ACIST Rxi: A Monorail pressure microcatheter

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Issues regarding the work flow of FFR

1. Set up/zero/drift
2. IV hyperemia
3. Pressure wire handling
4. Multiple pressure wire manipulations

Opportunities for Improvement

1. Increase stability
2. Improvement wire handling
3. Facilitate rapid pressure sensor placement

Available FFR Technologies

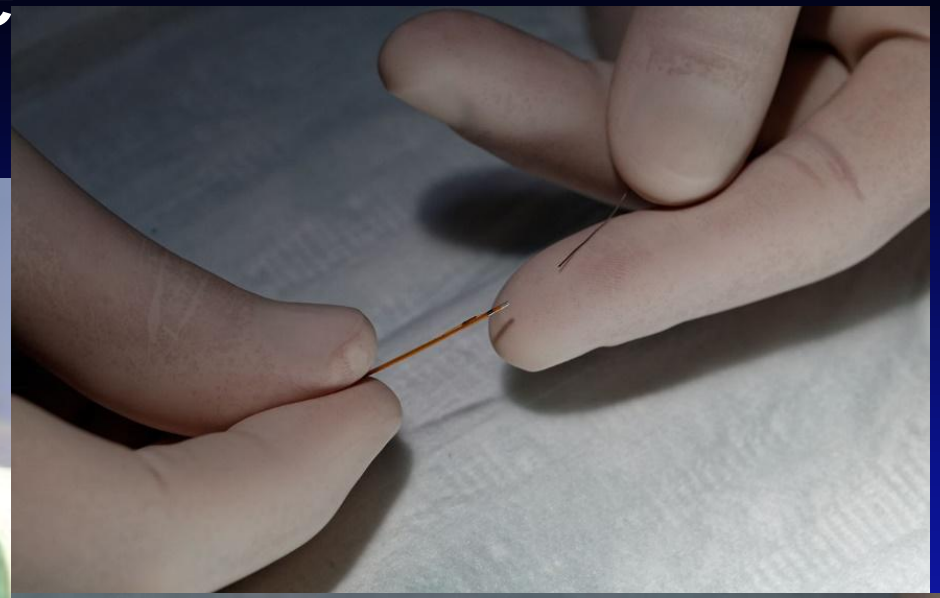
Pressure Wire Technology

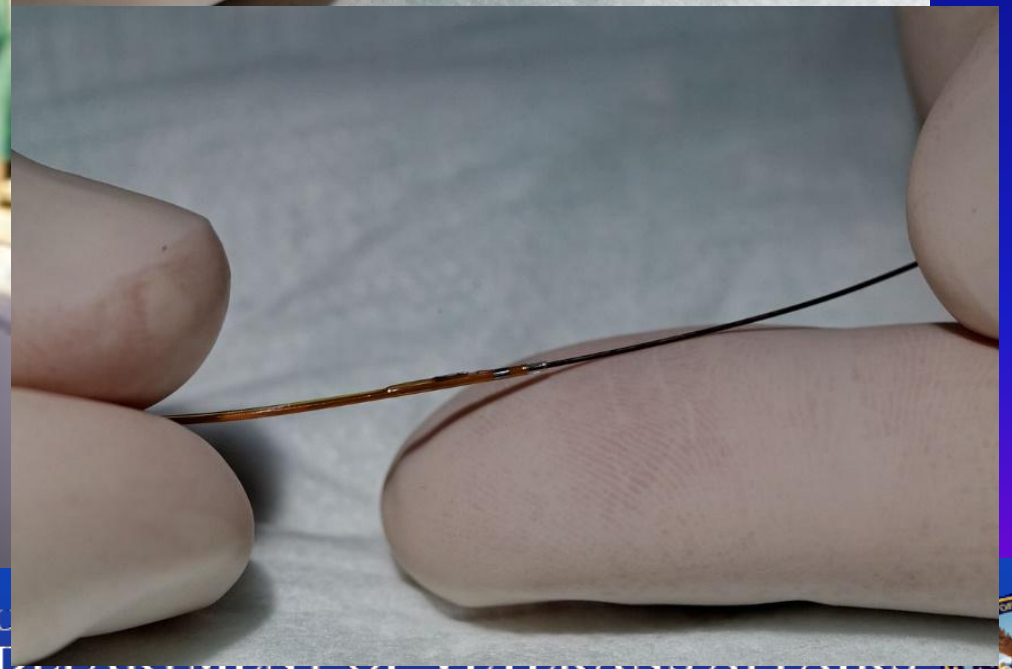
- Specially constructed 0.014” wire
- Sensor incorporated into distal end at junction of radiopaque and radiolucent segments
- Piezo-electric technology
- Performance not as robust as dedicated coronary wire

Micro-Catheter Technology

- Does not require a specialized guidewire but can be delivered over standard coronary wire (Rapid Exchange)
- Low-profile catheter with pressure sensor incorporated into distal end
- Fiber-optic technology

Microcatheter Rxi Pressure System





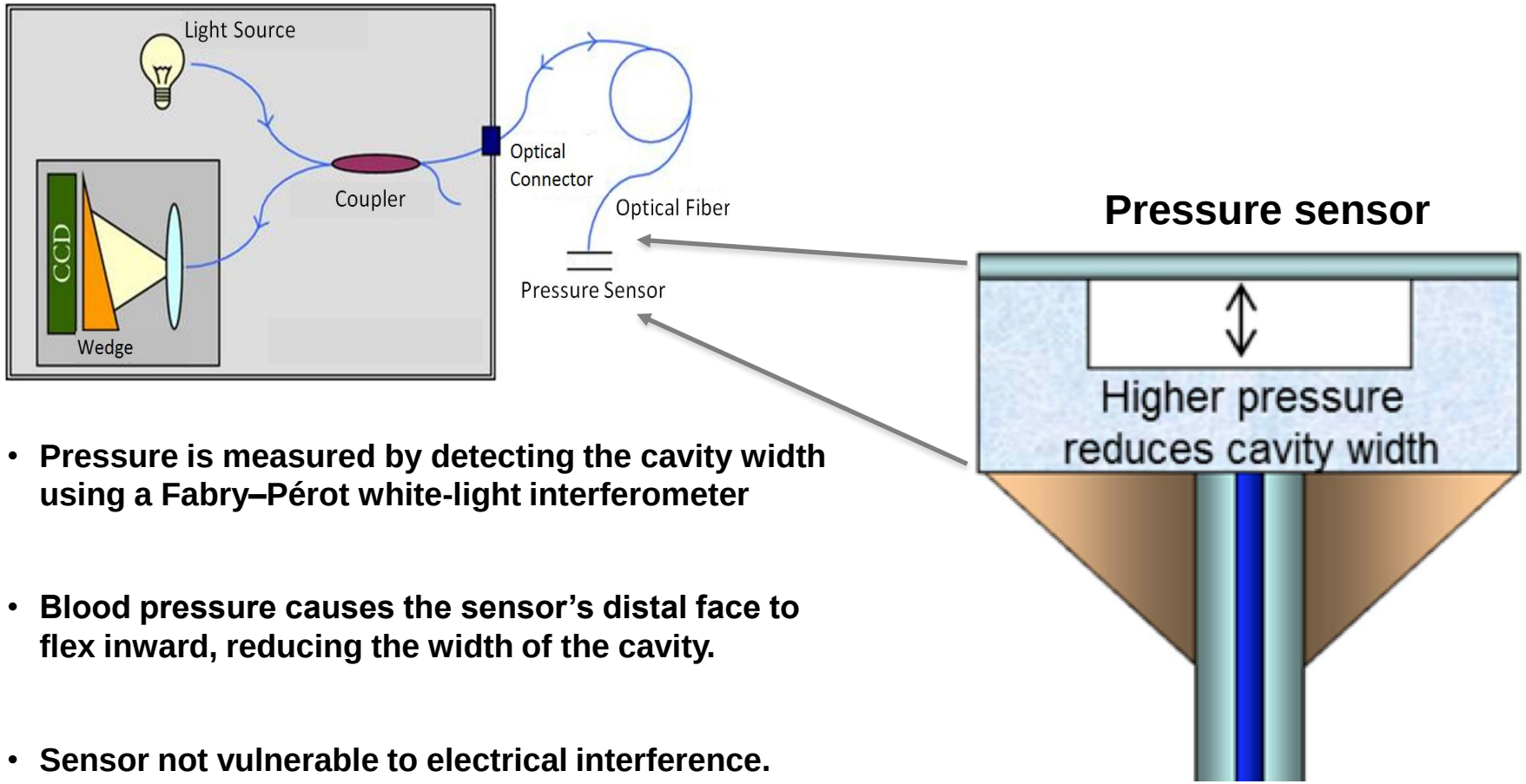
the Navvus MicroCatheter

- The RXi system combines fiber-optic technology with the ultra-thin ACIST Navvus™ Rapid Exchange FFR MicroCatheter delivered over any standard 0.014” guidewire. Minimizes wire exchanges

