Coronary Angiography-Derived FFR

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship	Company
Grant/ Research Support:	**Abbott, Medtronic, Acist, CathWorks, Edwards LifeSciences**
Consulting Fees/Honoraria:	**Boston Scientific**
Major Stock Shareholder/Equity Interest:	
Royalty Income:	
Ownership/Founder:	
Salary:	
Intellectual Property Rights:	
Other Financial Benefit:	**Stock Options HeartFlow**

Why We Don't Perform FFR

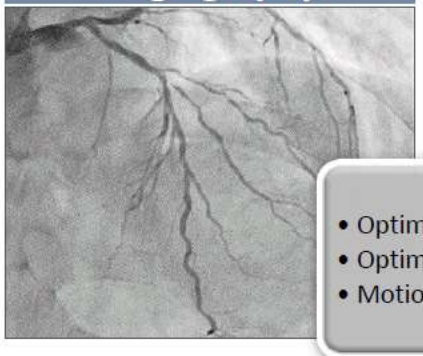
- $$$!!
- It takes time…
- Wire handling characteristics…
- Pressure drift is frustrating…
- Side effects of adenosine…
- It is expensive…
- There is a small risk…

Coronary Pressure Wire

Angiography-Derived FFR

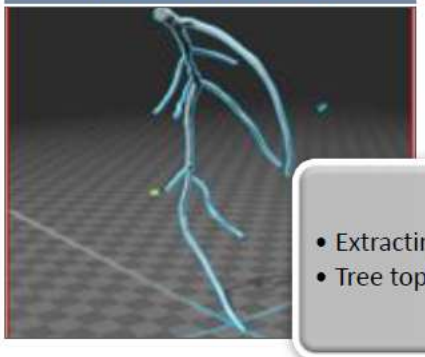
FFR$_{angio}$

1 **Optimal 2D Angiography**



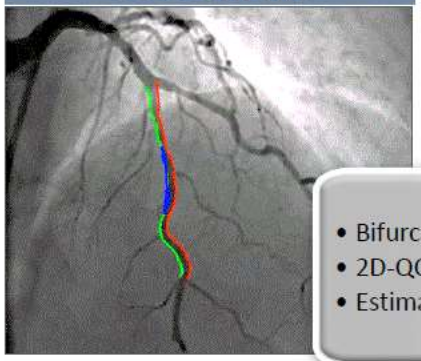
- Optimal projections
- Optimal Frame
- Motion compensator

2 **3D model reconstruction**



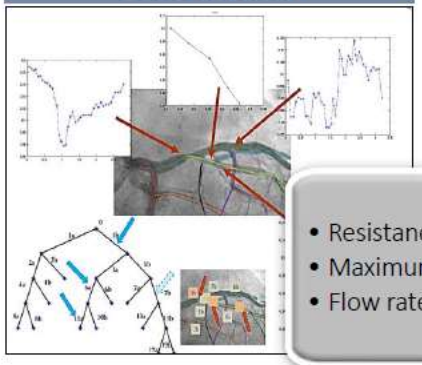
- Extracting centerlines
- Tree topology

