A Futuristic Vision of Next Generation IVUS Imaging Systems

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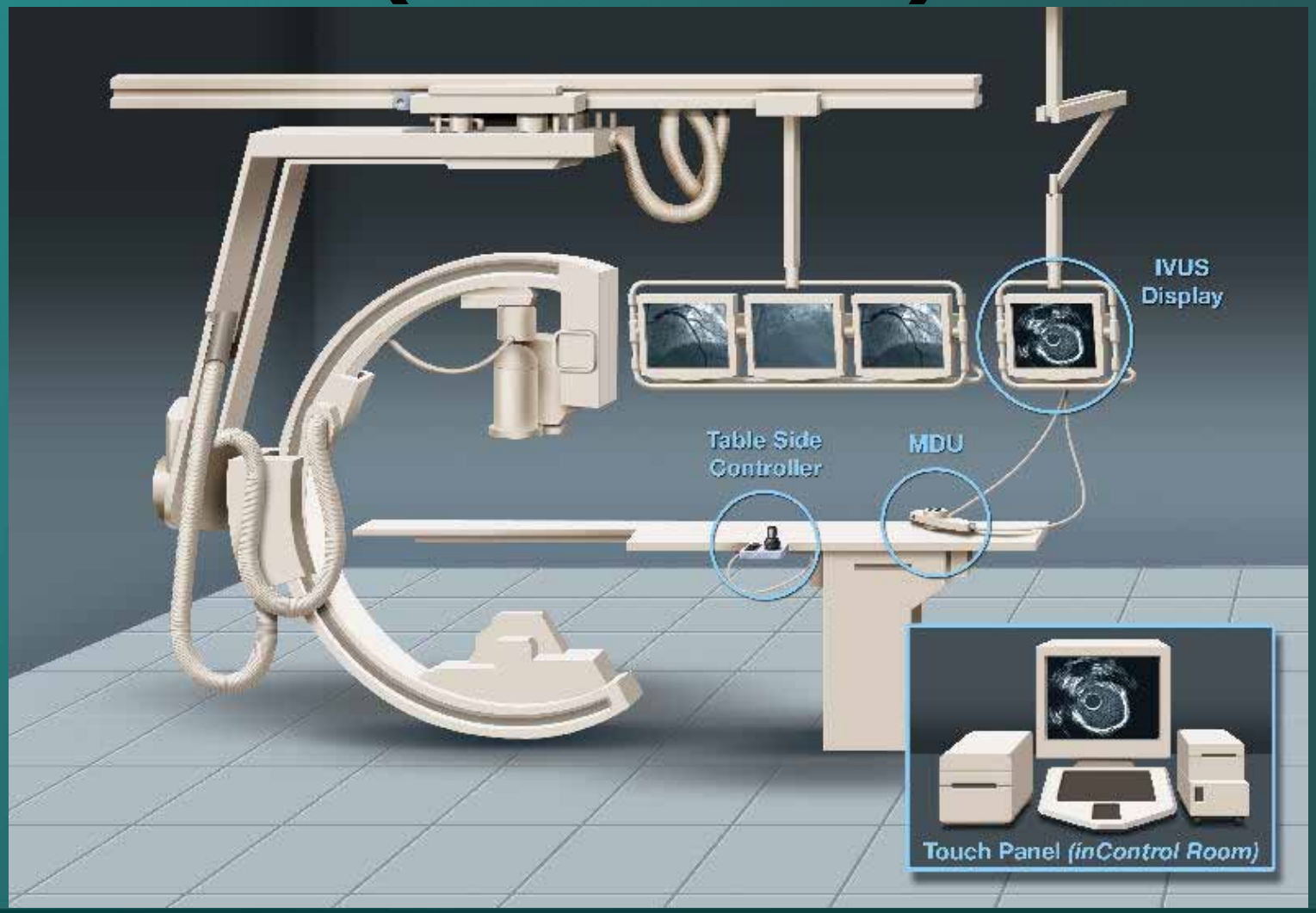
Disclosures

- Boston Scientific
- Volcano

Basics of an IVUS Apparatus

- System
- Transducer
- Catheter
- Pullback device
- Image
  - Presentation
  - Border recognition
  - Plaque composition
  - Lesion “pathophysiology”
- Data storage and retrieval

Full system integration (BSC iLab)



Control Room Hardware

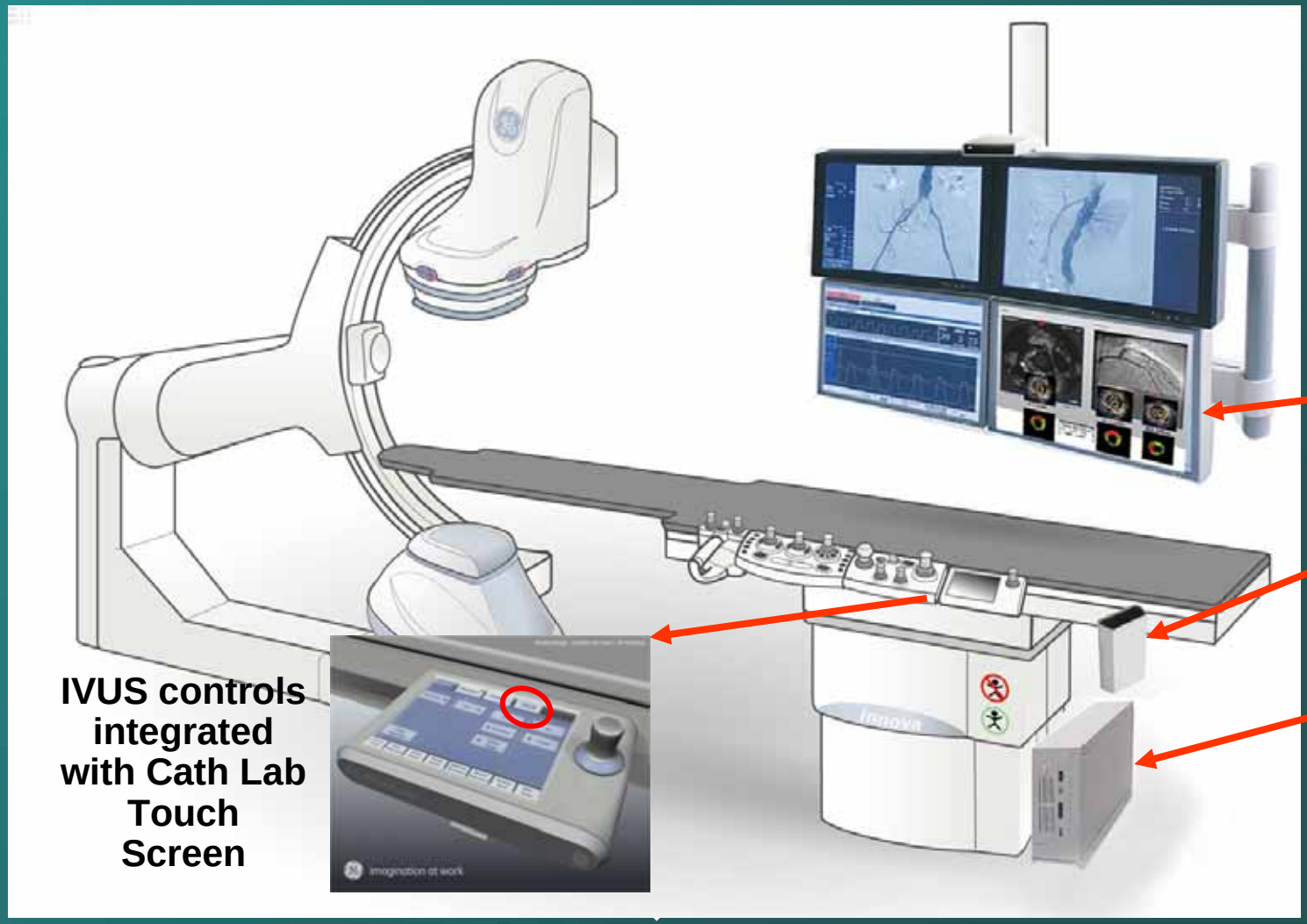
Bedside controls

- Fast Forward
- Rewind
- Play / Pause

•Measure images

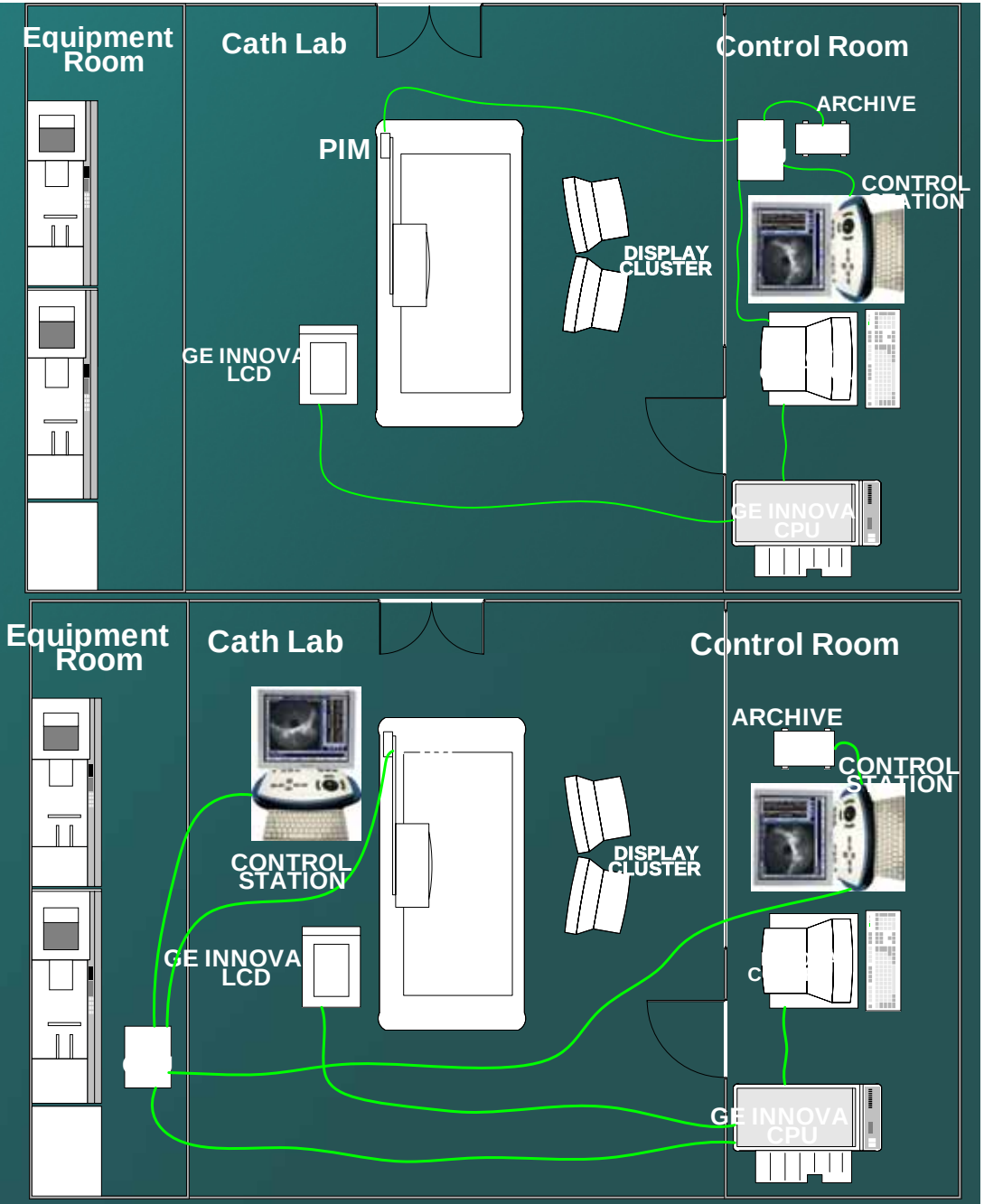
- Diameter /Area
- Bookmark
- TraceAssist