Micro-Catheter FFR Technology

Fiber Optic Pressure Sensor Technology

F-P Inferometer

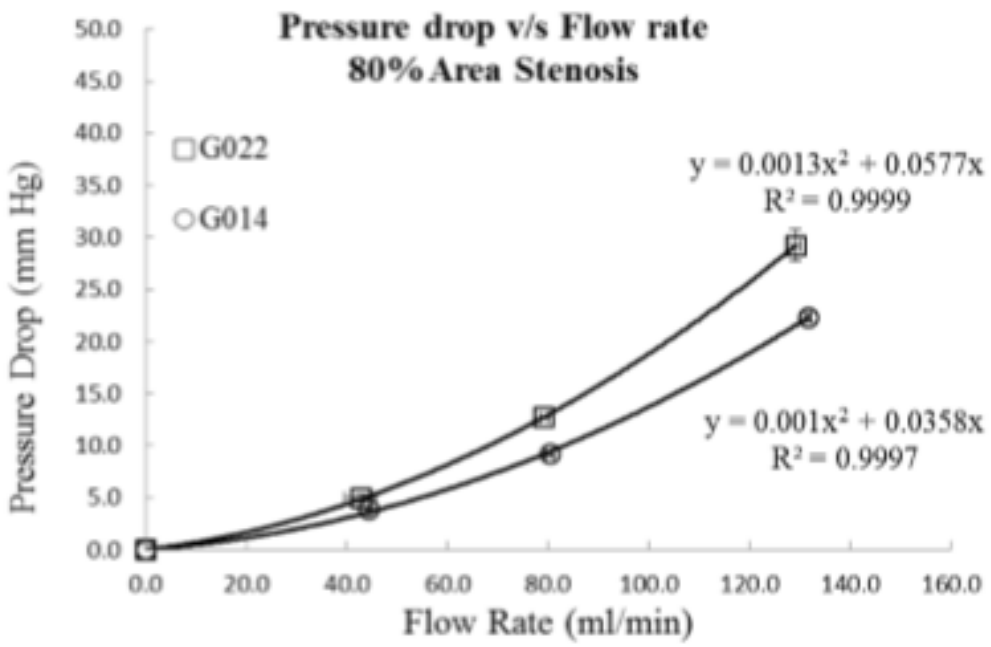


- **Pressure is measured by detecting the cavity width using a Fabry–Pérot white-light interferometer**
- **Blood pressure causes the sensor's distal face to flex inward, reducing the width of the cavity.**
- **Sensor not vulnerable to electrical interference.**

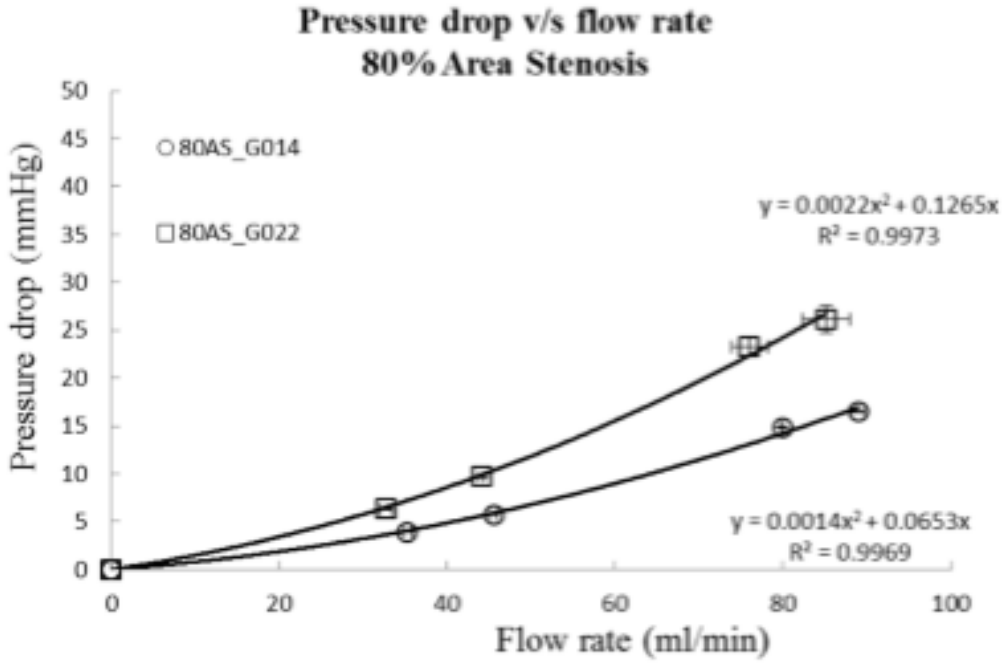
Pinet E, Journal of Sensors 2009

Bench Data: 80% AS

3 mm Vessel



2.5 mm Vessel



ACCESS-NZ Study

Micro-Catheter FFR vs. Pressure Wire Measurements

Clinical indication for coronary angiography
Native target vessel diameter > 2.5 mm with TIMI 3 flow
Investigator-determined indication for FFR

Micro-Catheter FFR System
ACIST Navvus RXI™ Rapid Exchange

+

Pressure Wire FFR System
St. Jude Medical Certus

Determine Agreement between FFR obtained with each system during maximum hyperemia

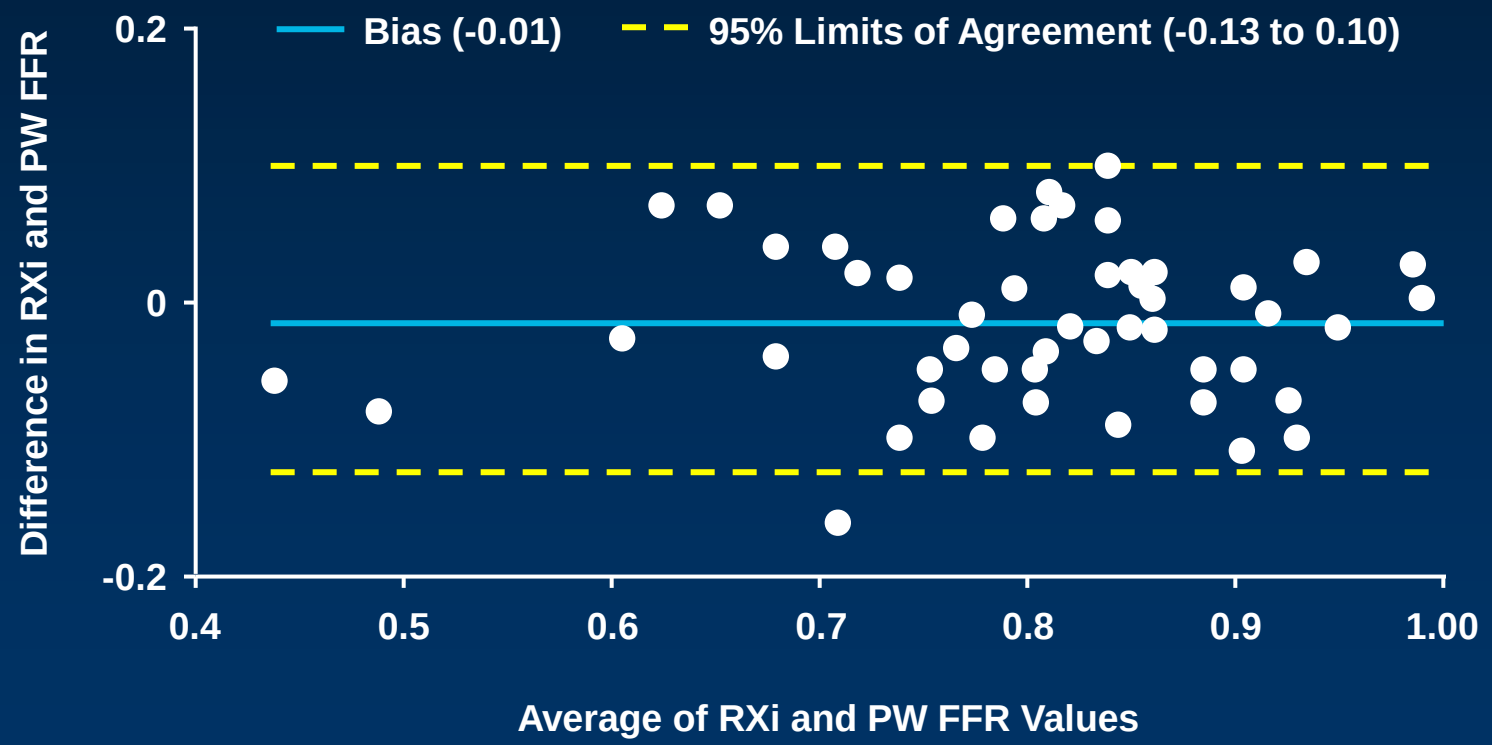
Patient Characteristics	
N	50
Age	42 – 86 (average 65.6 years)
Male	80%
NYHA Class I or II	54%

