
Bracco Group

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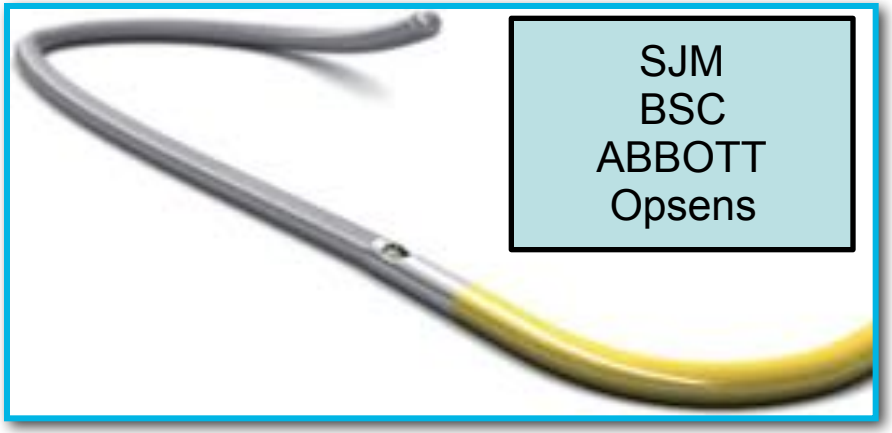
# Available FFR Technologies

## 4 Duplicate Pressure Wire Technologies




- Specially constructed 0.014” wire
- Sensor incorporated into distal end at junction of radiopaque and radiolucent segments
- Piezo-electric (SJM and Volcano) fiber-optic (BSC and Opsens)
- Performance challenges vs. dedicated coronary wire

## ACIST Micro-Catheter Technology


- Does not require a specialized guidewire and can be delivered over standard coronary 0.014” wire (Rapid Exchange)
- Low-profile catheter with pressure sensor incorporated into distal end
- Fiber-optic technology

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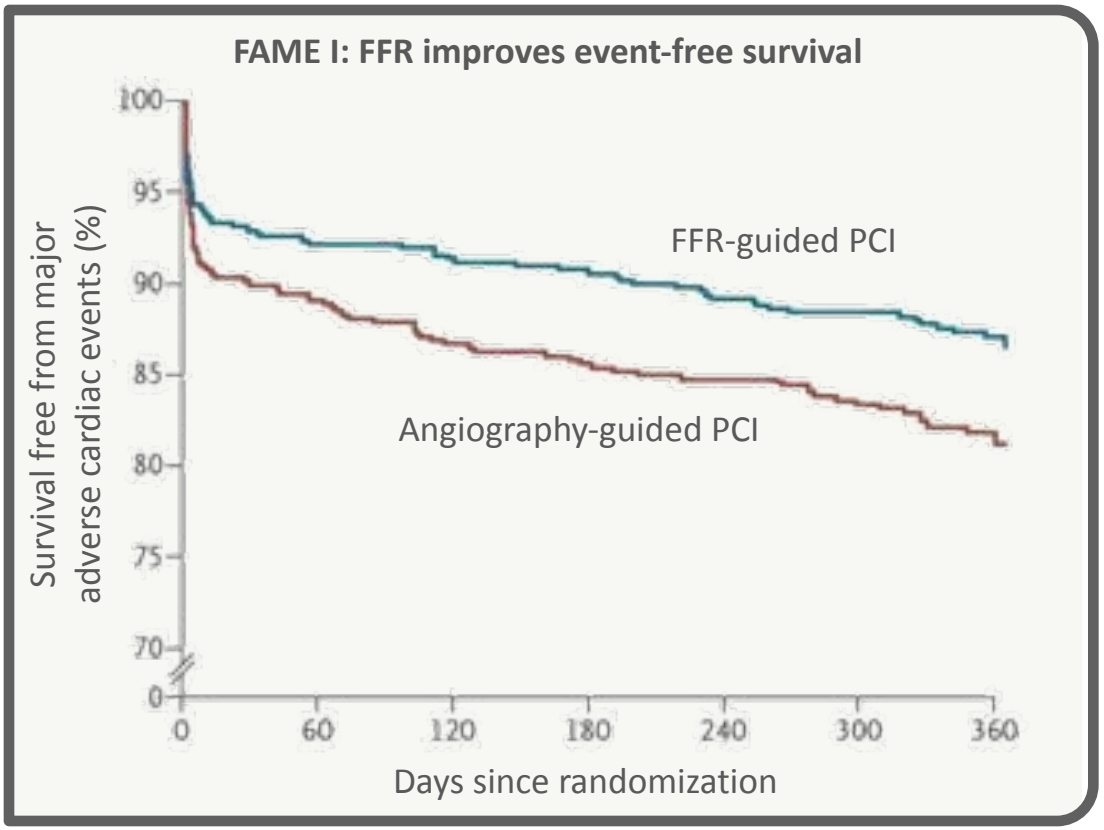
# Why FFR?

## FFR Impacts Outcomes

- The use of FFR has increased rapidly in recent years. The FAME I and II studies showed that FFR significantly improves outcomes[1,2]

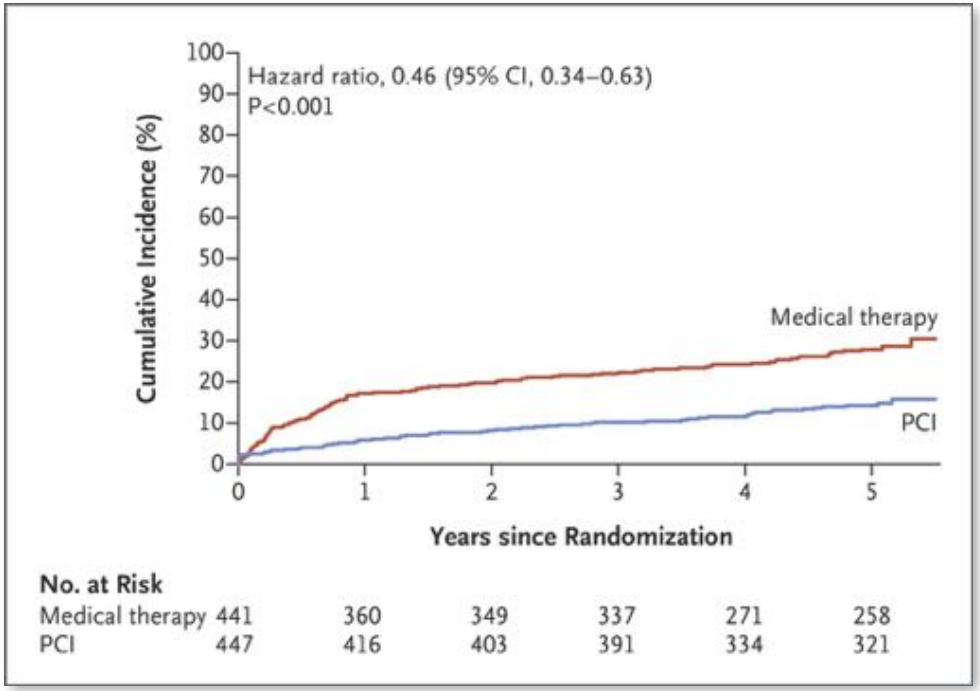
- In addition, FFR is included in the 2012 Appropriate Use Criteria (AUC) for diagnostic angiography and catheterization[3]

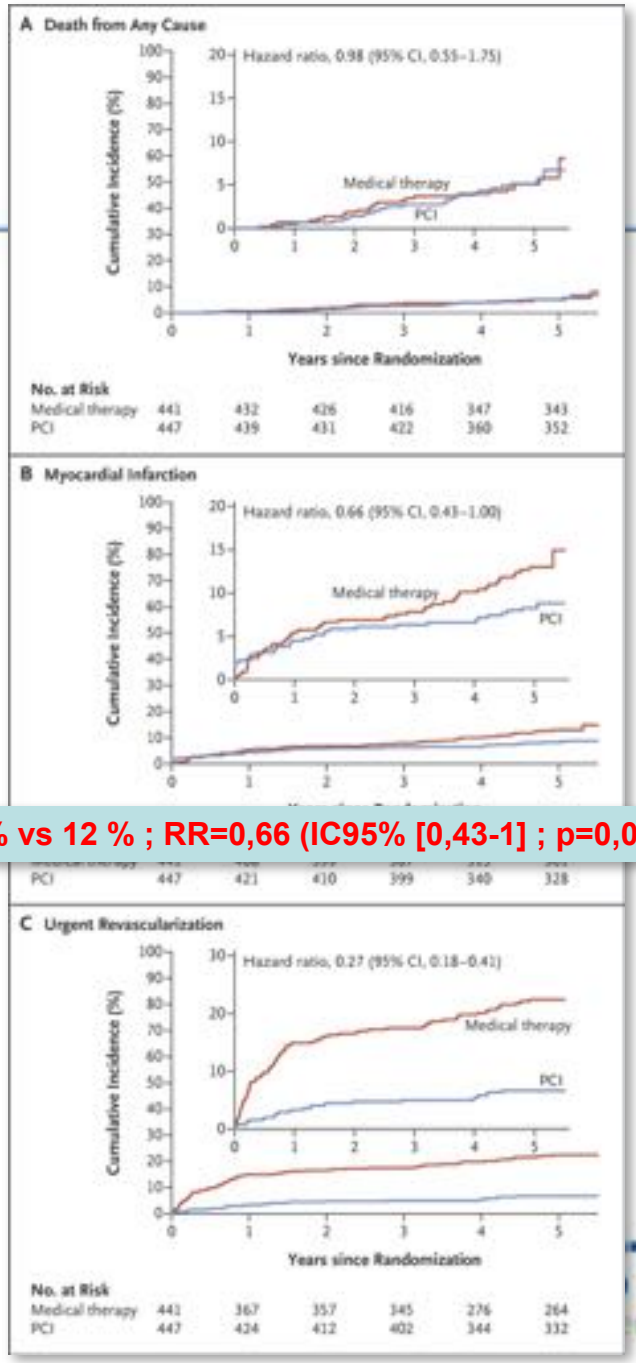




1. Tonino PA et al. *NEJM* 2009;360:213–24.
2. De Bruyne B et al. *NEJM* 2012;367:991–1001.
3. Patel MR. *Card Interv Today* 2013:64–74.

