The Unique Advantages of High Definition IVUS

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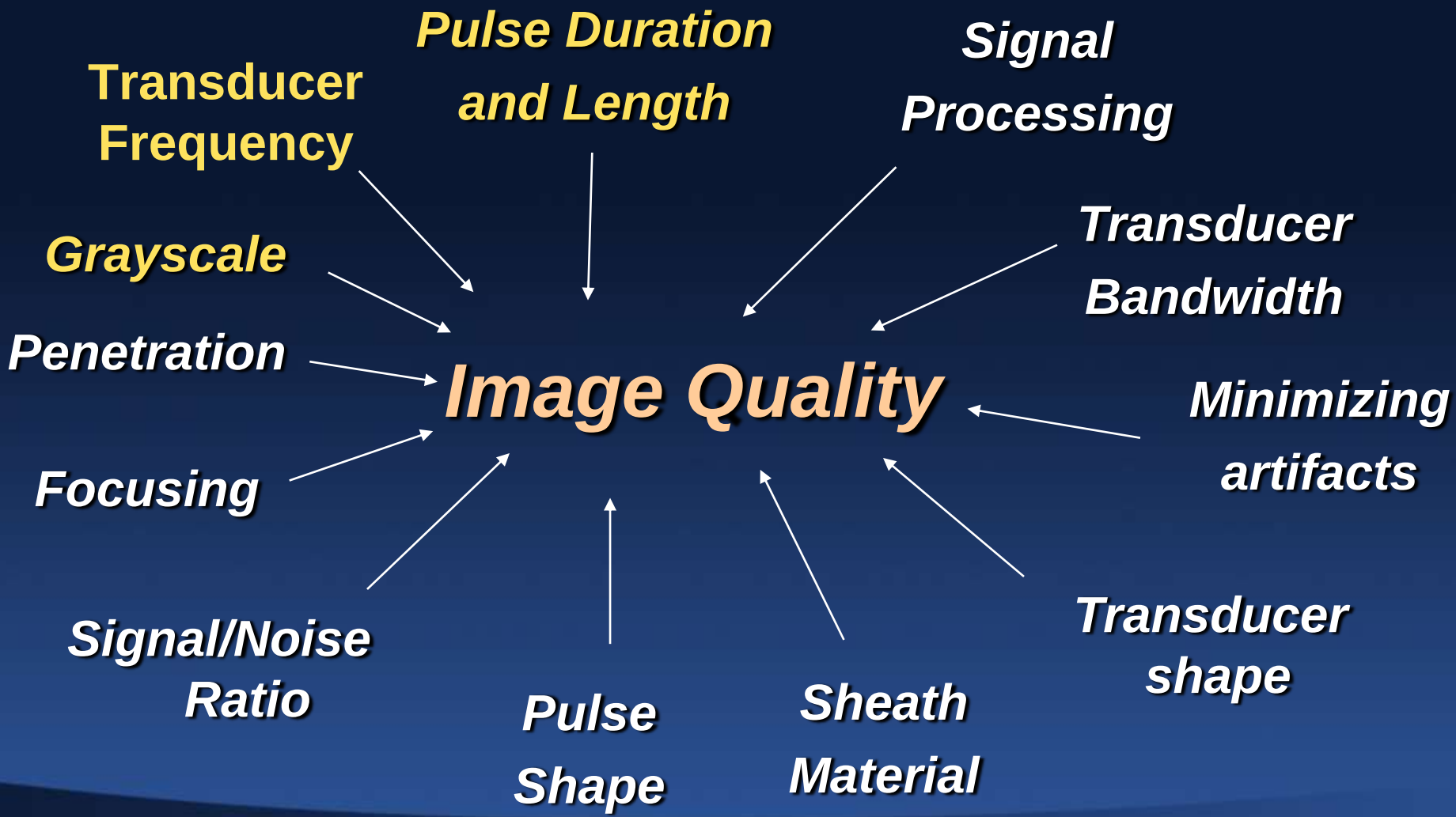
- **IVUS technology has been clinically available for over 20 years. *Yet. . .***
  - **Image quality has not improved in the last 10 years.**
  - **Poor spatial resolution and catheter-to-catheter imaging inconsistency are problematic.**
  - **Current IVUS systems are not capable of resolving structures <100 µm (and maybe <150µm) in size.**
  - **Poor image quality often requires expert interpretation, inhibits confidence in new users, and is a primary obstacle to maximizing growth and adoption of IVUS technology.**

What determines image quality?



Transducer Frequency

←Low Frequency High Frequency→

Signal Penetration Depth

EEM, vessel borders, positive remodeling

\+ See deeply into vessel tissue — Shallow depth-of-field -

Lumen Visibility

lumen darkness, differentiation of blood speckle from tissue

\+ Low blood speckle, easy to identify lumen — High blood speckle, less clear lumen borders -

Imaging Resolution

dissection, thrombus, rupture, etc.