ACCESS-NZ Study

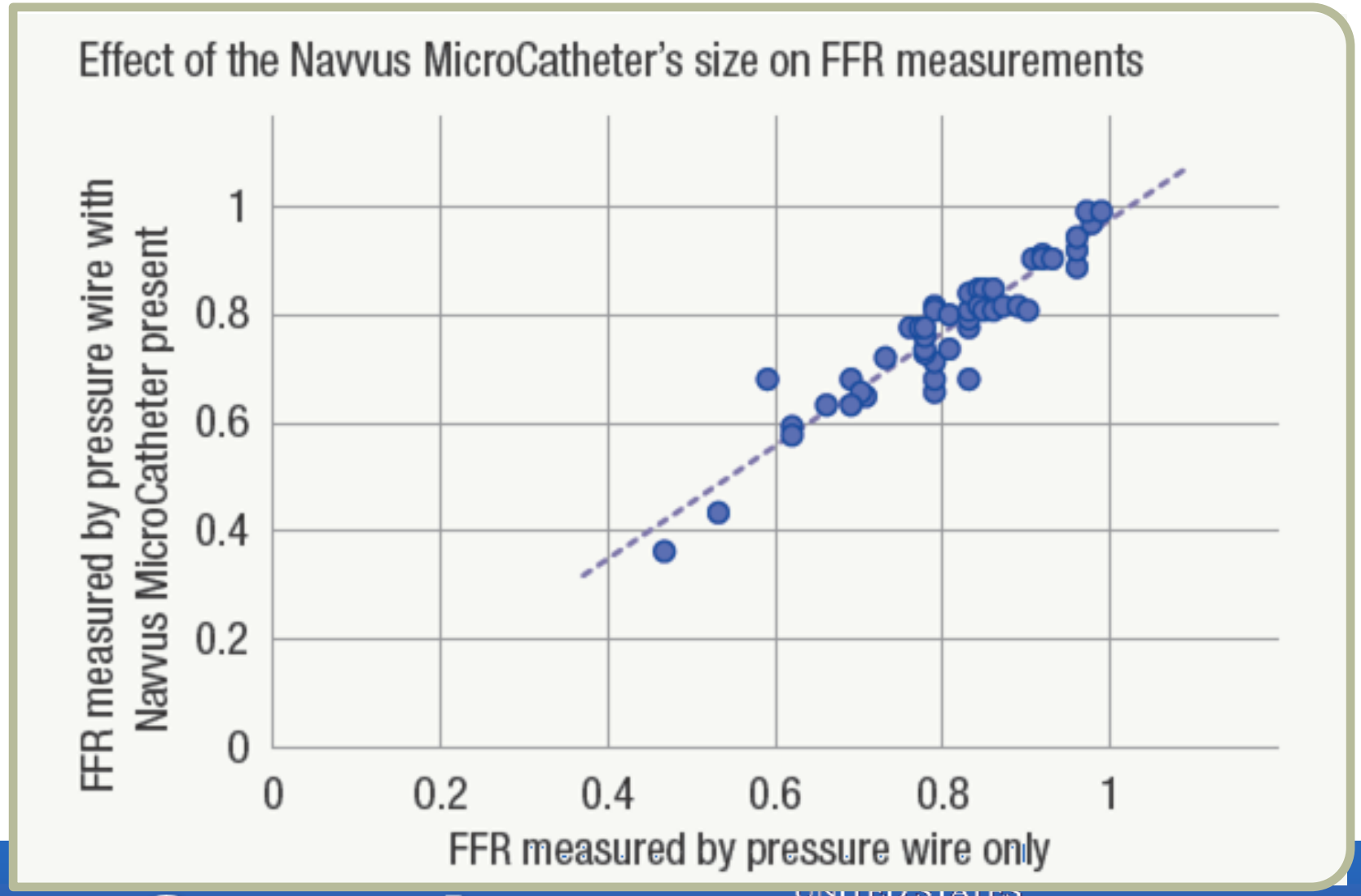
Micro-Catheter vs. Pressure Wire FFR Measurements

RXi Compared to PW Alone

Bland-Altman Plot of RXi and PW FFR's



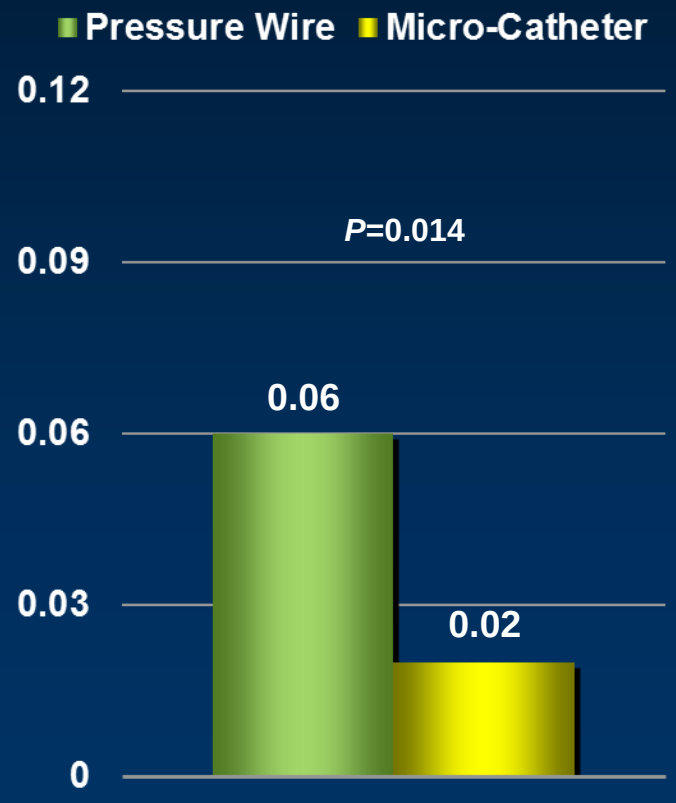
Agreement Between Systems – Navis+guide wire vs guidewire alone