3 **Stenosis assessment**



- Bifurcation analysis
- 2D-QCA assessment
- Estimating diameters

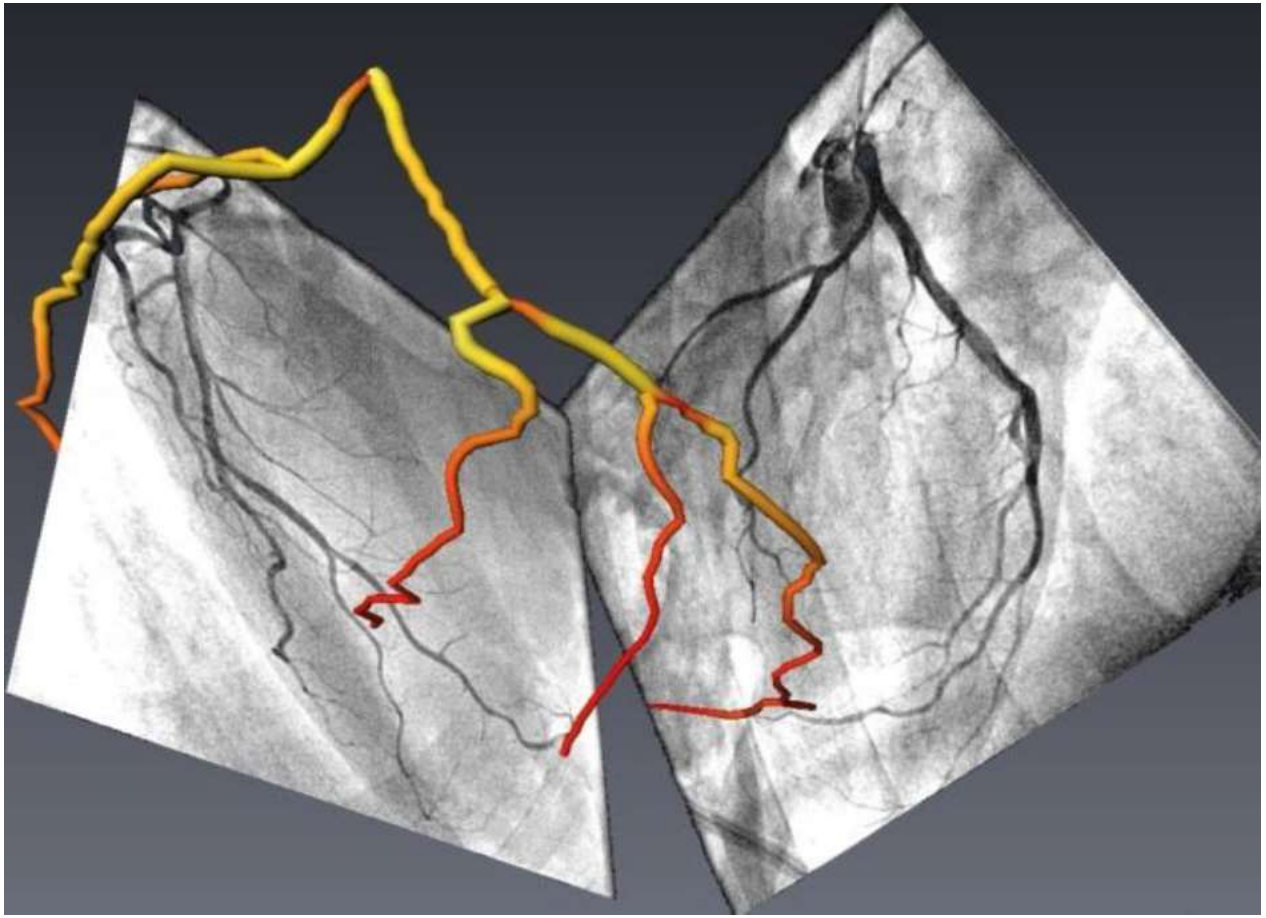
4 **Hemodynamic evaluation**



- Resistance mapping
- Maximum blood flow
- Flow rate ratio

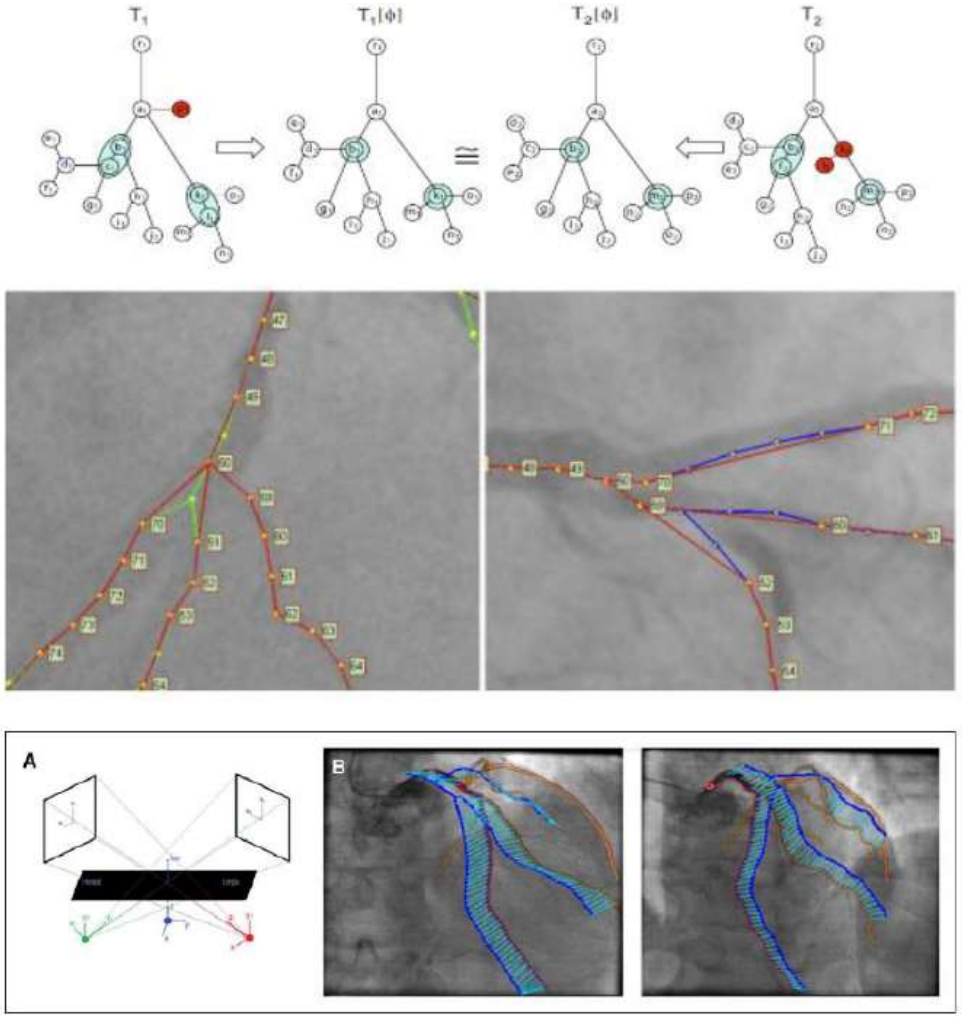
Courtesy of CathWorks

FFR_{angio}



Courtesy of CathWorks

FFR_{angio}

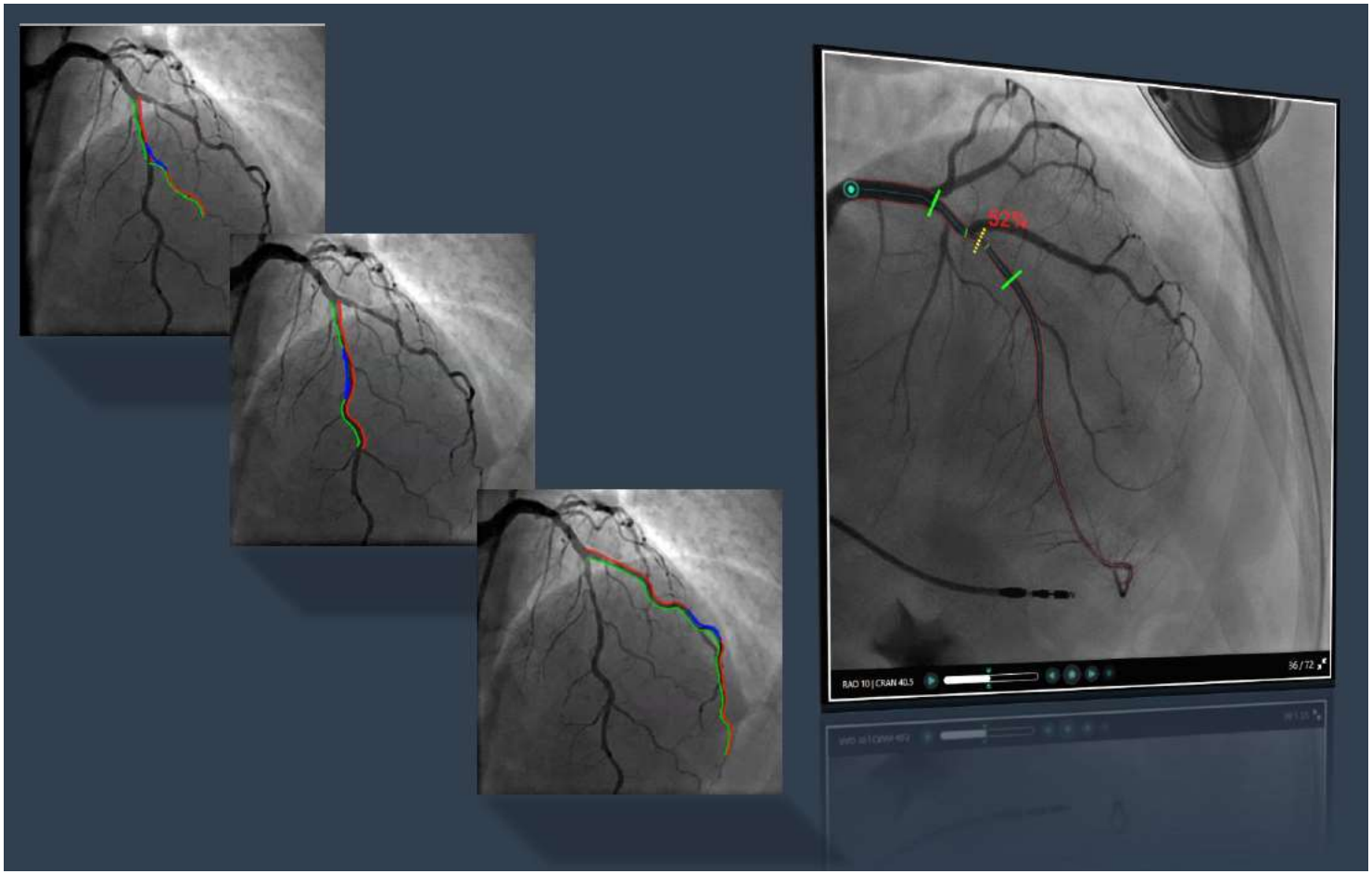


The 3D engine contains a compensation mechanism which uses all available projections to account for respiratory and cardiac motion and optimizes the 3D reconstruction.