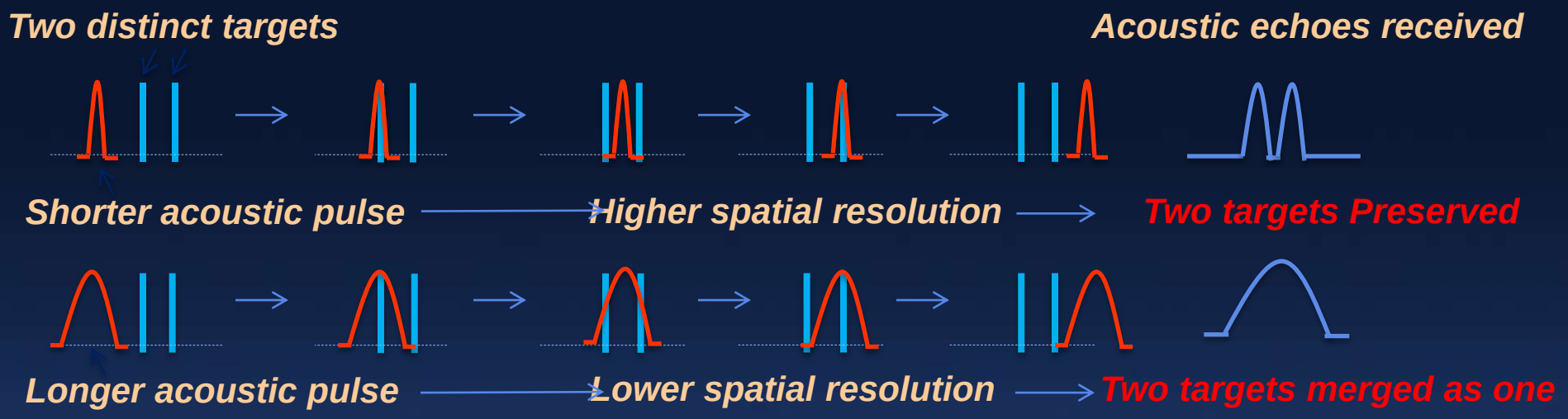
\- Low resolution, can't distinguish small structures — Crisp detail of small structures +

Tissue Visibility

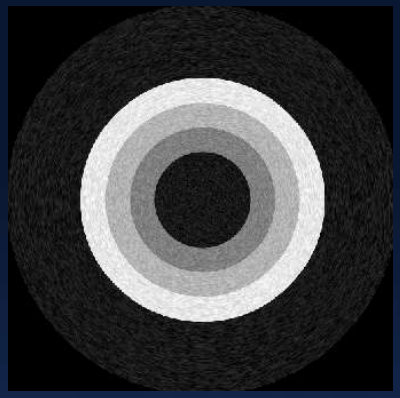
plaque layering, density of vessel tissue, etc.

\- Unable to differentiate tissue — Tissue variations evident +

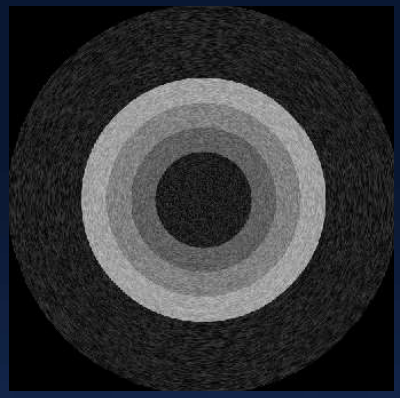
Pulse Duration and Length



Contrast Resolution



Higher contrast resolution



Lower contrast resolution

Lower contrast resolution

Blurred boundary

Visible noise

Dimness of overall image

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Four Companies Are Working on Next Generation IVUS Systems

- ACIST (purchased SVMI - has been working on next generation IVUS since 2007)
- InfraReDx
- BostonScientific
- Volcano