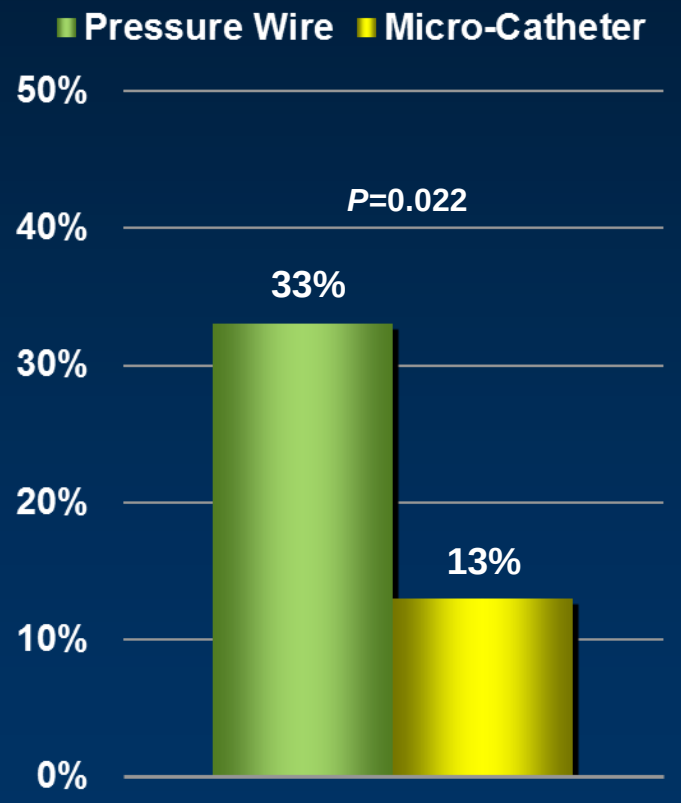
ACCESS-NZ Study

Pressure Drift: Pressure Wire vs. Micro-Catheter

Mean Drift



Clinically Significant Drift*

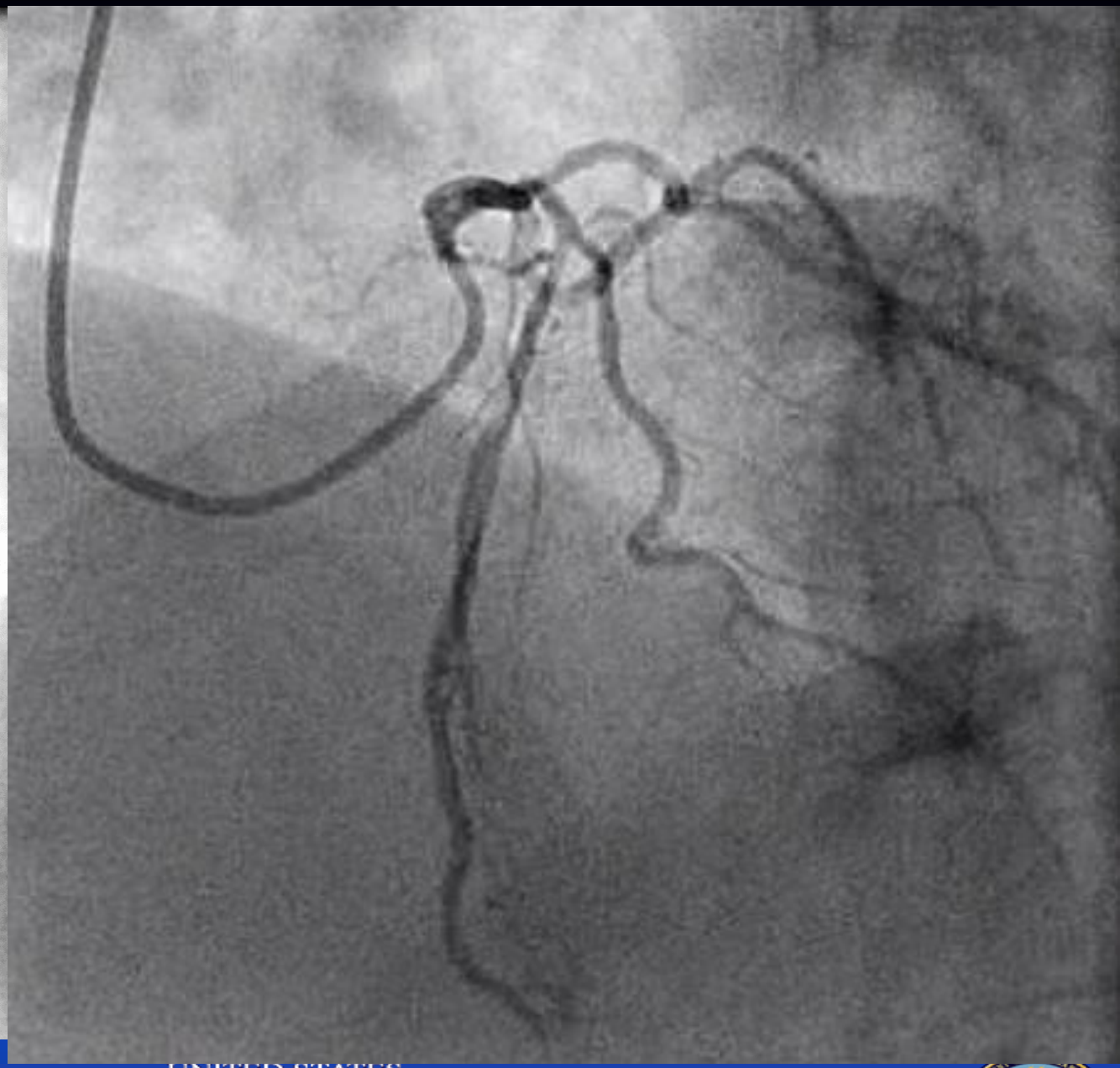


Case Example

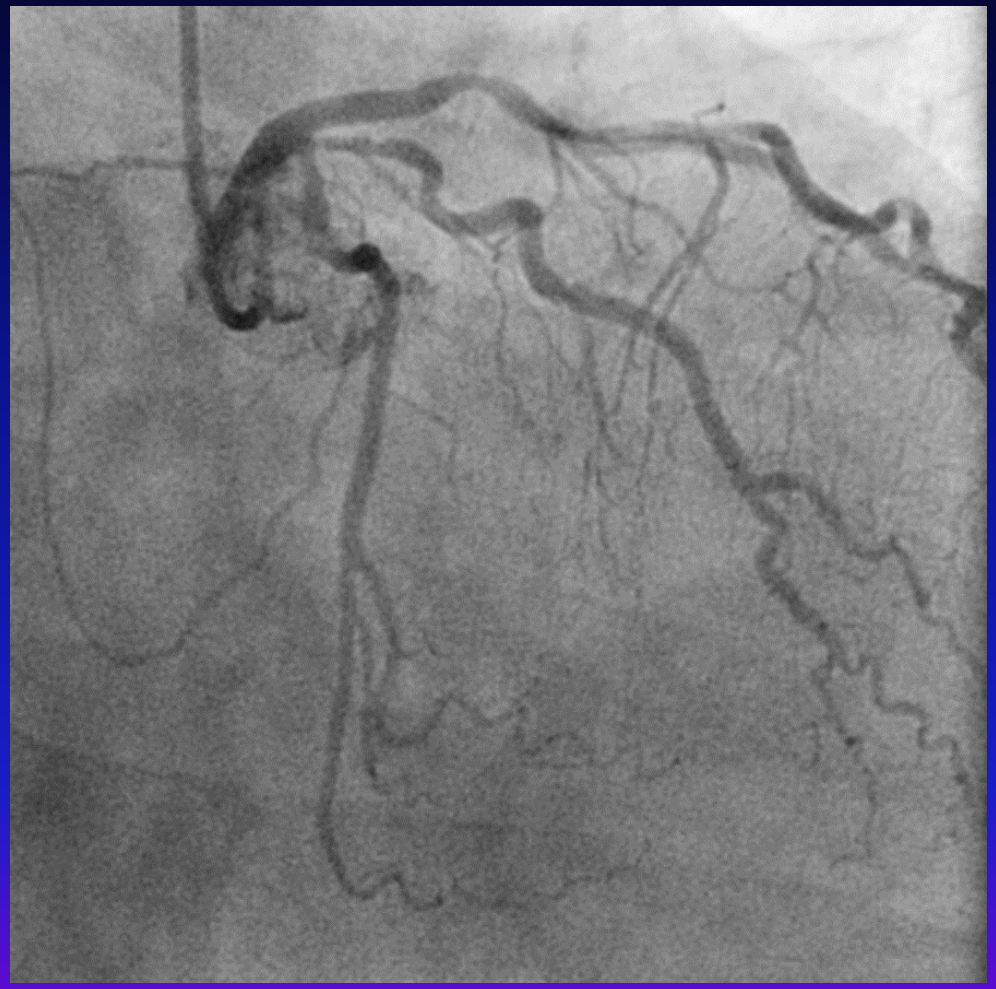
68-year-old man with chest pain to his left shoulder and arm walking on his treadmill. HBP, CHOL, GERD

ETT in hospital positive with ST changes and CP.

Symptoms have been ongoing for 2 months. Denies diaphoresis, nausea, or other associated symptoms.