Courtesy of CathWorks

FFR_{angio}

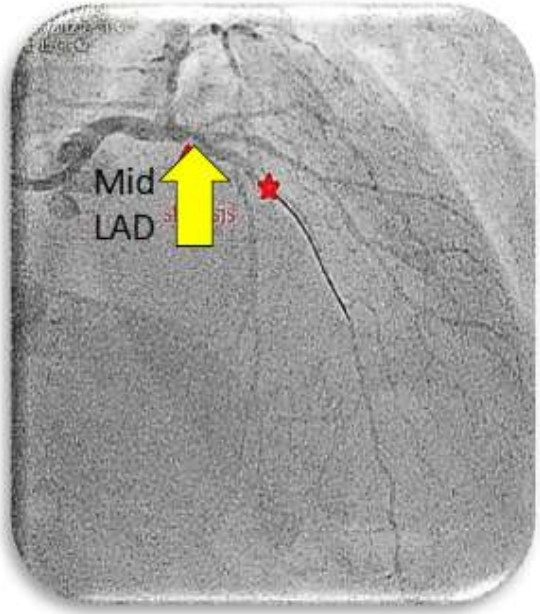
Automatic stenosis detection by scanning the entire 3D reconstruction

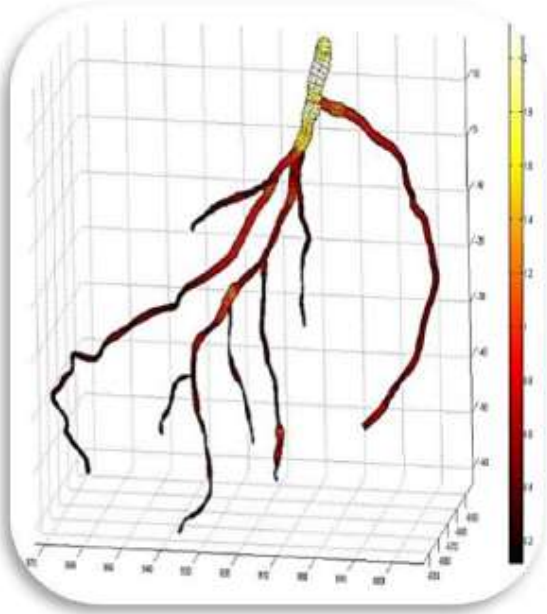


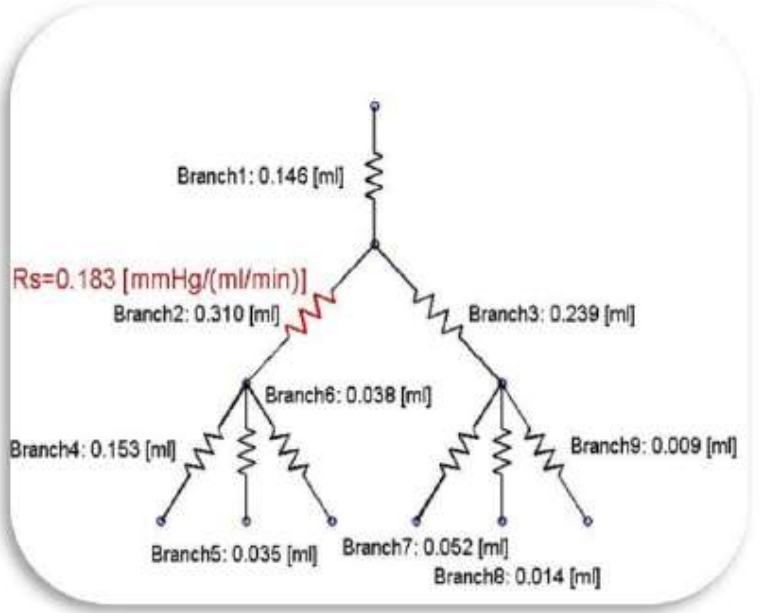
Courtesy of CathWorks

FFR_{angio}

The coronary arterial network is modeled as an electrical circuit with each segment acting as a resistor. The vessel resistance is estimated based on its length and diameter. Each vessel's contribution to flow is based on its impact on overall resistance depending on the arrangement.



