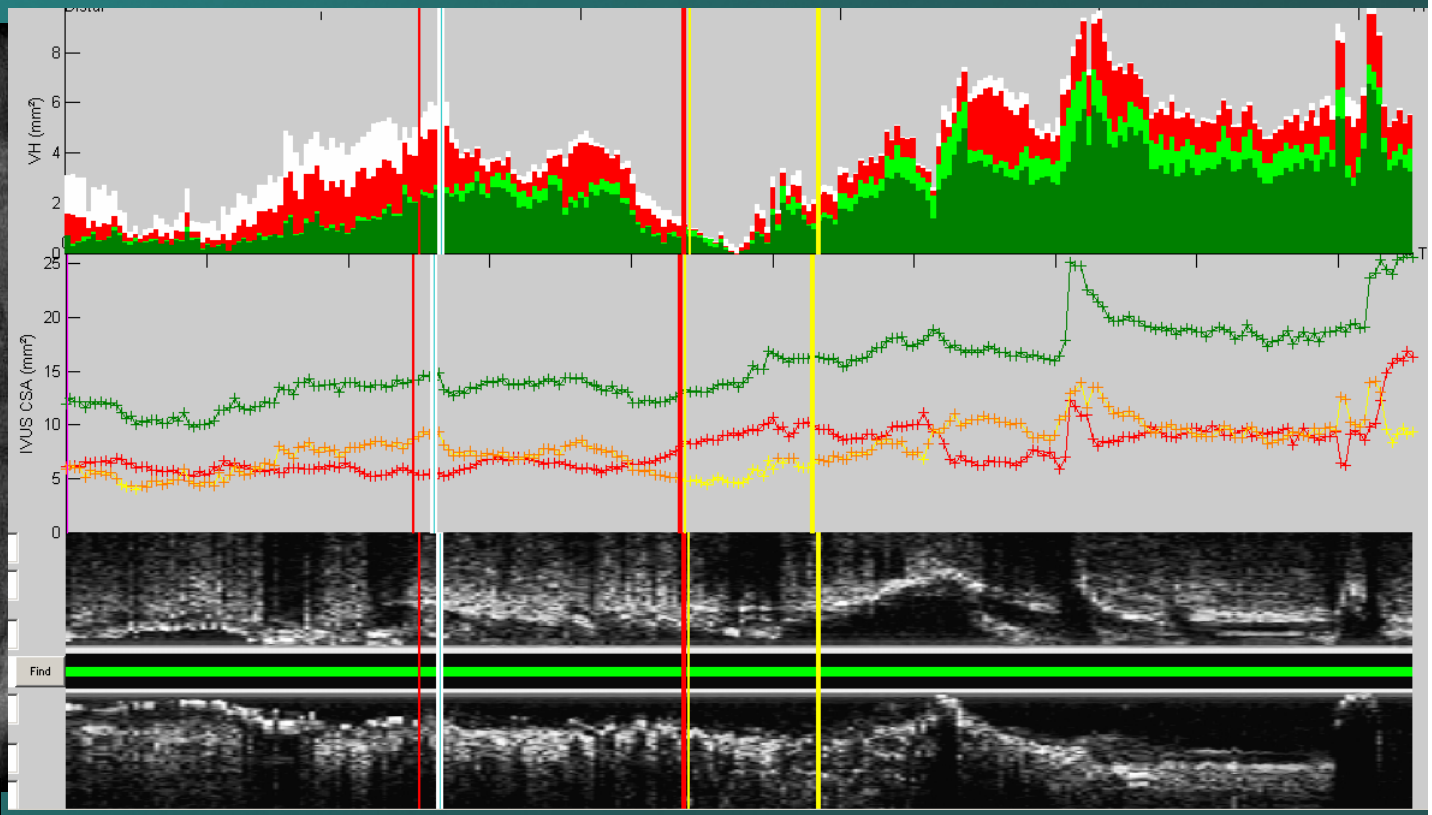
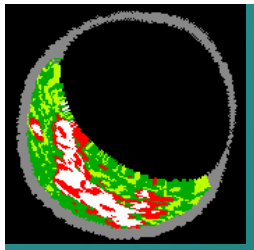






QCA
RVD 2.67 mm
MLD 2.52 mm
DS 9.4%



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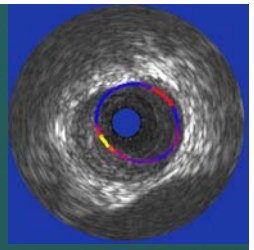
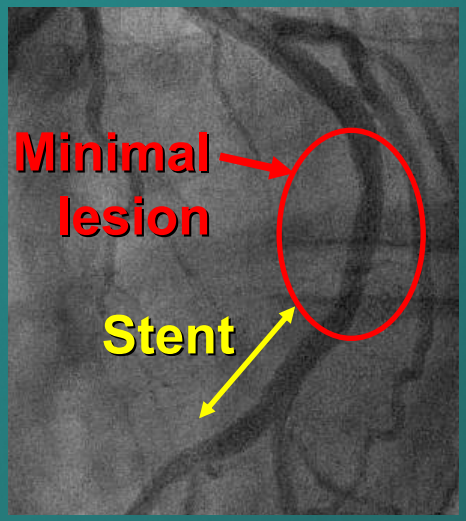
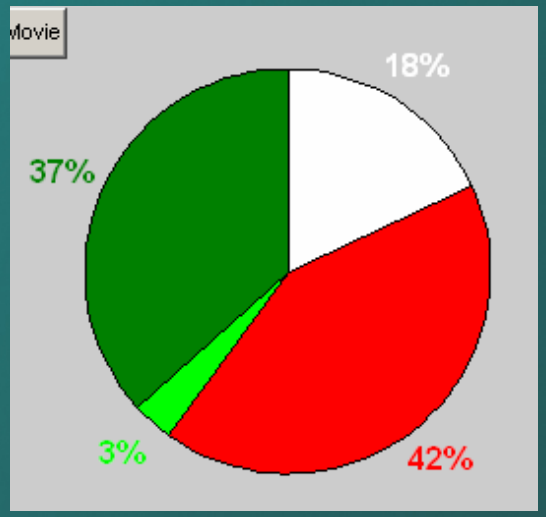
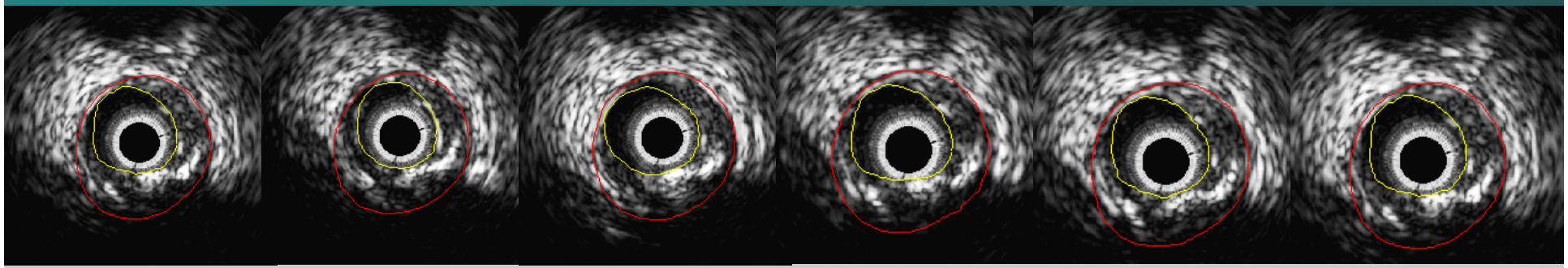
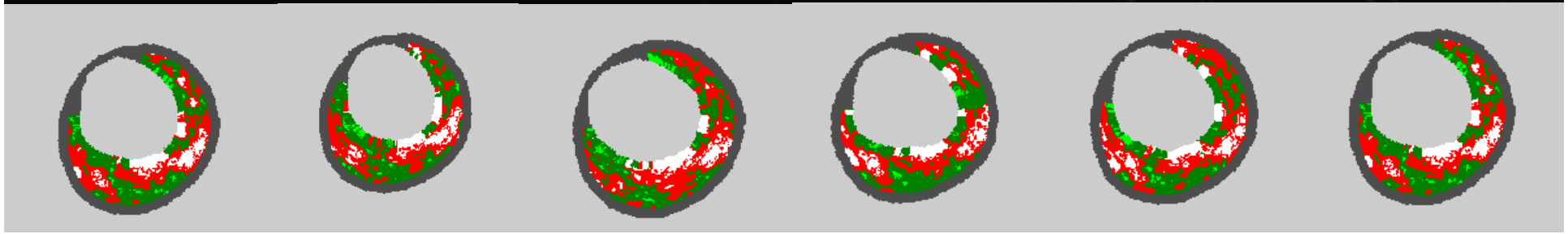