Available

Limited market release

Under development

Each is taking a very different approach

ACIST: HD-IVUS

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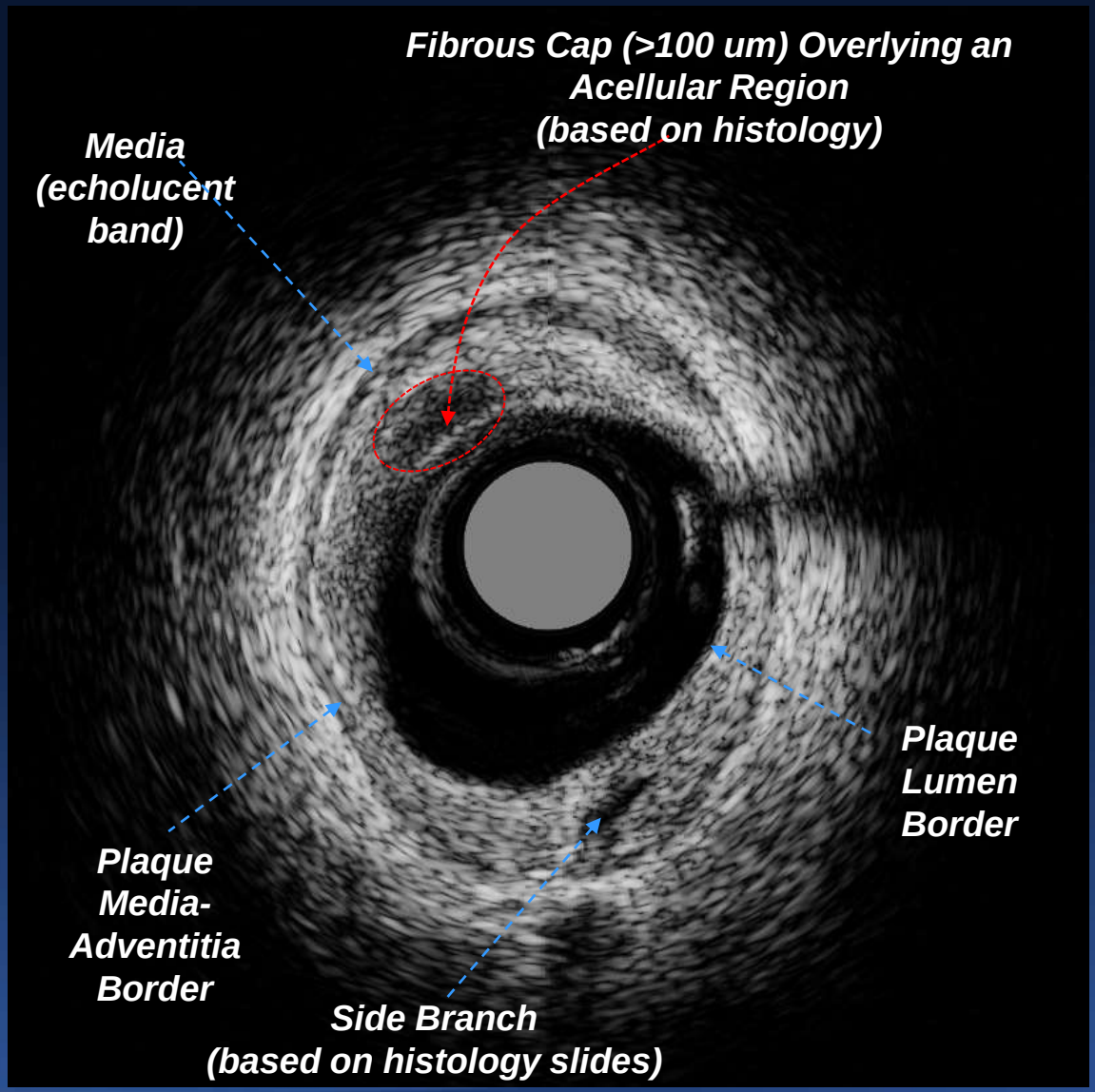
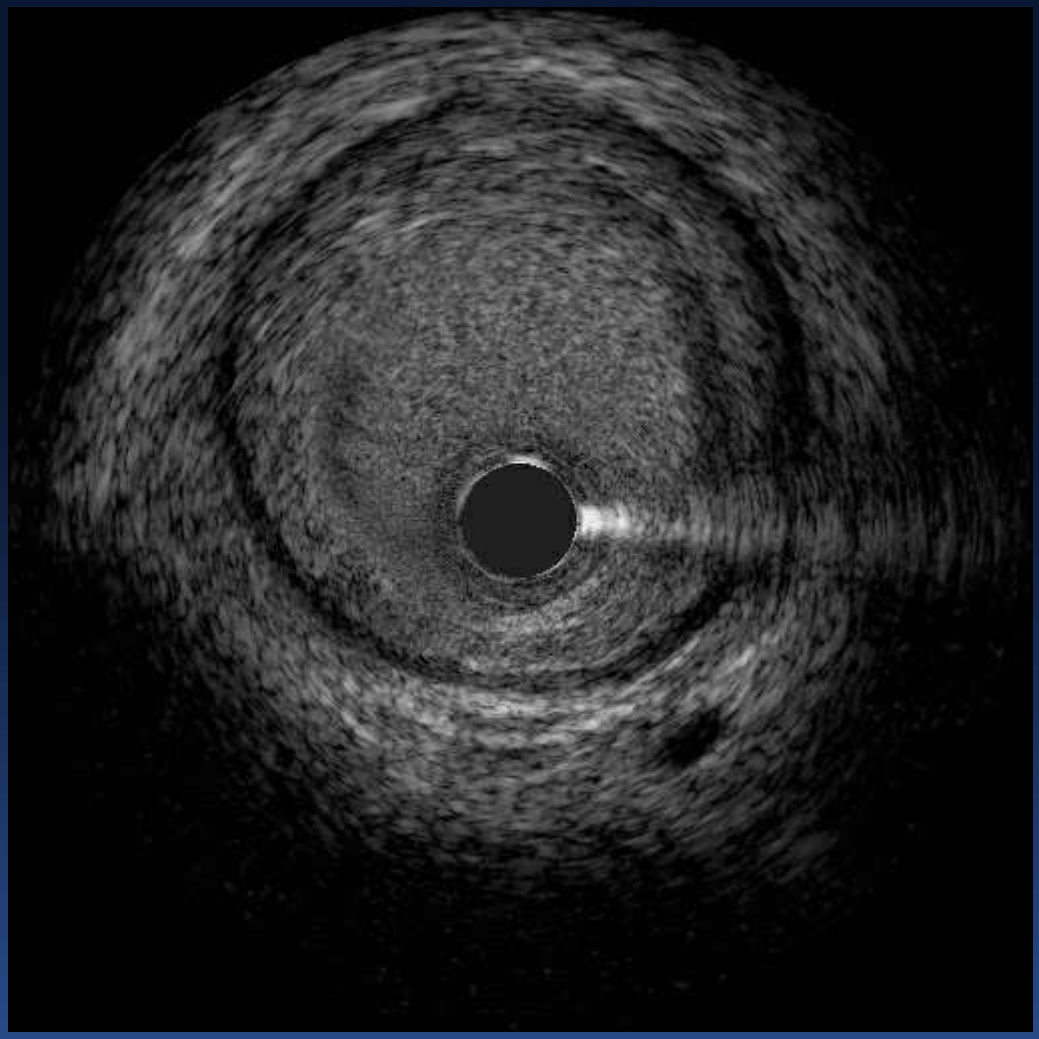
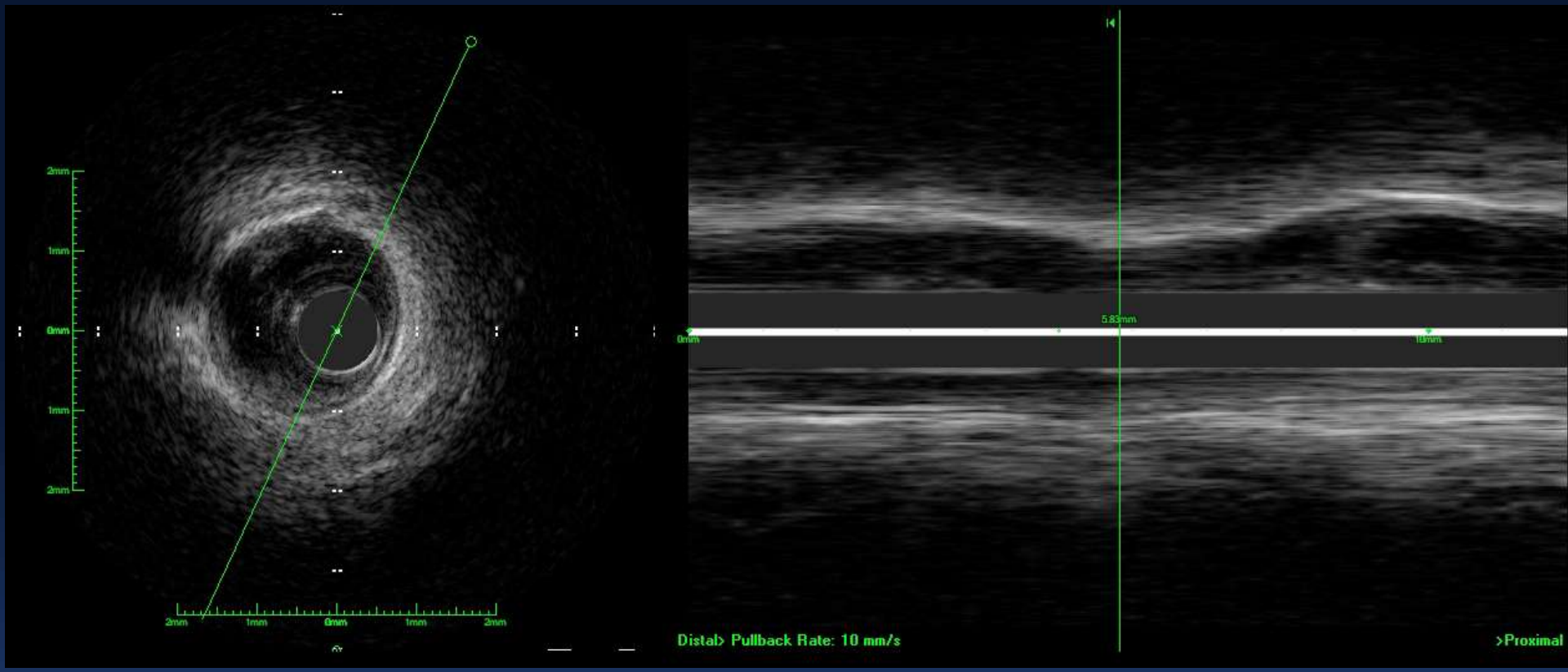
ACIST: HD-IVUS