# FAME 2 à 5 ans

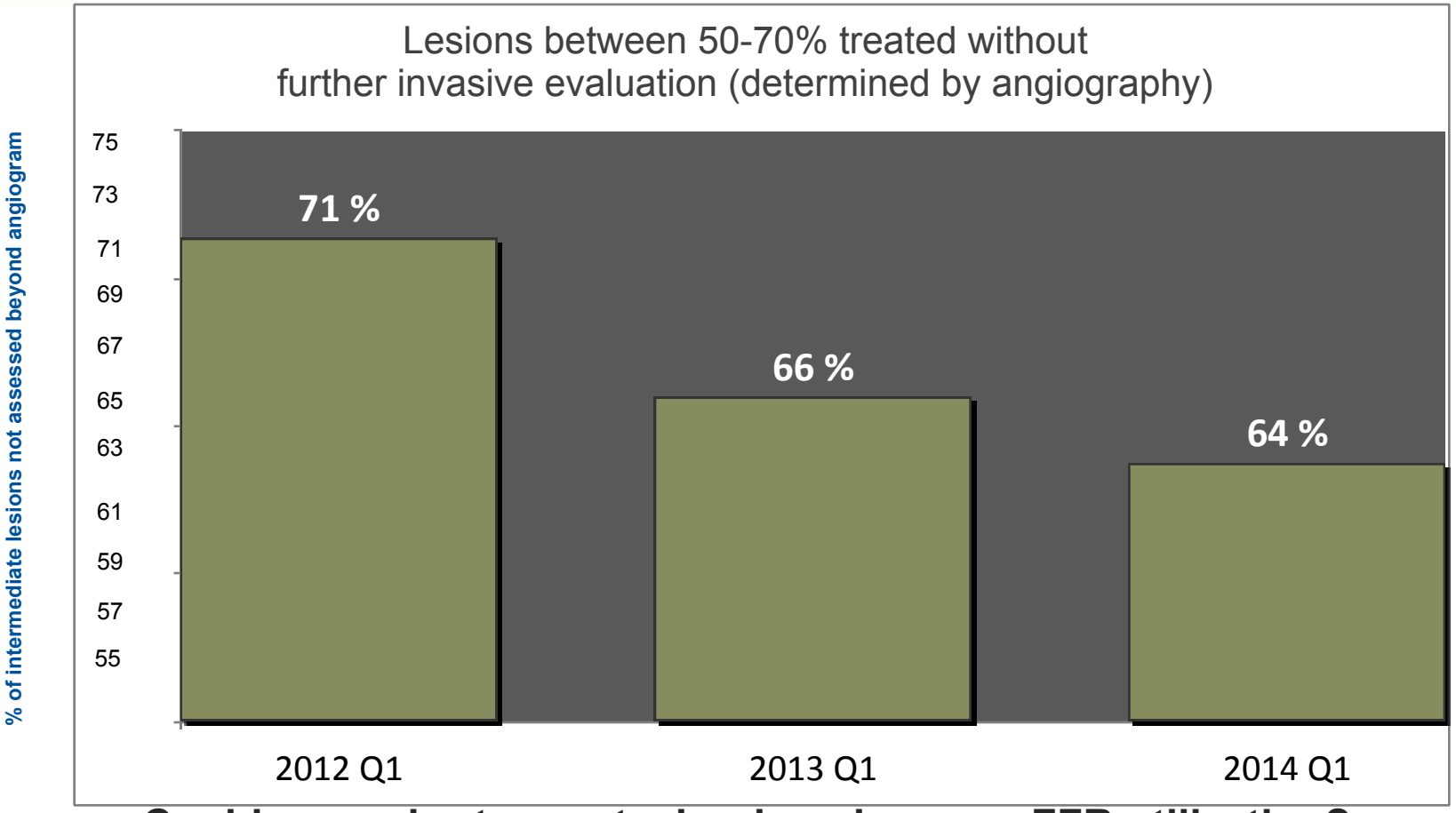



**8,1 % vs 12 % ; RR=0,66 (IC95% [0,43-1] ; p=0,049)**

Xaplanteris, NEJM; 2018 May 22

# Angiography Alone is Decreasing, But FFR Still has Room to Grow…




**Could an easier-to-use technology improve FFR utilization?**

NCDR data. Fraction of total # of PCIs over respective rolling 4 quarters

# Why is FFR Under-Utilized?

## Workflow Issues

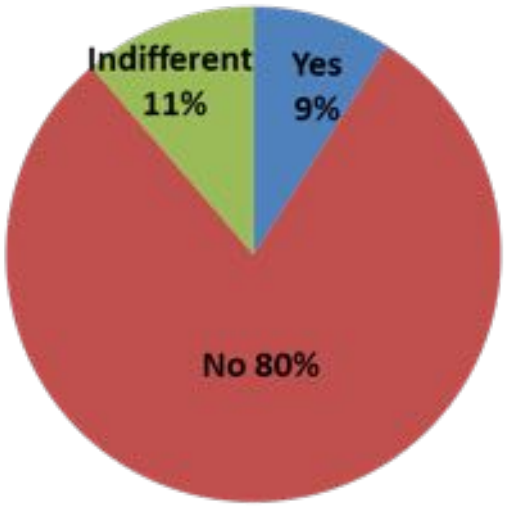
- Set up / zeroing / drift
- Reconnecting in MVD and post-PCI FFRs
- Pressure wire handling characteristics take more time

## Opportunities for Improvement

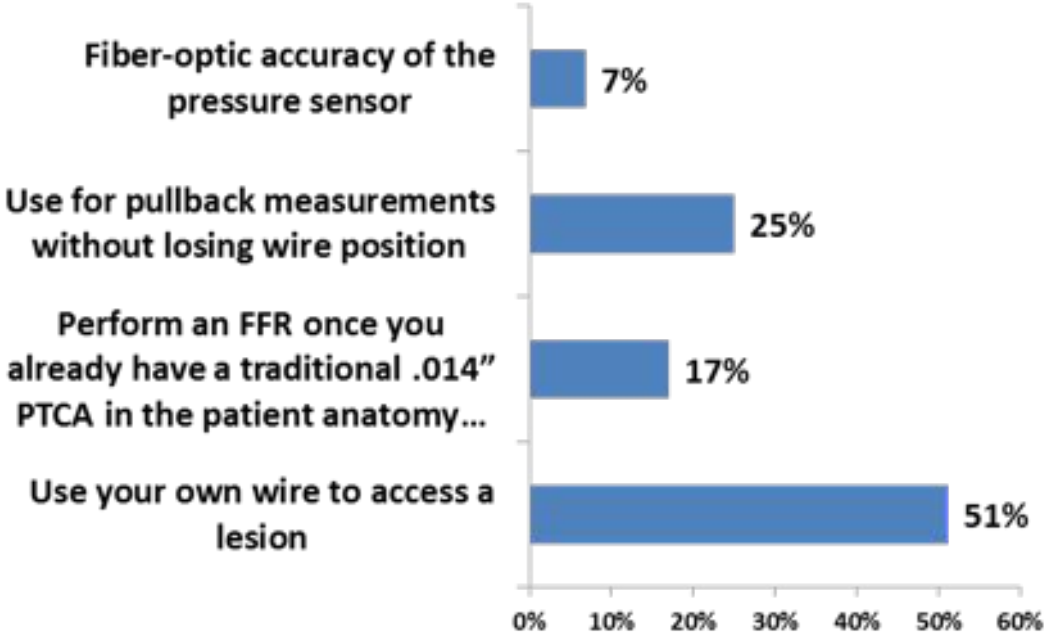
- More stable signal / less drift
- Eliminate need to connect / reconnect in MVD (multi-vessel disease) and when doing post-PCI FFR
- Better product handling characteristics to facilitate quicker placement of sensor in anatomy

# Why RXi?

80% of physicians are not satisfied with current FFR Pressure Wire performance




Physicians see several benefits with the ACIST RXi technology




N = 88, Based on survey at Medtronic Miami Technology Program
January 2015

Q. Are you satisfied with the guide-wire handling performance of FFR Pressure Wires?

Q. What do you see as the main benefit of the ACIST RXi Rapid Exchange Micro Catheter FFR System?

# ACIST|RXi™ Rapid Exchange FFR System

The RXi system, with the ACIST Navvus™ Rapid Exchange FFR MicroCatheter, gives you the freedom to quickly and easily assess FFR ***using your 0.014"wire of choice*.**


**INTENDED USE/INDICATIONS FOR USE**

The ACIST RXi System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The Navvus Catheter is intended for use with the RXi System.

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# Unique MicroCatheter vs. Duplicate Wire-Based FFR

## Benefits of catheter-based approach

- ✓ Delivers over your 0.014” guide wire
  - helps provide quick access to lesion site
  - facilitates improved FFR utilization in more complex anatomies
- ✓ Maintains wire position
  - eliminates need to re-cross lesion(s) with wire, even when performing a pullback assessment for multiple lesions
- ✓ Sensor located 5mm proximal to catheter tip (vs. 30mm with pressure-wires)
  - minimizes distance needed to go past lesion for measurement
- ✓ Fiber optic sensing technology
  - provides less drift than piezo-resistive technology of pressure wire-based systems

**MicroCatheter Technology**

**Pressure Wire Technology**

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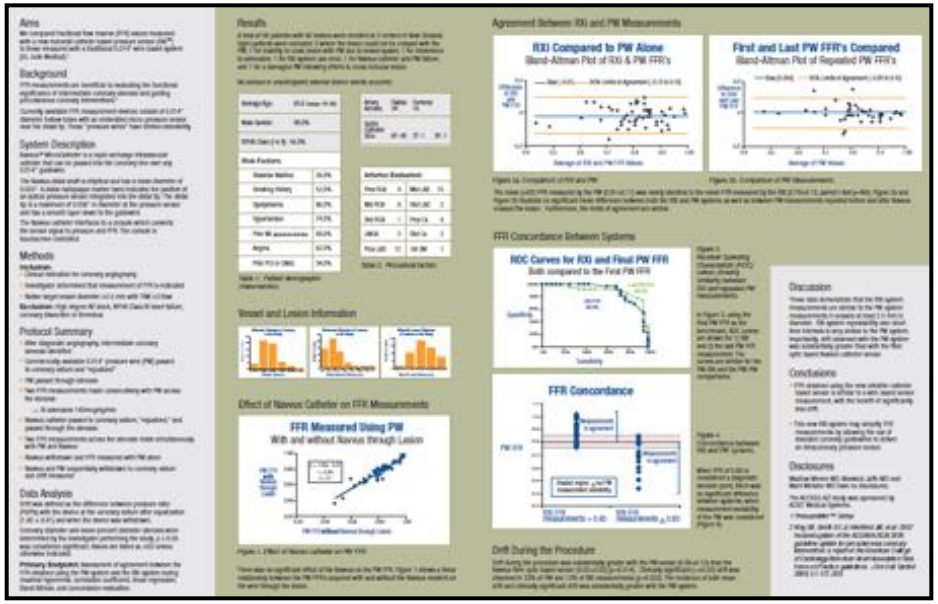
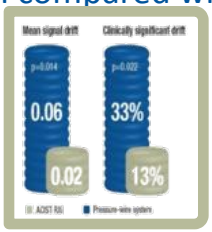
# Strong Data vs. Pressure Wire
# ACCESS-NZ Study

## Pivotal Data for FDA Clearance




- The RXi system and traditional FFR systems measured **nearly identical FFR values**; the limits of agreement were very similar
- FFR measurements were obtained with and without the Navvus MicroCatheter on the pressure wire; **the presence of the catheter did not affect the values obtained**
- **Signal drift was significantly lessened**, and clinically significant drift* was observed in fewer cases with the RXi system compared with the traditional system[1]




1 Menon M, Jaffe W, Webster M, for the ACCESS-NZ Investigators. Poster: FFR measurement using a new ultra-thin monorail catheter-based system. EuorPCR 2013, Paris France.

*Clinically significant drift defined as ± 0.03

2017 euro PCR

# Pressure Guidewire Compared With Microcatheter-Based Evaluation of Coronary Fractional Flow Reserve Measurements (PERFORM)

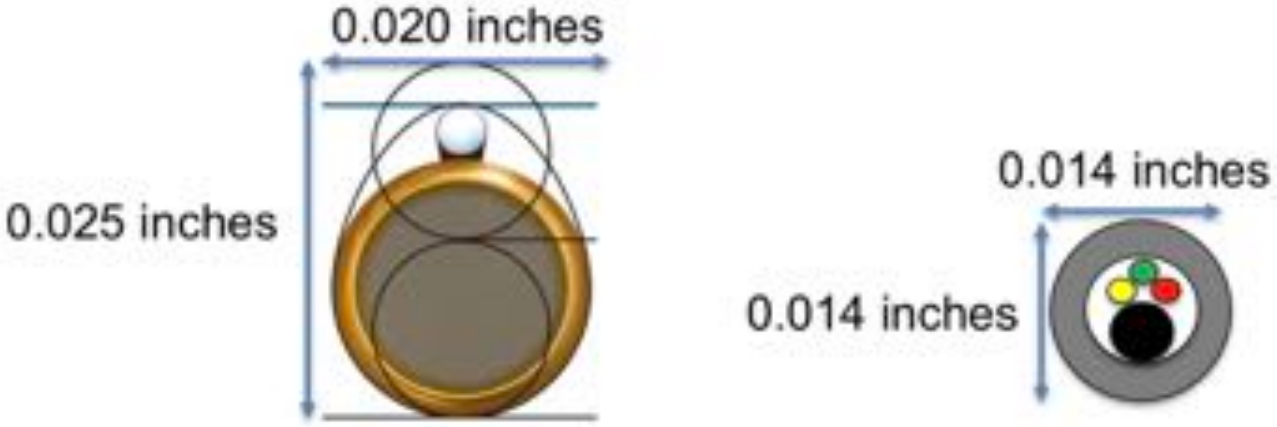
Z Ali, Y Parviz, M Brinkman, M Mitsumura, B Redfors, K Galougahi, T Nazif, J Moses, D Brogno, M Parikh, P Green, D Karmpaliotis, M Corral, K Fall, G Mintz, M Leon, O Ben-Yehuda, G Stone, A Maehara, A Jeremias, A Kirtane

# Background

- Randomized trials using a pressure guidewire (PW)-based system demonstrate clinical benefit for FFR- vs angiography-guided revascularization.

- Among technologies used to assess FFR, a novel monorail, sensor-tipped micro pressure catheter (PC) is advantageous for delivery and re-assessment and is designed to minimize drift.

- Whether its larger cross-sectional area influences trans-lesional pressure measurements is unclear.

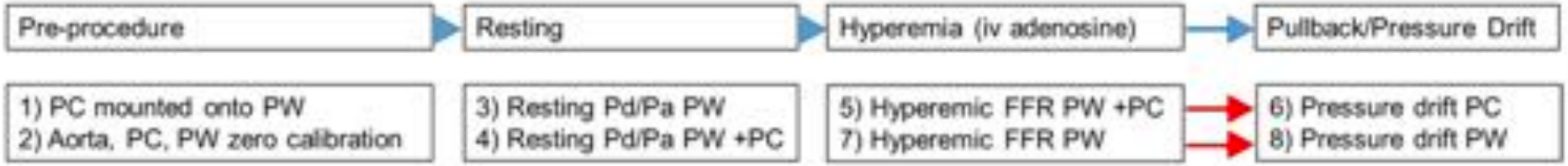


# Methods

- PERFORM was a single center, prospective study designed to determine the precision and accuracy of the PC compared to the PW.

- Eligible patients had native coronary artery target lesions with visually estimated diameter stenosis of 40-90%.