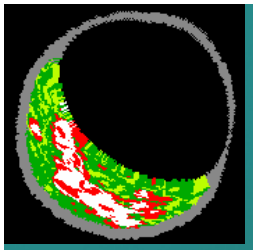




VH-TCFA
Calcified
Multiple layered
F 37%
FF 3%
NC 42%
DC 18%







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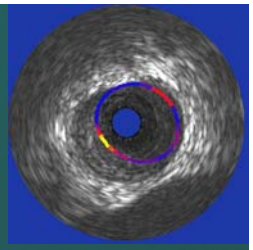
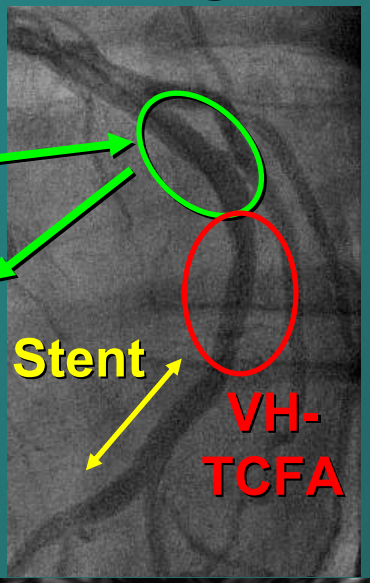
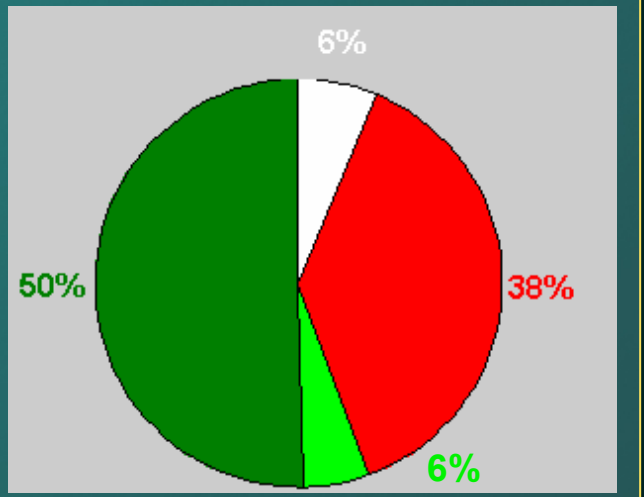