Full system integration (Volcano vFusion)



Multiple configurations become possible

- IVUS controls at the table
- IVUS controls in the control room
- IVUS controls both at the table and in the control room
- Fully integrated network operating IVUS in multiple labs



- **Full cathlab integration at a *total* cost comparable to “stand-alone” instruments (2.5-3 integrated labs should be equivalent to the cost of one “stand-alone” unit”)**

Catheter and Transducer

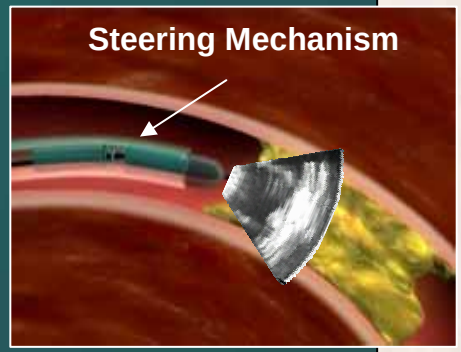
- Transducer
  - Higher frequencies
  - Dual frequencies
- Catheter
  - Handling equivalent to a balloon catheter
  - Imaging guidewire
  - Forward looking IVUS

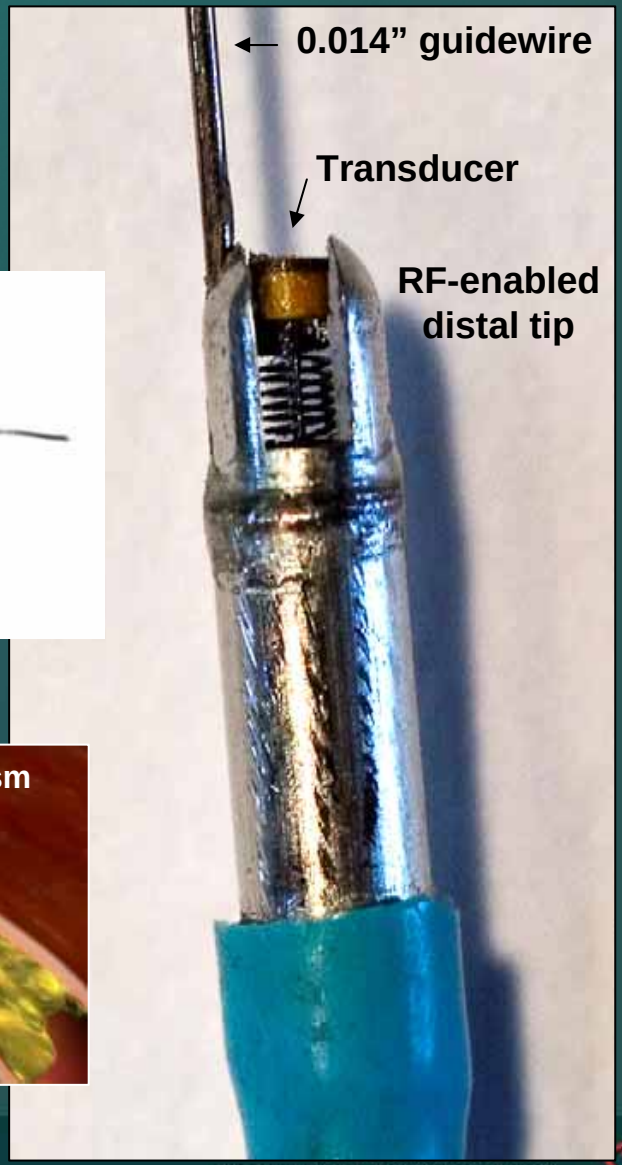
Forward looking IVUS catheter

- While prototypes have been suggested and developed, to date none have been shown to be practical and to yield diagnostically and therapeutically helpful images

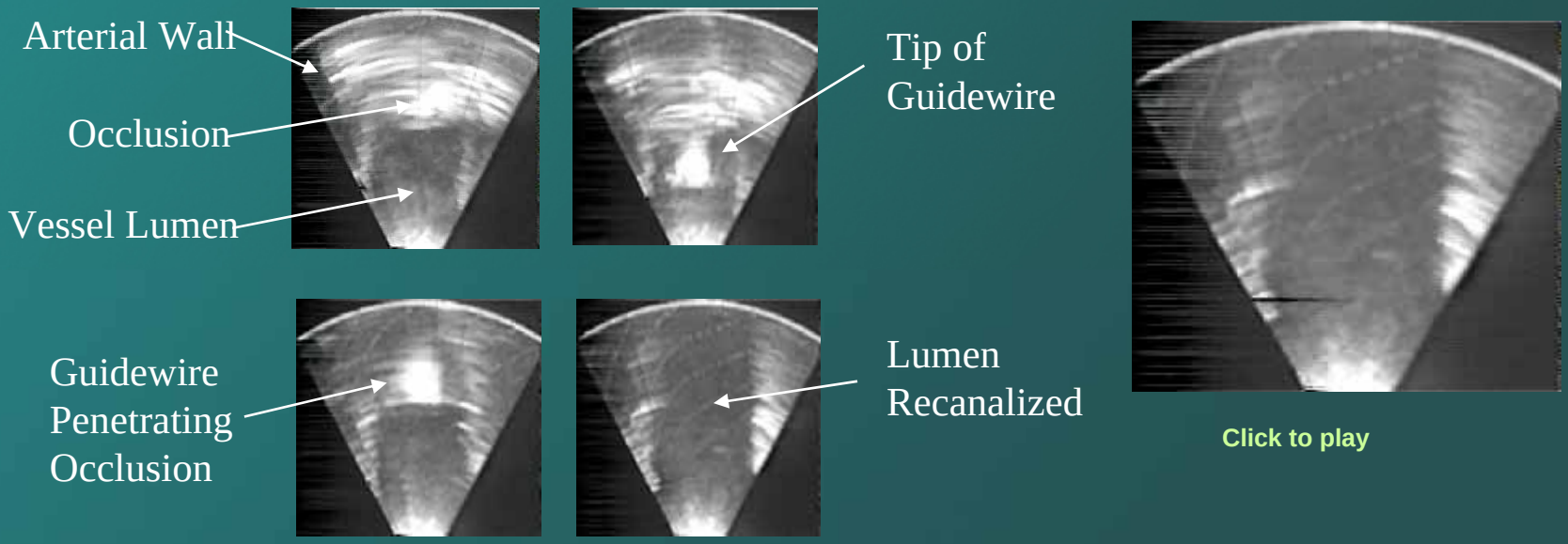
Prototype Forward-Looking CTO Device

- Visualization
  - Forward-looking IVUS using proprietary micromanipulator and shape memory actuation
- Steering
  - Steering with multiple degrees of freedom for distal tip
- Power
  - RF-enabled tip
- Usability
  - 0.014” guidewire of choice
  - 3 – 3.5F profile





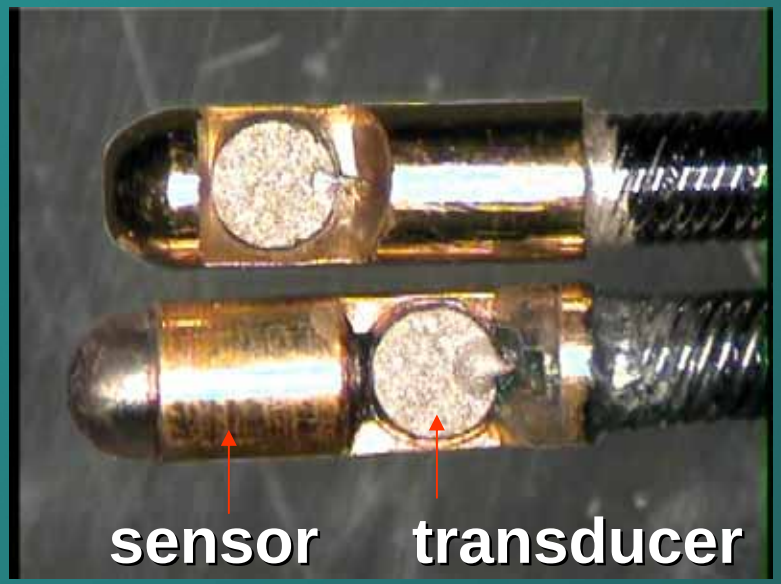
Forward Looking Navigational Ultrasound

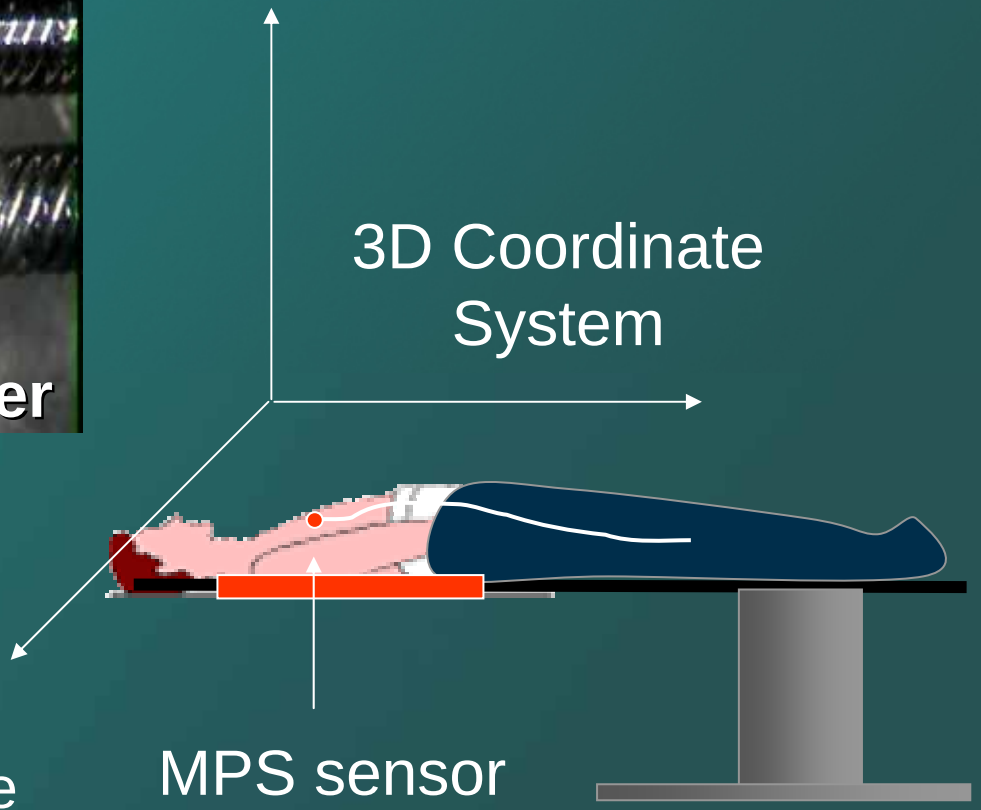


Pullback device

- Resurrect the H-P “Fishing Reel” - in my opinion, the best pullback device ever devised
- Or eliminate the pullback device completely while still maintaining accurate length measurements and good imaging habits