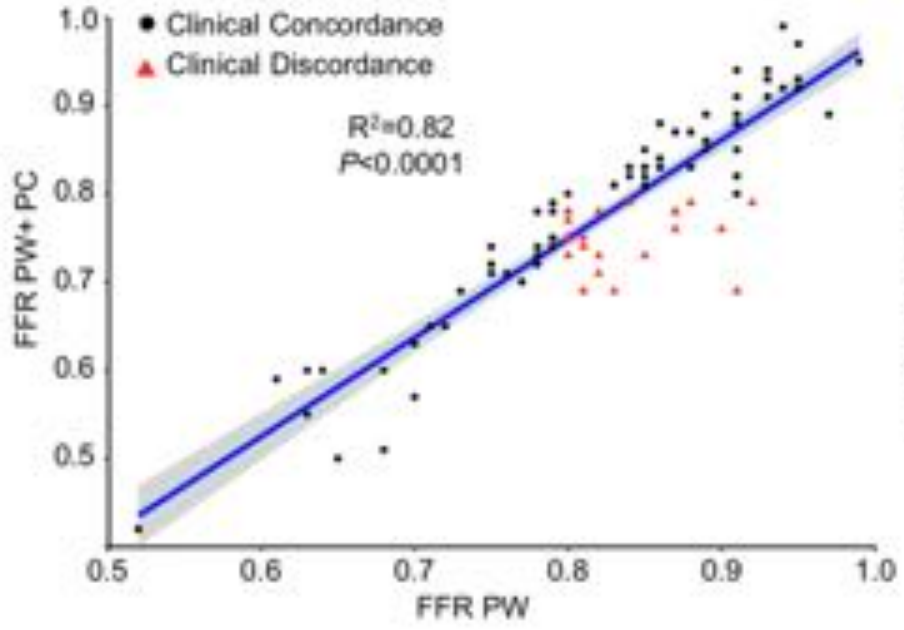
- The PC was pre-loaded onto the PW, and physiological measurements recorded using the PW at rest and during a single episode of hyperemia with or without the PC.

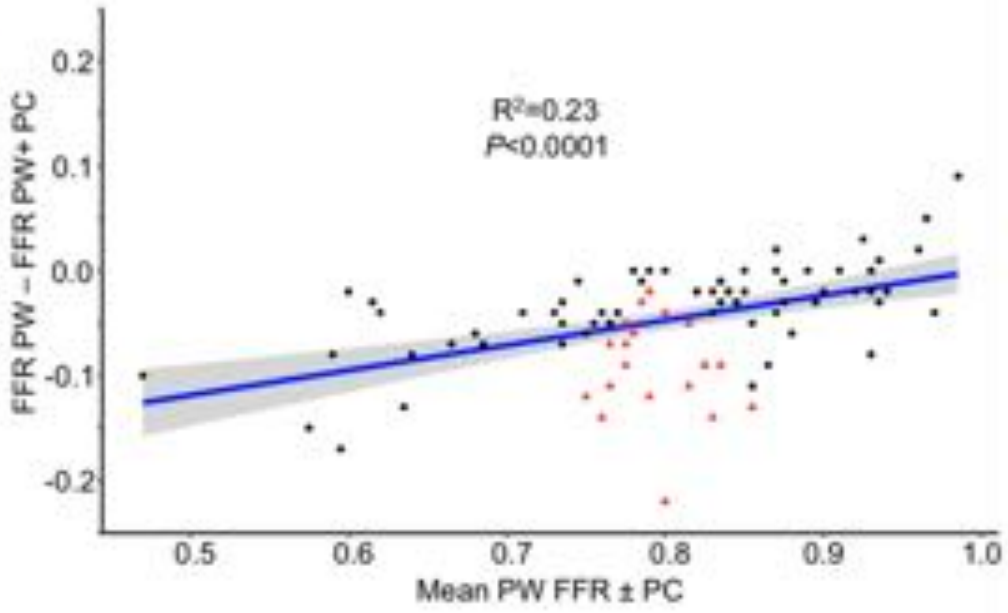



- **The powered and adjudicated primary endpoint was the difference in hyperemic PW-determined minimal FFR with and without the PC across the stenosis.**

# Hyperemic FFR

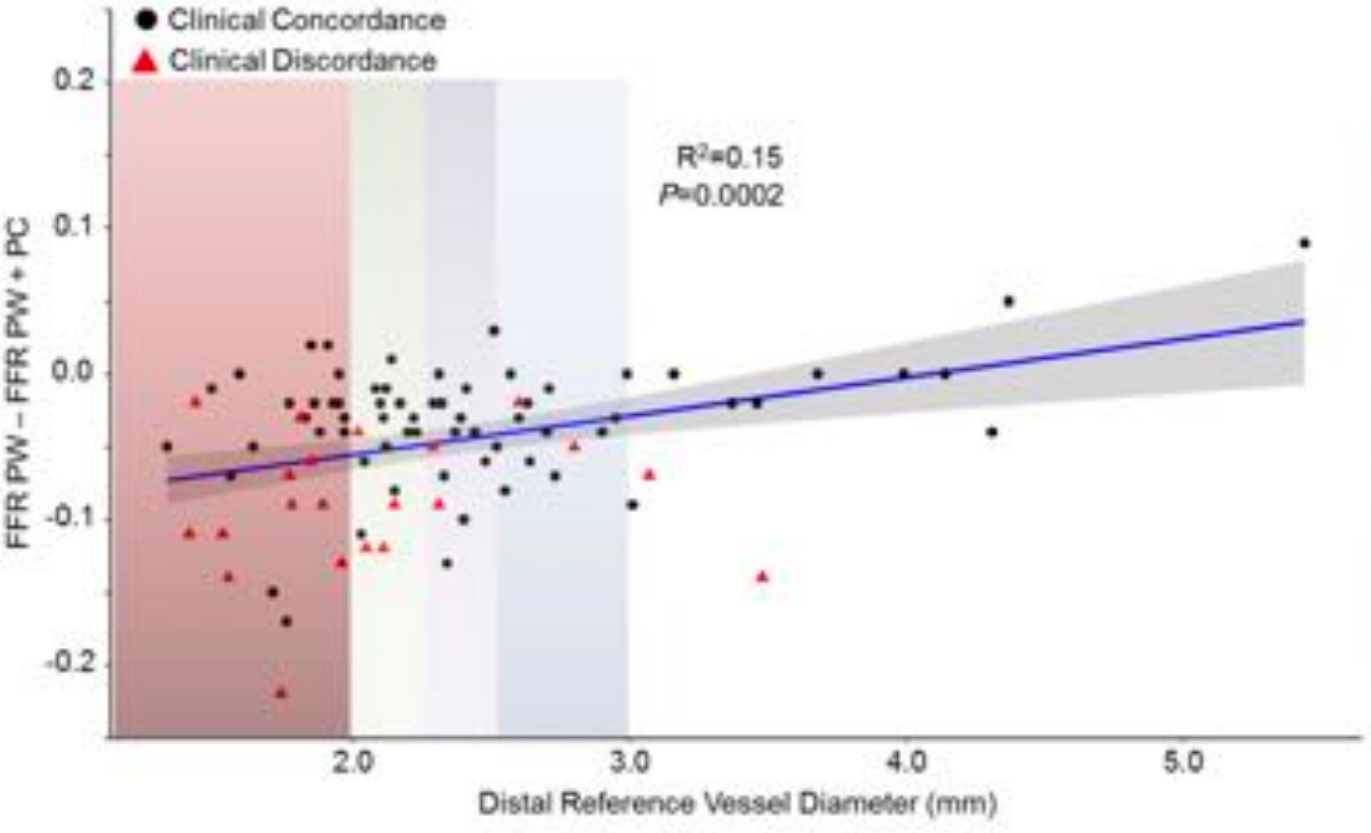
| (n=96 lesions) | PW | PC | *P* |
|---|---|---|---|
| Hyperemic FFR | 0.83 ± 0.09 | 0.78 ± 0.11 | <0.001 |
| Clinically Discordant, % | - | 20 | <0.001 |
| Difference ≥0.05, % | - | 40 | <0.001 |
| Difference ≥0.10, % | - | 14 | <0.001 |
| Drift | 0.03±0.03 | 0.02±0.04 | 0.32 |



# Independent Correlates of ΔFFR (PW-PC)

| Parameter | Difference (per 0.01) | 95% CI | *P* |
|---|---|---|---|
| Distal Reference Diameter (per 0.1mm) | 0.26 | 0.09 - 0.43 | 0.003 |
| Minimum Lumen Diameter (per 0.1mm) | -0.03 | -0.30 - 0.24 | 0.84 |
| Visual Diameter Stenosis (%) | -0.04 | -0.14 - 0.06 | 0.42 |
| Lesion Length | -0.07 | -0.19 – 0.05 | 0.26 |




| Cutoff | % | *P* |
|---|---|---|
| ≥2.0 | 17 | 0.04 |
| <2.0 | 37 | |
| ≥2.25 | 15 | 0.07 |
| <2.25 | 31 | |
| ≥2.5 | 15 | 0.20 |
| <2.5 | 27 | |
| ≥3.0 | 17 | 0.54 |
| <3.0 | 25 | |

# ACIST-FFR Clinical Study

2017 euroPCR

CVPIPELINE
BY MARKETMONITORS INC

# Primary Results of the Assessment of Catheter-based Interrogation and Standard Techniques for Fractional Flow Reserve Measurement Study

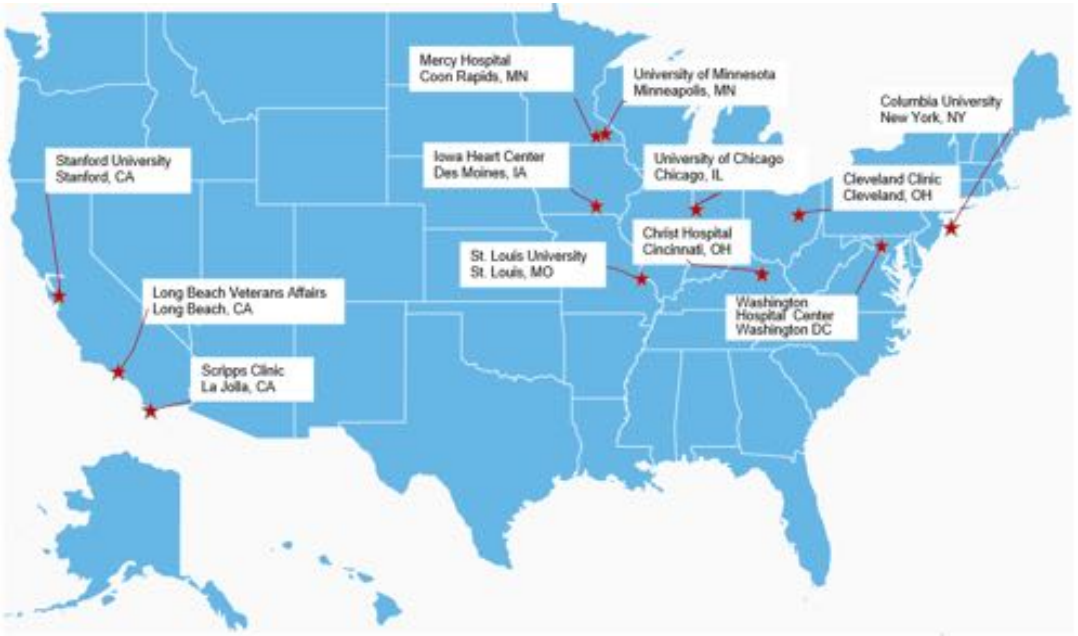
## The ACIST-FFR Study

William F. Fearon, MD, Jeffrey W. Chambers, MD, Arnold H. Seto, MD, Ian J. Sarembock, MD, Ganesh Raveendran, MD, Charlotte Sakarovitch, PhD[1], Lingyao Yang, MS, Manisha Desai, PhD[1], Allen Jeremias, MD, and Matthew J. Price, MD for

the ACIST-FFR Study Investigators

# ACIST-FFR Study

- Enrollment Complete
  - 246 patients
  - Expect >160 data points in the primary analysis
- Overall
  - Data is favorable
  - Further major investments in correlation studies are not expected
  - To be presented at Euro-PCR (May, 2017)



# The ACIST-FFR Study

**Assessment of Catheter-based Interrogation and Standard Techniques for Fractional Flow Reserve Measurement**

## Navvus® Microcatheter and Pressure Wire

- Diagnostic Agreement
- Measurement Correlation
- Device Success
- Incidence of Drift