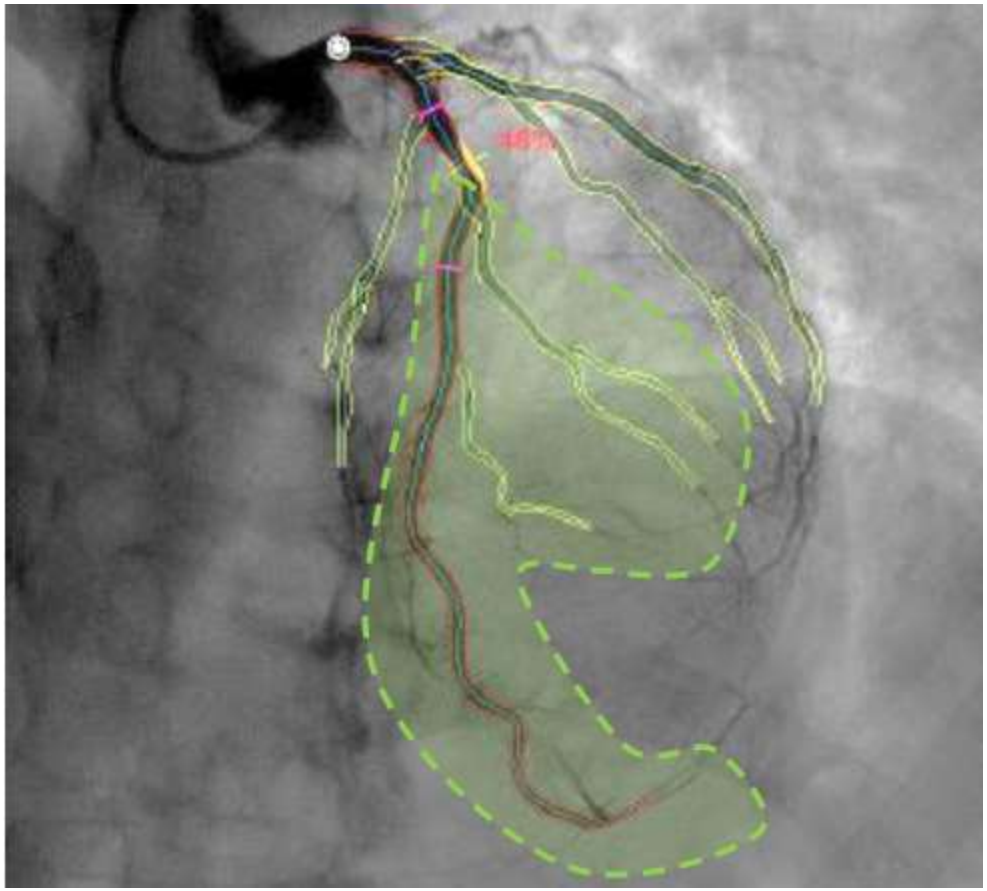




Courtesy of CathWorks

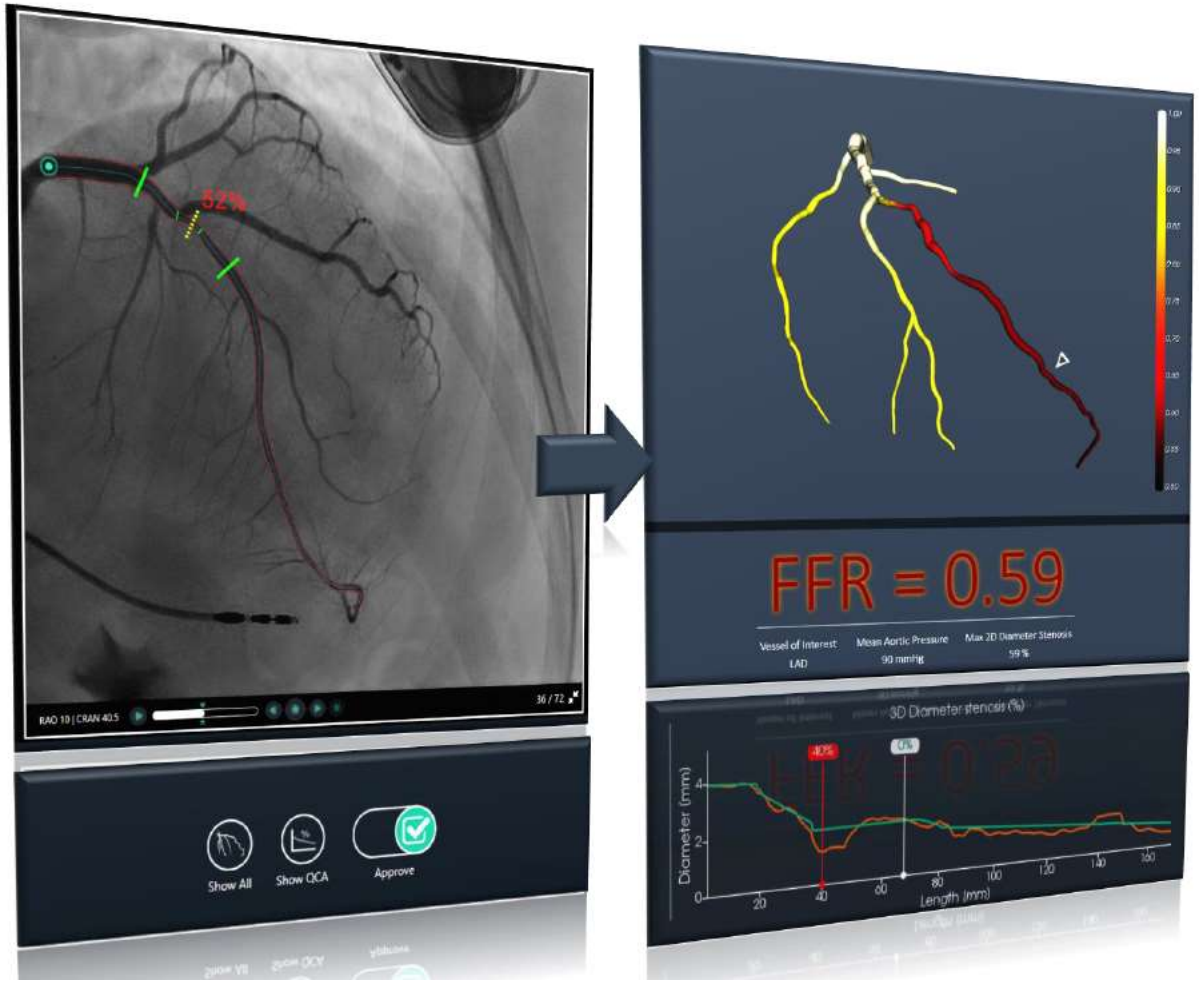
FFR_{angio}

Normal maximal flow is estimated based on the volume of coronary vessels and total coronary length.



Courtesy of CathWorks

FFR_{angio}



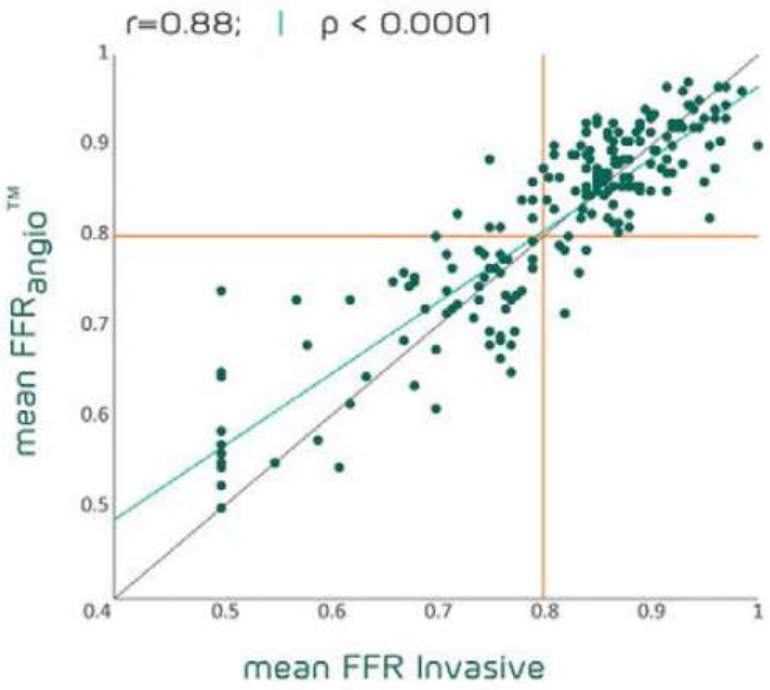
FFR_{angio} is then calculated as the ratio of the maximal flow rate in the stenosed