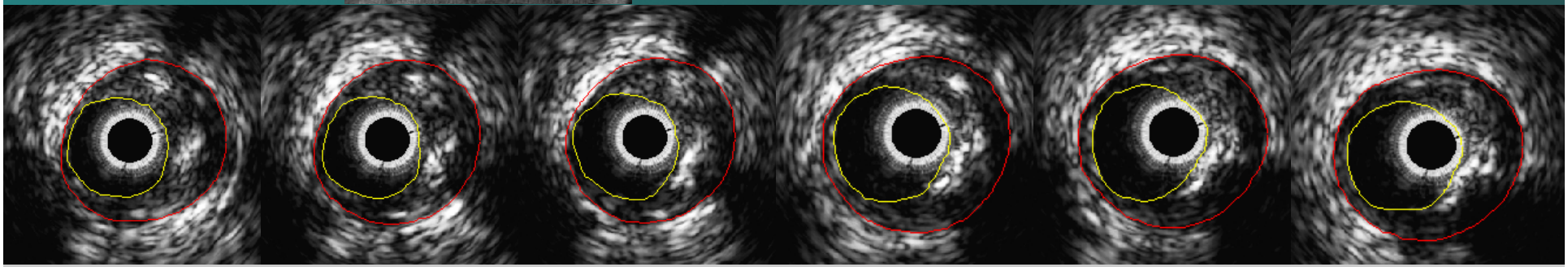
Nearly Normal vessel

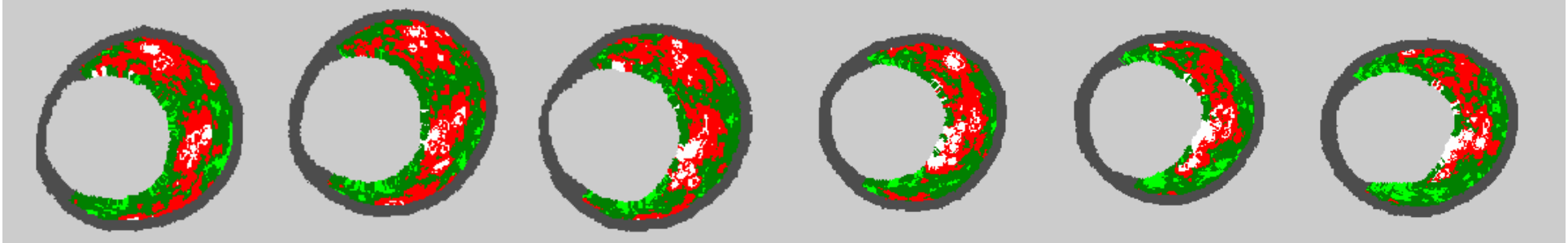


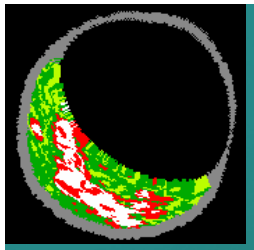
QCA
RVD 2.88 mm
MLD 2.81 mm
DS 2.4%



2nd VH-TCFA
Non calcified
Multiple layered
F 50%
FF 6%
NC 38%
DC 6%

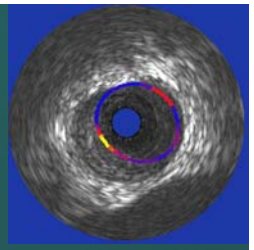


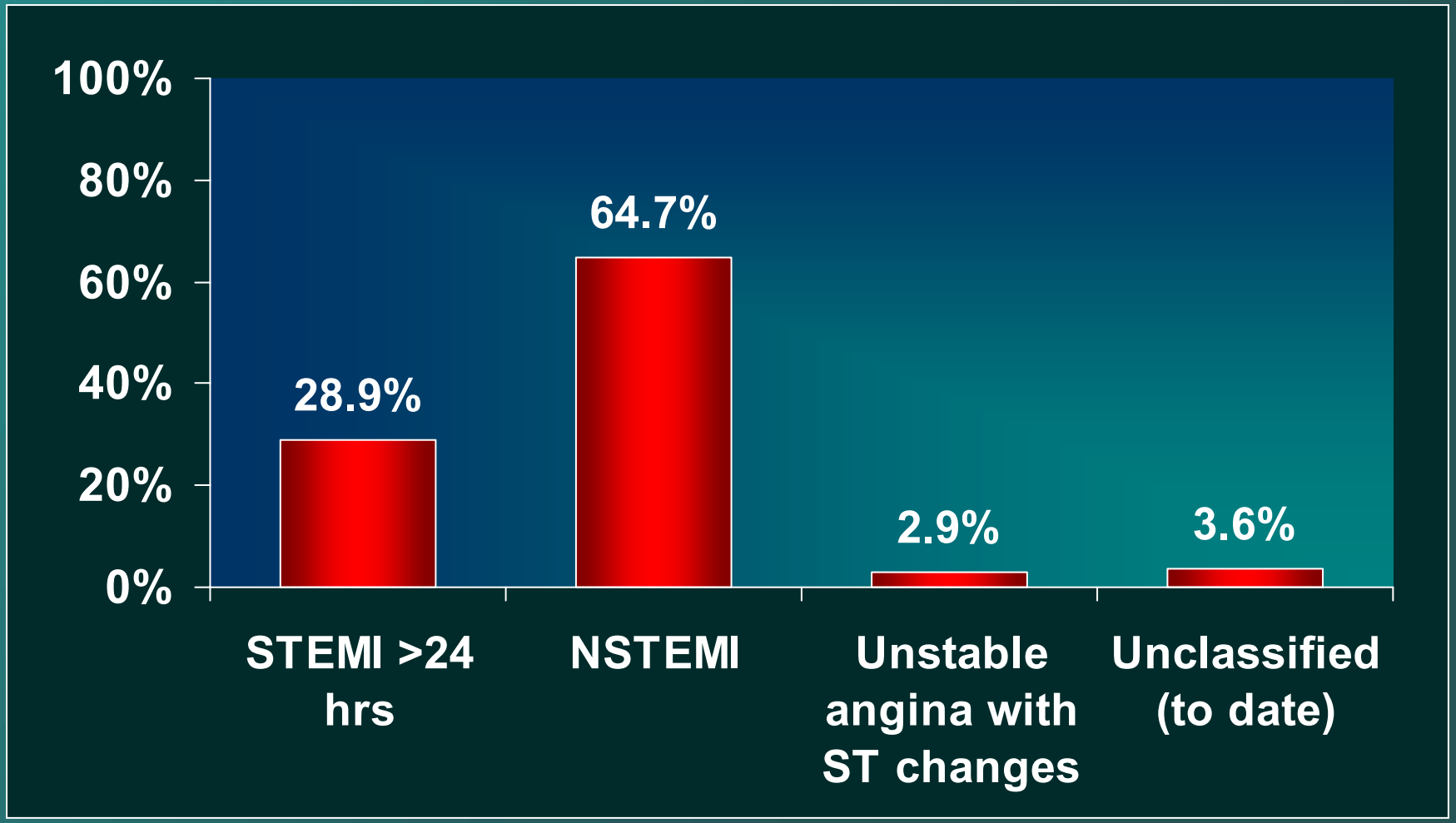


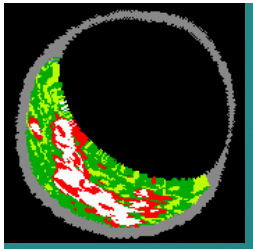


PROSPECT: Baseline features

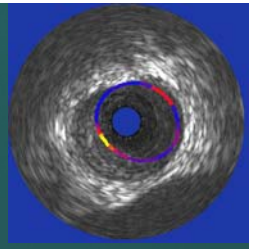
N = 700



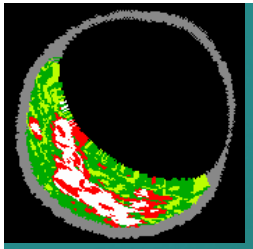




PROSPECT: Baseline features
N = 700 pts

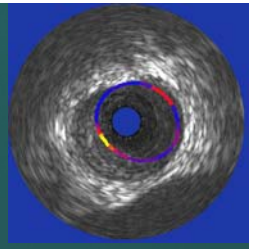


Age (yrs, median)	58 [50, 66]
Gender (female)	23.9%
Diabetes mellitus	16.8%
Current cigarette use	47.0%
Hypertension	45.2%
Hyperlipidemia	40.1%
Prior MI	10.6%
Total arteries with vs. without PCI	889, 1193
PCI in 1 or 2 arteries	72%, 28%
PCI LAD, LCX, RCA (per artery)	42%, 27%, 32%



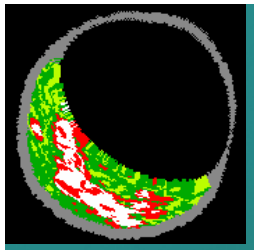
PROSPECT: Imaging Summary

Length of coronary artery analyzed



Mean (mm)	Angiography (n=250)	IVUS (n=241)	VH data* (n=241)
LM	9.7 ± 4.3	8.4 ± 6.3	8.0 ± 6.2
LAD	160.8 ± 44.3	74.4 ± 35.7	56.7 ± 35.0
LCX	137.2 ± 32.0	62.4 ± 22.5	44.6 ± 24.2
RCA	149.0 ± 45.1	83.0 ± 30.6	71.1 ± 31.5
Total per pt	454.2 ± 89.2	150.7 ± 77.7	119.3 ± 69.6
Total all pts	113,557.5	36,328.3	28,756.1

*Note: VH data doesn't register if there is no plaque



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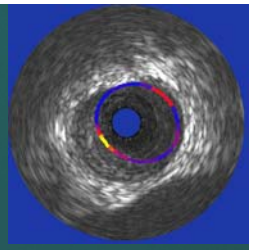
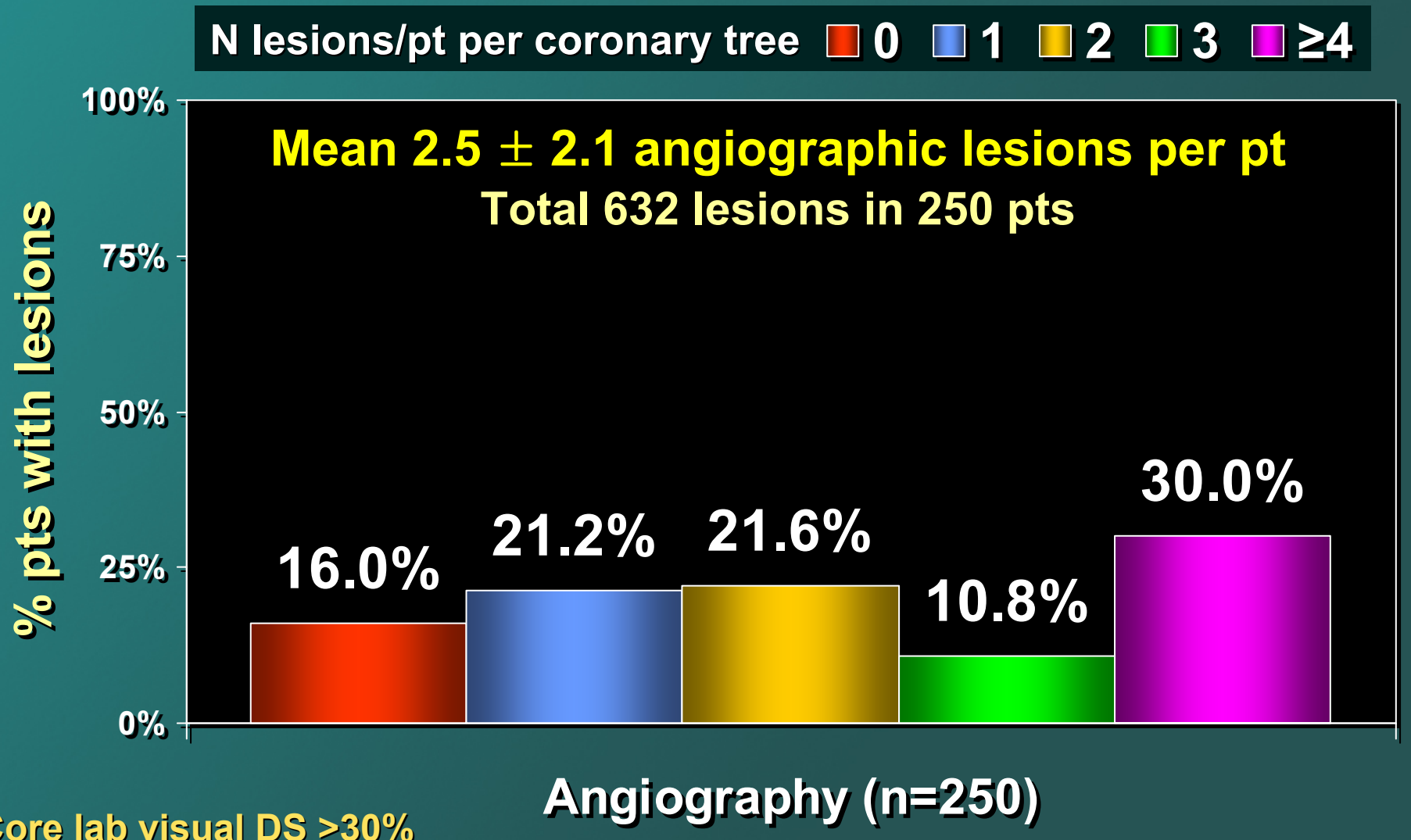
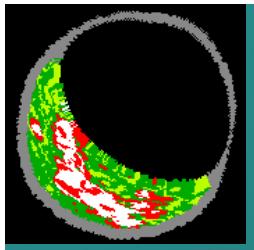