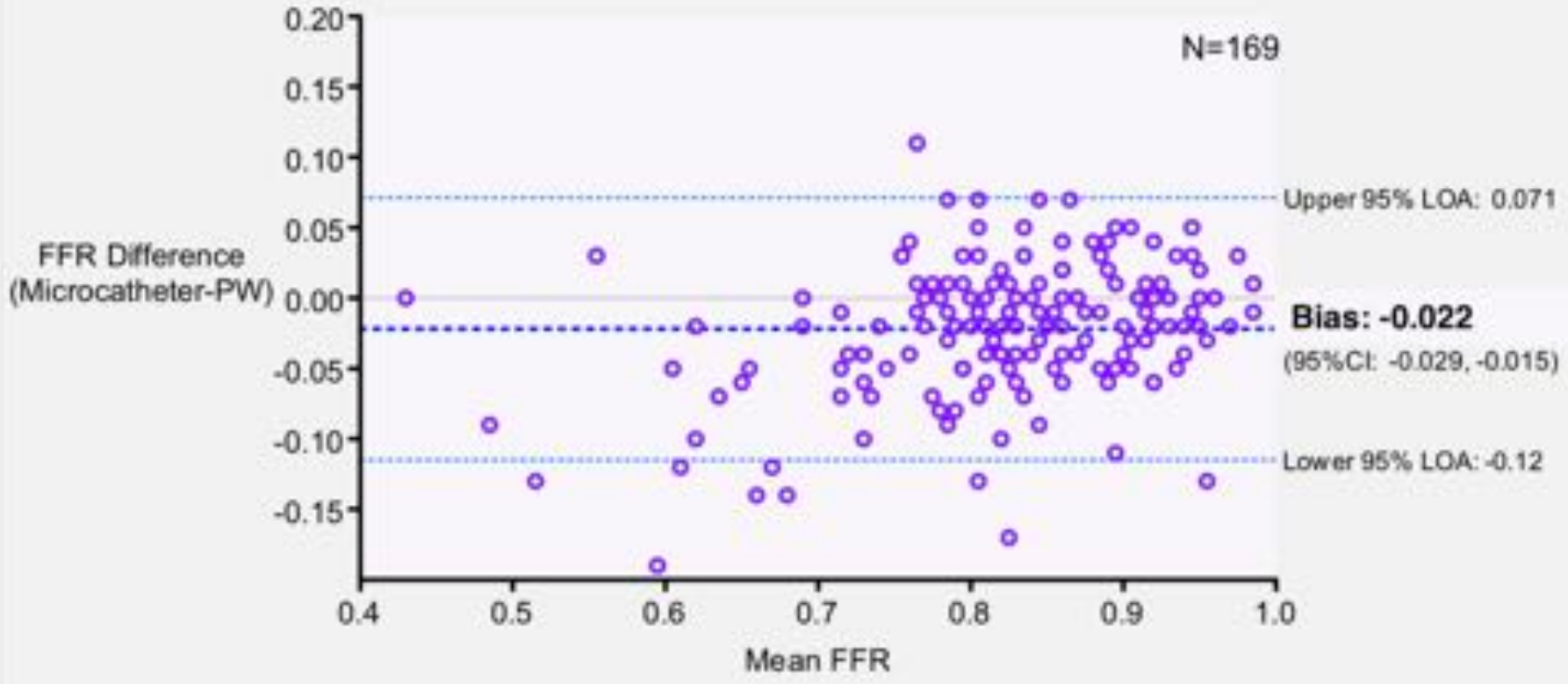
**246 Patients at 12 US sites**

Principal Investigators:

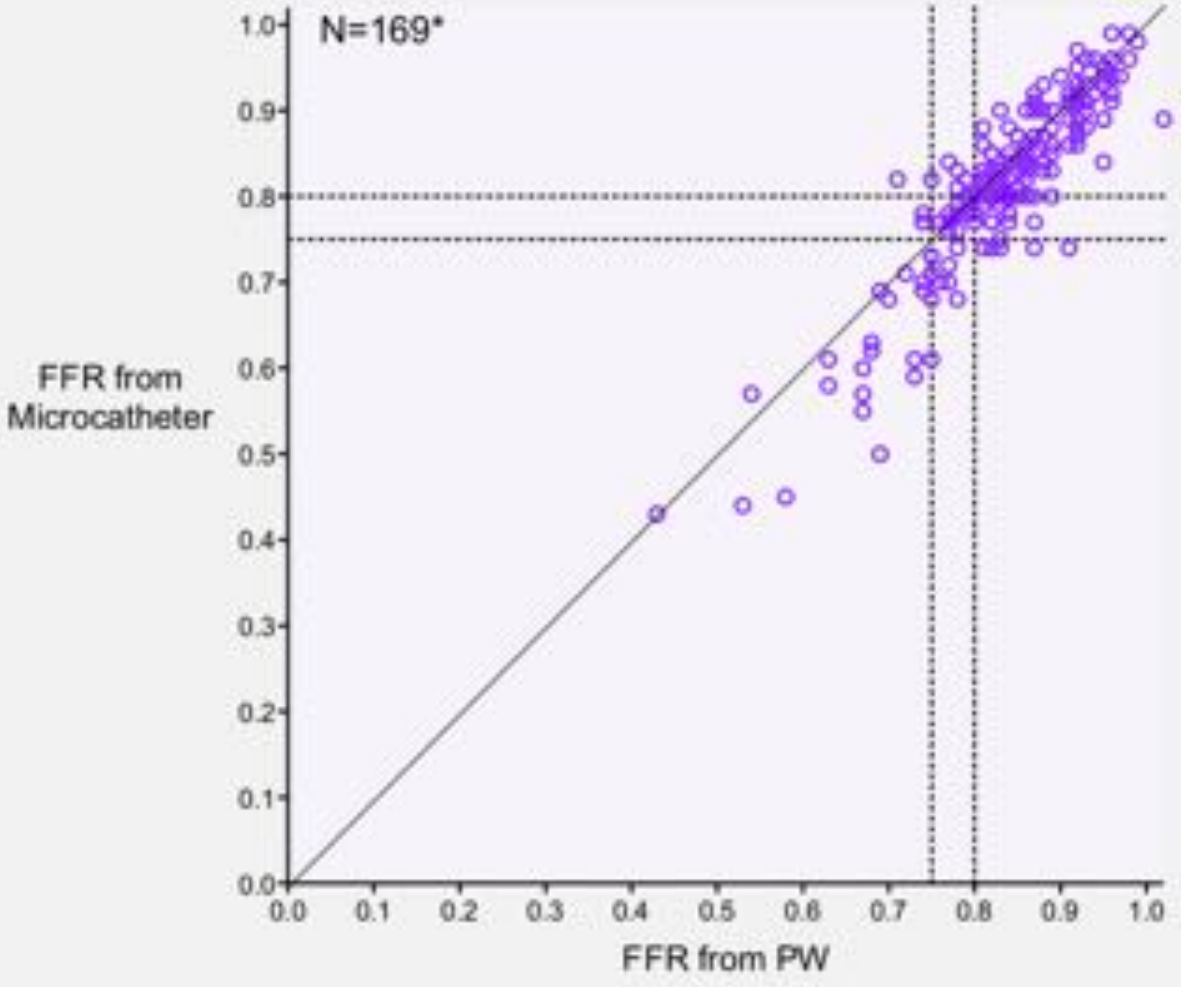
Dr. Matthew Price (Scripps Clinic), Dr. Bill Fearon (Stanford)

Enrollment began November 2015; complete December 2016

# Primary Endpoint: Microcatheter vs. Pressure Wire FFR, Core Lab Values, by Bland Altman Analysis



# Correlation Between Microcatheter and Pressure Wire FFR




Pearson coefficient = 0.901
P<0.001

**Sensitivity:**
88% (95% CI: 76-96%)

**Specificity:**
78% (95% CI: 69-85%)

**Diagnostic Agreement:**
81% (95% CI: 75-87%)

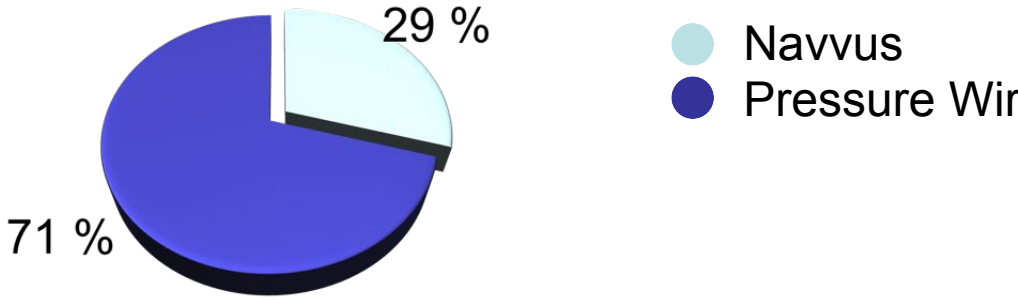
5 cases (2.9%) where PW FFR >0.80, microcatheter FFR <0.75

*Core laboratory values

# Notre expérience

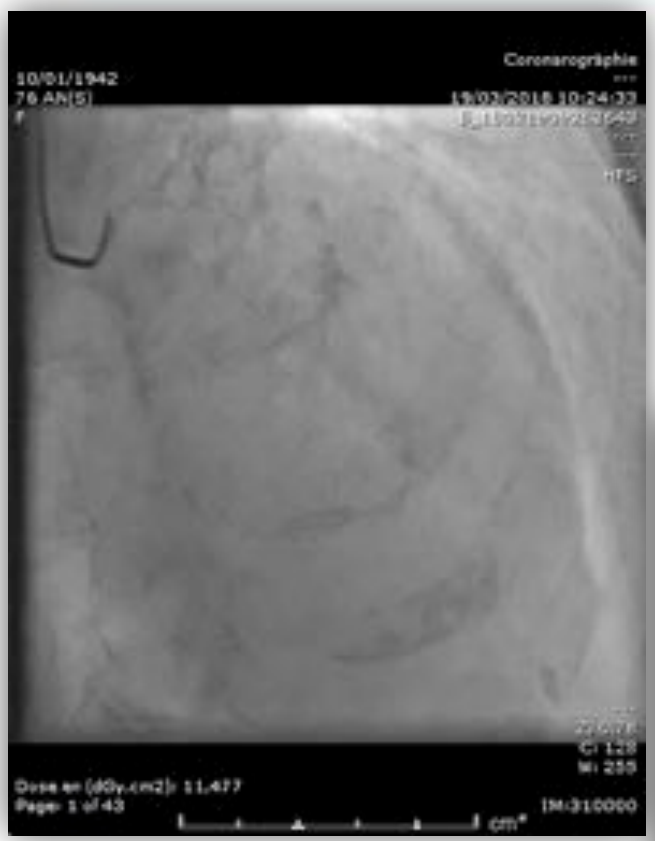
- FFR depuis 2003,
- Essais Navvus Avril 2017,

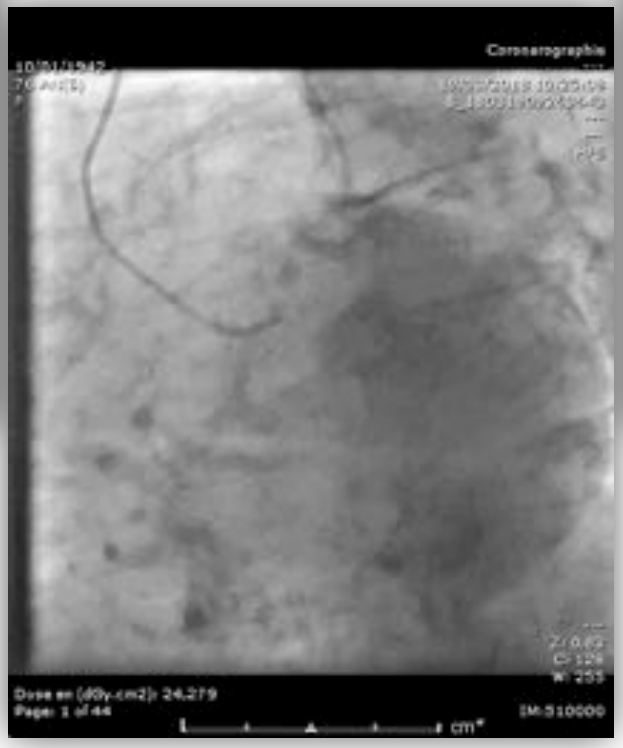
- Utilisation sur 1 an: 01/04/17 - 01/04/18
- 224 procédures FFR
  - 158 Pressure Wire,
  - 66 Navvus