artery compared with the flow rate in the absence of the stenosis:

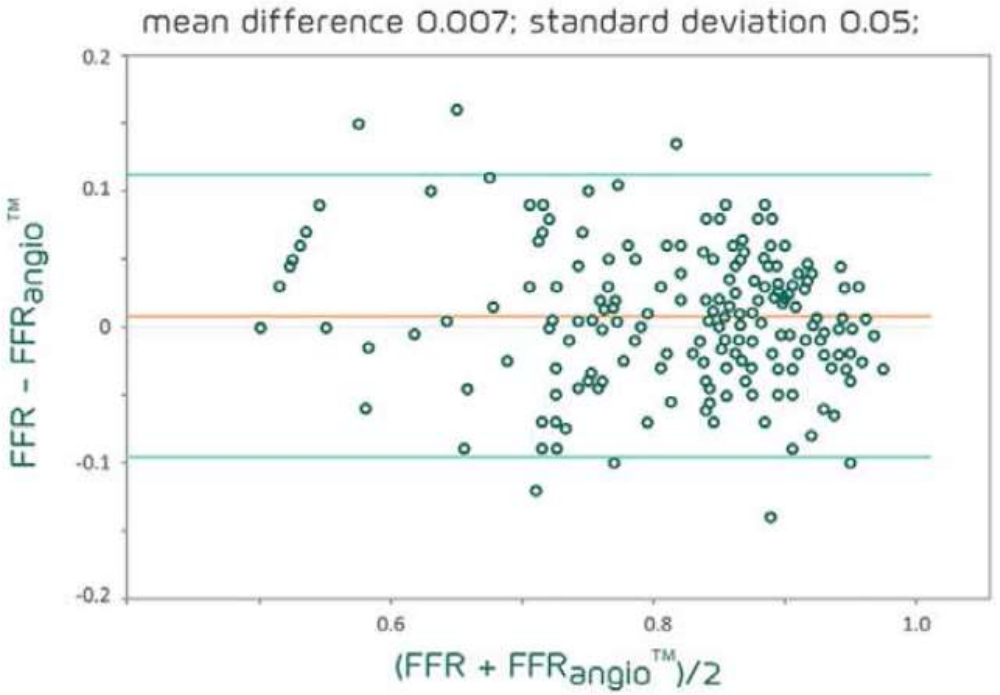
$$FFR_{angio} = Q_S / Q_N$$

Courtesy of CathWorks

FFR_{angio} Data

FFR_{angio} compared with invasive FFR in 203 lesions (184 patients)





Sensitivity, specificity and accuracy of FFR_{angio} was 88%, 95% and 93%

Pellicano, et al. Circ Cardiovasc Interv 2017;10:e005259.