Non culprit angiographic lesions*



*Core lab visual DS >30%



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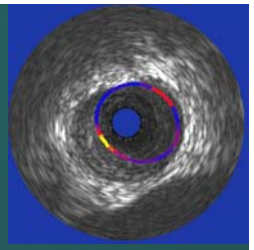
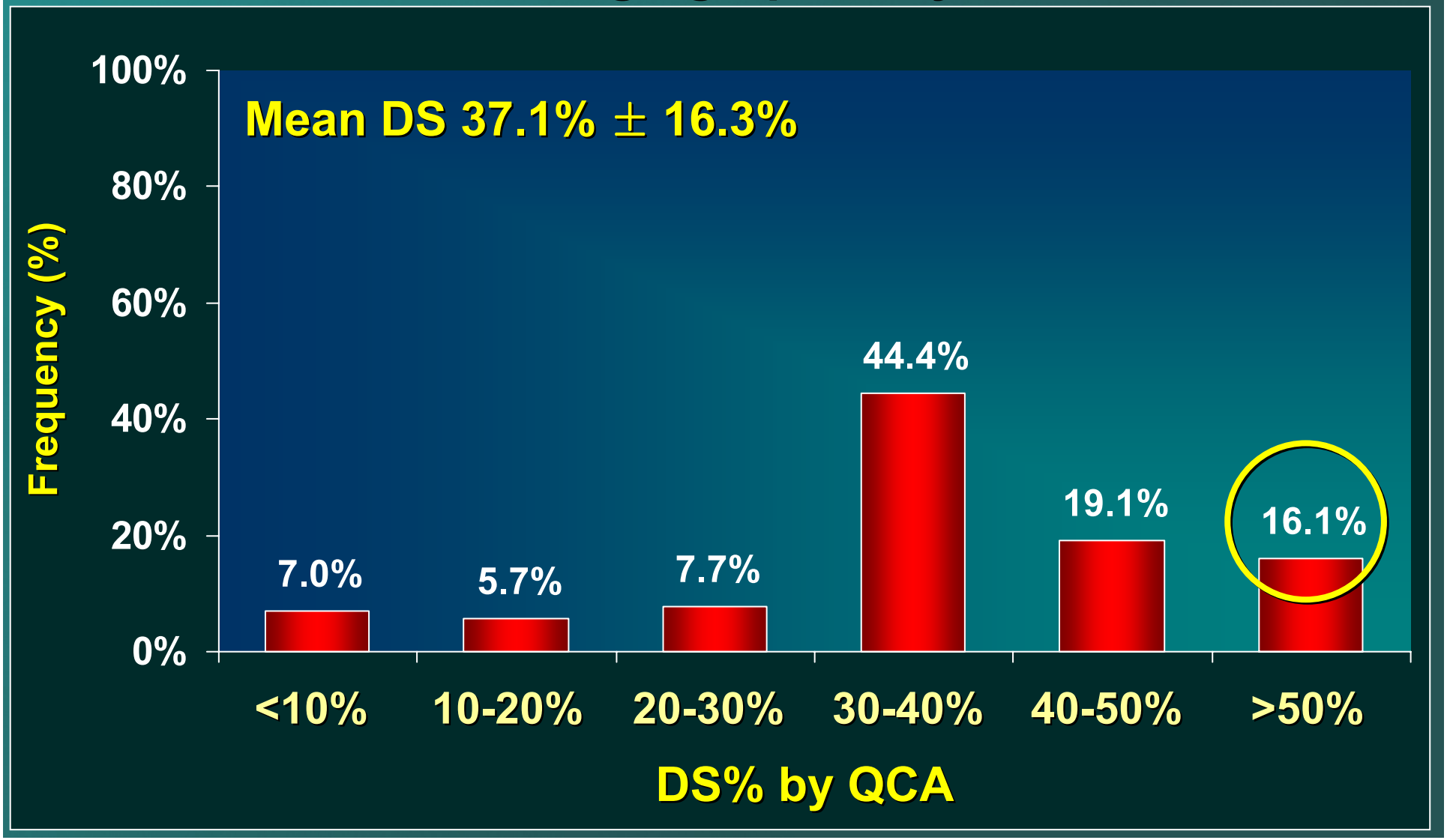
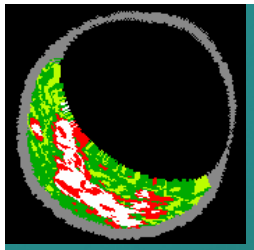


QCA DS% in 627 angiographically visible lesions





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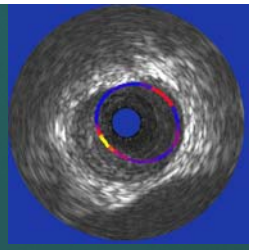
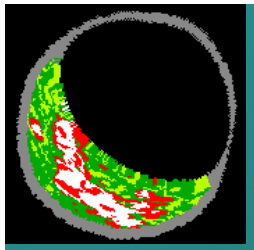


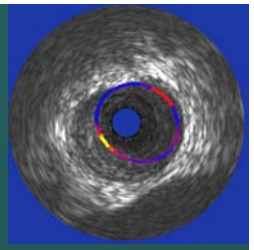
IVUS of angiographically visible lesions

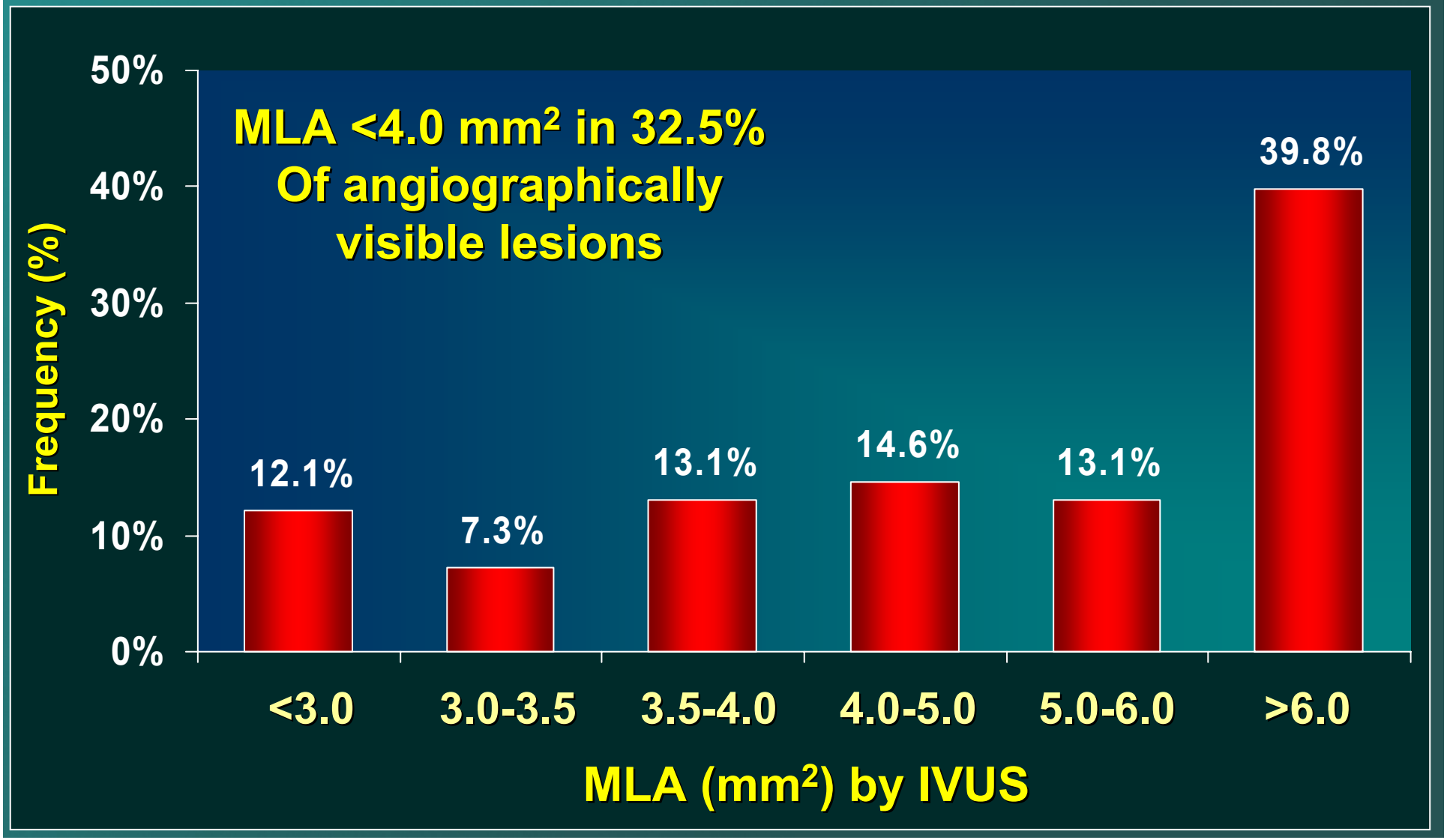
By IVUS (in 206 of the 632 total angiographic lesions)			
EEM area, mm^2	16.6±7.0	MLD, mm	2.78±0.73
Lumen area, mm^2	8.9±4.8	Mean LD, mm	3.24±0.82
Plaque area, mm^2	11.2±4.1	MVD, mm	3.99±0.97
Plaque burden %	47±11	Mean VD, mm	4.42±0.96
MLA, mm^2	6.7±4.5	Max VD, mm	4.93±1.06
Remodeling index	0.88±0.19	Lumen ecc.	1.00±0.69