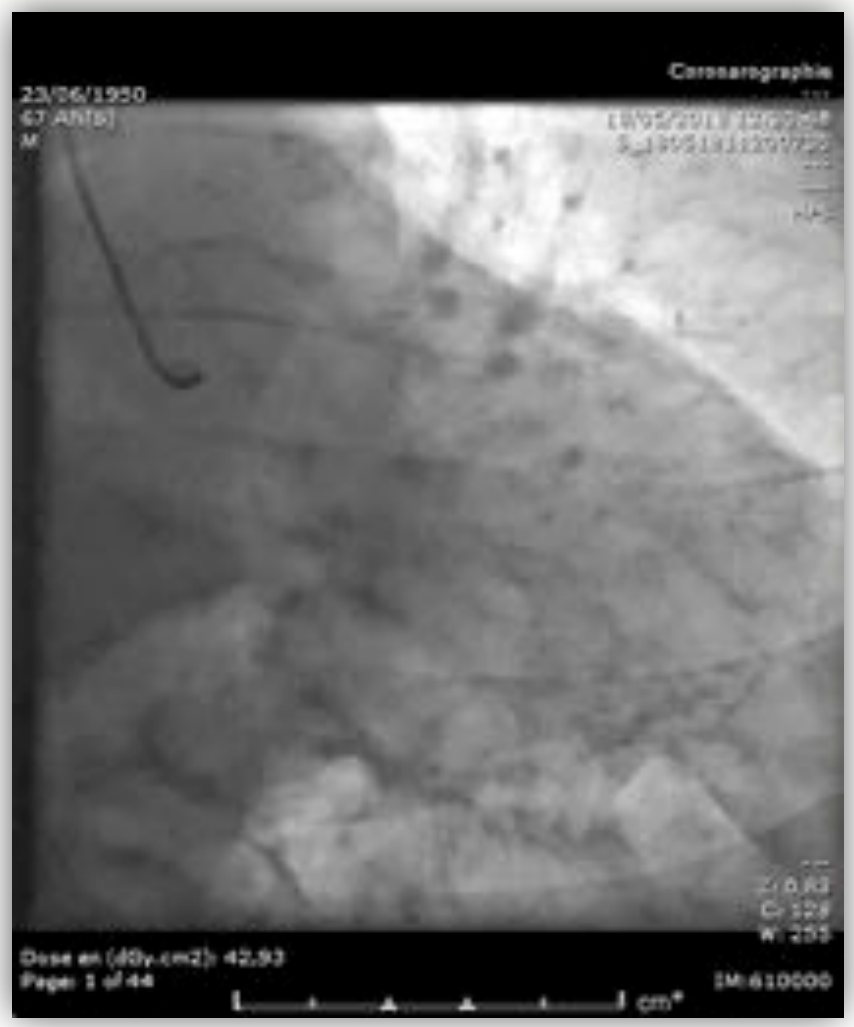
# SITUATIONS CLINIQUES

# Pluritronculaire



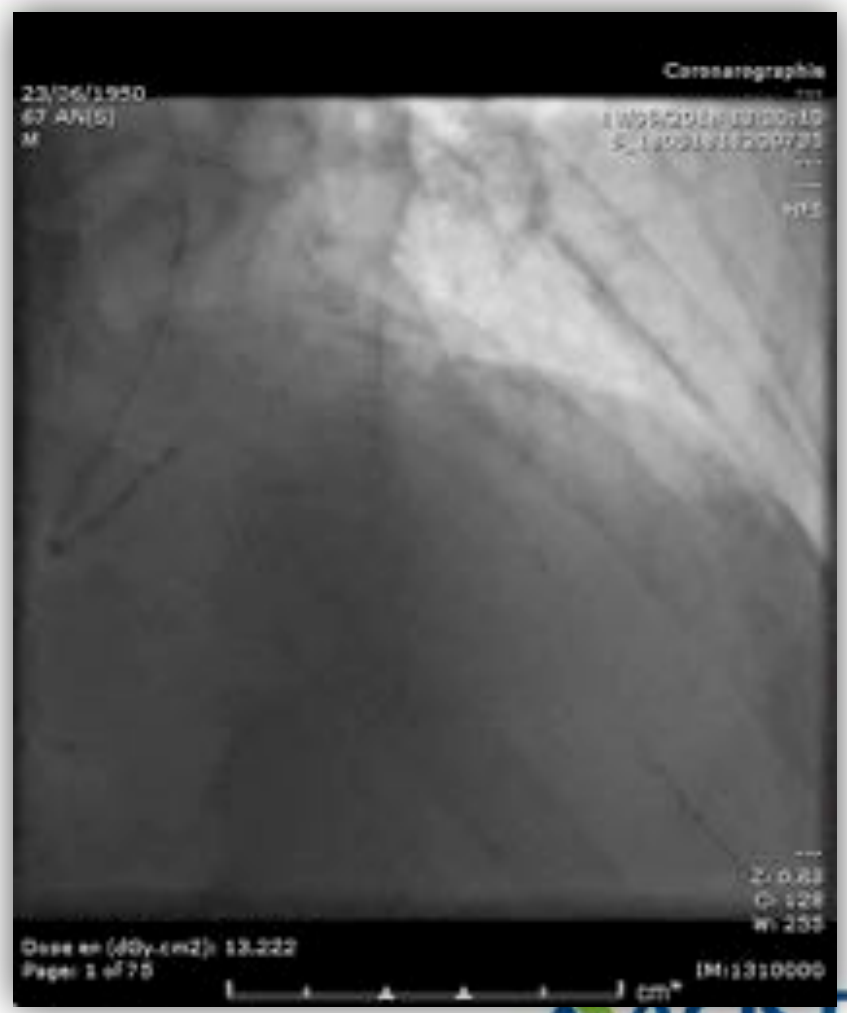




# Tronc Commun

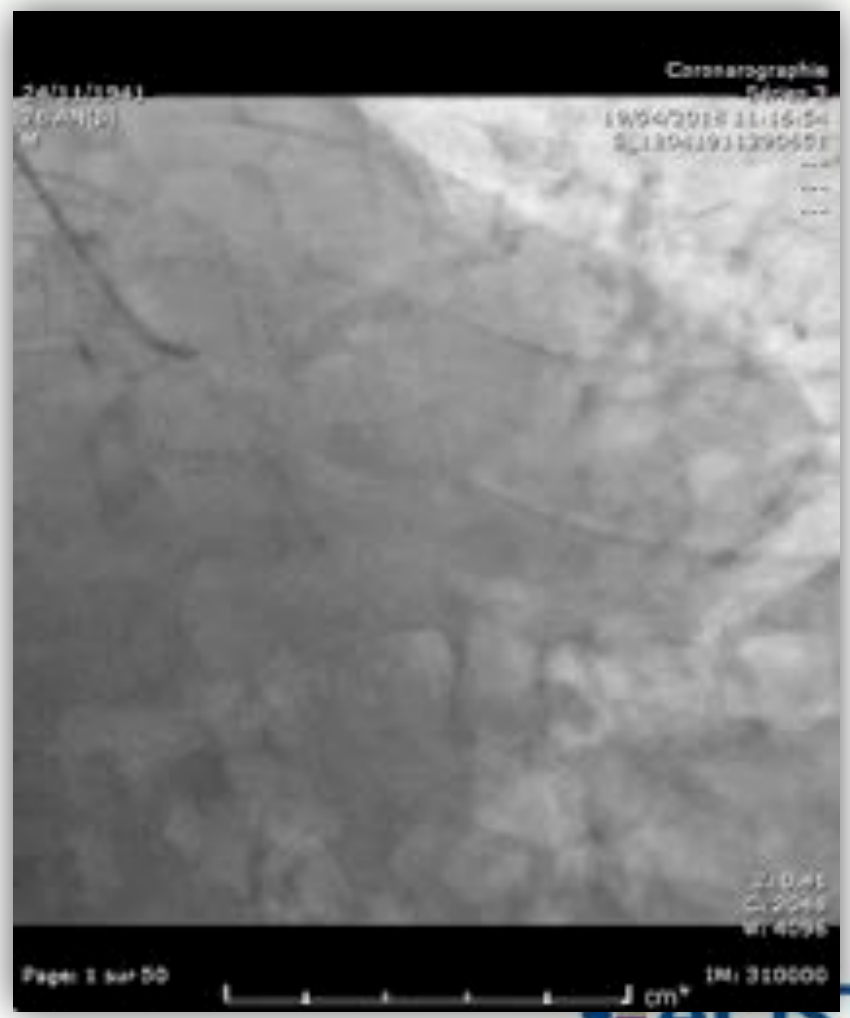




Coronarographie
23/06/1950
Dose en (dGy-cm2): 32.094
Page: 1 of 60
[M:1110000


Coronarographie
23/06/1950
67 AN(S)
M
Dose en (dGy-cm2): 13.222
Page: 1 of 75
[M:1310000

# Anatomies difficiles


24/11/1941
76 AN(S)
Coronarographie
Série: 11
Page: 1 sur 80
IM: 1110000

# Lésions calcifiées


# Synthèse

Positif

- Tronc commun
- Pluri-tronculaire
- Lésions en série
- Tortuosités

- Pas de retrait du guide (dérive?)

Négatif

- Lésion calcifiée
- Petits vaisseaux
- Surcoût éventuel du guide

# Thank You!

ACIST RXi™
Rapid Exchange
FFR System

ACIST CVi®
Contrast
Delivery System

ACIST HDi™
HD IVUS System

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# Continuous Innovation: Navvus Interface

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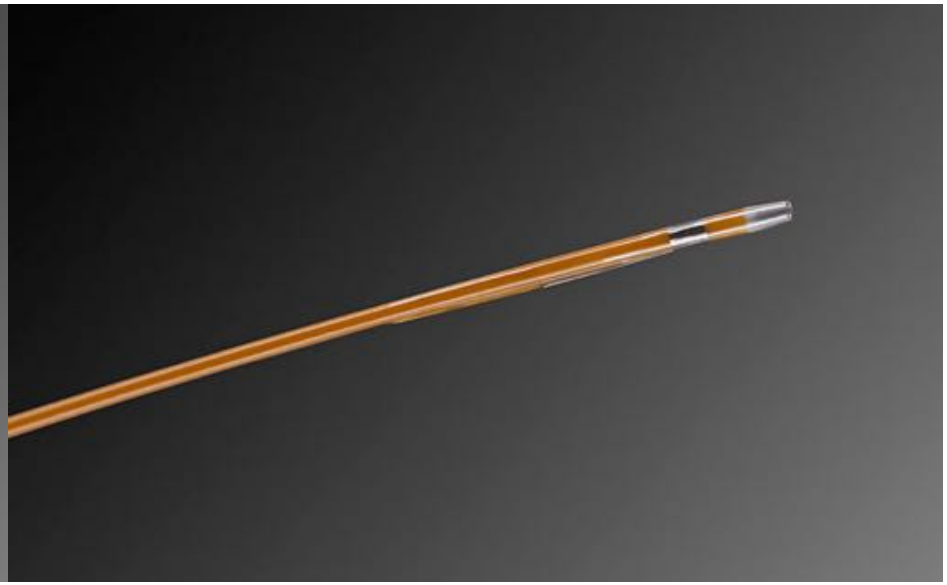
# Continuous Innovation
# 18% Lesion Entry Profile Reduction

**OLD**

**NEW**

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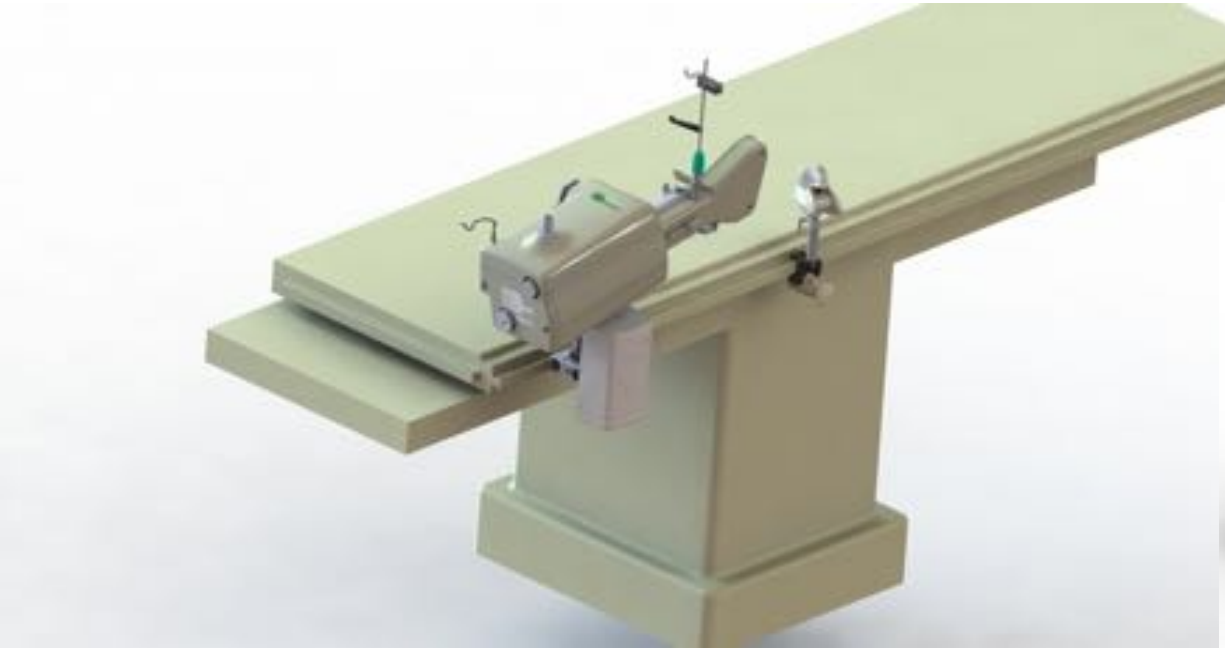
# ACIST|RXi™ Rapid Exchange FFR System