Medical Positioning System (MPS)

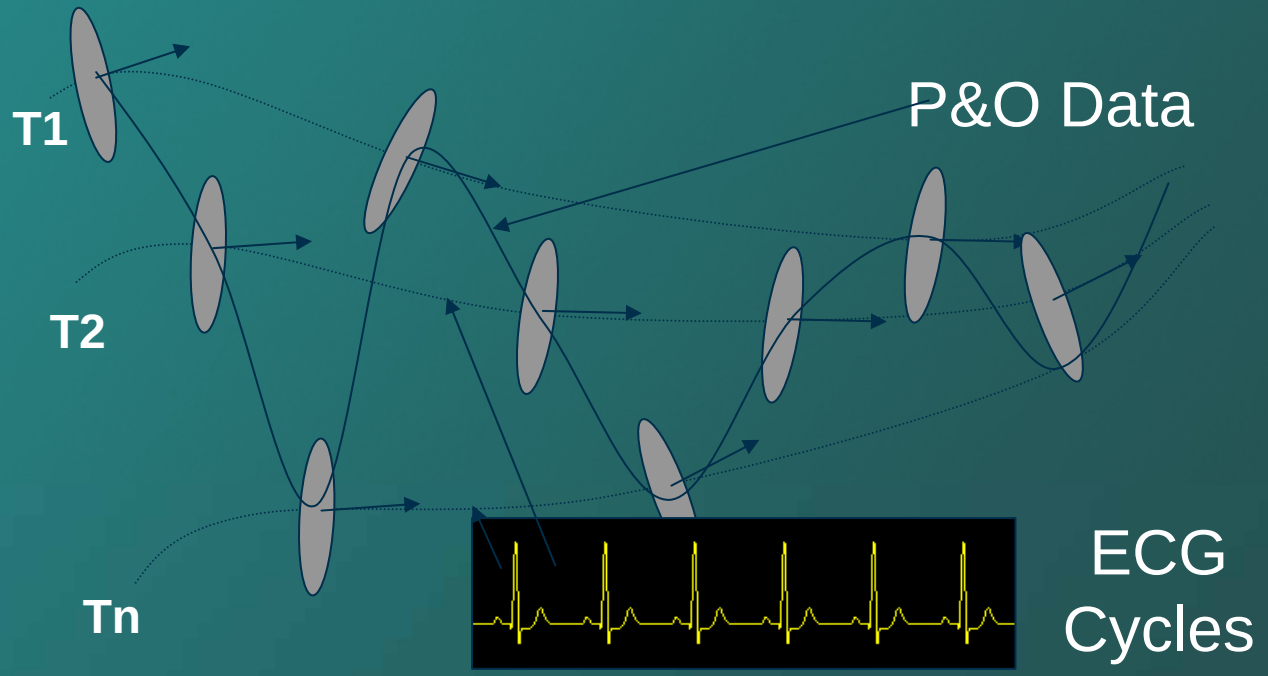




Miniature sensors provide Position and Orientation (P&O) projected on 3D imaging model

Accuracy < 1mm

ECG and Position & Orientation (P&O) data integration



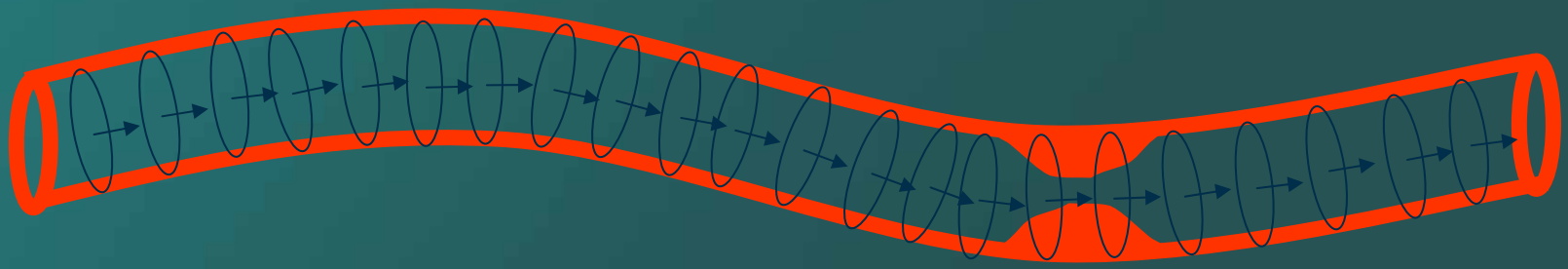
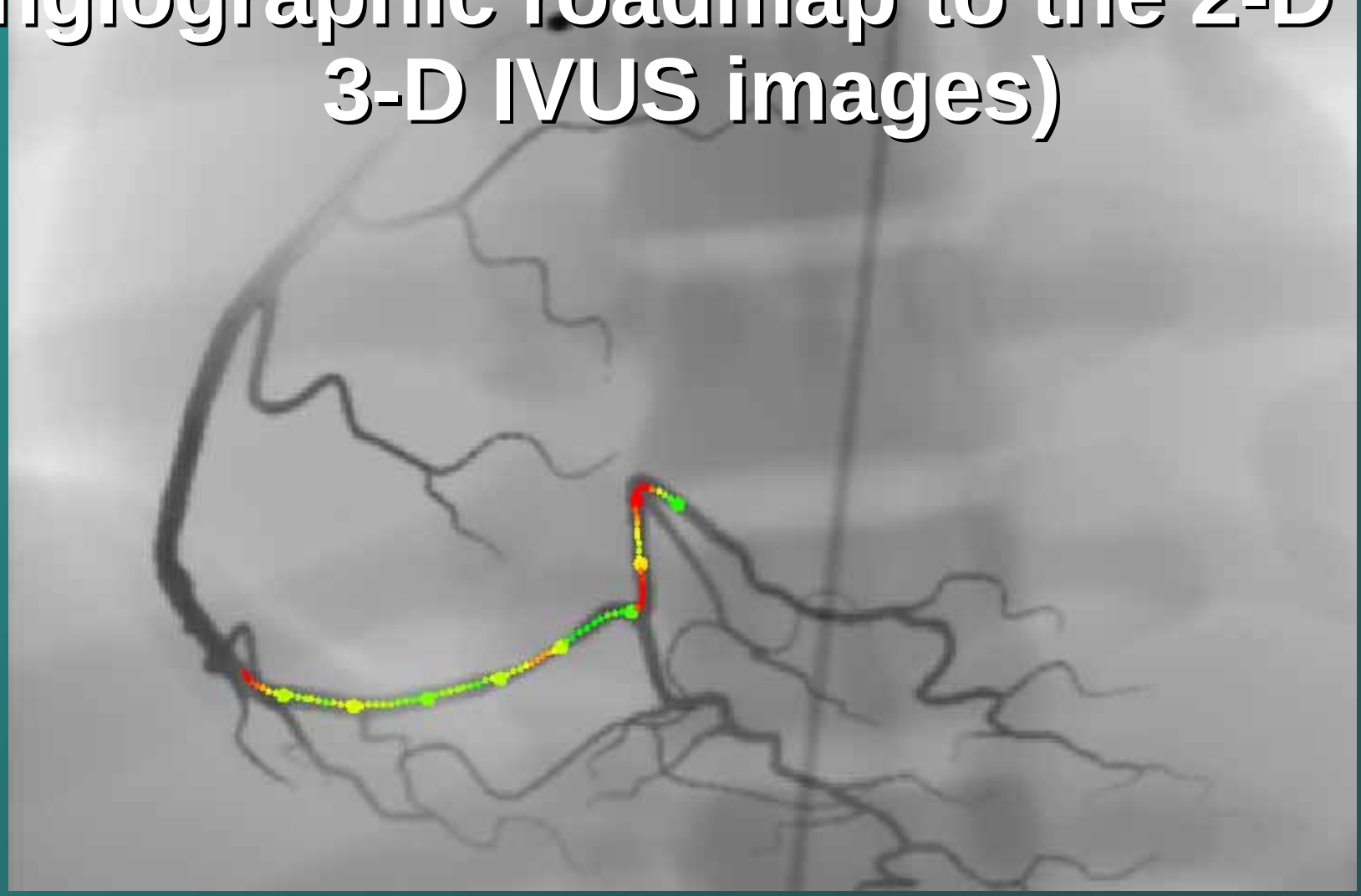
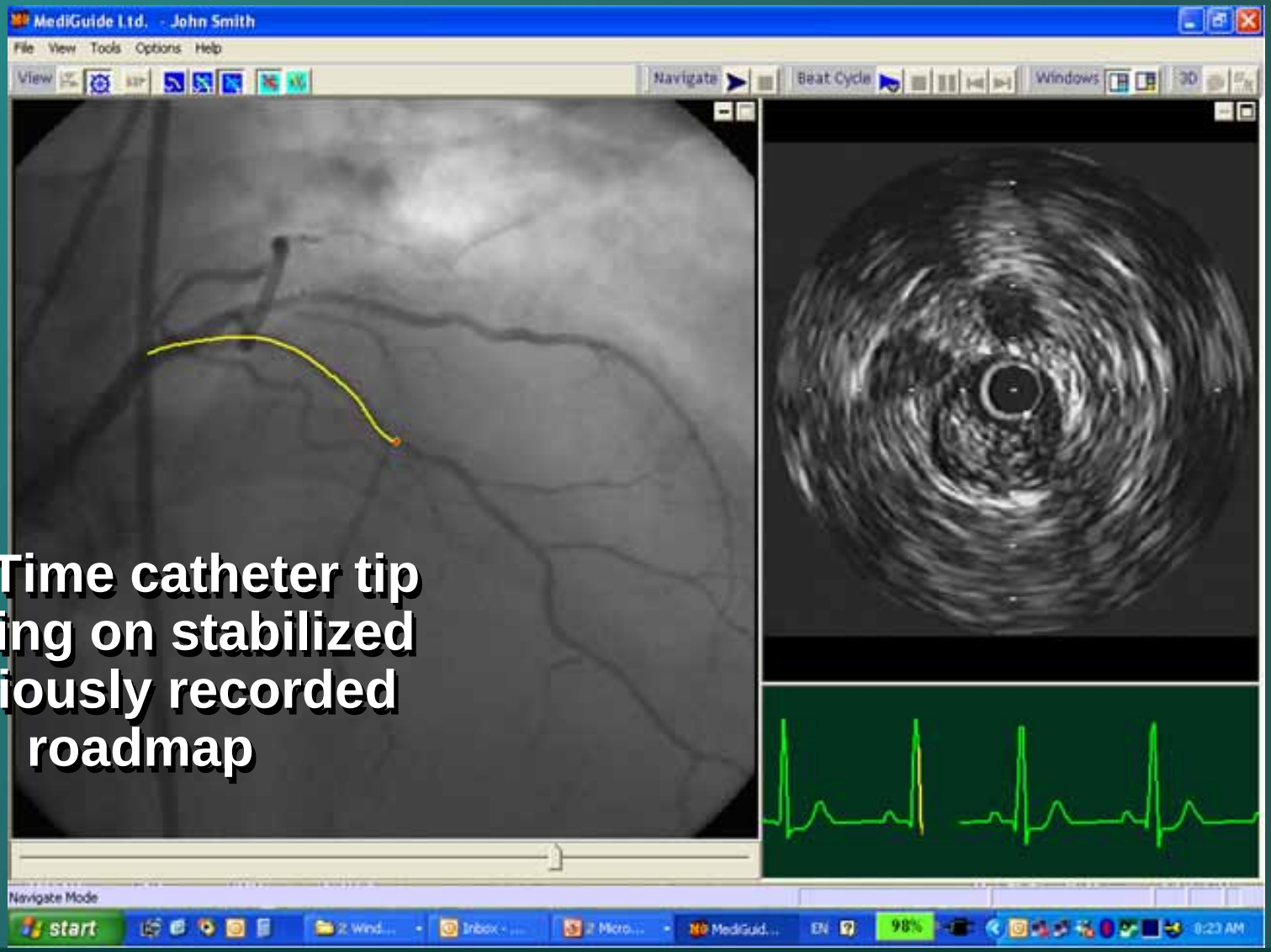