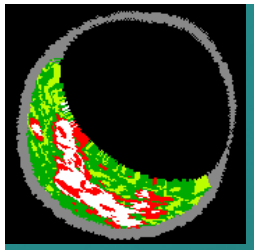


PROSPECT: Imaging Summary

IVUS MLA (mm^2) in 206 angiographically visible lesions







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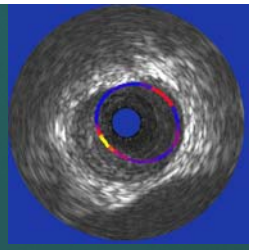
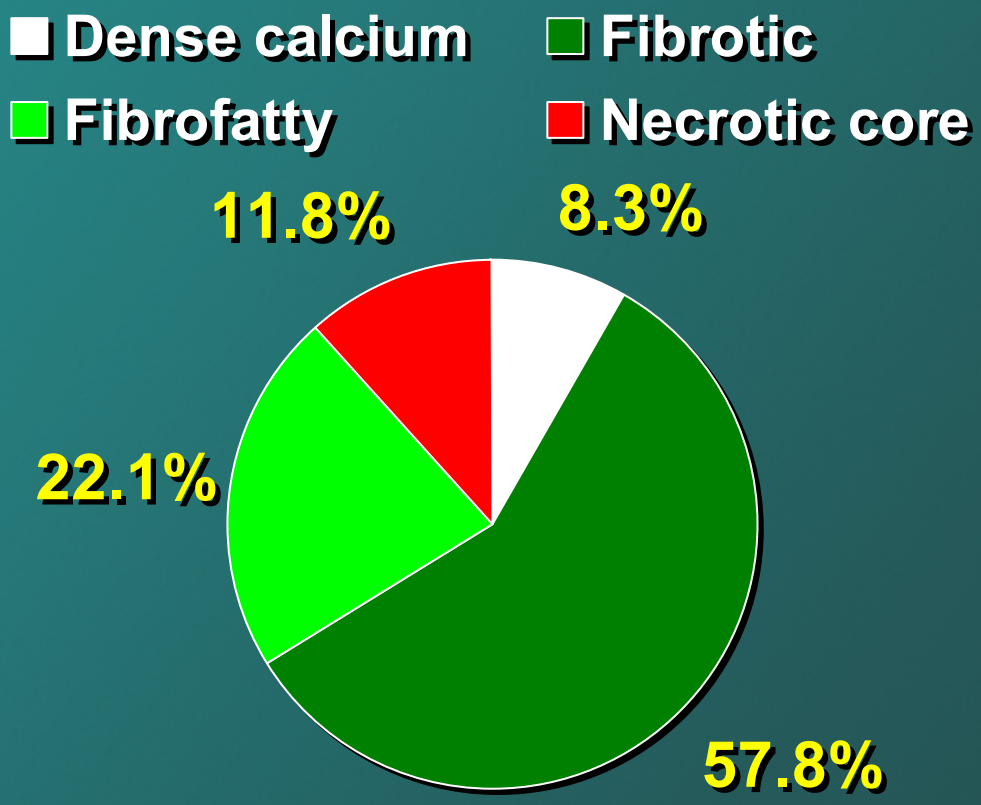


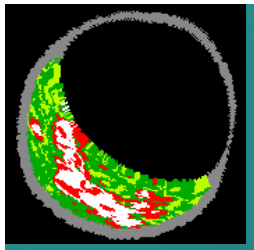
VH of angiographically visible lesions

Virtual histology (N=203)
- Mean plaque composition-



Plaque subtype*	N=203
Fibrotic	2.5%
Fibrocalcific	3.5%
PIT	21.7%
Fibroatheroma	30.0%
- Thick cap	15.3%
- TCFA	14.8%
- Single, - Ca	6.4%
- Single, + Ca	2.9%
- Multiple, - Ca	2.5%
- Multiple, + Ca	2.9%

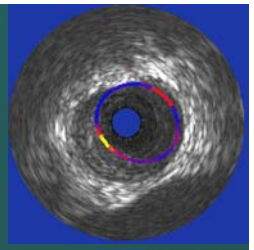
*Only 117 true IVUS lesions are VH lesions

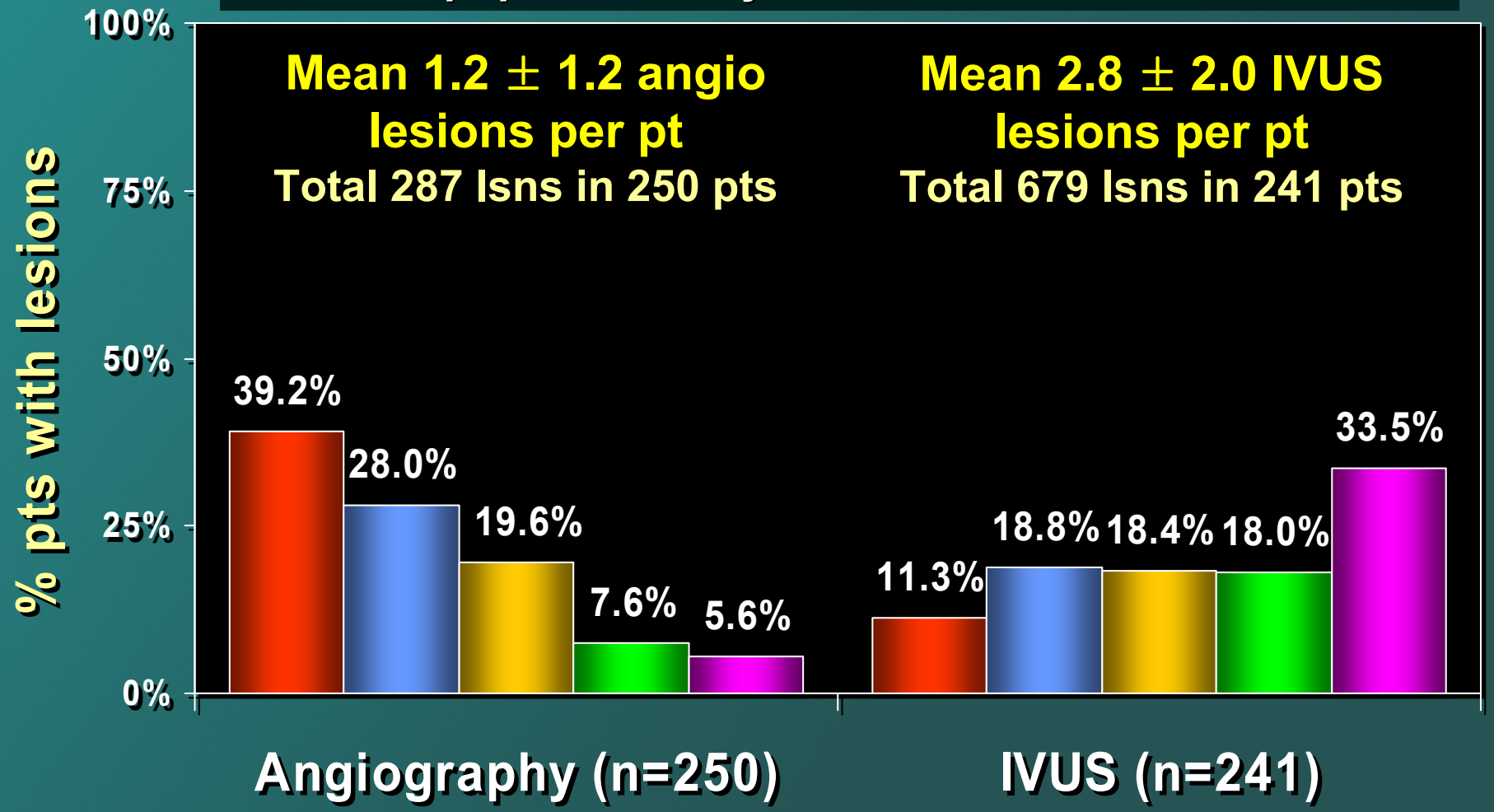


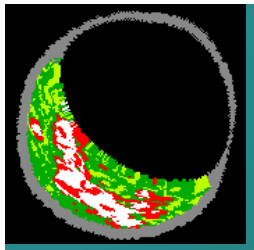
PROSPECT: Imaging Summary

Non culprit angio and IVUS lesions

(LM, P/MLAD, PLCX and P/M/DRCA only)