# Small Integrated Footprint Connects Into Hemo System

Processing Unit on CVi

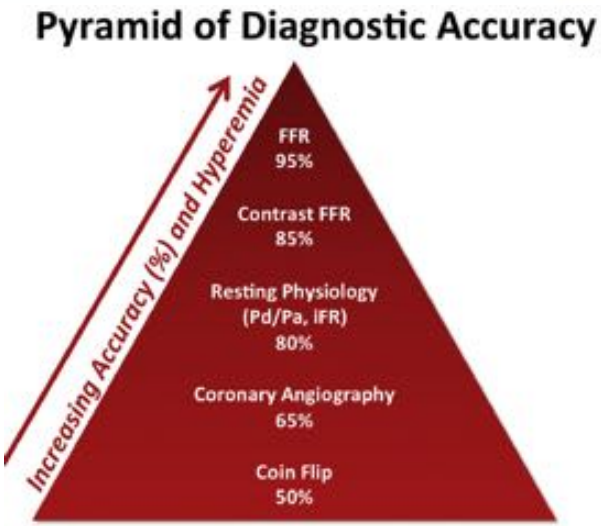


**Step Wise Approach to Hyperemia w Navvus**

1. Resting Pd/Pa
2. Contrast FFR (cFFR)
3. IC Adenosine or IV Adenosine

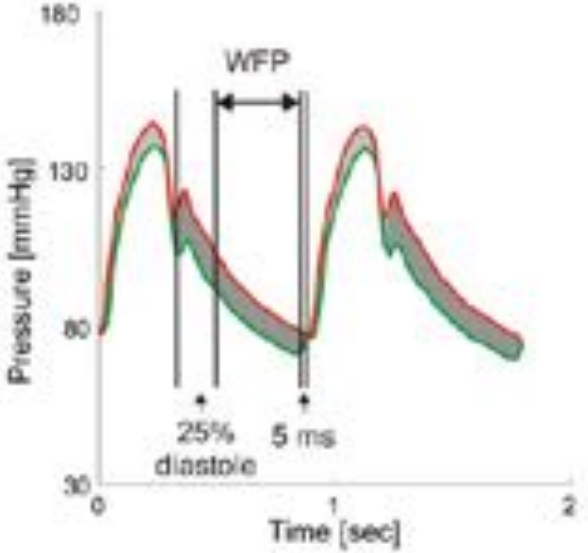
## Hyperemia without Adenosine

- Contrast induced FFR (with power injector)
- NAVIGATE Study




## Resting metrics

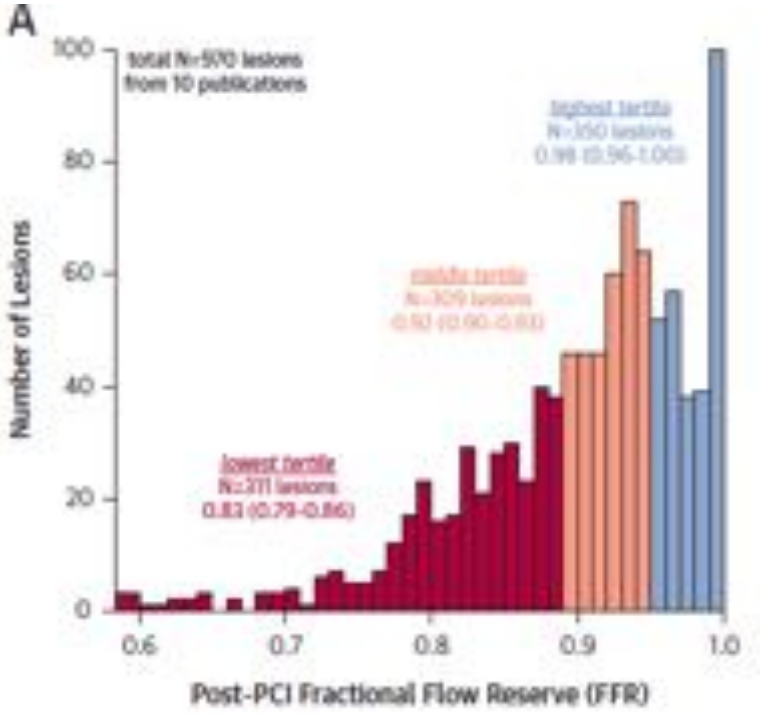
- iFR licensing options may exist
- Developing an iFR-like algorithm
- Considering the data supporting equivalence of iFR and Pd/Pa

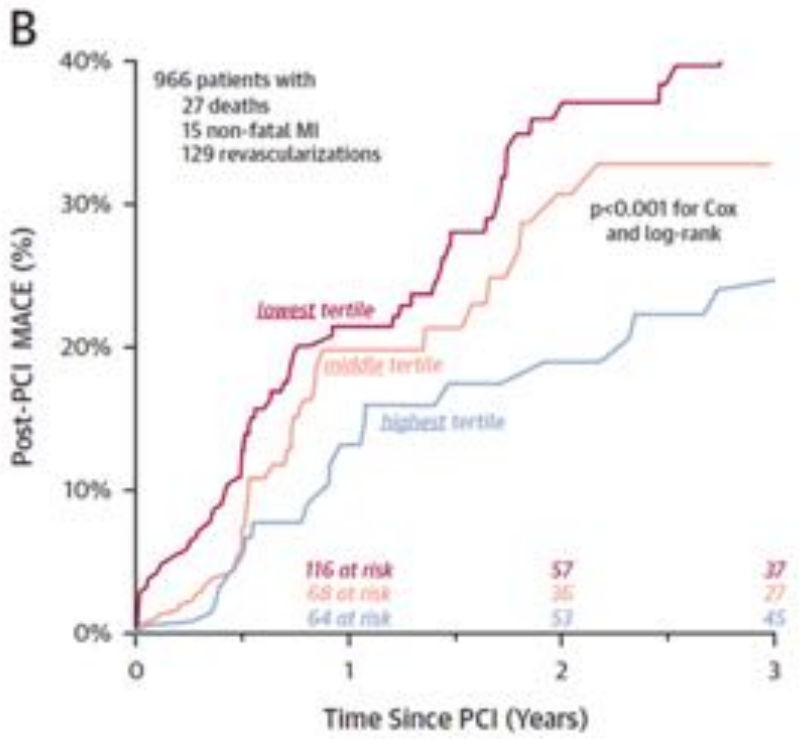


# Post-PCI FFR

# Johnson Meta-analysis:
## Post-PCI FFR has Prognostic Value

- Patient-level meta-analysis (6,961 lesions): post-PCI FFR predicts MACE
- Moving from lower to highest tertile suggests a significant reduction in MACE



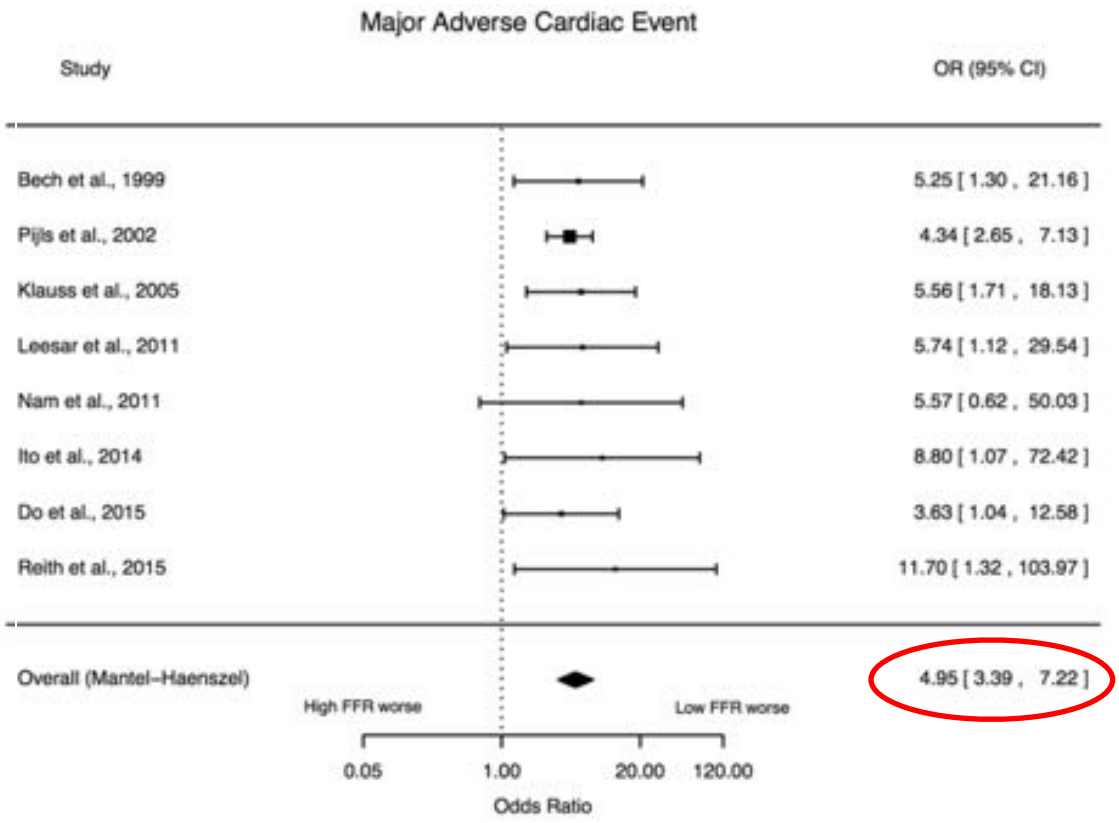




Johnson NP, et al. Prognostic value of fractional flow reserve: linking physiologic severity to clinical outcomes. J Am Coll Cardiol. 2014 Oct 21;64(16):1641-54. doi: 10.1016/j.jacc.2014.07.973.

# Wolfrum Meta-analysis:

## Post-PCI FFR has Prognostic Value

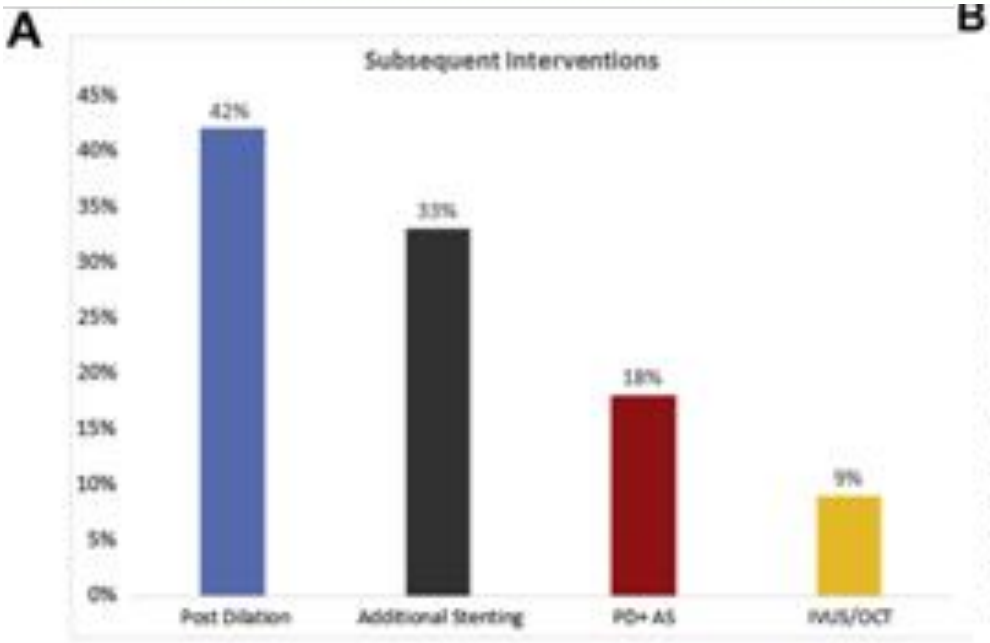
- 8 studies
- 1337 patients
- Conclusion:
  - Low Post-PCI FFR is associated with worse clinical outcomes
  - Most common definition: FFR <0.9
- Odds Ratio:
  - Low FFR/MACE: 4.95
  - (95% CI 3.39 to7.22, p<0.001)

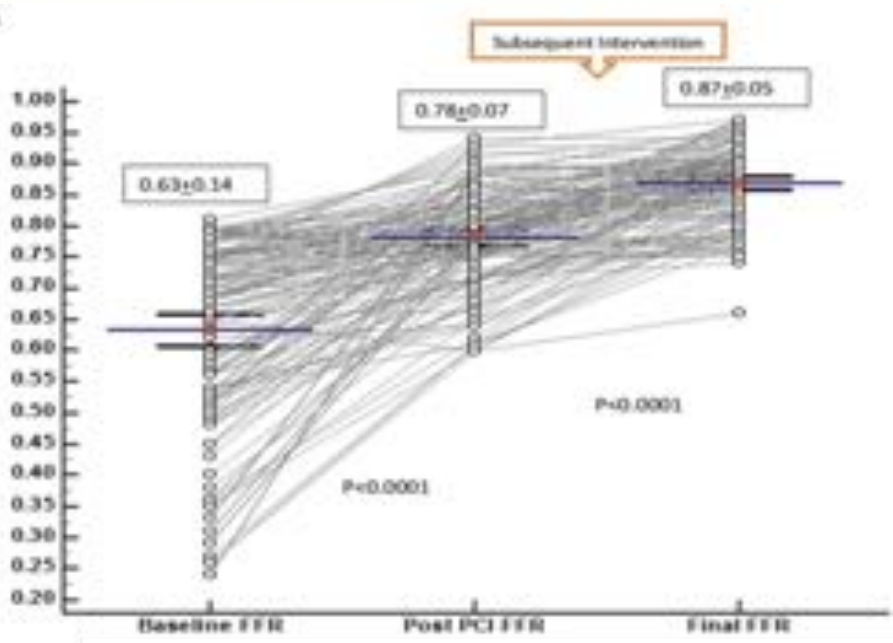



Wolfrum M et al. Impact of impaired fractional flow reserve after coronary interventions on outcomes: a systematic review and meta-analysis. BMC Cardiovasc Disord. 2016 Sep 8;16(1):177. doi: 10.1186/s12872-016-0355-7

# Agarwal Study:

## Optimization of Acute Results with Post-PCI FFR




- Retrospective review (1 center); 664 lesions/575 subjects
- Post-PCI FFR reclassified 20% of angiographically satisfactory lesions, which required further intervention
- Post-PCI FFR is an independent predictor of long-term outcomes

Agarwal SK et al, Utilizing Post-Intervention Fractional Flow Reserve to Optimize Acute Results and the Relationship to Long-Term Outcomes.. JACC Cardiovasc Interv. 2016 May 23;9(10):1022-31. doi: 10.1016/j.jcin.2016.01.046

# ACC 2017 Poster: Post-PCI FFR

## Post-PCI FFR has equivalent prognostic value as Pre-PCI FFR: no difference in MACE (median 3.2 years)

### Does Post-PCI FFR carry the same prognostic weight as non-ischemic FFR in deferred lesions?

Mohammed Eid Madmani MD, Amjad Abualsuod MD, Mohan Edupuganti MD, Shiv Kumar MD, Srikanth Kasula MD, Naga V Pothineni MD, Ahmed Almomani MD, Jason Payne MD, Barry Uretsky MD, Abdul Hakeem
University of Arkansas for Medical Sciences
Central Arkansas Veterans Health Care System CAVHS

#### Introduction

- Growing evidence suggests an increasingly important role of post-PCI FFR in outcome prediction.
- Whether the FFR value post-PCI contains the same prognostic weight as FFR in deferred lesions is not known

#### Methods

- Major adverse cardiac events (MACE) were compared between 547 patients in whom PCI was performed (and post-PCI FFR measured) and 576 patients in whom PCI was deferred based on a non-ischemic FFR.
- To account for significant differences in baseline differences between the two groups, a propensity matched cohort was analyzed with 340 patients in each group.