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



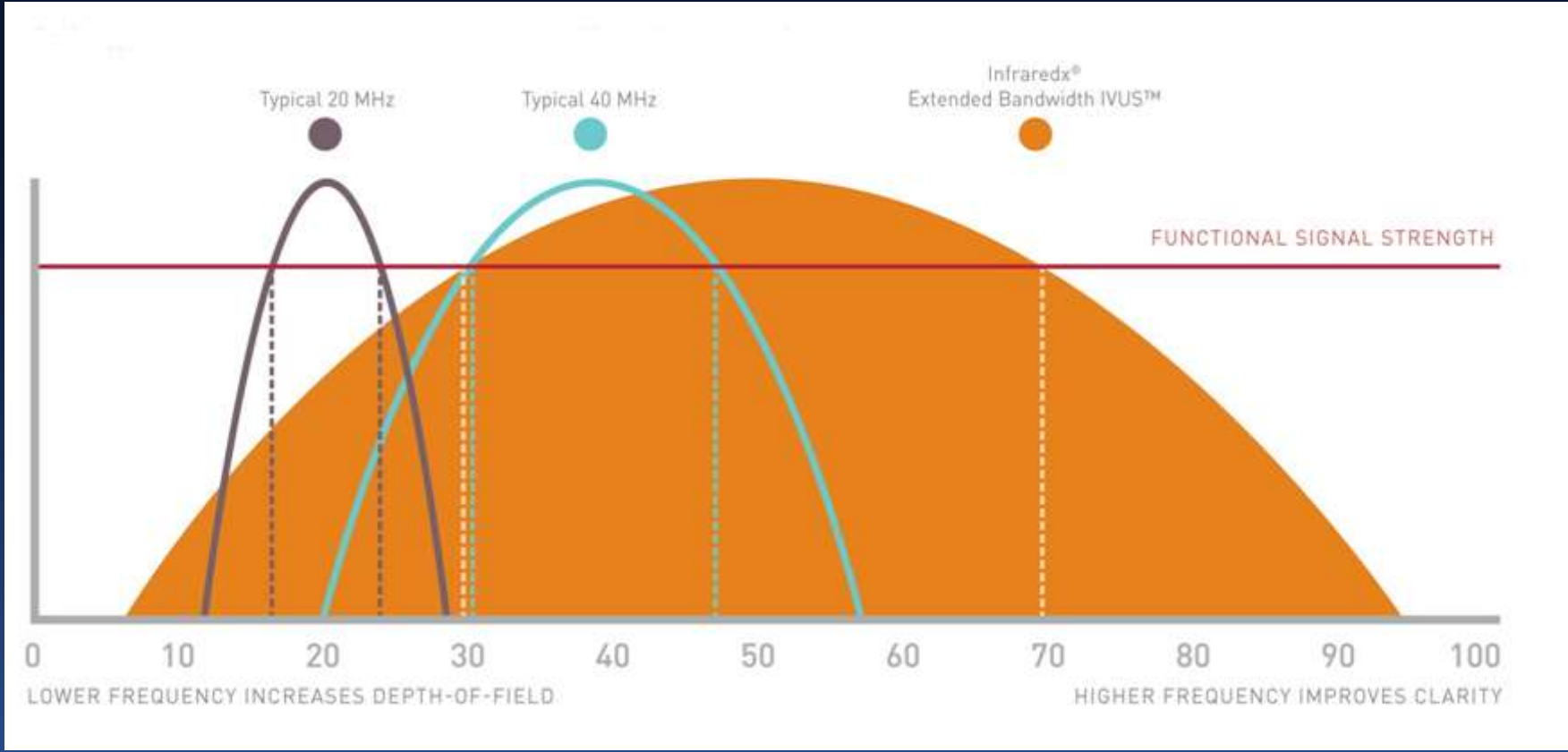




60MHz @ 60 frame/sec
Acquisition time: 10 sec
Pullback speed: 10.0 mm/sec
Pullback length: 96mm
567 Frames acquired (200 viewed)
Frame spacing: 167 µm
File size: 149 MB (10MB WMV viewed)

Infraredx: Next Generation IVUS

An extended bandwidth transducer is designed to combine the advantages of high and low frequency



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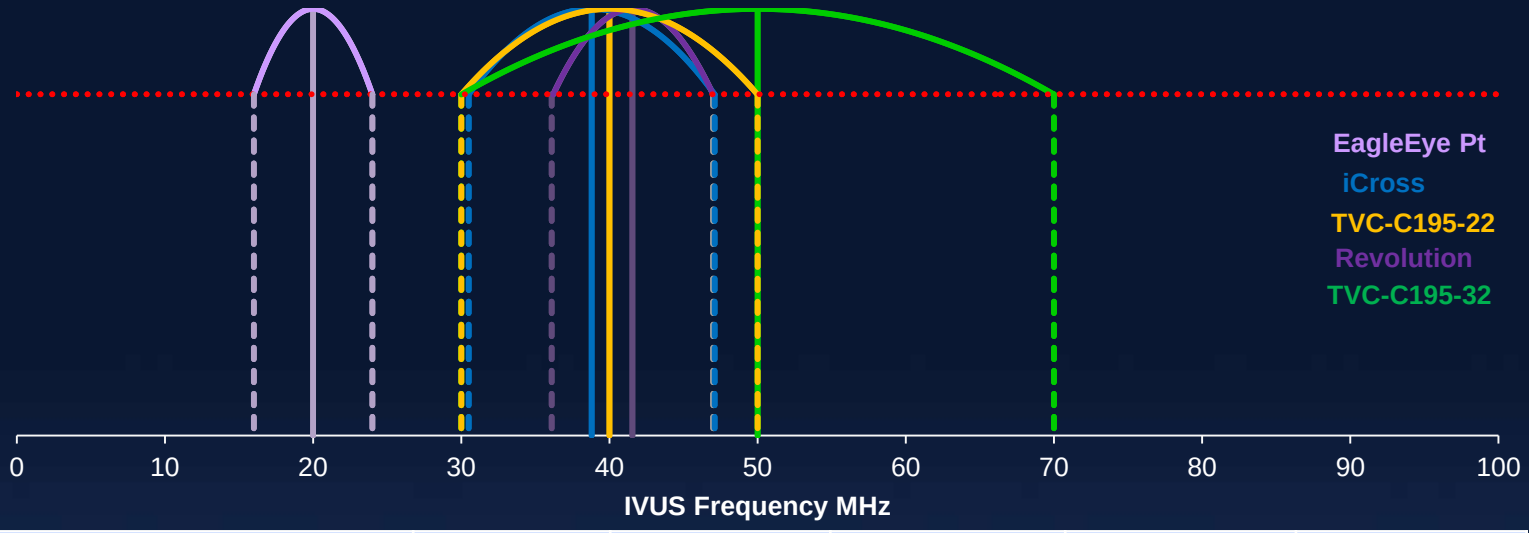
Center Frequency and Bandwidths