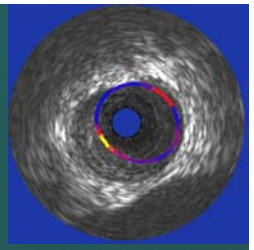




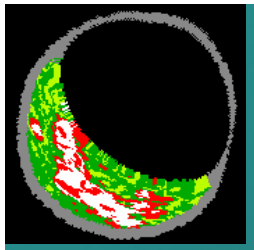


PROSPECT: Imaging Summary

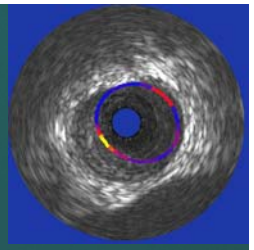
Analysis of IVUS detected lesions



IVUS	LAD (n=277)	LCX (n=174)	RCA (n=242)	All (n=693)
Length, mm	16.7±14.2	14.8±13.5	17.9±16.4	16.7±14.9
EEM area, mm^2	16.2±6.5	14.7±5.2	17.7±6.4	16.4±6.3
Lumen area, mm^2	7.9±3.3	7.5±2.7	8.8±3.5	8.1±3.3
Plaque area, mm^2	11.8±4.2	10.5±3.3	12.5±3.9	11.7±3.9
Plaque burden, %	51 ± 6	49 ± 6	51 ± 7	50 ± 6
MLA, mm^2	5.9 ± 2.8	5.7 ± 2.4	6.7 ± 3.1	6.1 ± 2.8



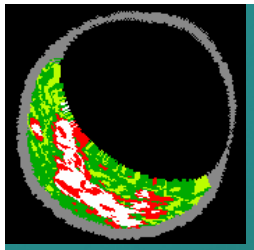
PROSPECT: Imaging Summary



Analysis of IVUS detected lesions

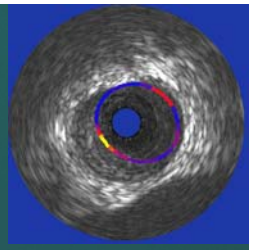
IVUS	LAD (n=277)	LCX (n=174)	RCA (n=242)	All (n=693)
Length, mm	16.7±14.2	14.8±13.	17.9±16.	16.7±14.9
EEM area, mm			.4	16.4±6.3
Lumen area,			5	8.1±3.3
Plaque area, mm²	11.8±4.2	10.5±3.3	12.5±3.9	11.7±3.9
Plaque burden, %	51 ± 6	49 ± 6	51 ± 7	50 ± 6
MLA, mm²	5.9 ± 2.8	5.7 ± 2.4	6.7 ± 3.1	6.1 ± 2.8

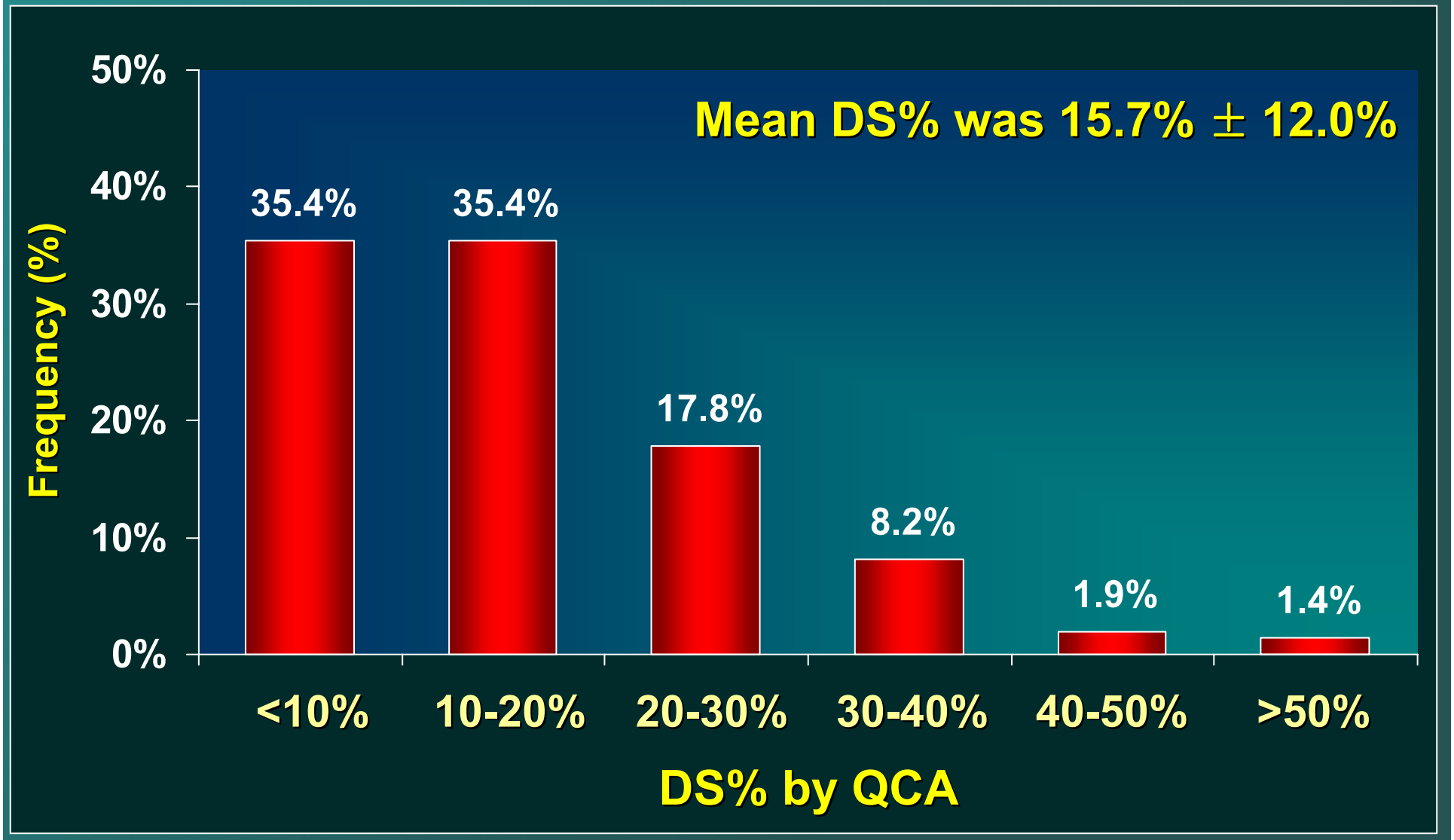
24% of IVUS lesions had had an MLA <4.0 mm²

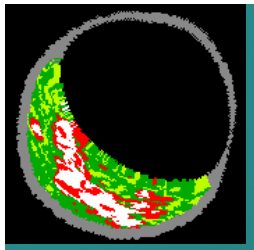


PROSPECT: Imaging Summary

QCA DS% in 625 IVUS lesions

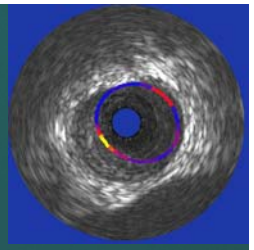




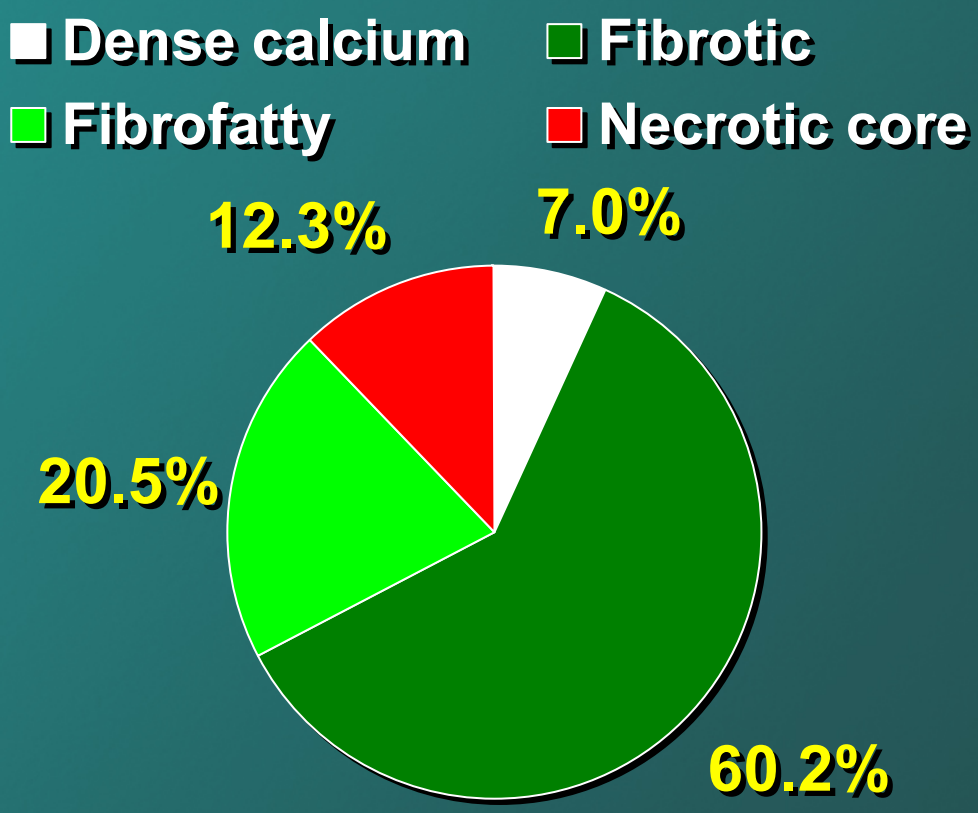


PROSPECT: Imaging Summary

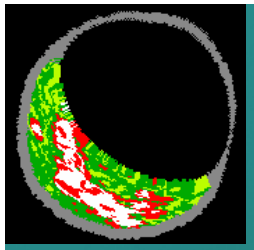
VH of IVUS detected lesions



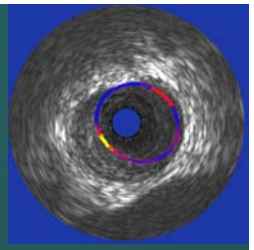
Virtual histology (N=693)
- Mean plaque composition-