#### Results

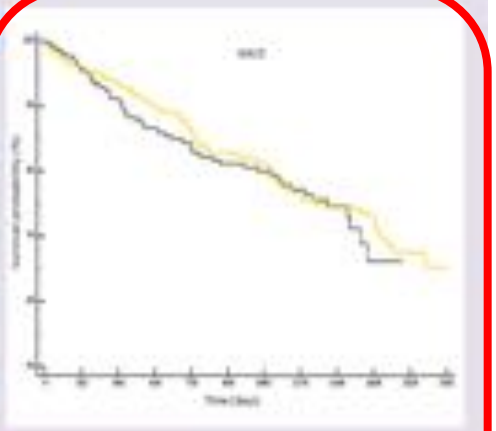
- The two groups were similar in baseline characteristics after propensity matching except for a higher proportion of diffuse disease in the PCI group.
- The median FFR with deferral was 0.87 and for post-PCI FFR was 0.88.
- During a median follow up of 3.2 years, there was no significant difference in MACE between the deferred and PCI groups (Figure).
- Similarly, across all FFR categories, the annualized MACE rate was similar between both groups.
- On Cox proportional hazards analysis for MACE, age (HR 1.02; 95% CI 1.007, 1.04), ACS (HR 1.7; 95% CI 1.3, 2.4), prior MI (HR 1.8; 95% CI 1.3, 2.4) and FFR (0.009; 955 CI 0.0006, 0.16) were independent predictors of MACE.
- There was no interaction between PCI (vs. deferral) and FFR for long-term MACE.

Baseline Characteristics

| | Deferred group | Perform group | P value |
|---|---|---|---|
| Age | 66.1+7.8 | 65.2+7.7 | 0.19 |
| Diabetes | 185(54%) | 170(50%) | 0.29 |
| Hypertension | 284 (83.5%) | 286(84%) | 0.85 |
| Hyperlipidemia | 324(96.2%) | 323(95%) | 0.90 |
| CKD | 69(20%) | 69(20.3%) | 0.92 |
| ACS | 105(31%) | 105(31%) | 0.99 |
| Prior MI/revasc | 163(48%) | 166(48.5%) | 0.91 |
| Smoking | 133(39%) | 143(42%) | 0.42 |
| Diffuse Disease | 98 (29%) | 160(47%) | <0.001 |

Multivariable analysis (Cox Proportional Hazards Analysis)

| Covariate | HR | P |
|---|---|---|
| Age | 1.02(1.008-1.03) | 0.0004 |
| DM | 1.13(0.87-1.45) | 0.3528 |
| CKD | 1.36(1.01-1.82) | 0.0375 |
| ACS | 1.81(1.40-2.33) | <0.0001 |
| Hypertension | 1.28(0.93-2.42) | 0.0253 |
| Hyperlipidemia | 0.5(0.40-0.80) | 0.0016 |
| Smoking | 1.14(0.88-1.48) | 0.3107 |
| prior_Mi/revas | 1.56(1.23-1.96) | 0.0002 |
| FFR | 0.01(0.0009-0.17) | 0.0011 |
| Defer vs perform | 0.87(0.65-1.16) | 0.3418 |



#### Conclusion

- FFR value post-PCI carries the same prognostic significance as FFR value in deferred lesions

#### Disclosure

All authors have no relationships to disclose.

# Other Post-PCI FFR/iFR Studies

- **DEFINE PCI (NCT03084367) Volcano**
  - Uses iFR pullback to assess the distribution of coronary atheroma/stenoses
    - As identified by Quantitative Coronary Angiography (QCA)
    - After angiographically successful PCI
  - 500 subjects (29 centers: US/UK/NL)
  - Enrollment to begin June 2017
- **PERSPECTIVE (NCT01873560) – Korean registry**
  - Evaluate influence of physiologic parameters on the clinical outcome after DES implantation (cut-off FFR<0.90)
  - 1250 subjects
  - Enrollment began May 2013, currently recruiting; primary endpoint @ 2 years

# FFR-SEARCH: Overview

## Erasmus Medical Center

- Determine impact of FFR values post PCI on clinical outcomes
- All patients successfully treated with PCI at EMC
- FFR assessed with Navvus after PCI
  - FFR value 20mm distal to the (most distal) stent
  - Pull-back (distal stent edge, proximal stent edge, equalization point)
- Endpoints: MACE: all-cause mortality, cardiac mortality, myocardial infarction, TLR, TVR
  - 30 days, 1 year, 2 years and 5 years

# FFR-Search Registry

## Initial Data from TCT 2016

ACIST RXi

### ROUTINE FRACTIONAL FLOW RESERVE MEASUREMENT AFTER PERCUTANEOUS CORONARY INTERVENTION WITH A NOVEL FFR MICRO CATHETER, INSIGHTS FROM THE FFR-SEARCH REGISTRY

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Erasmus MC Zaluno

**Background:**
Fractional Flow Reserve (FFR) after Percutaneous Coronary Intervention (PCI) is a predictor of adverse cardiovascular events during follow-up. Most studies so far only included patients with stable coronary lesions and used a dedicated pressure wire for pre- and post-PCI FFR measurements. The aim of the current registry study was to investigate the safety and feasibility of performing routine post-PCI FFR measurements using a novel monorail catheter.

**Methods:**
All patients who underwent successful PCI were eligible for this study. The FFR measurements were performed with a novel over-the-wire Monorail Catheter (Navvus, ACIST Medical Systems, Eden Prairie, MN) inserted over the previously used coronary guidewire, Figure 1.

Figure 1: Navvus micro catheter. At the top, the entire device is shown. The distal tip construction is shown below in detail

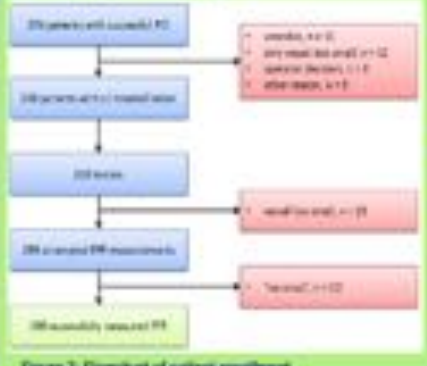


Figure 2: Flowchart of patient enrollment

After PCI, the Navvus catheter was advanced over the guidewire and the optical pressure sensor was positioned approximately 20mm distal of the most distal stent edge. All the FFR measurements (including manual pull-backs) were performed in resting conditions and under maximum hyperemia with Adenosine, administered intravenously.

**Results:**
A total of 274 patients were included. In 41 patients, FFR measurement was not performed due to unstable hemodynamic conditions (n = 11), only vessel considered too small for FFR measurement (n = 12), operator decision (n = 9) or other reasons (n =9), Figure 2. In the remaining 233 patients, 318 lesions had been treated successfully. Baseline characteristics of these patients are displayed in Table 1. In 19 lesions, the outflow vessel was considered too small for FFR measurement and therefore finally 299 lesions were attempted for FFR measurement. Failure to cross the treated lesion occurred in 10 (3,3%) cases. In the 289 successfully measured lesions, mean FFR value during resting condition was 0.96±0.04 and 0.91±0.07 under maximum hyperemia. In 21 lesions (7%) an FFR value ≤0.80 was observed after angiographically successful PCI. Average time for the FFR measurement was 5.3±1.9 minutes. Mean signal drift was 0.01±0.02. No FFR related complications occurred.

| Variable (n = 233) | |
|---|---|
| Age (years) | 64±12 |
| Male gender (n) | 159 (68.2%) |
| Hypertension (n) | 117 (50.2) |
| Hypercholesterolemia (n) | 102 (43.8%) |
| Smoking history (n) | 110 (47.2%) |
| Prior PCI | 68 (29.2%) |
| Prior CABG | 13 (5.6%) |
| Indication for PCI<br>• Stable angina<br>• Unstable angina / NSTEMI<br>• STEMI | <br>66 (28.3%)<br>92 (39.5%)<br>75 (32.2%) |

Table 1: Baseline characteristics

| Variable | |
|---|---|
| FFR value in resting condition | 0.96±0.04 |
| FFR value during hyperemia | 0.91±0.07 |
| Drift | 0.01±0.02 |
| Time (minutes) | 5.3±1.9 |

Table 2: FFR measurements in 289 lesions

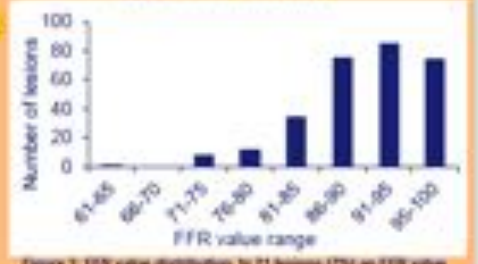



Figure 3: FFR value distribution. In 21 lesions (7%) an FFR value ≤0.80 was observed

**Conclusions:**
- Performing routine FFR measurements with the novel Navvus over-the-wire monorail catheter is safe and feasible in 96.7% of the attempted treated lesions.
- Average FFR after PCI was 0.91±0.07.

# FFR-SEARCH Registry

## Preliminary results

**Preliminary overall results:**

- Average value post PCI in resting condition: 0.96
- Average value post PCI under hyperemia: 0.91
- Average drift value: 0.011
- "No-cross" in 37 out of 1008 attempted lesions: 3.7%