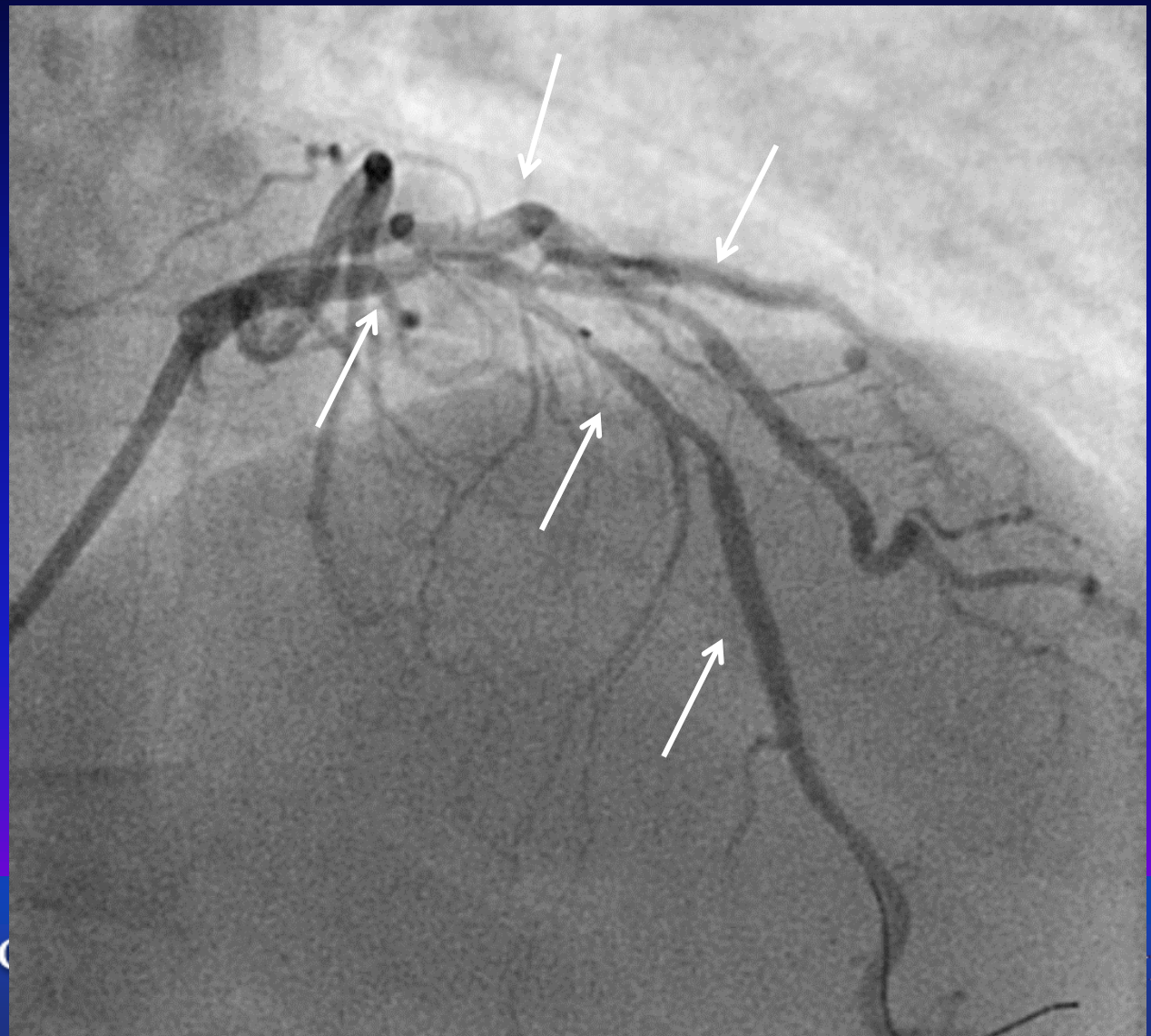


LCA, RAO cr

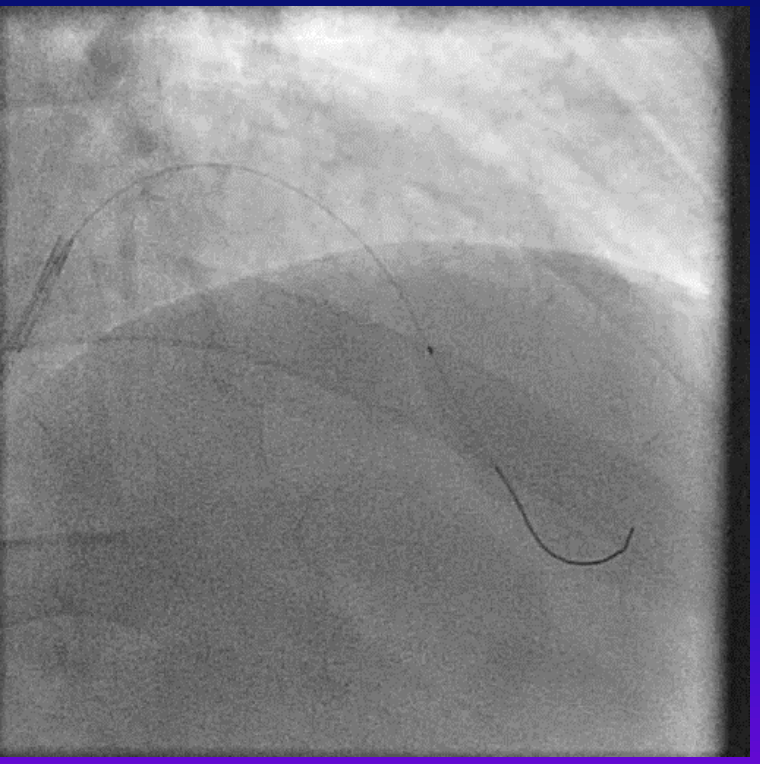


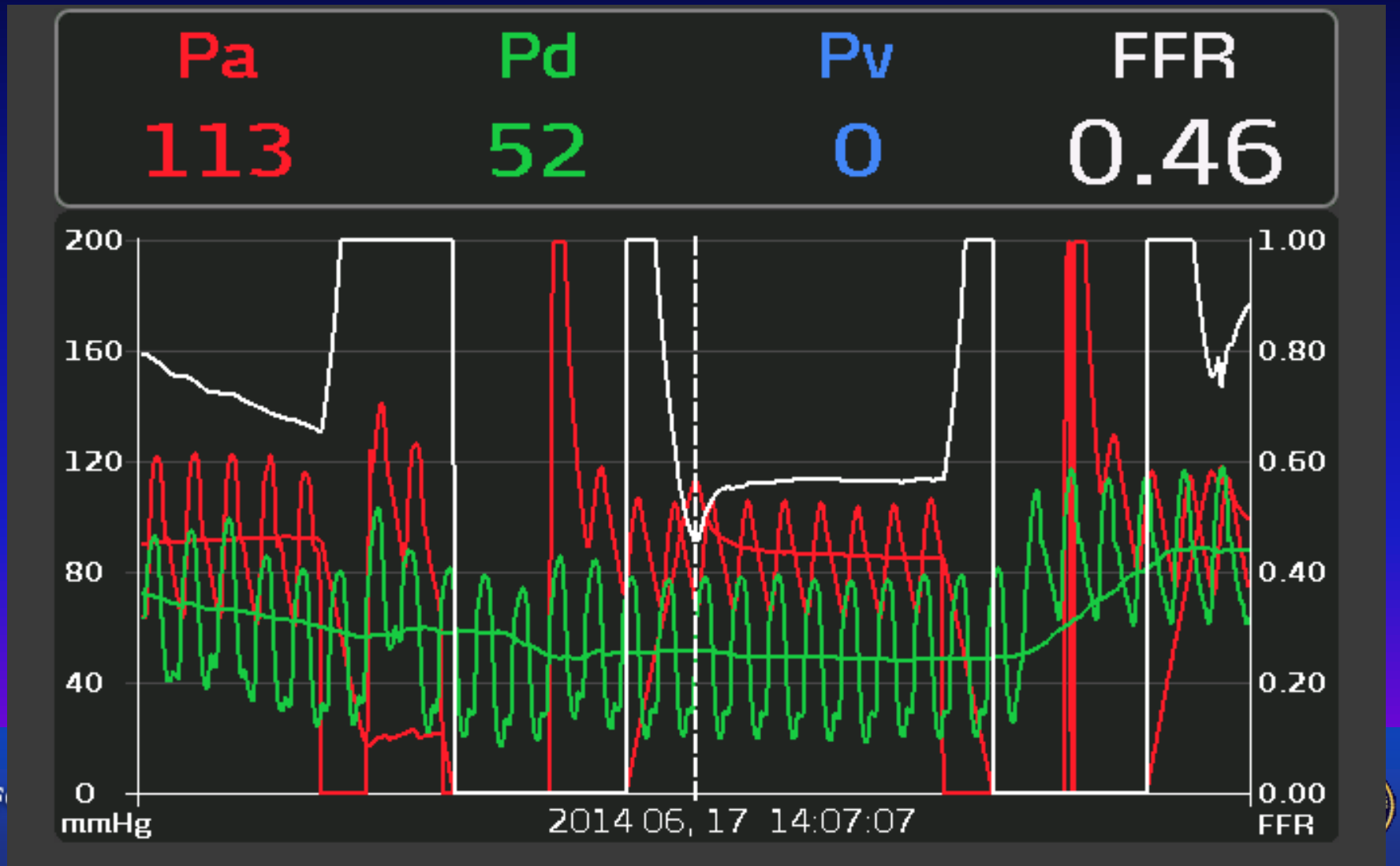
LAO, caud

FFR Assesment of Long LAD w pullback and of D1 ostial lesion

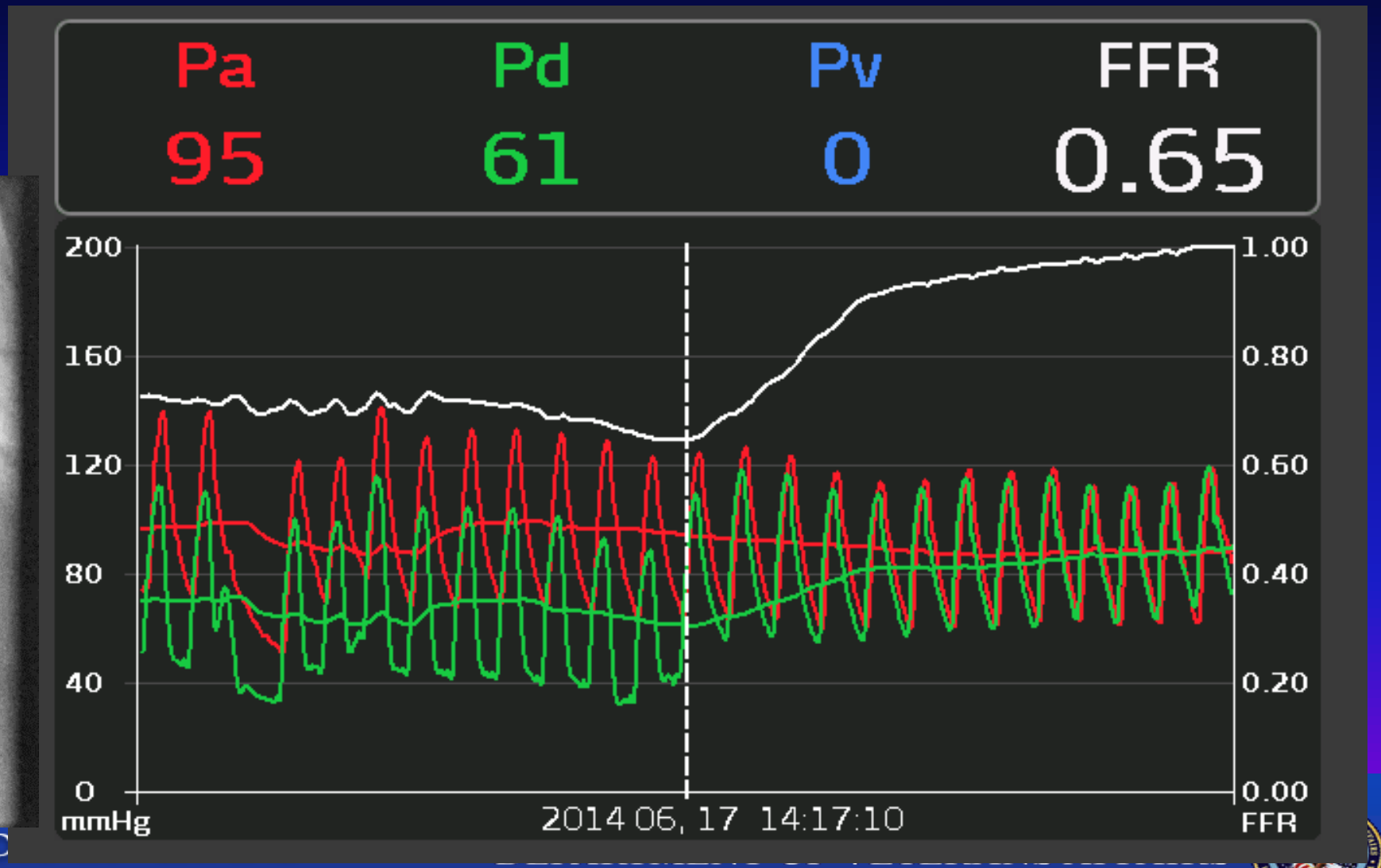