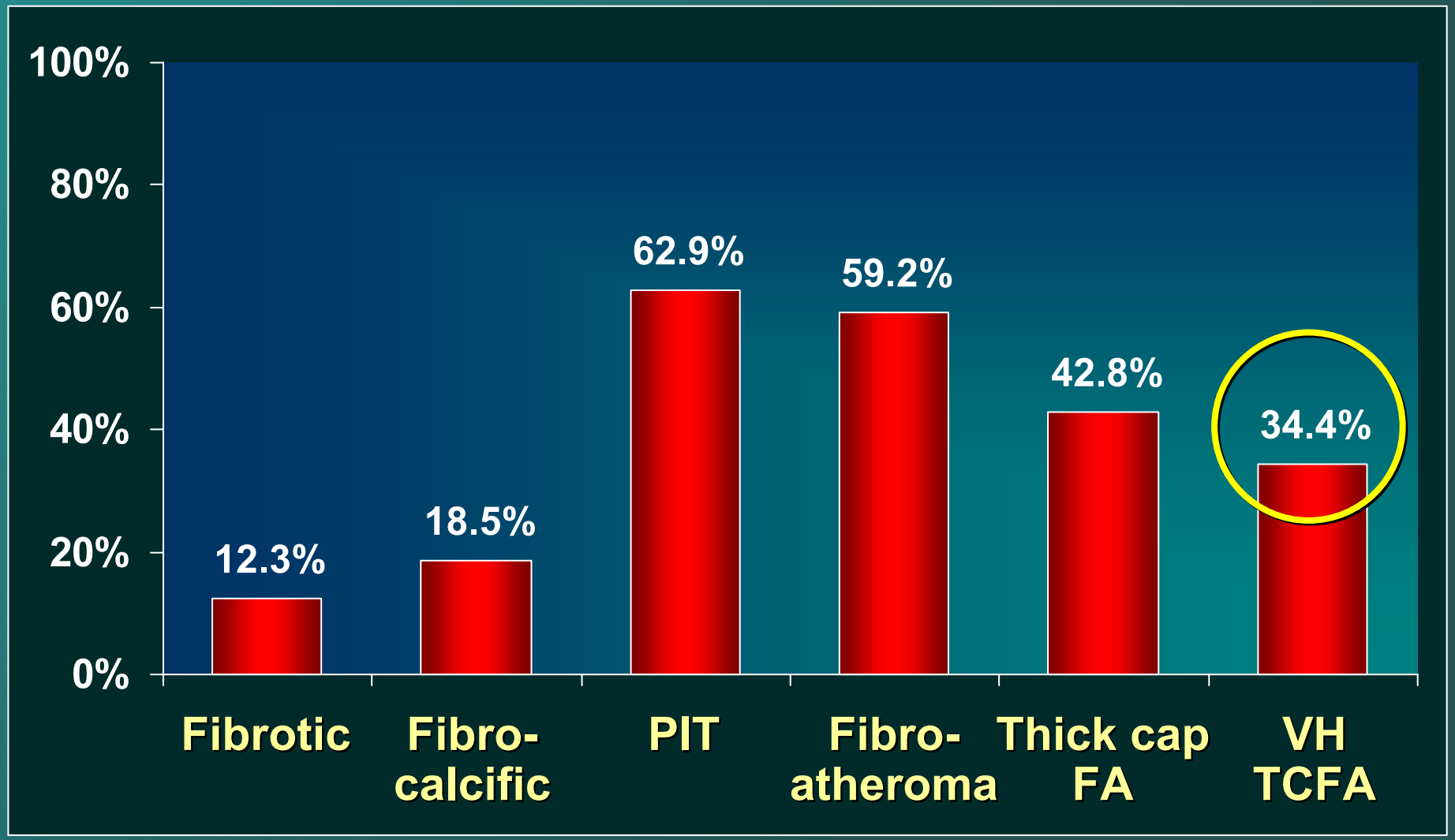


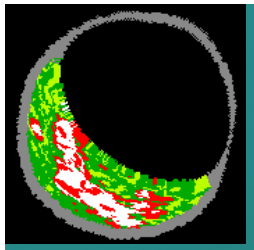
Plaque subtype	N=681
Fibrotic	5.6%
Fibrocalcific	8.5%
PIT	42.9%
Fibroatheroma	43.0%
- Thick cap	23.8%
- TCFA	19.2%
- Single, - Ca	6.8%
- Single, + Ca	4.8%
- Multiple, - Ca	3.3%
- Multiple, + Ca	4.3%



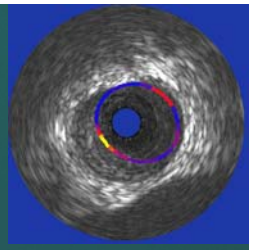
PROSPECT: Baseline features
Presence of ≥1 VH lesion subtypes (in 241 pts)