- HDi-IVUS performed in case of FFR ≤0.85: 60 patients

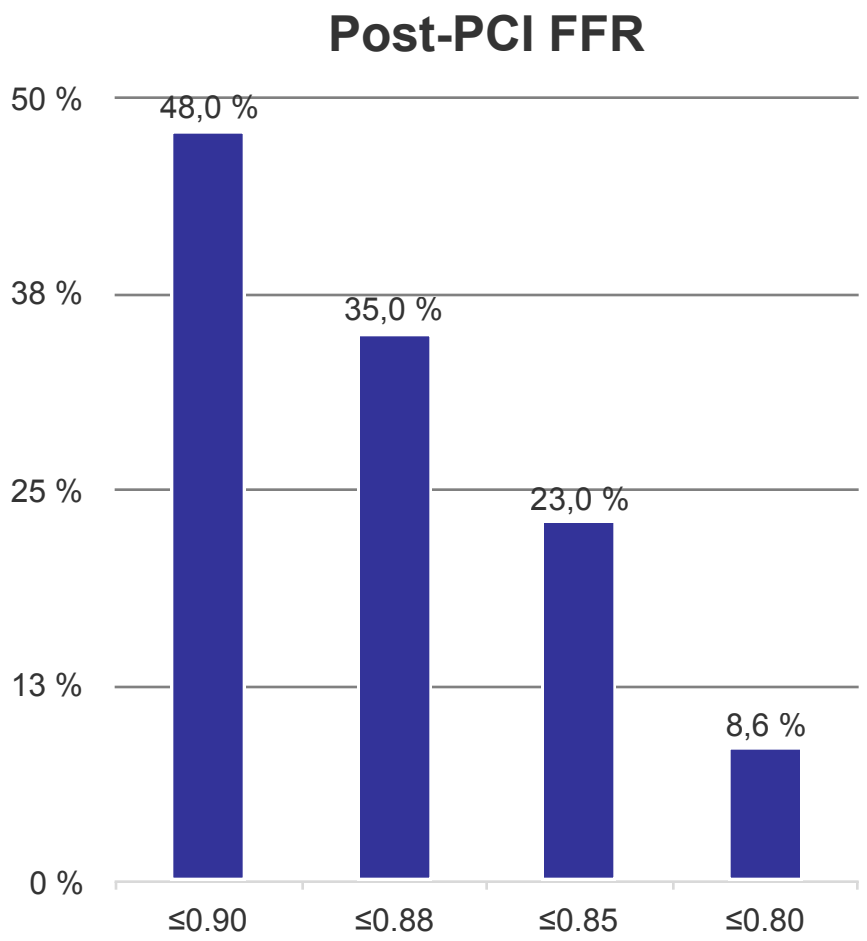
# FFR-SEARCH Registry

## Preliminary results

### **Patient data** (all cases)

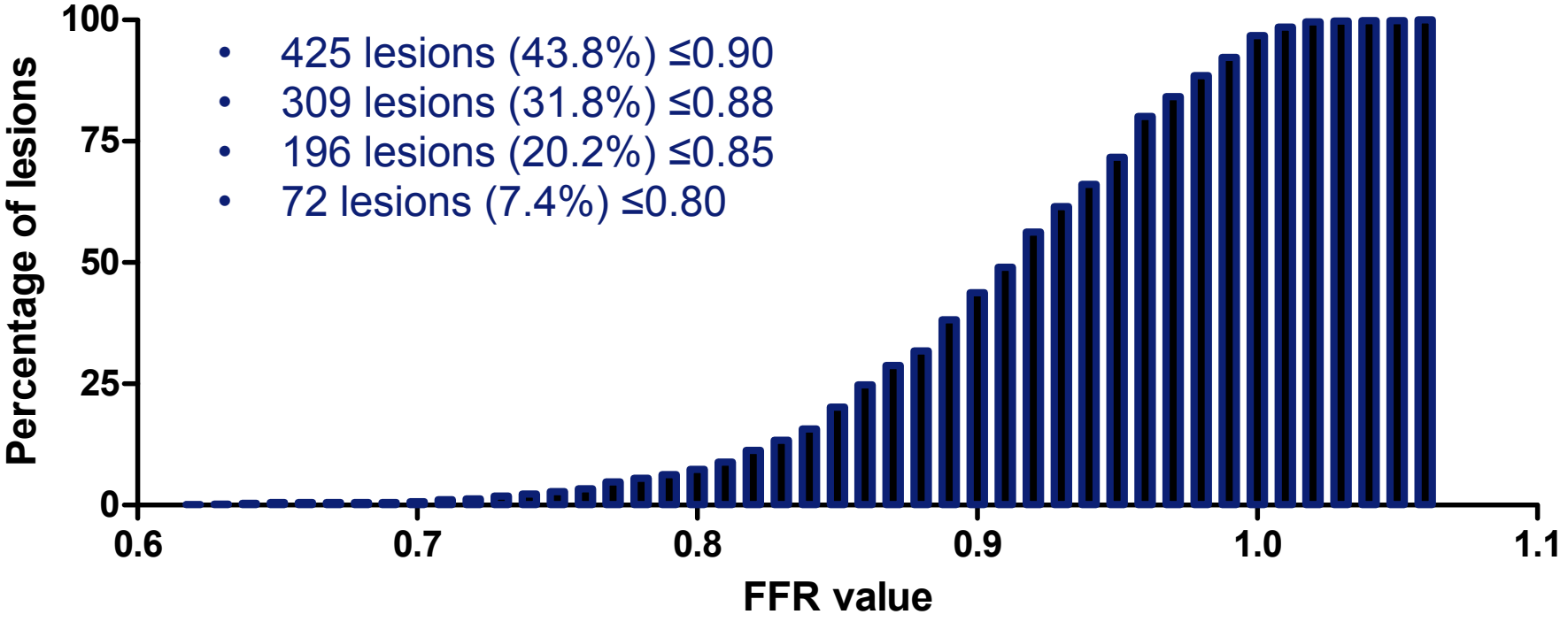
**805** patients with **971** measured lesions (1.2 lesions per patient)

- 386 patients (**48%**) with ≥1 lesion ≤0.90
- 285 patients (**35%**) with ≥1 lesion ≤0.88
- 186 patients (**23%**) with ≥1 lesion ≤0.85
- 69 patients (**8.6%**) with ≥1 lesion ≤0.80



# FFR-SEARCH Registry

## Preliminary results




Cumulative percentage per 0.01 FFR increment

**(all cases, N = 971 lesions)**

# FFR-SEARCH Registry

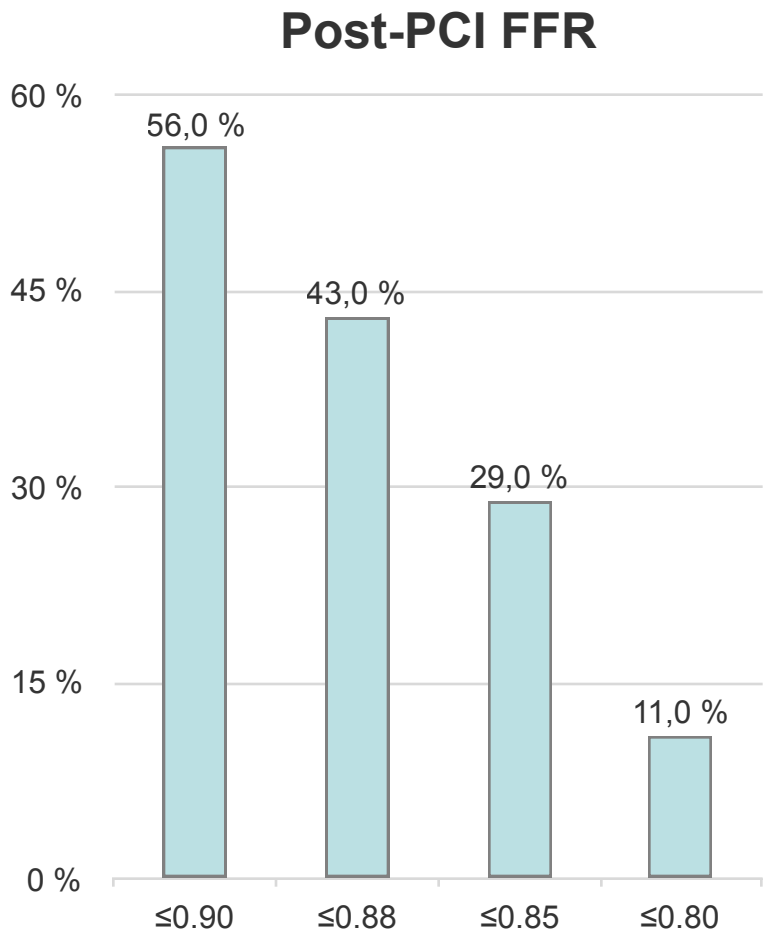
## Preliminary results

## Patient data

(excluded 263 STEMI patients [32%])

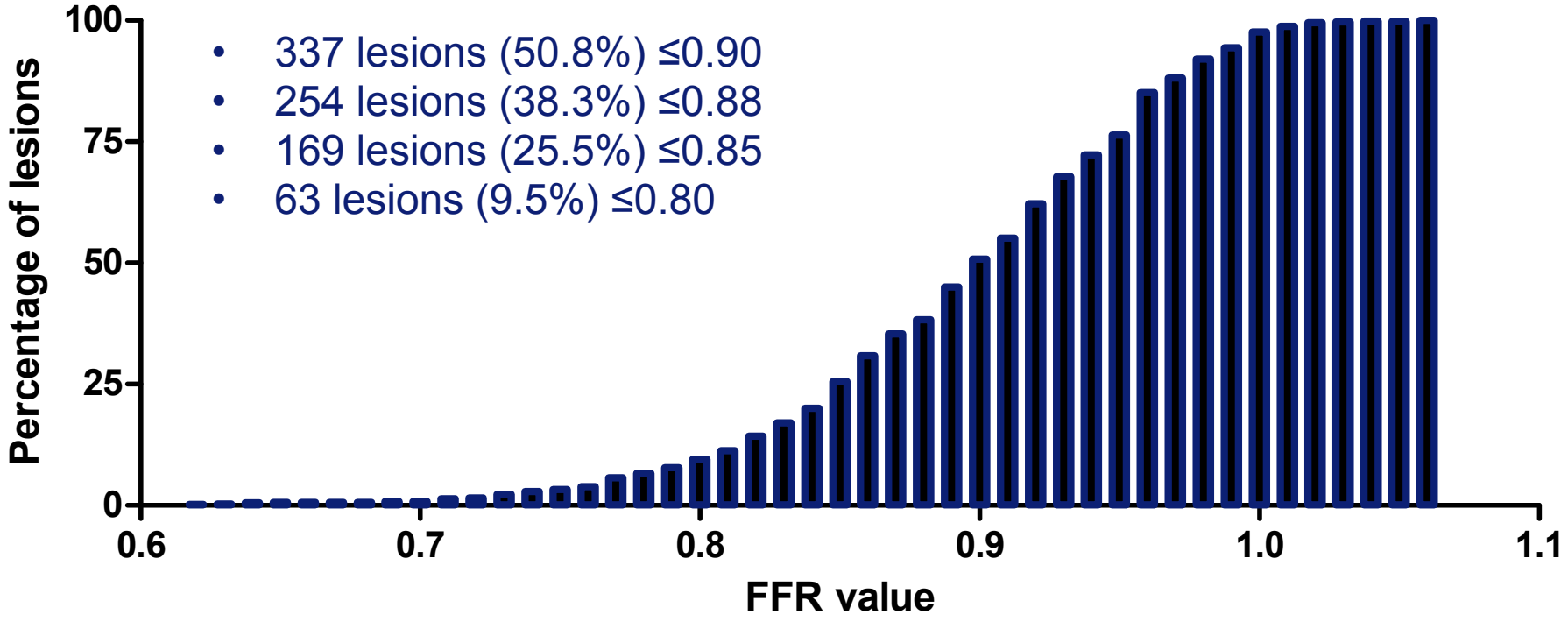
542 patients with 664 measured lesions (1.2 lesions per patients)

- 306 patients (56%) with ≥1 lesion ≤0.90
- 233 patients (43%) with ≥1 lesion ≤0.88
- 159 patients (29%) with ≥1 lesion ≤0.85
- 60 patients (11%) with ≥1 lesion ≤0.80



# FFR-SEARCH Registry

## Preliminary results

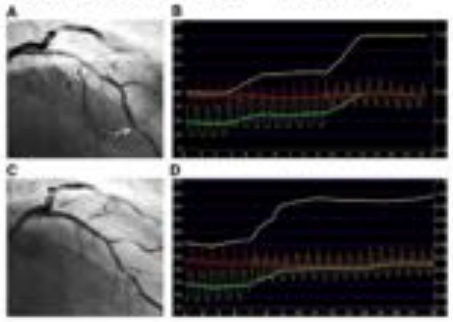



Cumulative percentage per 0.01 FFR increment

**(STEMI excluded, N = 664 lesions)**

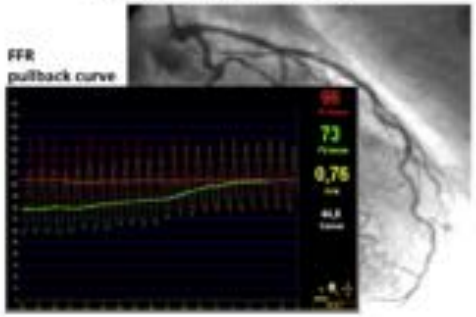
# Postulated Mechanisms: Low FFR after PCI

### *Unmasked 2nd lesion*



- Tandem or serial lesions
- Post-PCI FFR mandatory
- Largest gains in FFR

### *Diffuse disease*



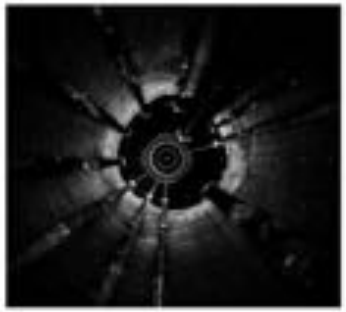

- Pre-PCI selection vital
- High risk post-PCI
- Untreatable with more PCI

Tonino and Johnson J Am Coll Cardiol Intv. 2016;9(10):1032-1035

### *Pressure drift*


- Technical artifact
- 10% incidence
- Re-equalize wire

### *Optimization necessary*



- Stent itself causes gradient
- Larger balloon, higher pressure
- Expect FFR gain of 0.05

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# FFR-SEARCH Registry

## IVUS subgroup

In patients with a post procedural FFR ≤0.85, intravascular high definition ultrasound analysis were performed at a pullback speed of 2.5 mm/sec at 60 MHz to identify potential reasons for a low post procedural FFR. Images were analyzed every 0.5 mm.

**Preliminary overall results:**

- Mean luminal area 5.99+/-1.33 $mm^2$
- Minimal lumen area 2.2+/-0.77 $mm^2$
- Minimum stent area 4.02+/-1.38 $mm^2$
- Significant focal lesions distal to stent 52%
- Significant focal lesion proximal to stent 43%
- Stent underexpansion 84%
- Stent malapposition 22%

# FFR-SEARCH Registry

## Clinical Evidence at Euro PCR

- 30-day outcomes for entire cohort
- Sub-analysis
  - DM vs. Non-DM patients
  - STEMI vs. Stable CAD
  - IVUS:  Low FFR may be addressed with additional stenting/stent optimization

# Post-PCI FFR Summary

- Evidence is growing that low FFR is not resolved in a significant proportion of current PCI's
- Post-PCI FFR is the largest single opportunity to increase Navvus revenue
- ACIST has an active collaboration with the Erasmus center to build evidence
- Major opportunity where ACIST technology could disproportionately capture market share



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