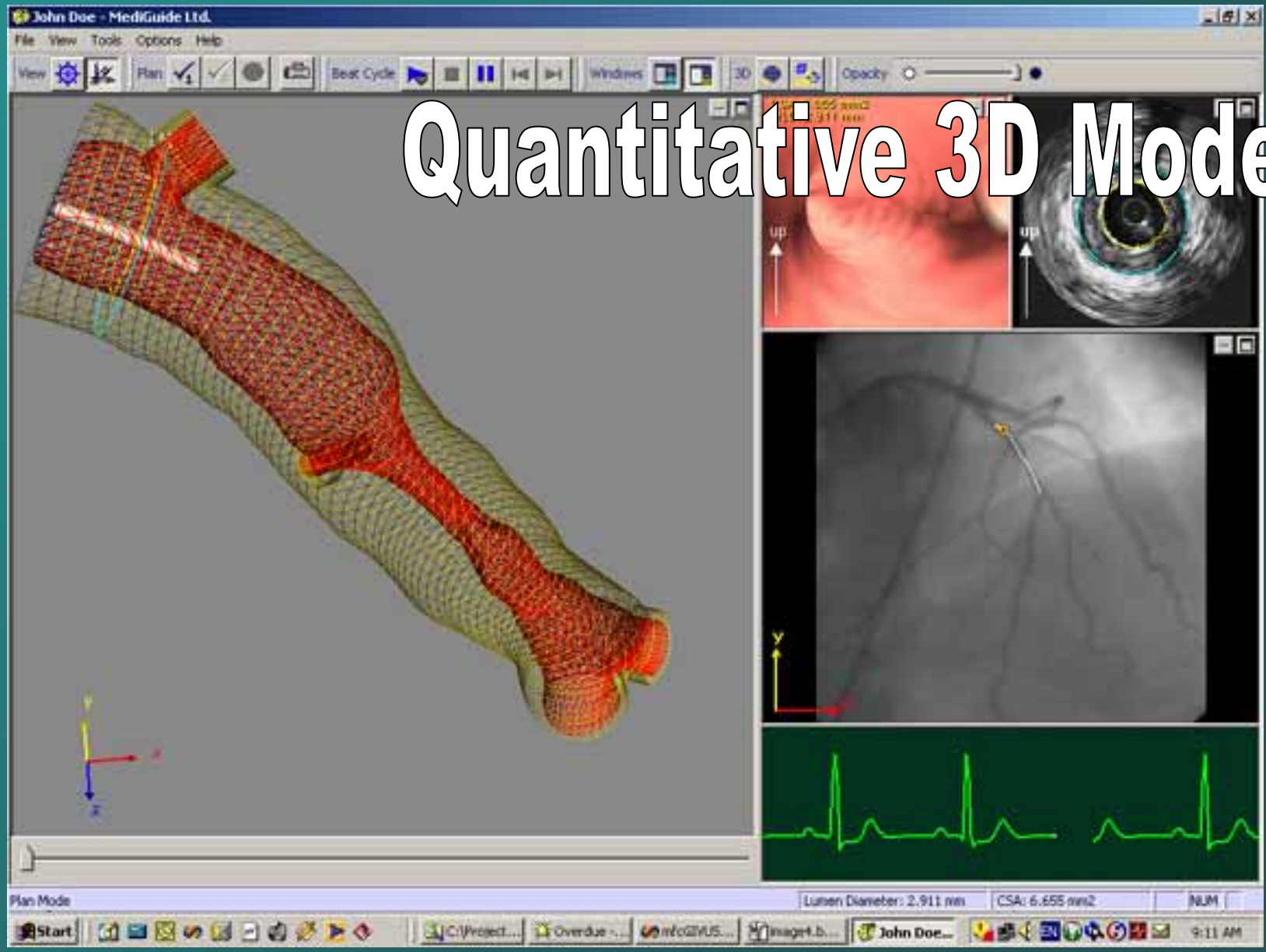
Image Co-Registration (linking the angiographic roadmap to the 2-D or 3-D IVUS images)



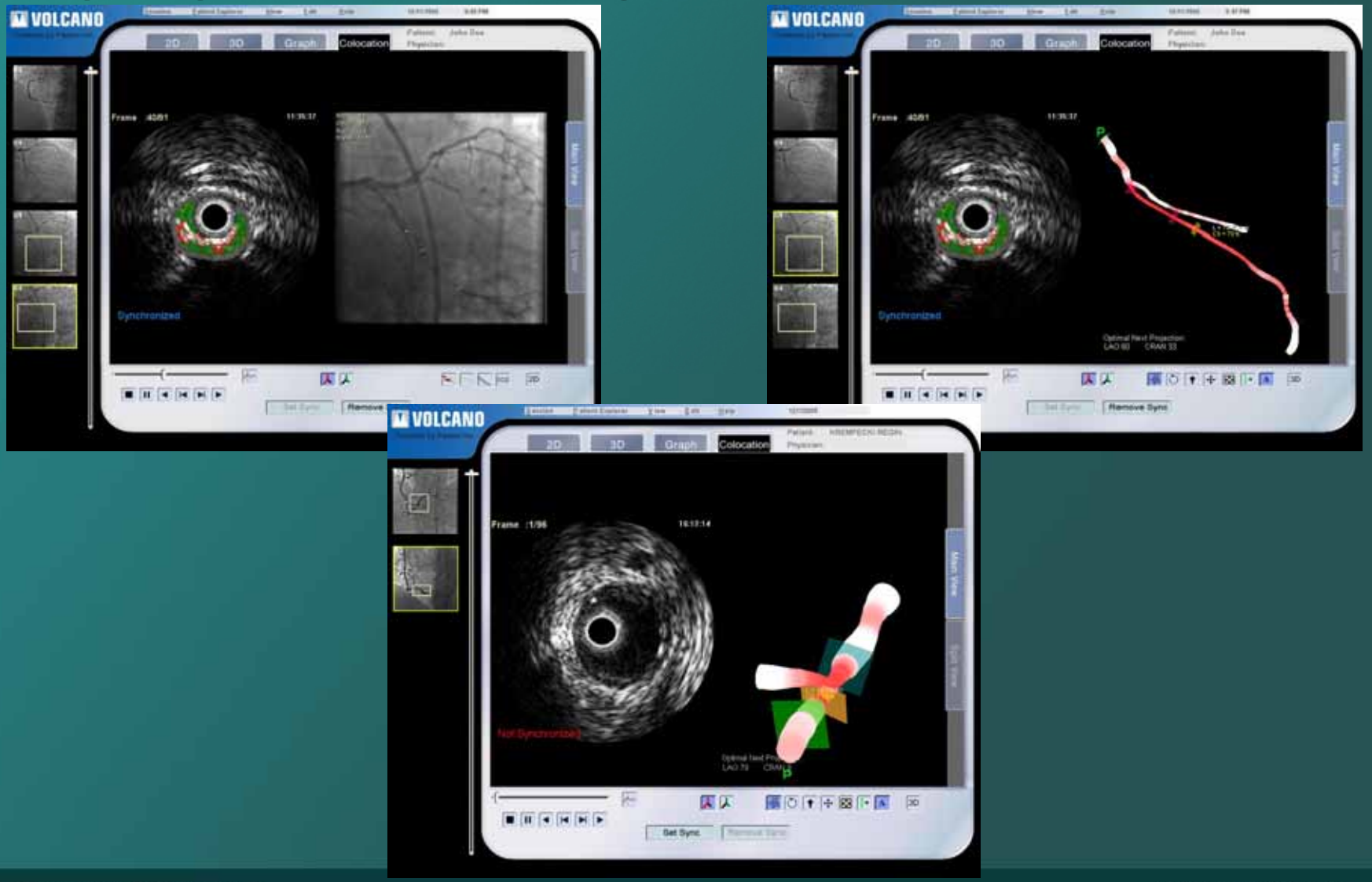
Co-Registration of IVUS and angiographic images (MediGuide)



Real Time catheter tip tracking on stabilized previously recorded roadmap


John Doe - MediGuide Ltd.
File View Tools Options Help
Quantitative 3D Model
Plan Mode
Lumen Diameter: 2.911 mm
CSA: 6.655 mm2
NUM
Start
9:11 AM