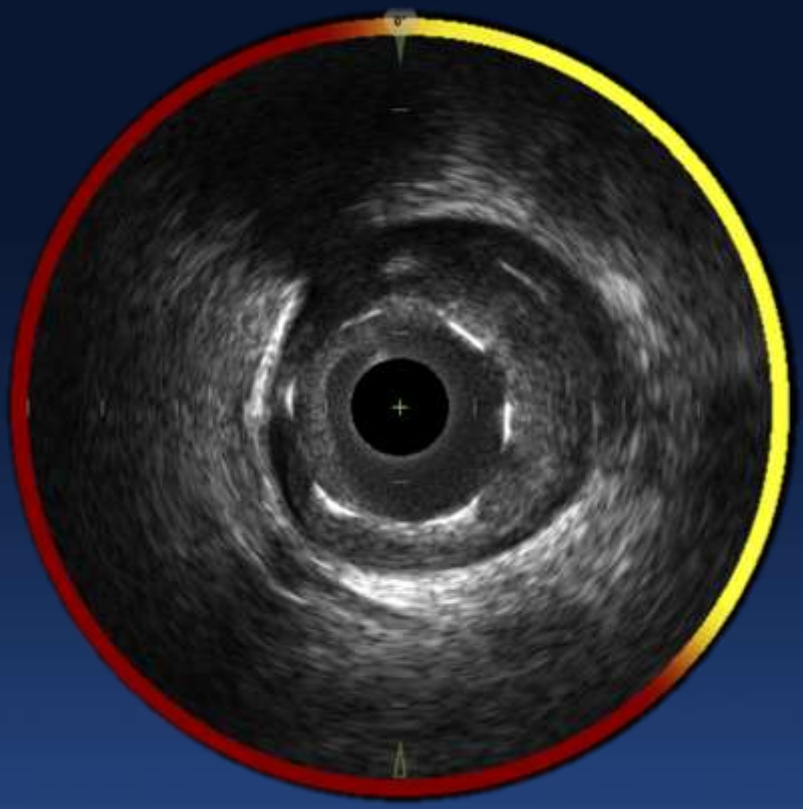


Catheter	Label Freq.	Center Frequency	Approx Functional Bandwidth	Approx. Functional IVUS Range	Calculated Axial Resolution*
VOLCANO Eagle Eye	20 MHz	20 MHz	40%	16-24 MHz	< 170 microns
VOLCANO Revolution	45 MHz	41.5 MHz	27%	36-47 MHz	50 microns
BSC iCross / Opticross	40 MHz	38.8 MHz	43%	30-47 MHz	43/38 microns
Infraredx Insight (TVC-C195-22)	40 MHz	39.5 MHz	50%	30-50 MHz	40 microns
Infraredx Muller (TVC-C195-32)	50 MHz	50.0 MHz	80%	30-70 MHz	20 microns