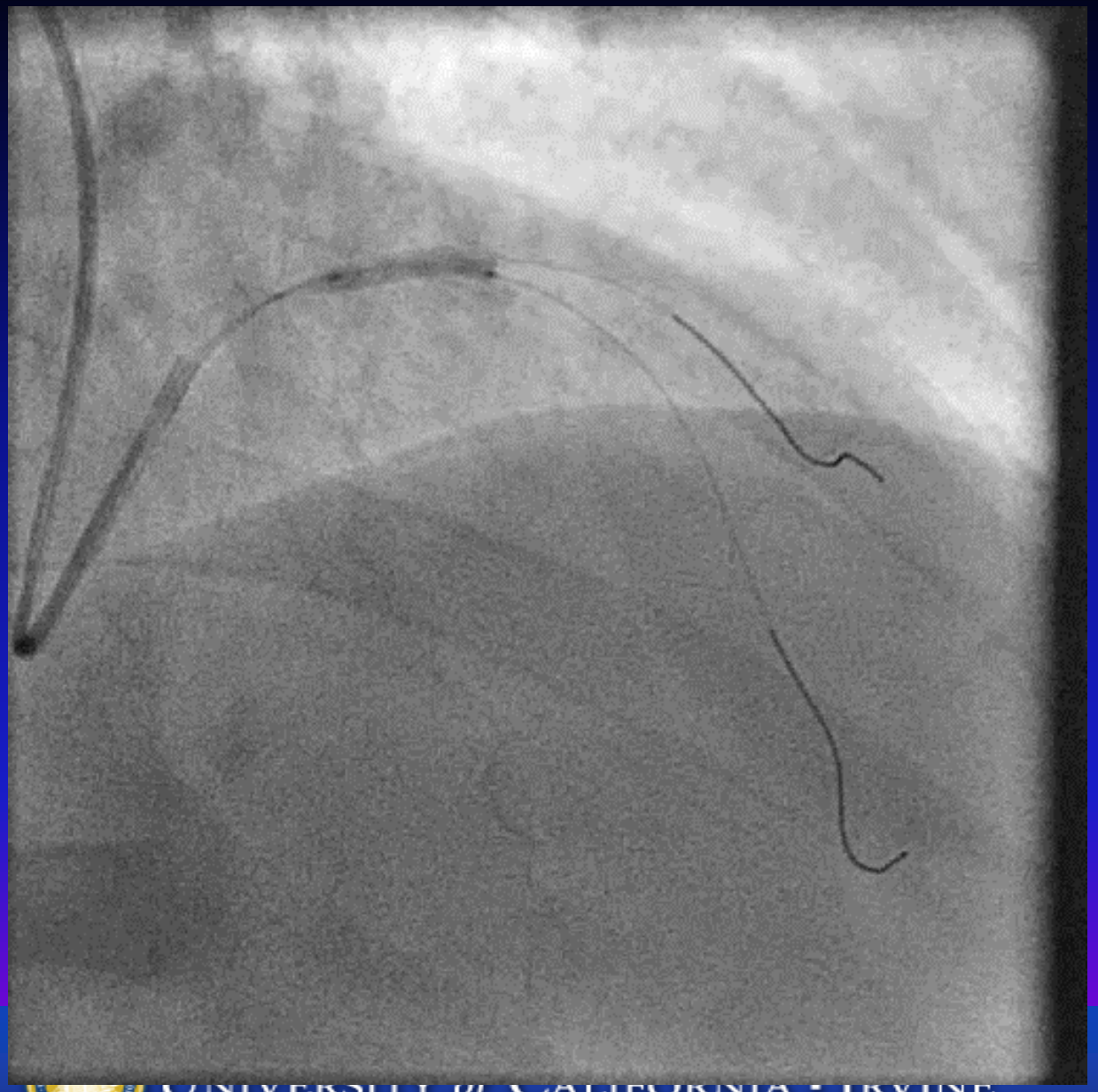
FFR of LAD w microcatheter

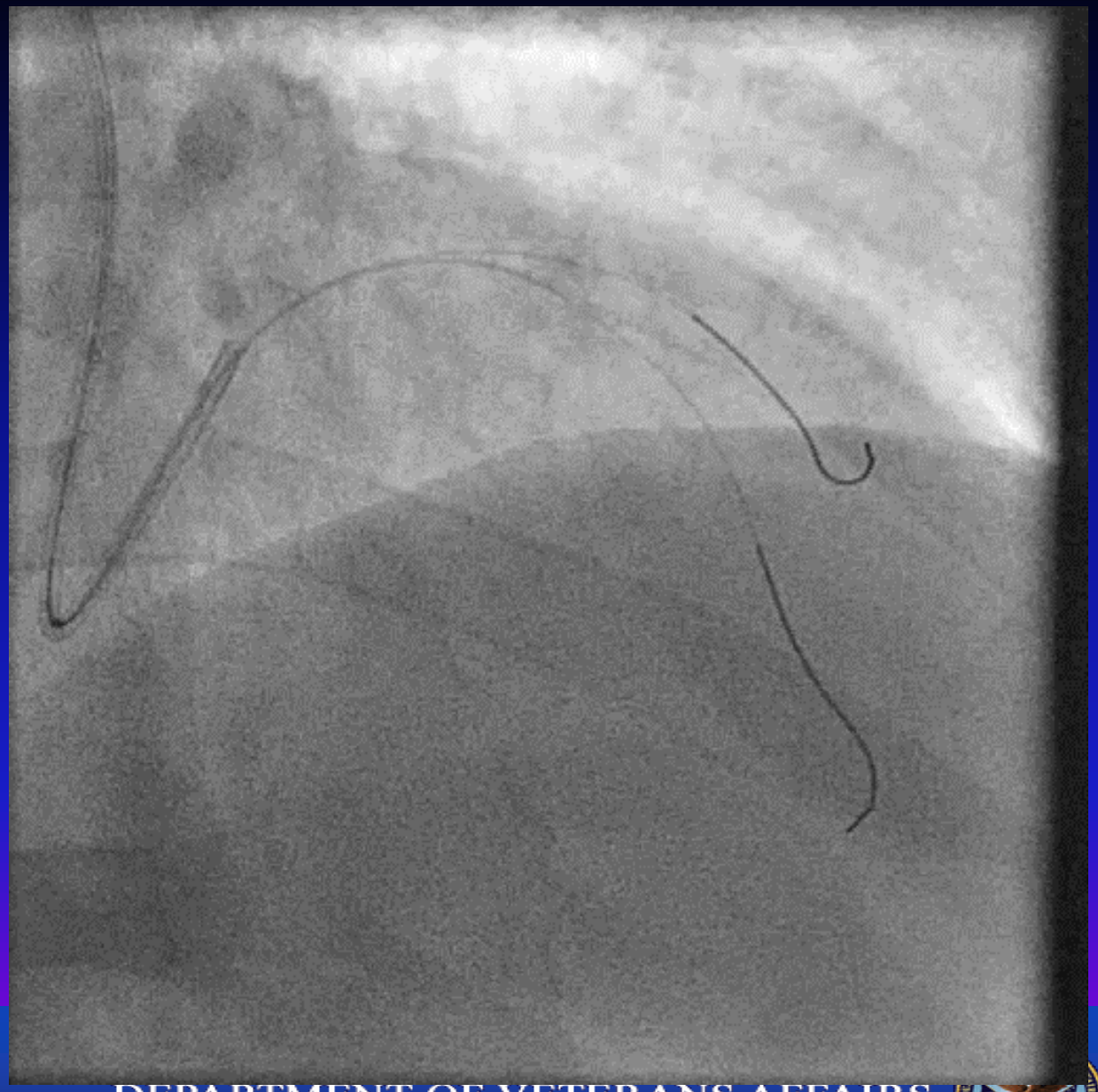




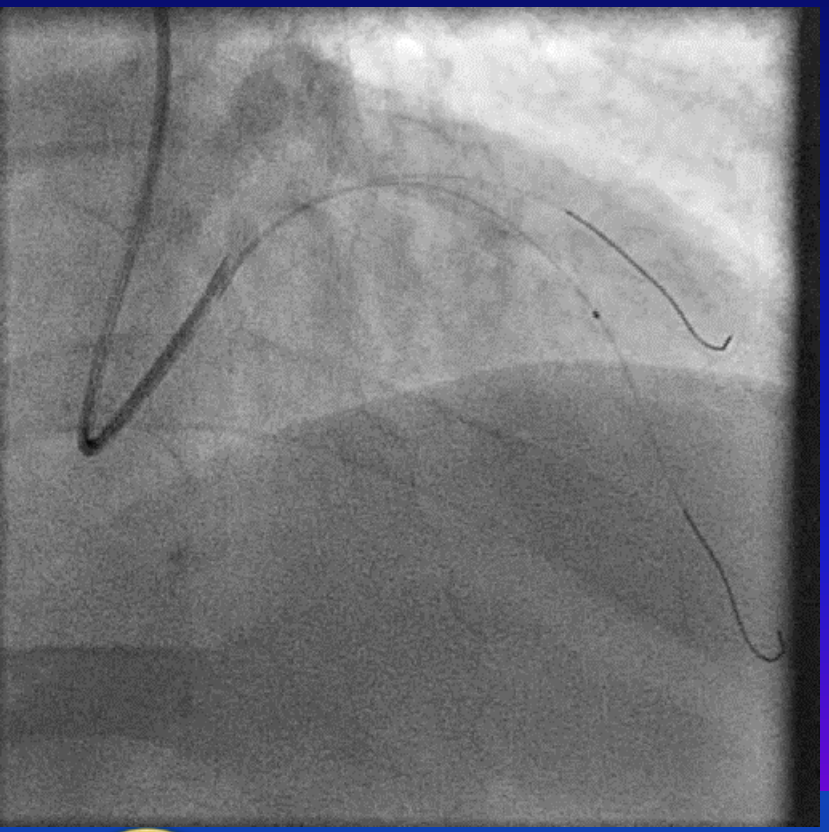
FFR of Diagonal branch

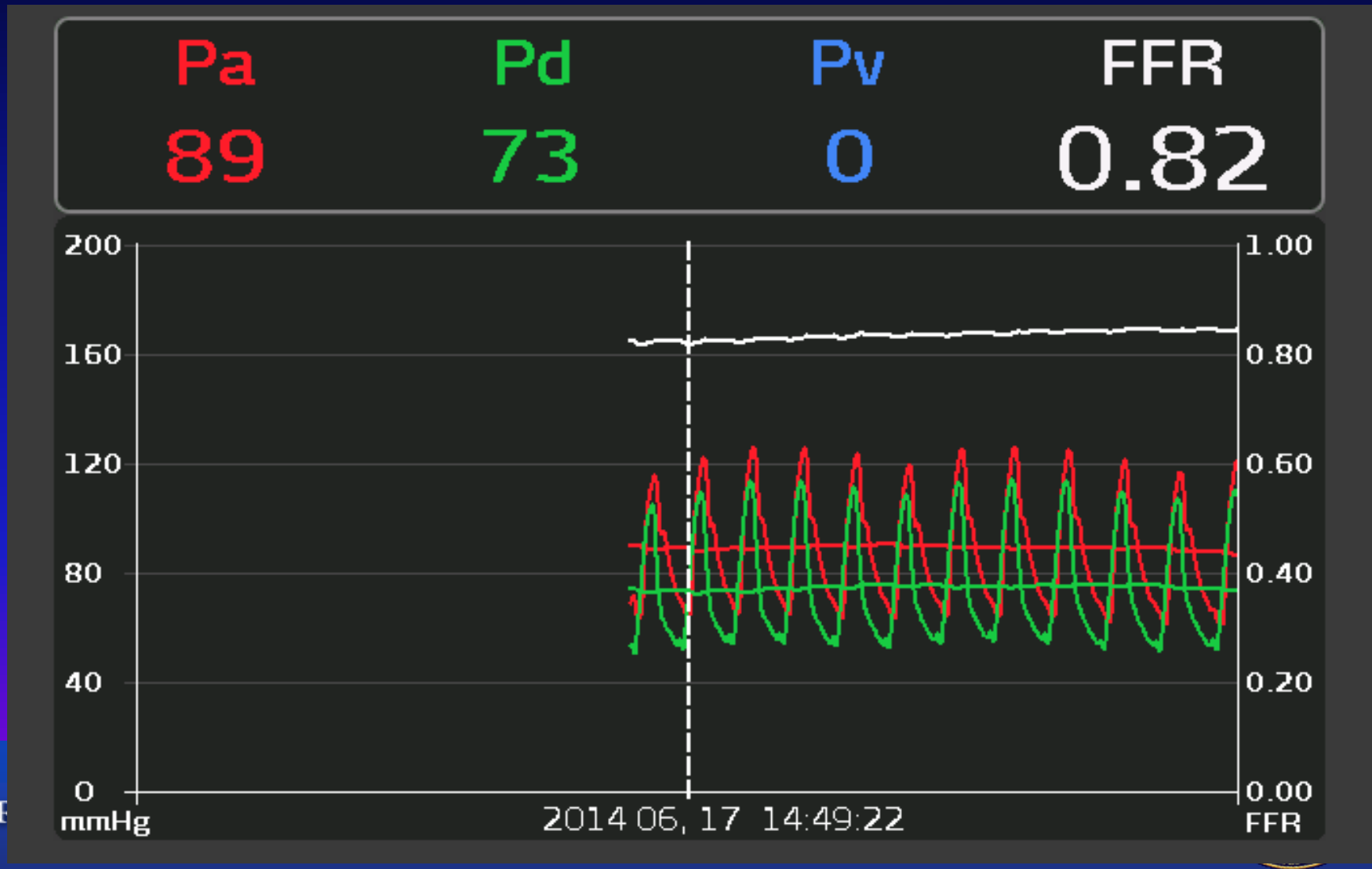




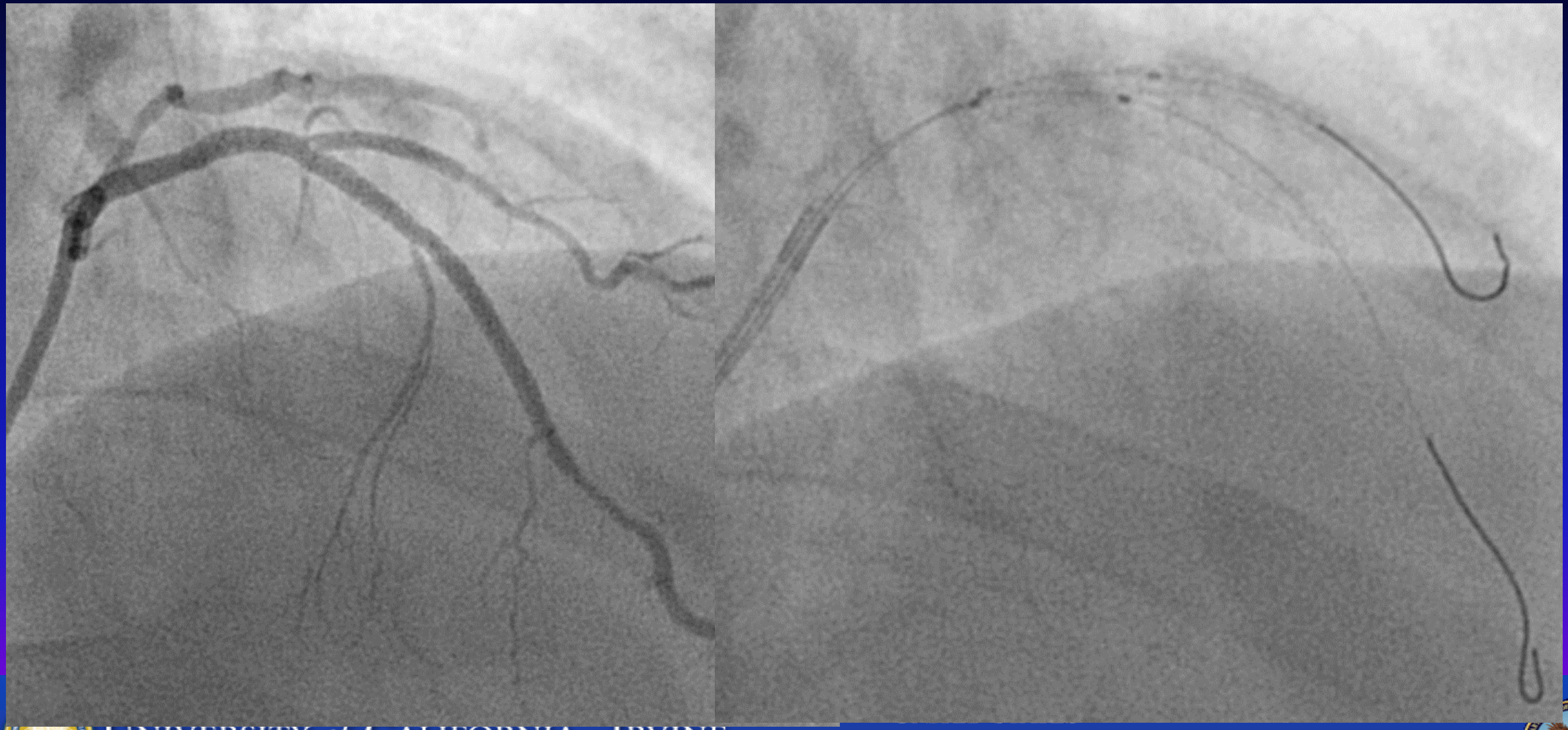