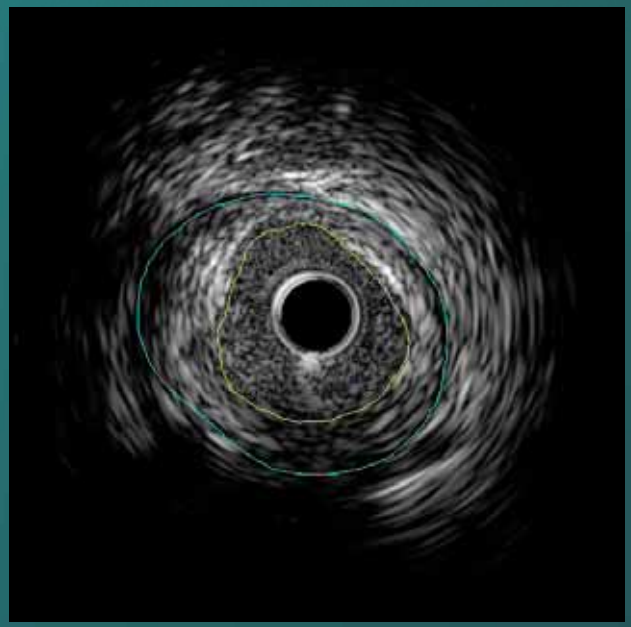
Co-registration of IVUS and angiographic images (Volcano&Paieon)



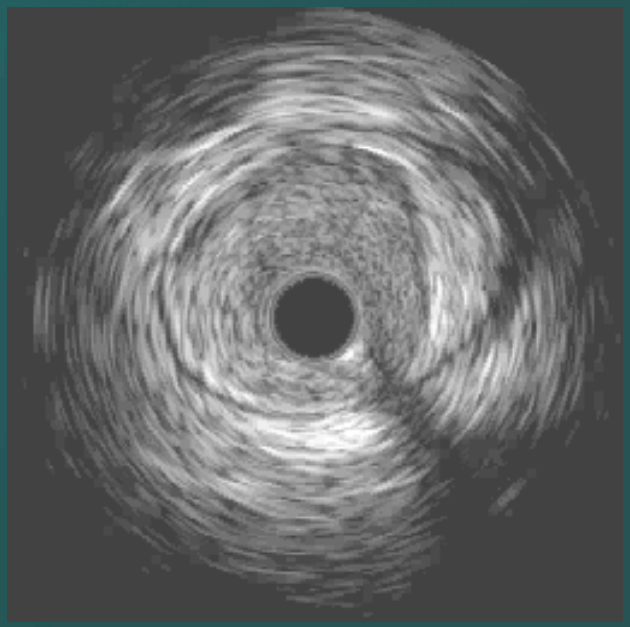
Enhanced border recognition

Especially important if transducer frequency increases because blood speckle will become more intense and closer in appearance to plaque. Therefore, correlation algorithms to remove blood speckle may be necessary.

Accurate segmentation algorithms



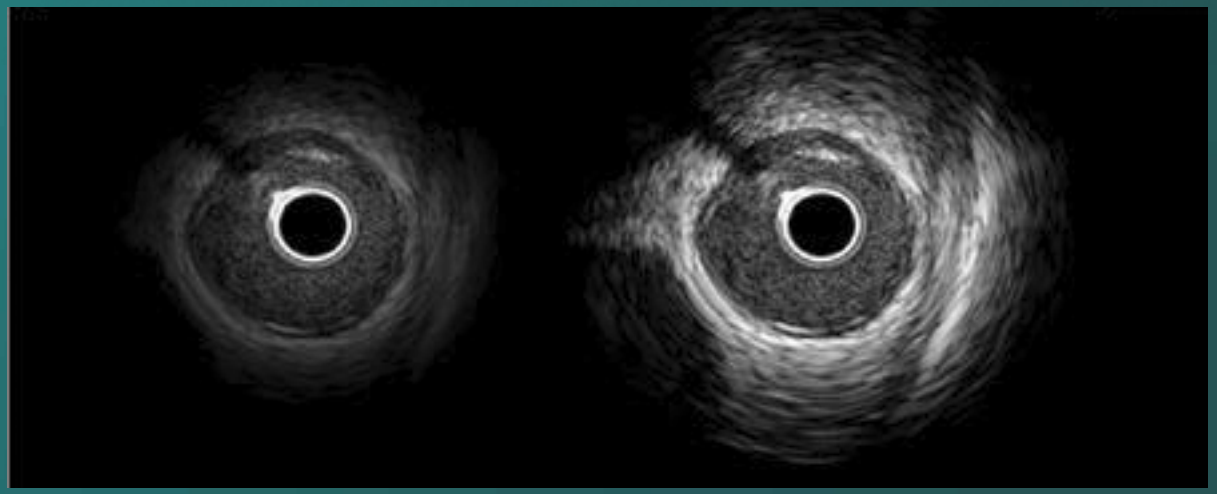
Dynamic review (BostonScientific)



Smart TGC

Time Gain Compensation (TGC) is the process of enhancing signals which progressively weaken with depth. Conventionally, it is adjusted manually.

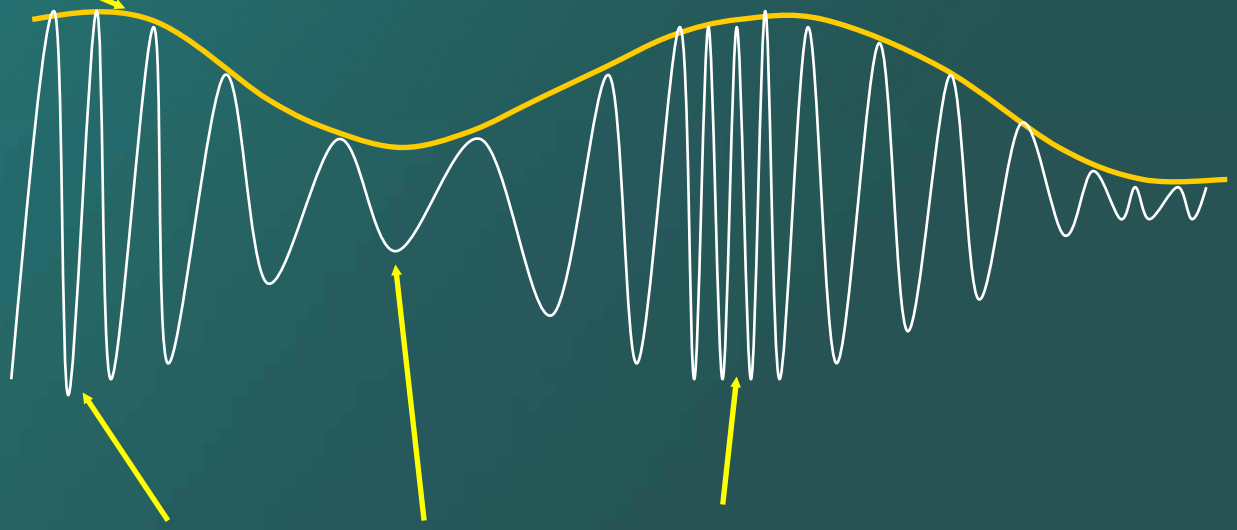
No TGC Smart TGC



Virtual Histology™ IVUS

Only the envelope amplitude (echo intensity) is used in formation of the gray-scale IVUS image

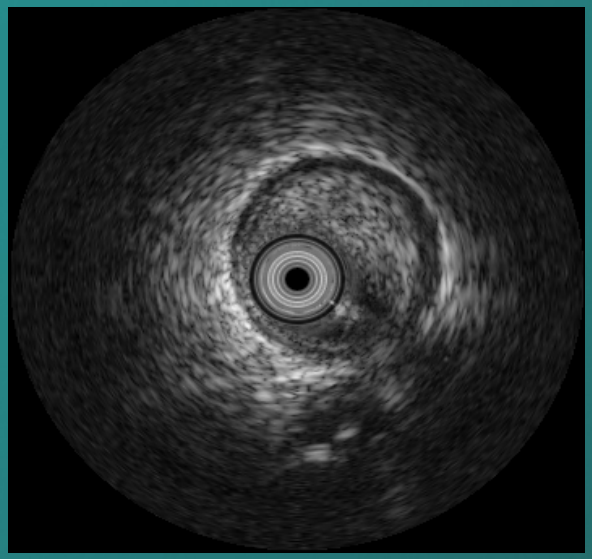
Eight amplitude *AND* frequency parameters are used in Virtual Histology



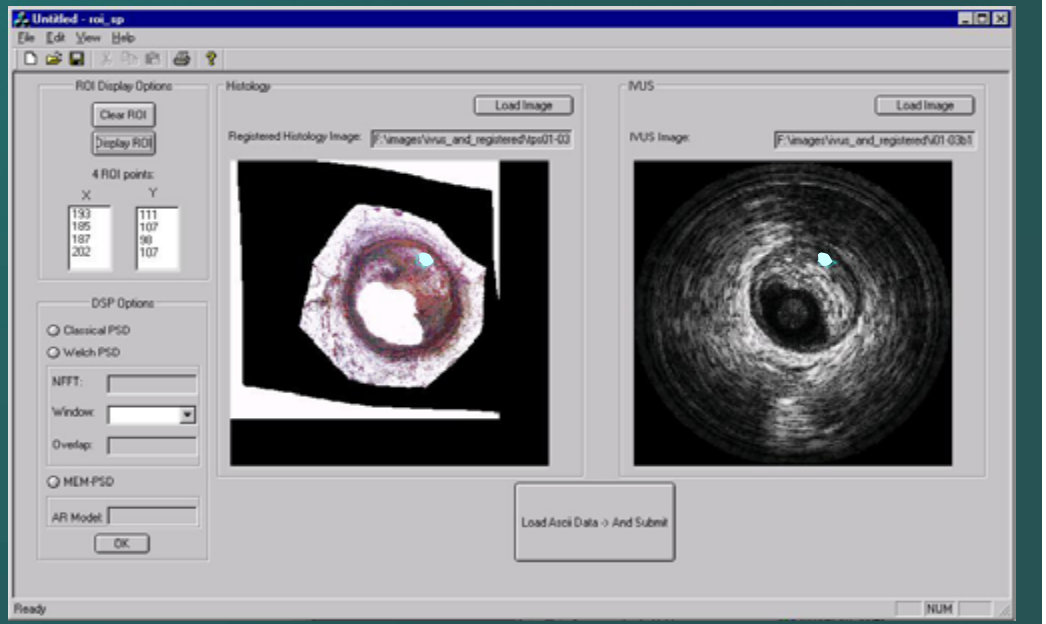
Frequency of echo signal can also vary, depending on the tissue

Thin plate spline morphing of distorted histologic image after which the computer was taught to recognize four basic tissue types