***Theoretical estimates based on design**:

http://users.tpg.com.au/mcgrath_/Calculators/Axial_Resolution_Calculator.htm

Infraredx: Next Generation IVUS



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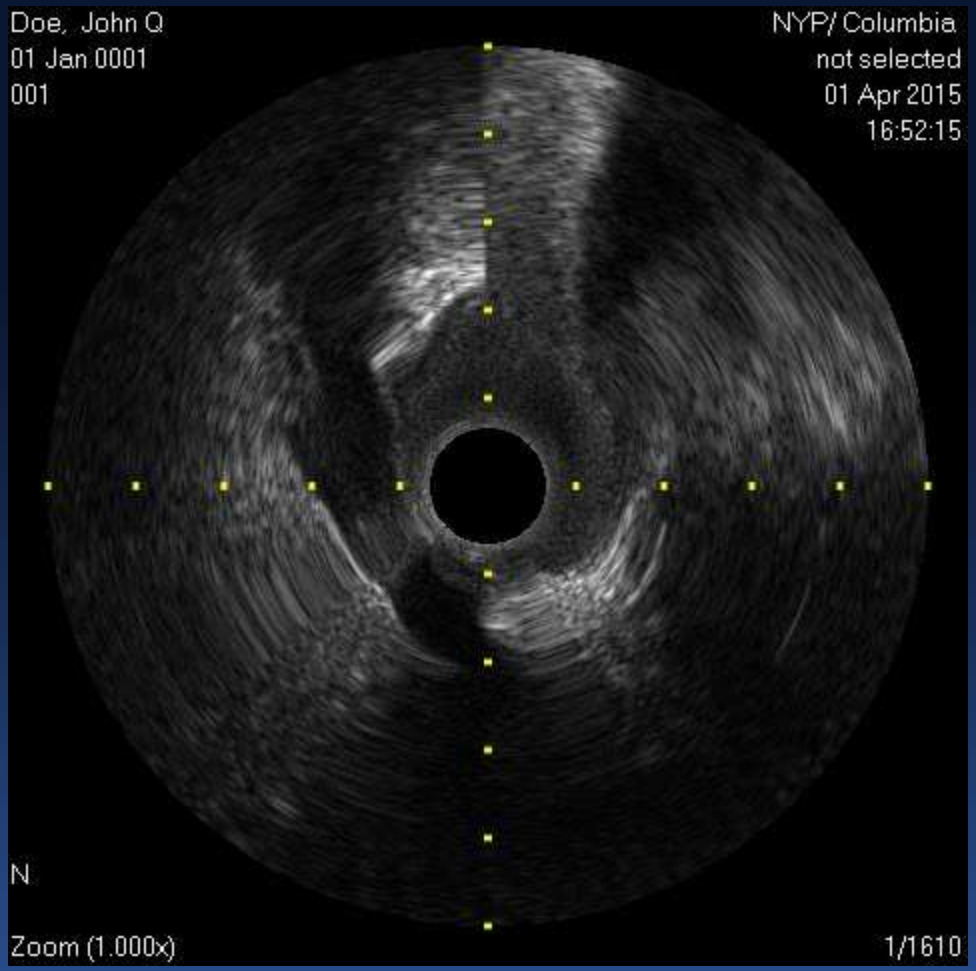
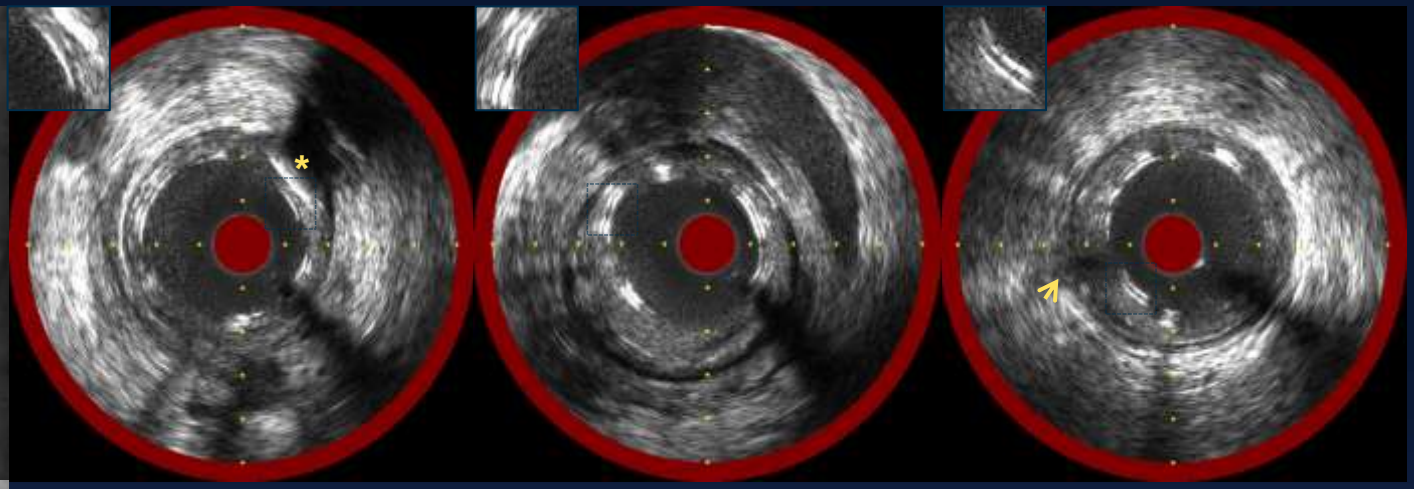
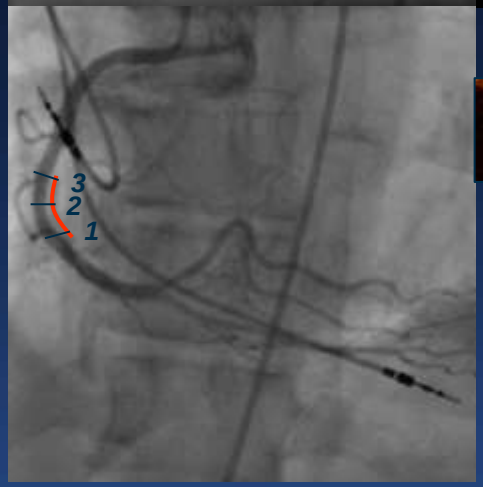
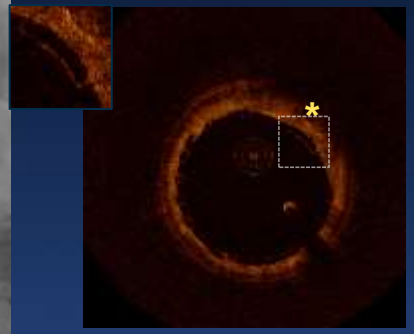
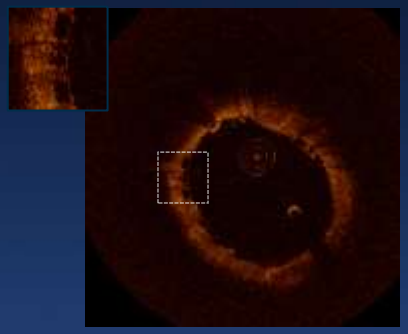
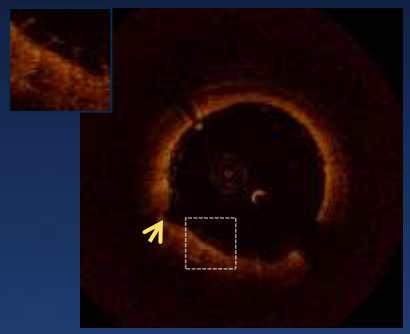