FAST FFR Trial

FFR$_{angio}$ Accuracy versus STandard FFR

- Objective:
  - To estimate the efficacy of FFR$_{angio}$ compared with invasive FFR to diagnose significant coronary stenosis (≤0.80)

FAST FFR Trial

Inclusion Criteria

- Male or female, >18 years
- Stable or unstable angina, or NSTEMI.
- Undergoing invasive FFR with Adenosine.
- Provides written, informed consent (where required).

FAST FFR Trial

Exclusion Criteria

- Presenting with STEMI OR documented prior target vessel STEMI.
- Chronic total occlusion in target vessel.
- Prior CABG, heart transplant, severe aortic stenosis or valve surgery.
- Known LVEF ≤45%.

FAST FFR Trial

Angiographic Exclusion Criteria

- ≤TIMI 2.
- Left Main stenosis >50%.
- Recent stent in target vessel (12 mo) or in-stent restenosis.
- Severe, diffuse disease.
- Target vessel supplied by major collaterals.
- Coronary angiogram not acquired per instructions.

FAST FFR Trial Design

SA, UA, NSTEMI patients will be screened

↓

FFR of ≥ 1 lesion as part of standard care

↓

3 roll-in patients / site

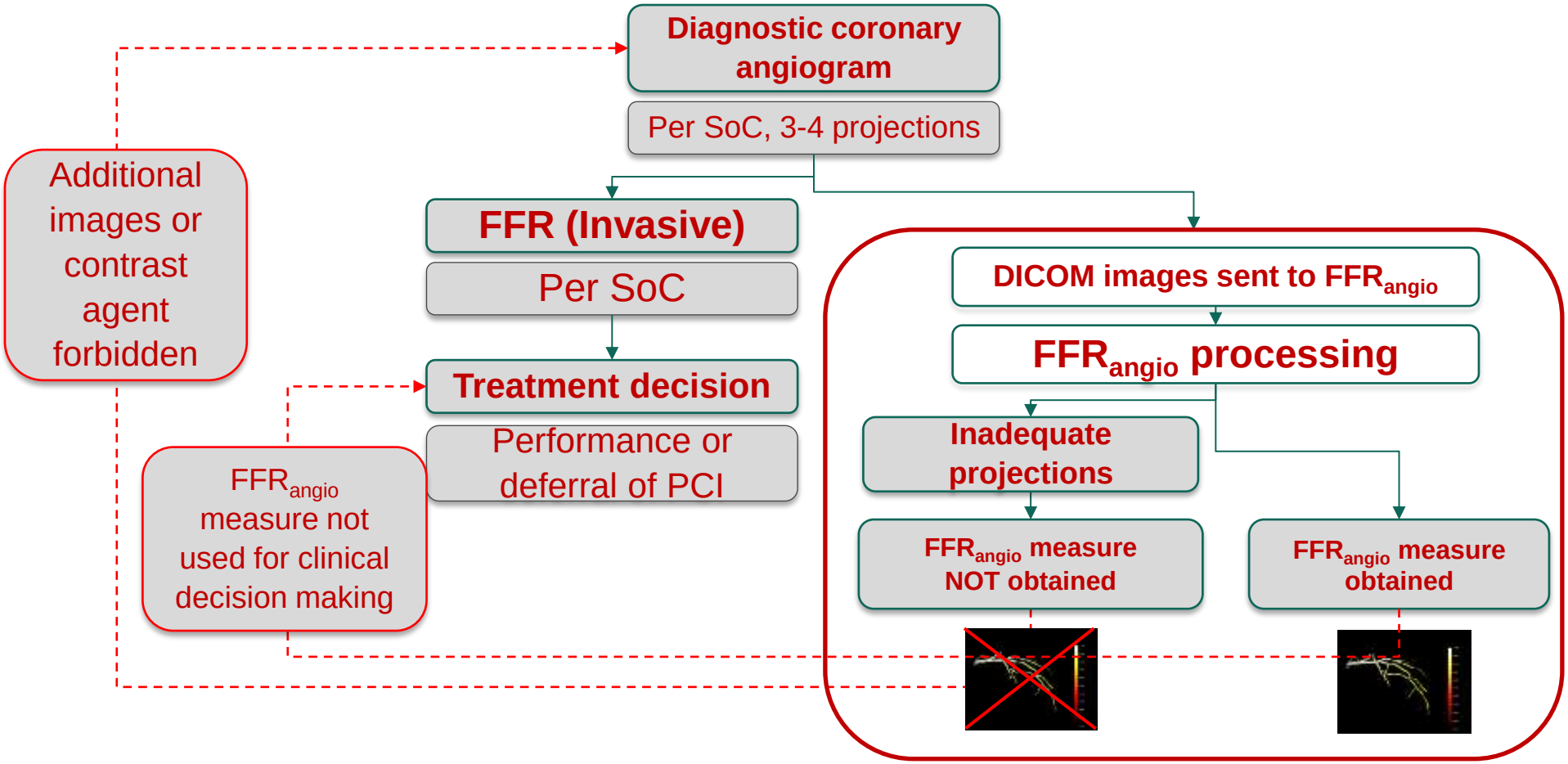
350 study patients

386 patients in total, max 95/site

↓

Simultaneous blinded FFR_{angio}

FAST FFR Trial Flow



FAST FFR Trial Endpoints

Primary Endpoint

- Lower bound of the 95% CI of the sensitivity and specificity for dichotomously scored FFR_{angio} measured index per vessel as compared with invasively-derived FFR.