IVUS B scan



Movat pentachrome stain



Accurate tissue characterization

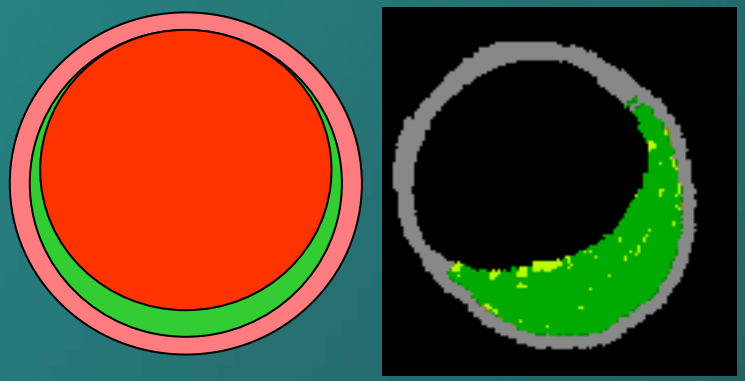
Eagle Eye VH Accuracy

VH IVUS vs histopathology from fresh post-mortem coronary arteries

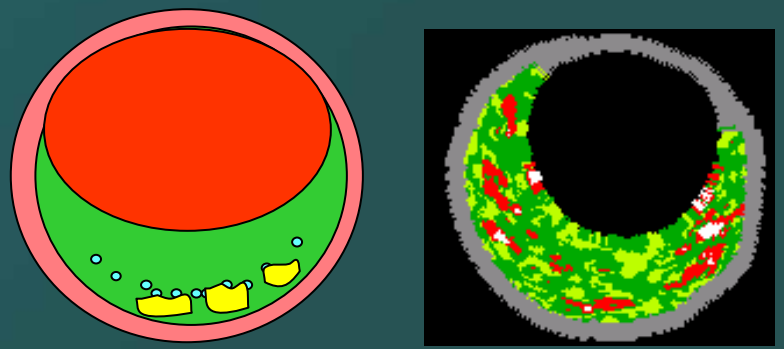
	Sensitivity	Specificity	Predictive Accuracy
Fibrous tissue (n=162)	84.0%	98.8%	92.8%
Fibrofatty (n=84)	86.9%	95.1%	93.4%
Necrotic core (n=69)	97.1%	93.8%	94.4%
Dense calcium (n=92)	97.8%	99.7%	99.3%

Plaque Classification - I

Adaptive Intimal Thickening
Plaque comprised of nearly all fibrous tissue. (<5% of fibrofatty, calcification and/or NC plaque).
(Generally not viewed by Dr. Virmani to be acutely dangerous)

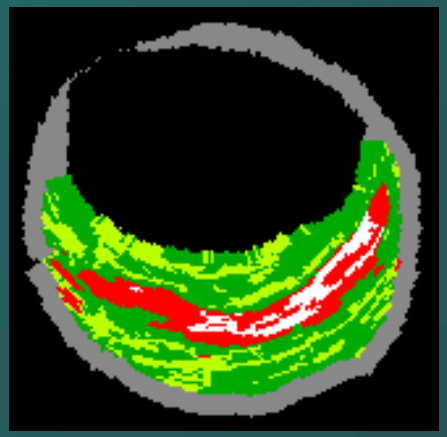


Pathological Intimal Thickening – Mainly mixture of fibrous, fibrofatty (>5%), and necrotic core and some calcified tissue <5%.



Plaque Classification - II

“Fibro-Atheroma” – Fibrotic cap and significant Necrotic Core in fibrotic and/or fibrofatty tissue



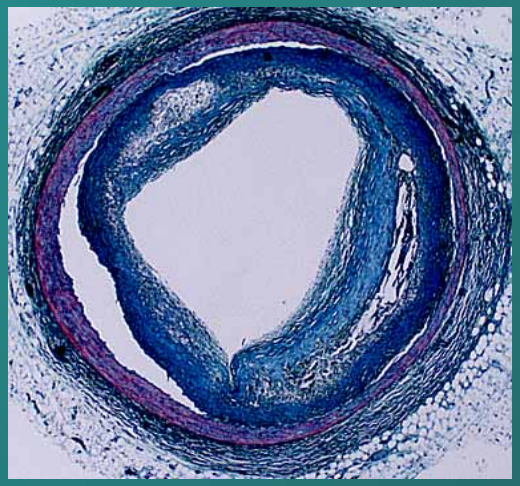
It is very likely be that the most important goal is to differentiate the FibroAtheroma plaque types from the other three plaque types during assessments of high risk lesions for rupture.

Diagnostic accuracy of real-time IB (integrated Backscatter)-IVUS

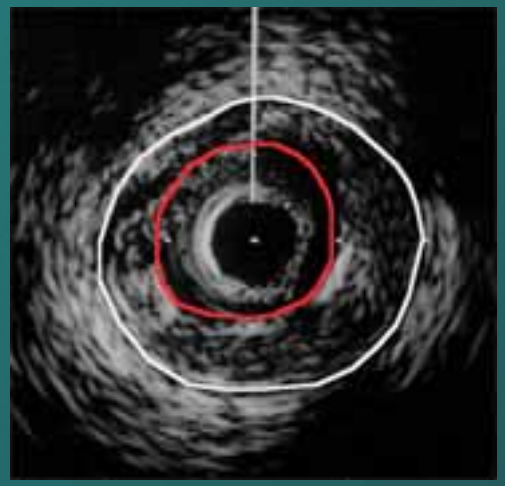
	Sensitivity	Specificity	PPV	NPV
Calcification (n=144)	95%	99%	93%	99%
Fibrosis (n=335)	94%	93%	93%	94%
Lipid pool (n=205)	90%	92%	85%	90%

(Kawasaki et al. Circulation2002;105:2487-92)

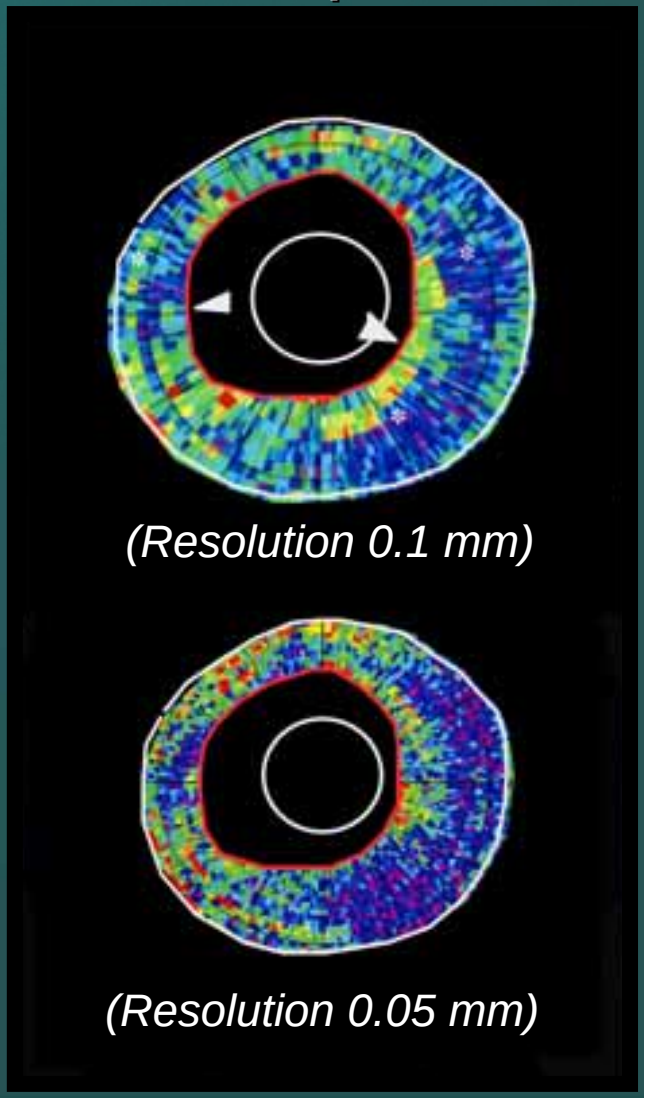
Masson Trichrome Staining



Conventional IVUS



Integrated Backscatter Intravascular Ultrasound (IB-IVUS) Color-coded Map



(Resolution 0.1 mm)

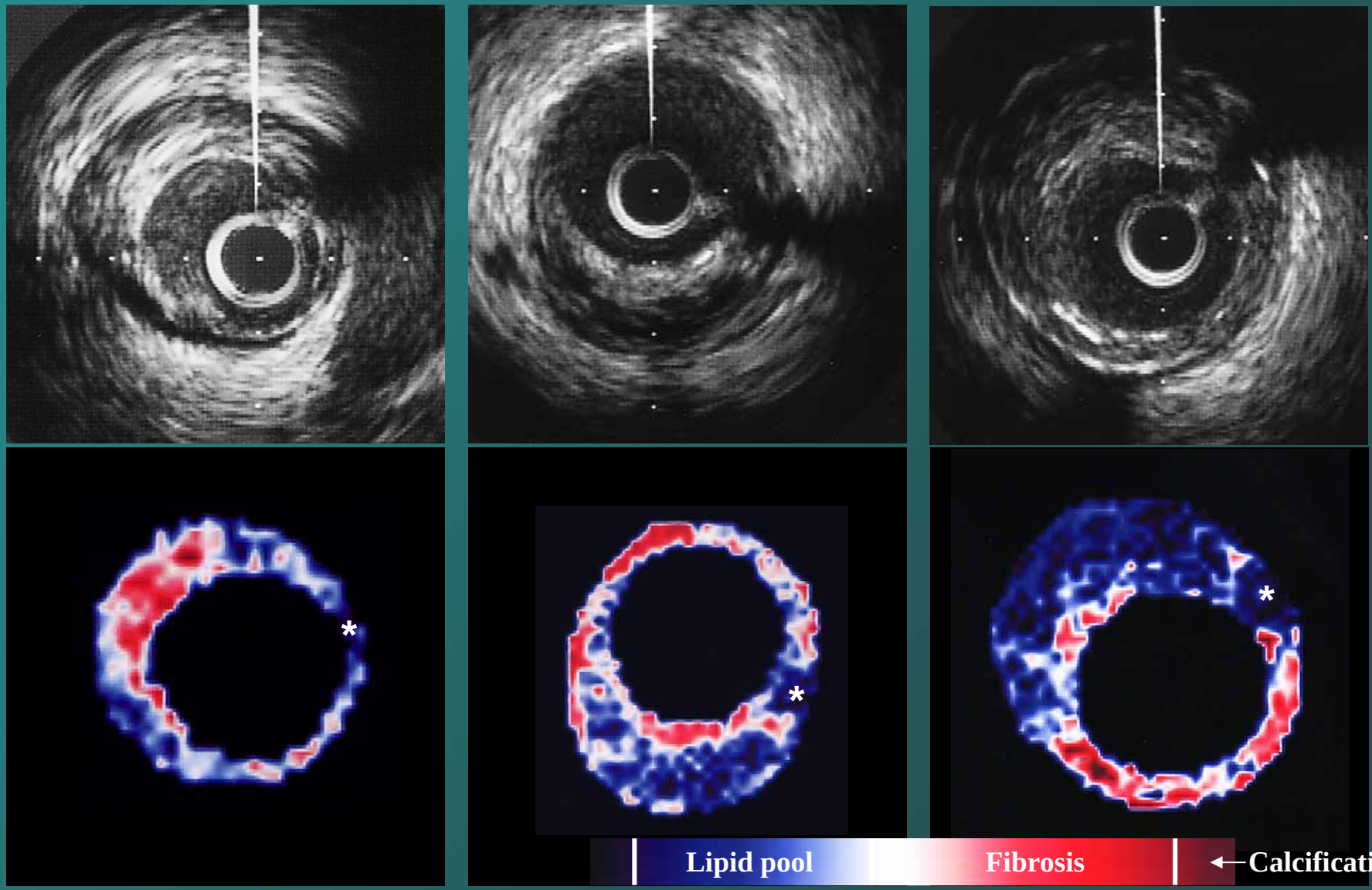
(Resolution 0.05 mm)