Resting Ratio after POBA of LAD

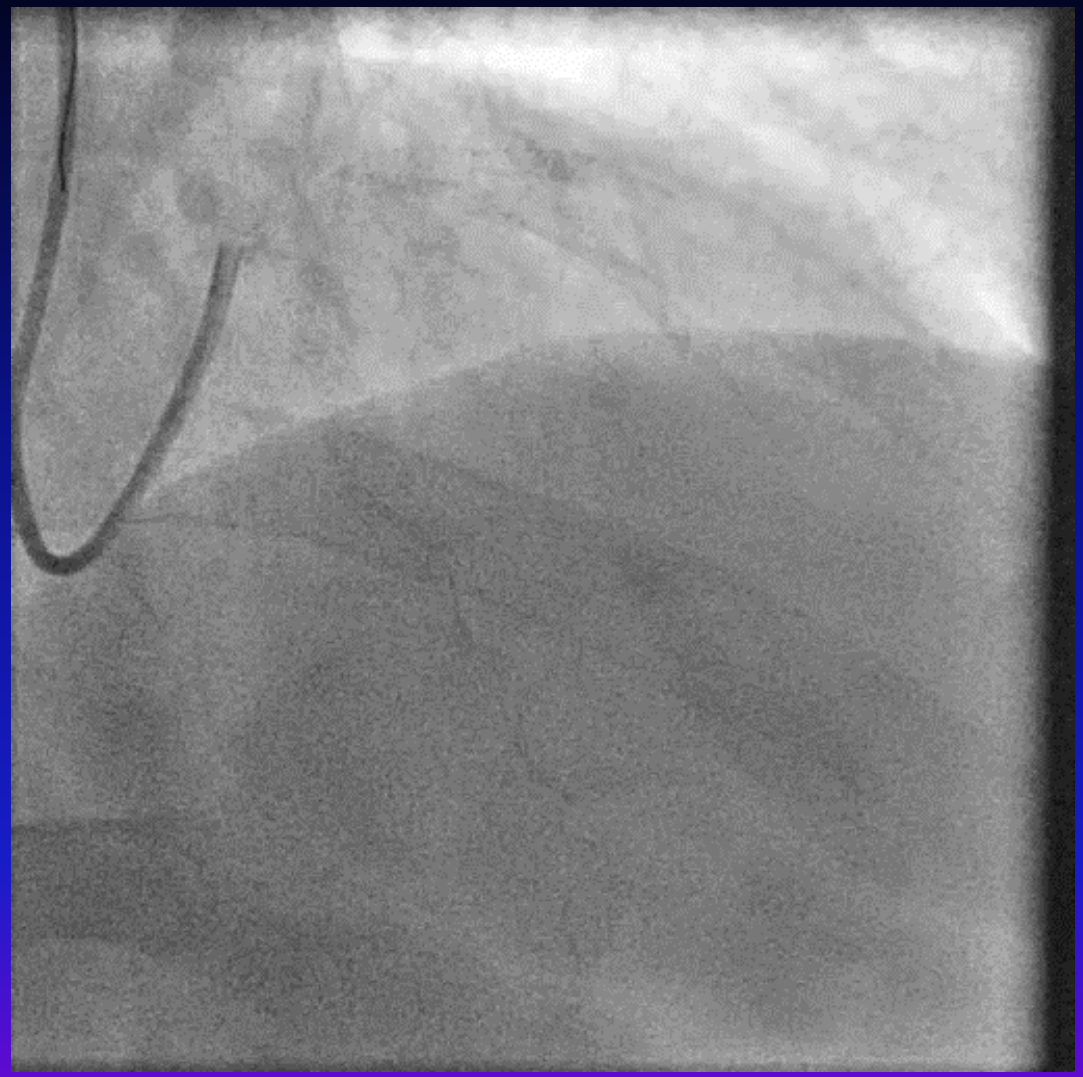


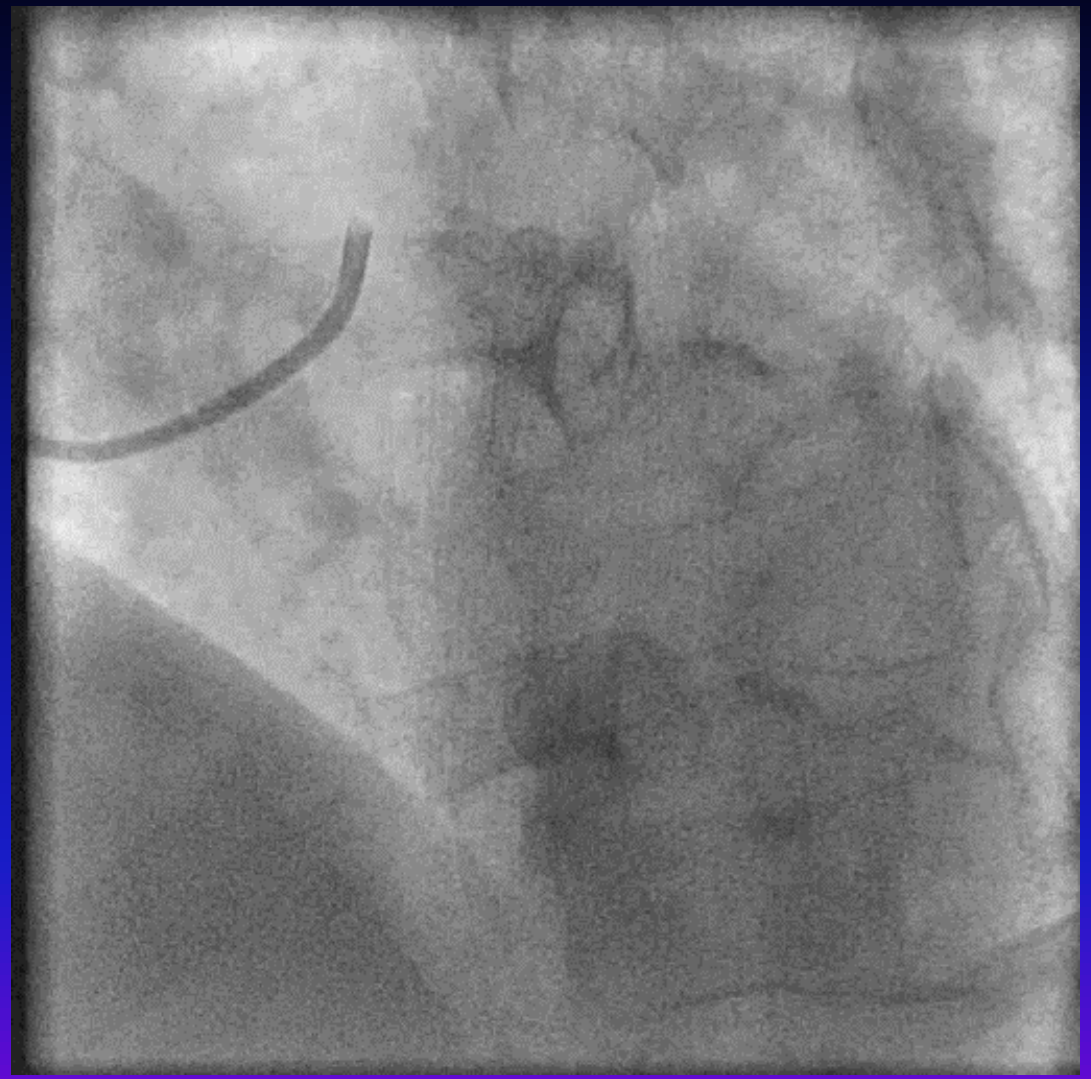


Despite multliple Sequential Balloon inflations, kissing balloon inflation needed



Final. The enemy of good is better





FFR in complex lesions

- Microcatheter Rxi facilitates multiple pressure/FFR measurements over your chosen best guidewire(s)
- Eliminates need to recross lesions with guidewire
- Promotes rapid pressure without loosing wire position
- Facilitates rapid FFR at any time during procedure