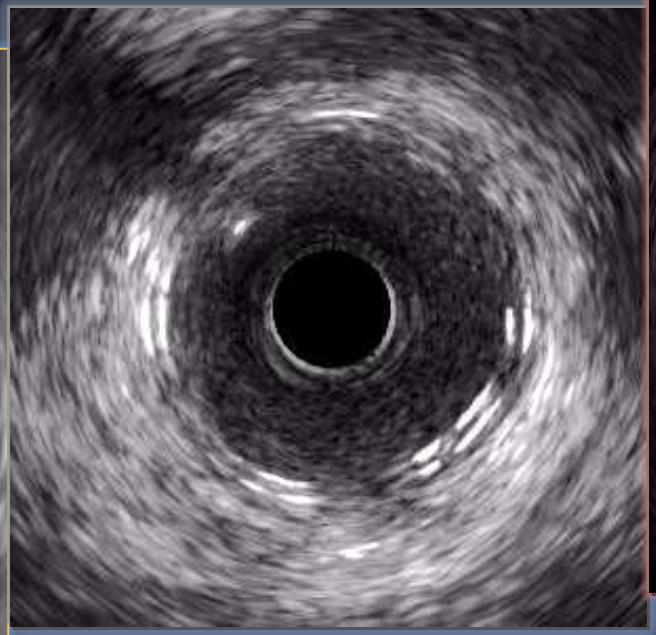




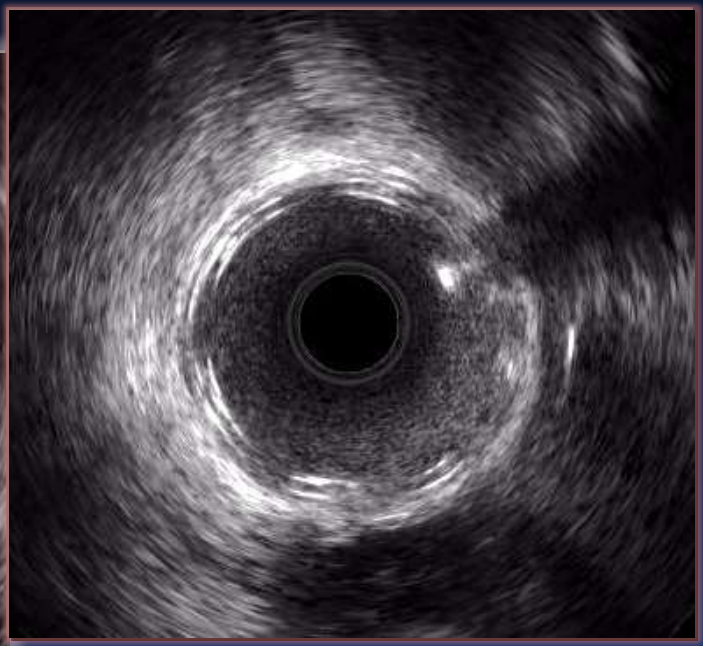
BostonScientific: HD-IVUS and Bioresorbable Vascular Scaffolds

Pro/iCross 40 MHz
43 micron axial*

OptiCross 40 MHz
38 micron axial*



Next Gen IVUS 55 MHz
22 micron axial*



***Theoretical estimates based on design**:

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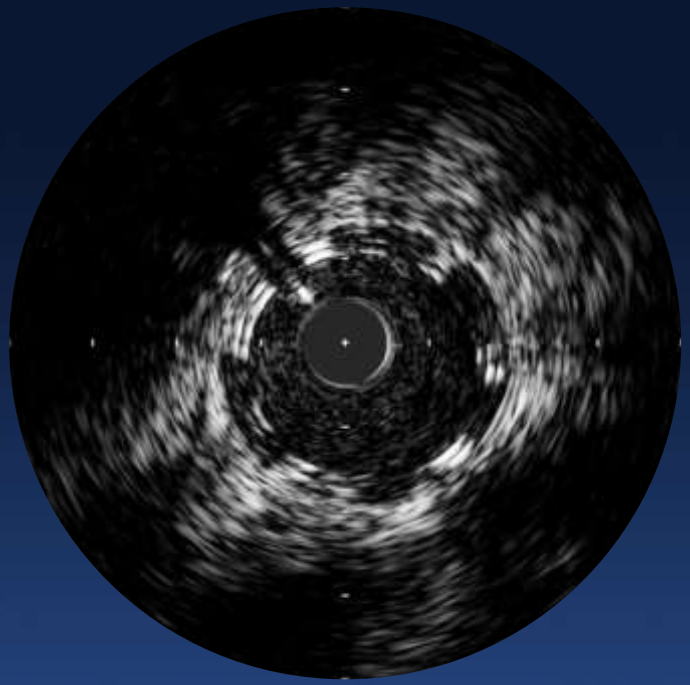
Volcano: FACT (Focused Acoustic Computed Tomography) and Bioresorbable Vascular Scaffolds



FACT ultrasound transducer intented to generate a "cleaner" signal than traditional PZT, near field resolution close to OCT, visibility of the entire plaque and vessel wall, and without the need for a blood clearing flush

What is new and different?

- **Just about everything except the use of ultrasound**
  - **Better resolution and tissue characterization without sacrificing penetration**
  - **Improved system design and user-interface**
  - **More rapid image acquisition**
  - **More accurate longitudinal (L-Mode) reconstruction**
- **Caveats**
  - **Necessary to separate imaging and science versus marketing**
  - **Trust your eyes.**
  - **Don’t trust in vitro images or images obtained in animal models**
  - **Ask for measured and not theoretical resolution(s)**
  - **Still works in progress**