- *Calcification*
- *Dense fibrosis*
- *Fibrosis*
- *Lipid pool or Intimal Hyperplasia*

(Kawasaki et al. Circulation2002;105:2487-92)

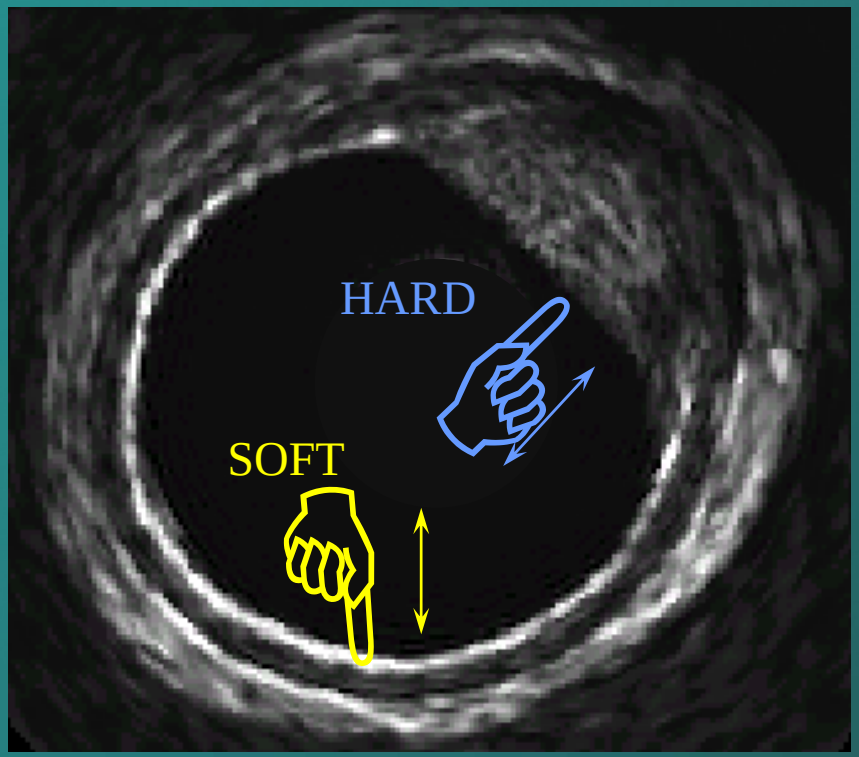
Stable Plaque

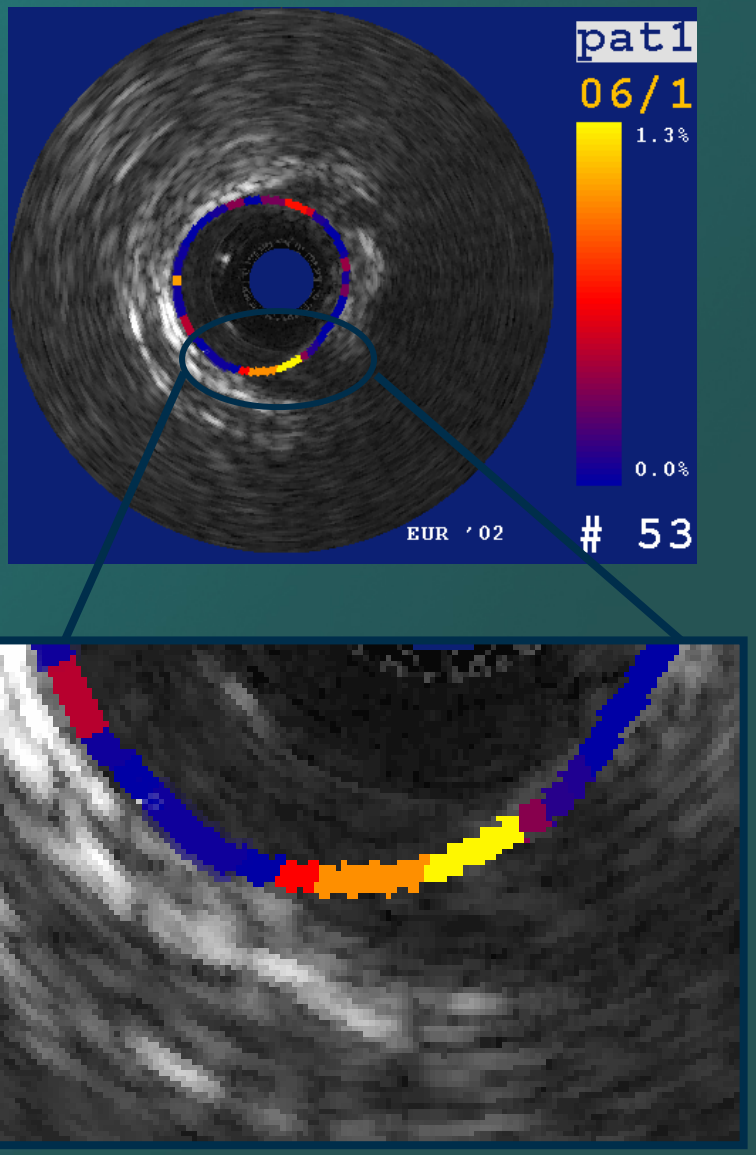
Vulnerable Plaque Causing ACS



* guidewire artifact

(Sano et al. J Am Coll Cardiol in press)

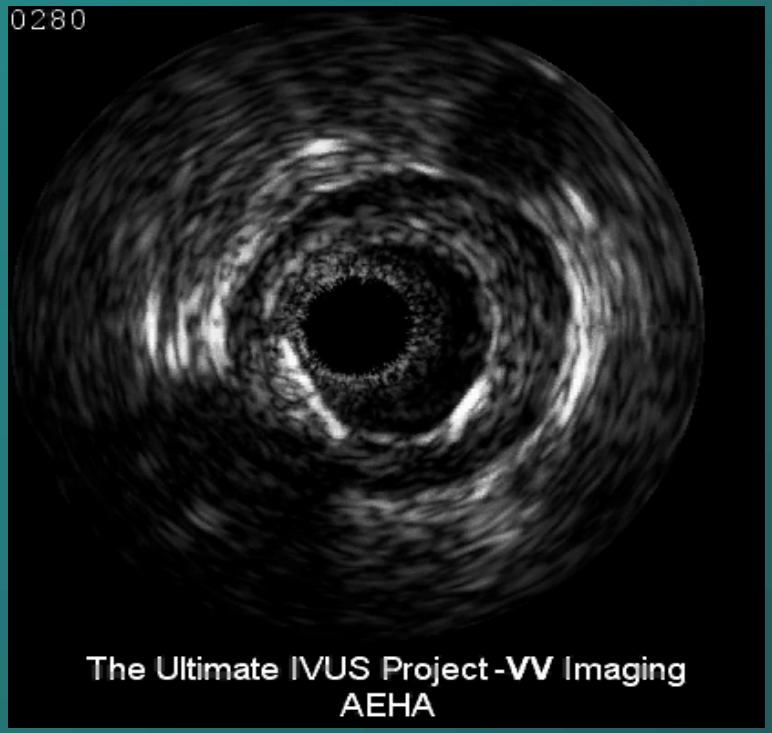


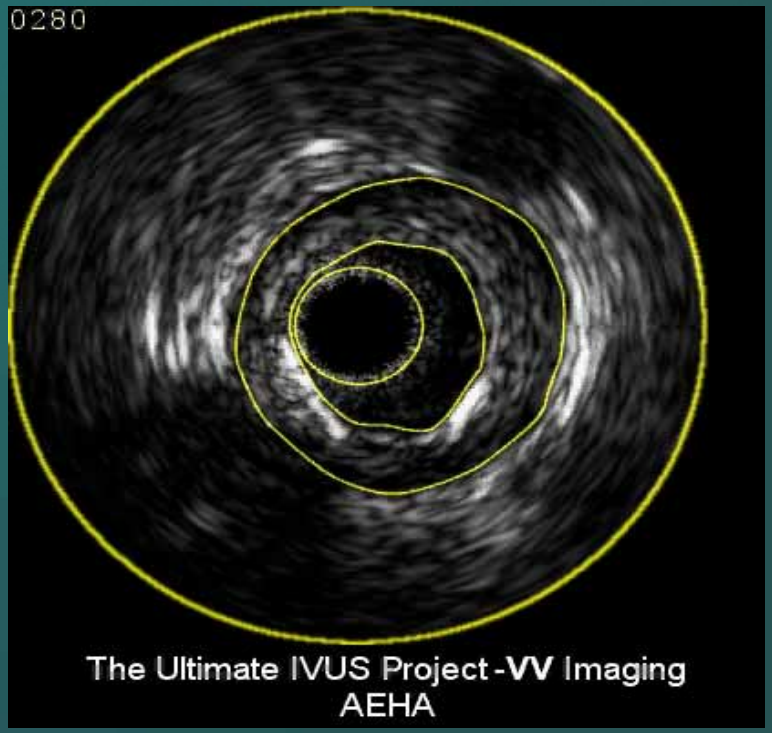


Independent predictors of strain were macrophages (p=0.006) and smooth muscle cells (p=0.0001)