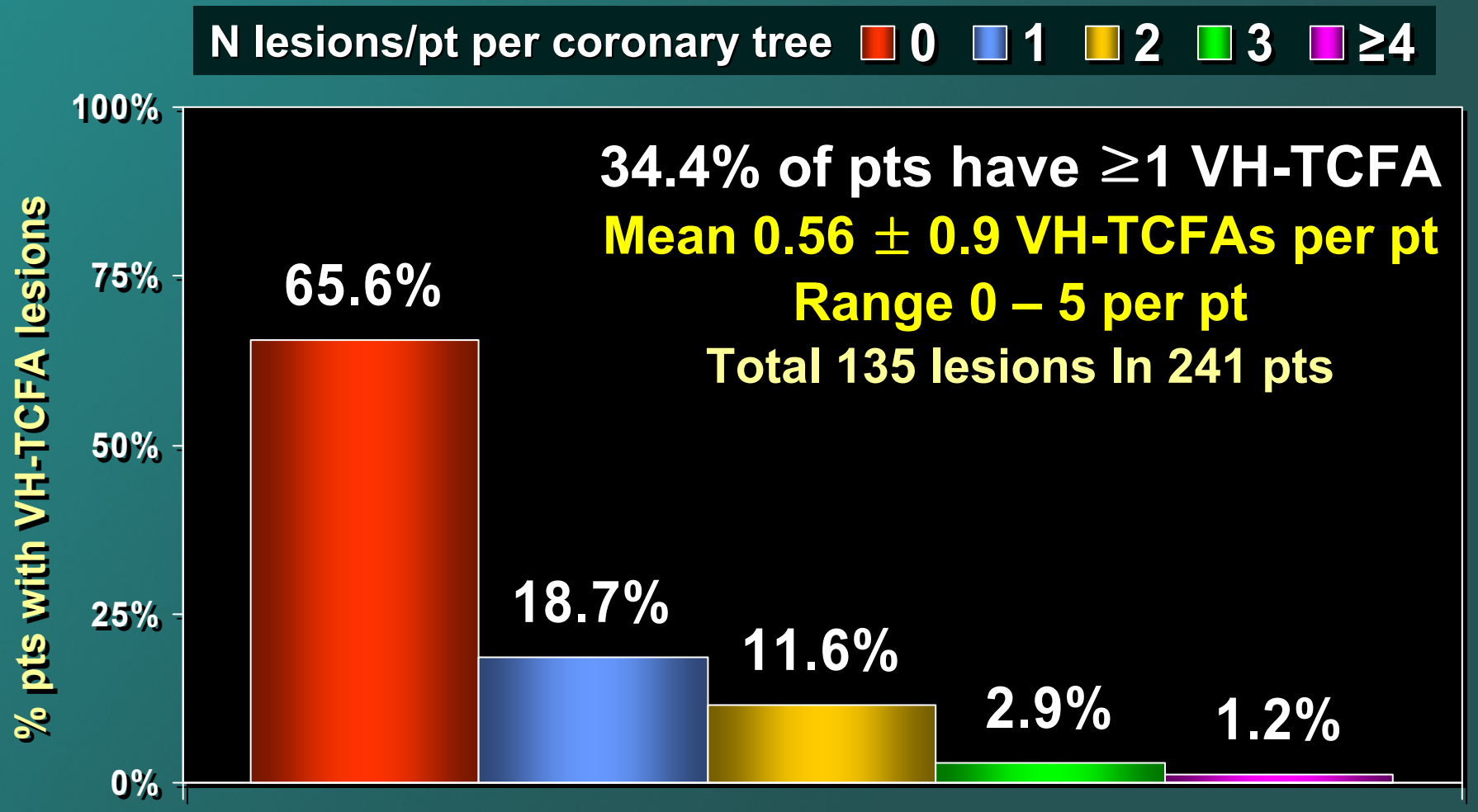


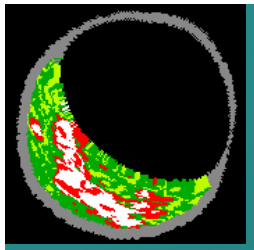


PROSPECT: Imaging Summary



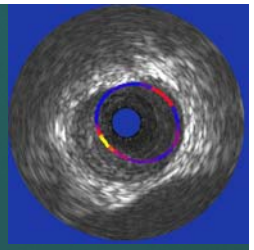
Per pt incidence of VH-TCFAs

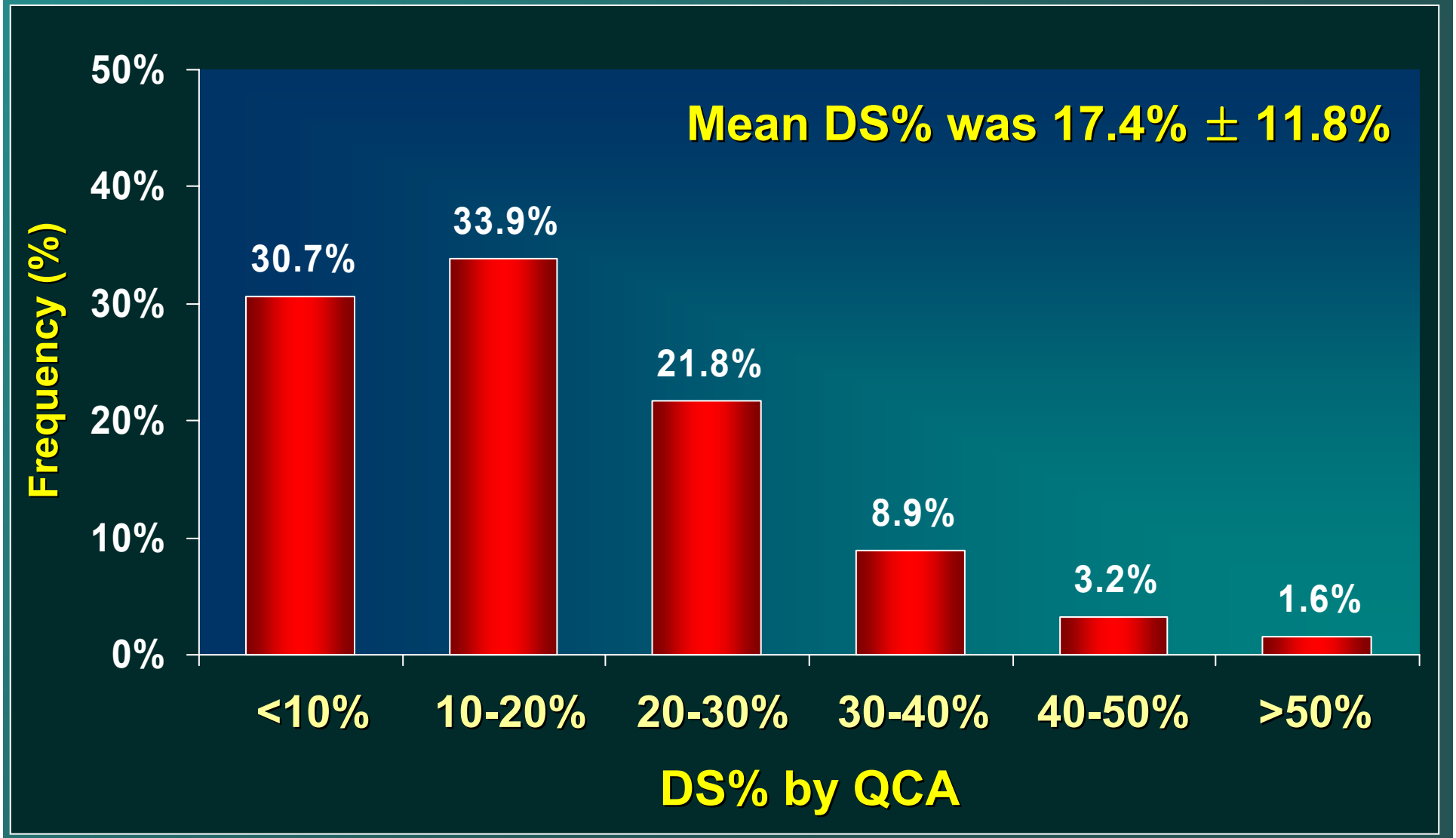


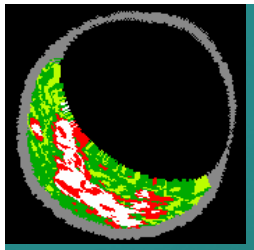


PROSPECT: Imaging Summary

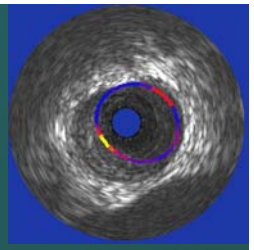
QCA DS% in 124 VH-TCFA lesions







PROSPECT: Imaging Summary



709 IVUS lesions

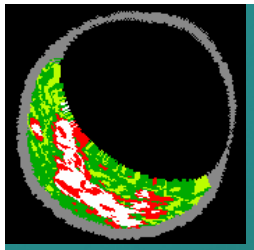
302 fibroatheromas (42.6%)

135 VH-TCFAs (19.0%)

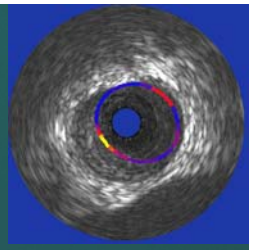
Only 40/135 (29.6%) VH-TCFAs were severe by IVUS (MLA <4.0mm^2)

40 MLA <4.0 mm^2 (5.6%)

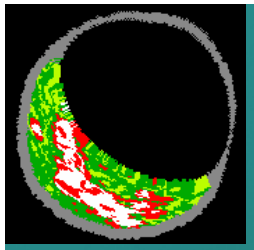
95 MLA ≥4.0 mm^2 (13.3%)



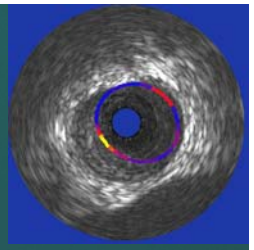
PROSPECT Baseline Analysis
Interim Conclusions



- After stenting of all visibly ruptured and angiographically significant lesions in pts with ACS:
  - 3-vessel imaging is feasible in most pts, with IVUS and VH data acquired in ~2.1 vessels/pt, ~6-8 cm/vessel, ~15 cm/pt
  - Angiographically, ~2.5 (±2.1) lsns/pt (visible DS>30%) are left behind; ~16% are severe (DS >50%) by QCA
    - ~1/3 are severe by IVUS (MLA <4.0 mm^2)
  - By IVUS, ~2.9 (±1.9) untreated lesions/pt are present in the proximal and mid coronary tree
    - ~1/4 are severe, and ~20% are VH-TCFAs



PROSPECT Baseline Analysis Interim Conclusions



- VH-TCFAs were identified in the proximal and mid coronary tree in ~35% of pts (0.56 ± 0.92/pt, range 0-5 per pt), 70% of which are not severe by IVUS

- Completed analysis from the entire 700 pt baseline PROSPECT dataset will more precisely characterize the coronary tree of ACS pts after stenting of culprit lesions
- Follow-up is ongoing to determine whether baseline demographics, biomarkers, angiography, IVUS, VH, and palpography can identify pts and lesions at risk for future adverse CVS events