- Performance goal for sensitivity = 0.70

- Performance goal for specificity = 0.75

FAST FFR Trial Endpoints

Secondary Endpoint

- Sensitivity and specificity of site-reported invasively-derived FFR
- Device Success
- Usability of the FFR_{angio} system.
- Procedure and device related AEs and SAEs.

FAST FFR Trial

Enrolment

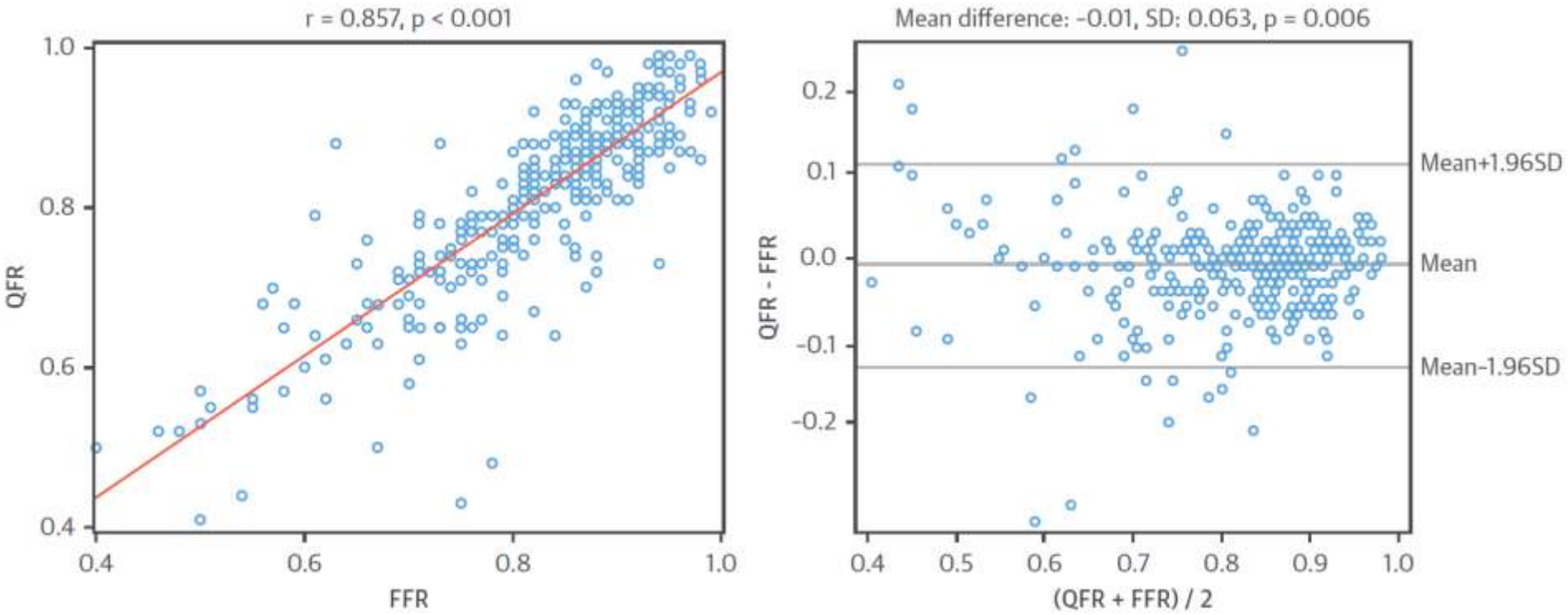
PI	Site name	Country	Enrollment
Abid Assali	Rabin Medical Center	Israel	47
Thomas Engstrøm	Rigshospitalet	Denmark	47
Allen Jeremias	St. Francis Hospital	USA	35
Stéphane Fournier	OLV Aalst	Belgium	26
Bill Fearon	Stanford University	USA	25
Stephan Achenbach	University of Erlangen	Germany	23
Ajay Kirtane	Columbia University	USA	20
Gabriel Greenberg	HaSharon Medical Center	Israel	10
Rami Jubeh	Shaare Zedek Medical Center	Israel	10
Daniel Kolansky	University of Penn	USA	8
Total enrollment			251