Schaar et al. Circulation 2003;108:2535-41

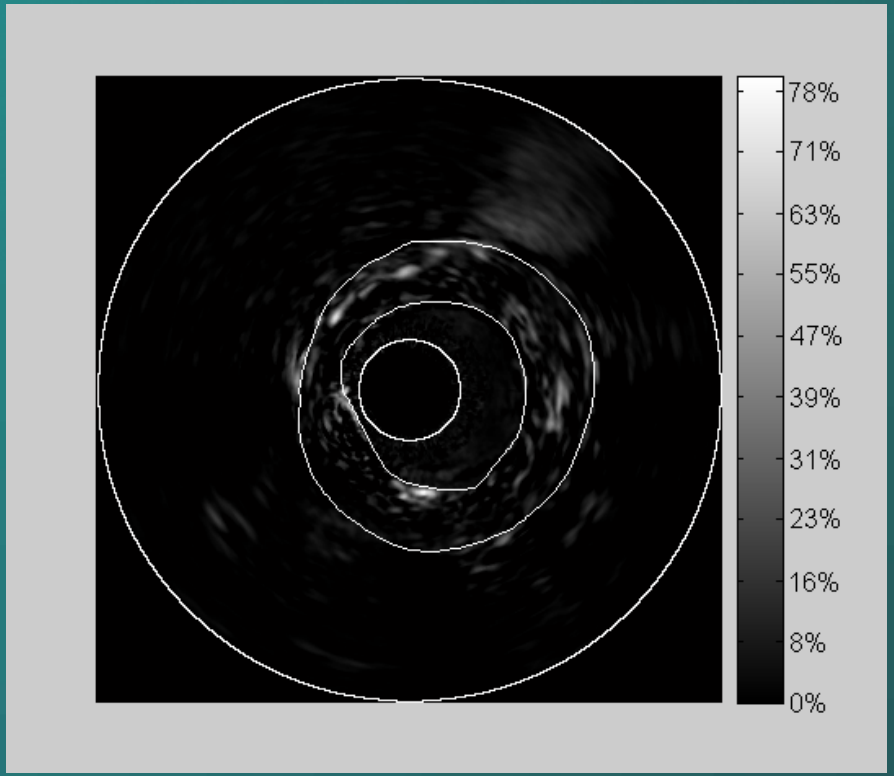
Baseline images are acquired for 20 seconds, and regions of interest are assigned

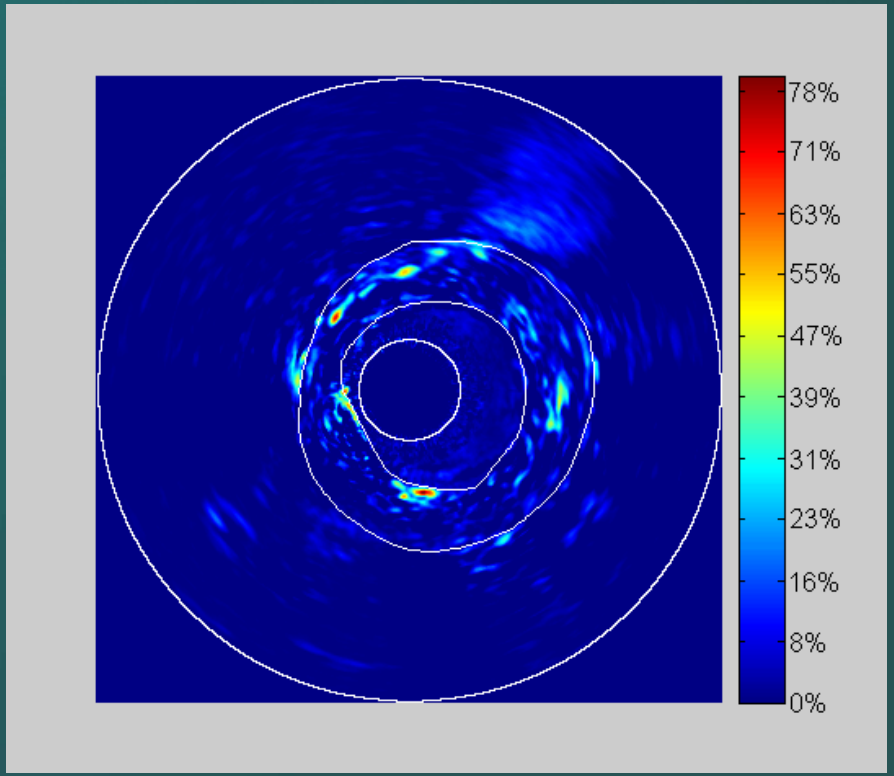


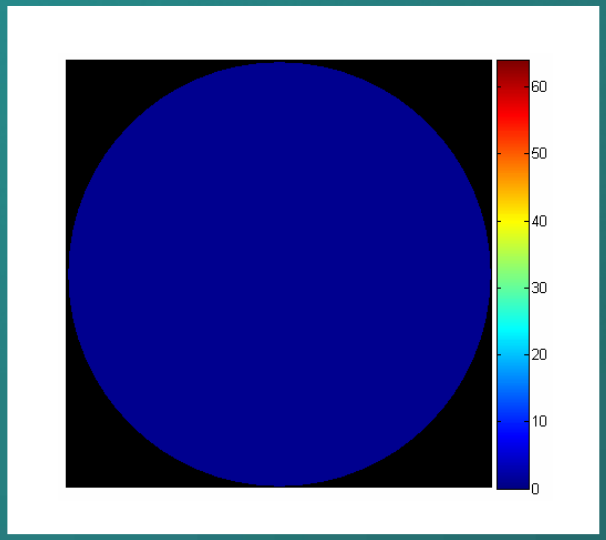


Contrast is injected, images are acquired for 120 seconds post-injection, and baseline images are subtracted

Range of enhancement

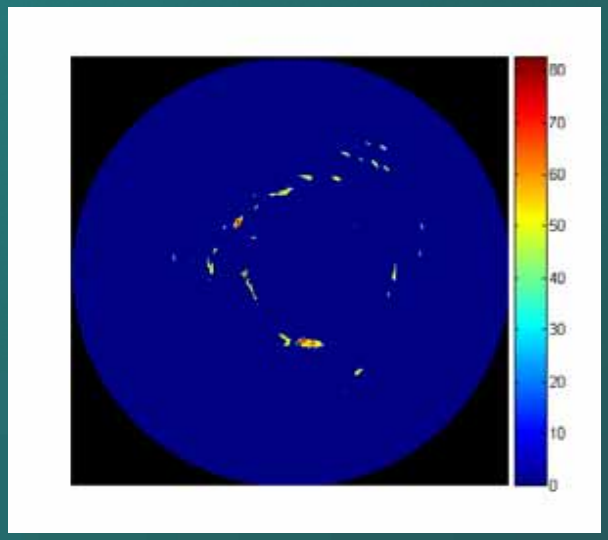






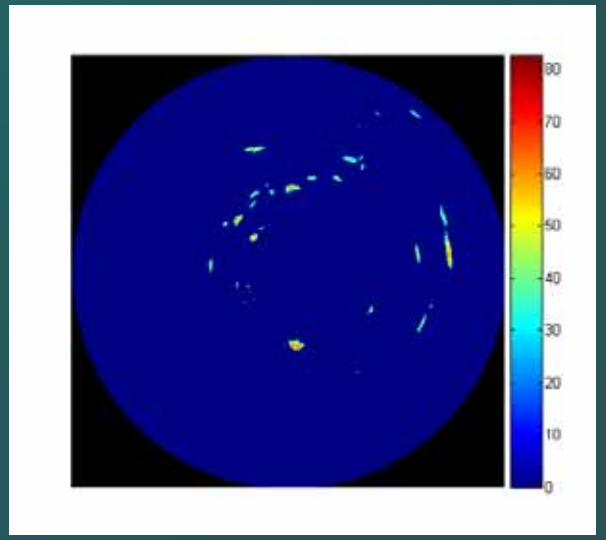
Pre-injection
(Frame #200)

Background motions are cancelled



Peak Injection
(Frame #600)

Lumen subtracted (microbubble shadow effect is not calculated)



Post-injection
(Frame #800)

The enhancement lasts for at least 25 seconds.

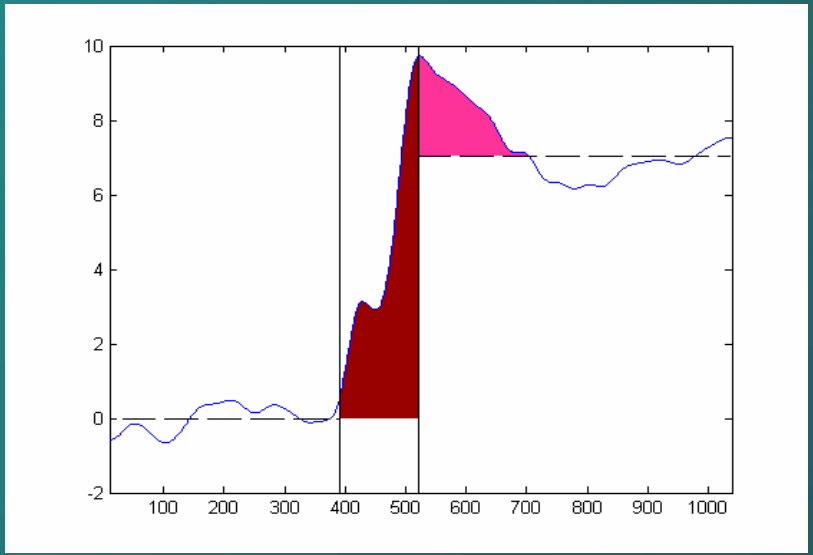
Storage of IVUS with the angiograms

- Only one set of patient demographics
  - Minimizes errors
  - Minimizes on-screen annotation
  - Enhances “plug-and-play” concept
- The IVUS imaging runs can be viewed as they occurred in sequence during the case without having to “match” IVUS and angiographic runs. The IVUS images can be related to the flow of the case.

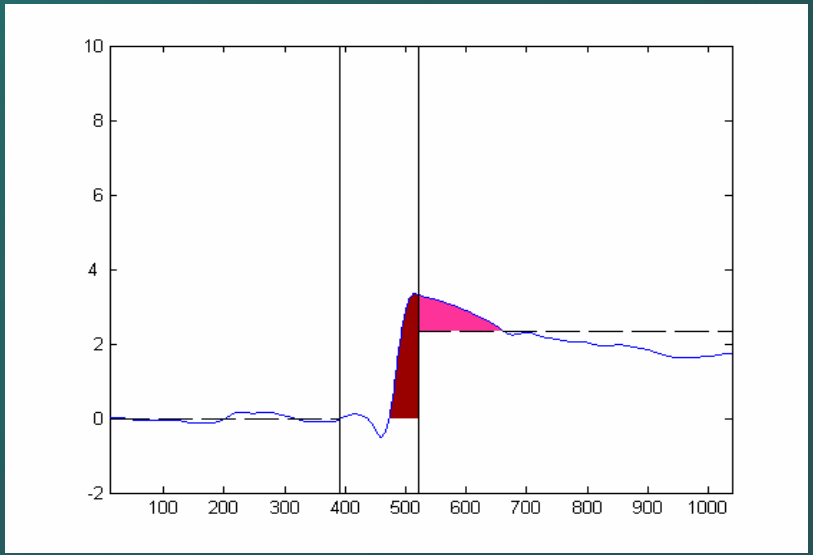
At the very least, IVUS studies should be completely DICOM compatible

Time-activity curves with quantitative monitoring of plaque perfusion

Intimo-Medial and Plaque Area



Adventitia Area



Conclusion

- IVUS should be “plug-and-play”
- With the exception of transducer design and catheter improvements, each component of this “futuristic vision” is possible (and even available!) now.
- The problem is that these efforts are not coordinated, nor are they likely to be. And no one company has the ability to deliver the entire package. This forces the consumer (us) to chose between equally desirable, but mutually exclusive features.
- So, the final element of this “futuristic vision” is one of a coordinated or cross-licensed effort among the companies.