FFR_{angio} Case Examples

FFR_{angio} Case Examples

Other Angiography-Derived FFR

Quantitative Flow Ratio (QFR) compared with invasive FFR in 328 lesions

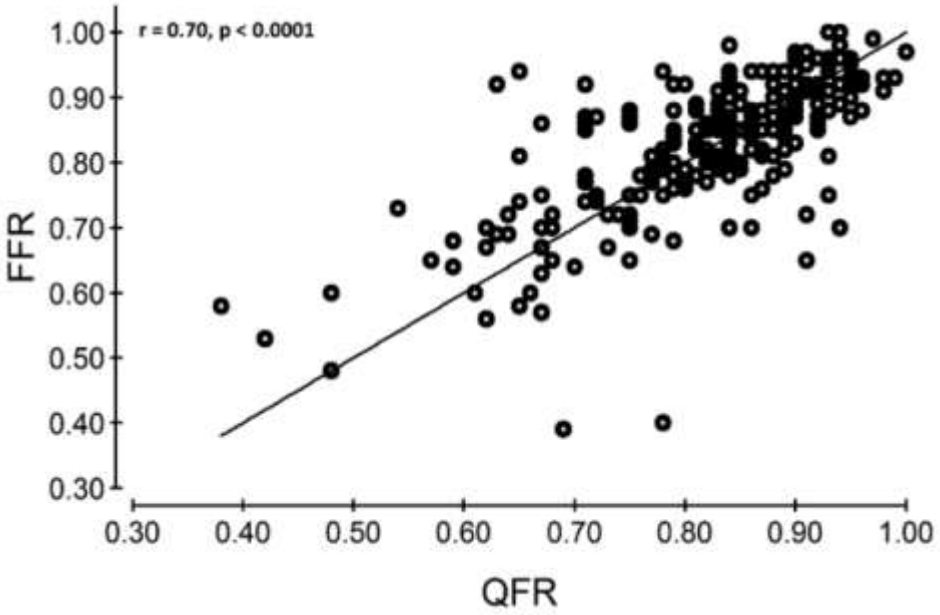


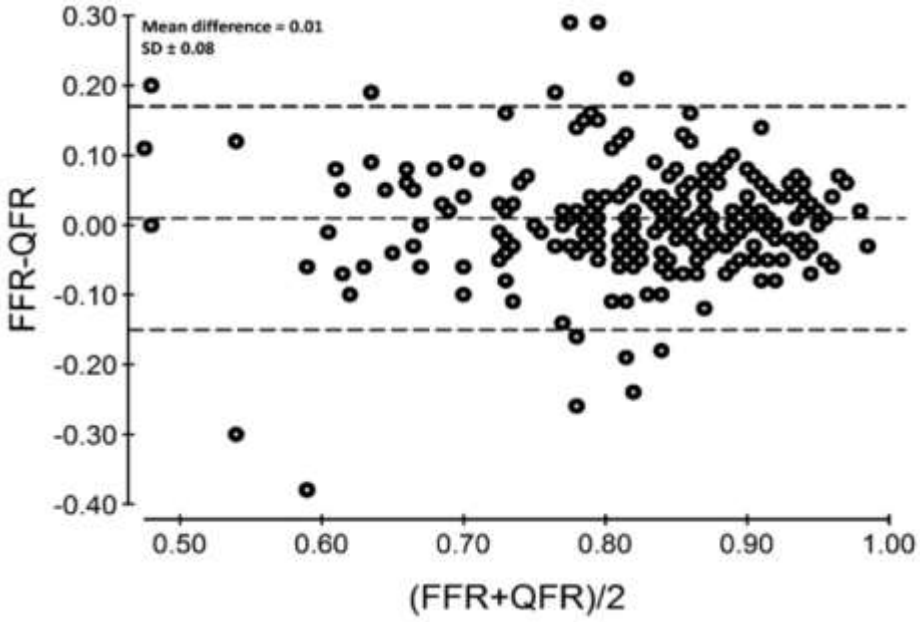
Sensitivity, specificity and accuracy of QFR was 95%, 92% and 93%

Xu, et al. J Am Coll Cardiol 2017;70:3077-87.

Other Angiography-Derived FFR

Quantitative Flow Ratio (QFR) compared with invasive FFR in 255 lesions



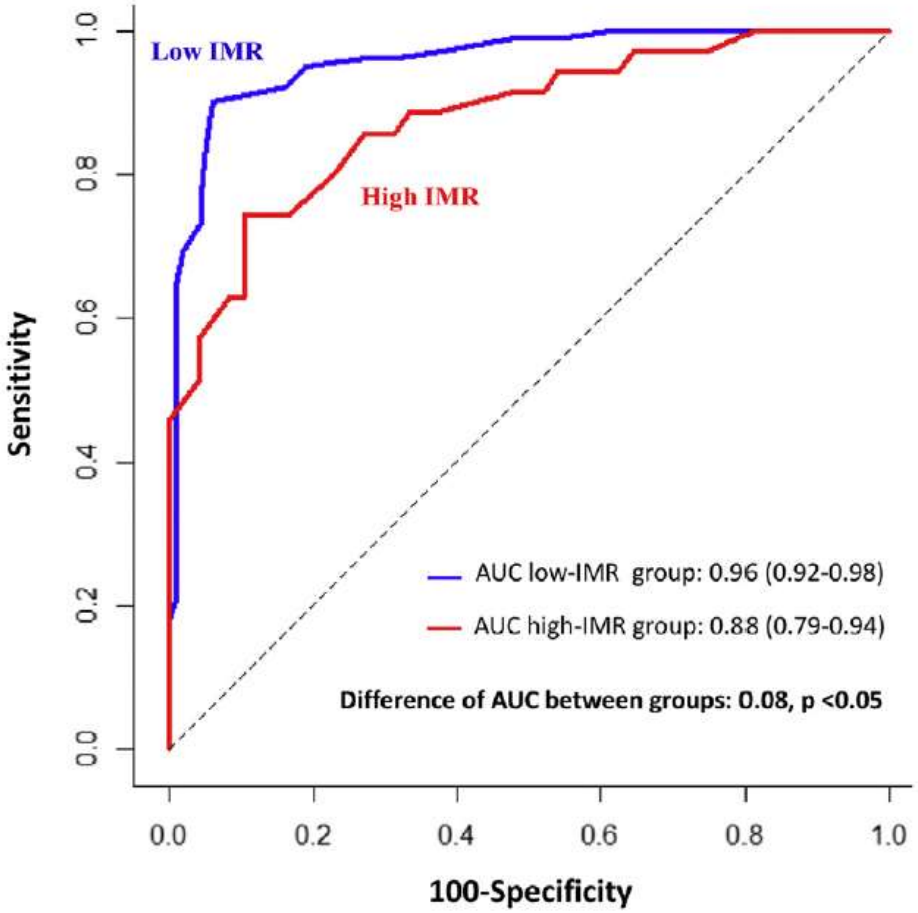


Sensitivity, specificity and accuracy of QFR was 77%, 86% and 83%

Westra, et al. Circ Cardiovasc Imaging 2018;11:e007107.

Other Angiography-Derived FFR

FFR and IMR measured in 300 vessels and compared with QFR



Accuracy of QFR was significantly lower in vessels with microvascular dysfunction based on a high IMR (76 vs 92%, p<0.001).

Mejia-Renteria, et al. J Am Coll Cardiol Intv 2018;11:741-53.

Conclusion

- Angiography-derived FFR is a promising new technique for diagnosing functionally significant coronary disease.
- It simplifies physiologic lesion assessment and may increase physiology-guided revascularization.
- This will require further study demonstrating improved outcomes with its use.