Invasive coronary diagnostics: research tools or clinically relevant ?

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Invasive coronary diagnostics:
research tools or clinically relevant ?

FFR

IVUS

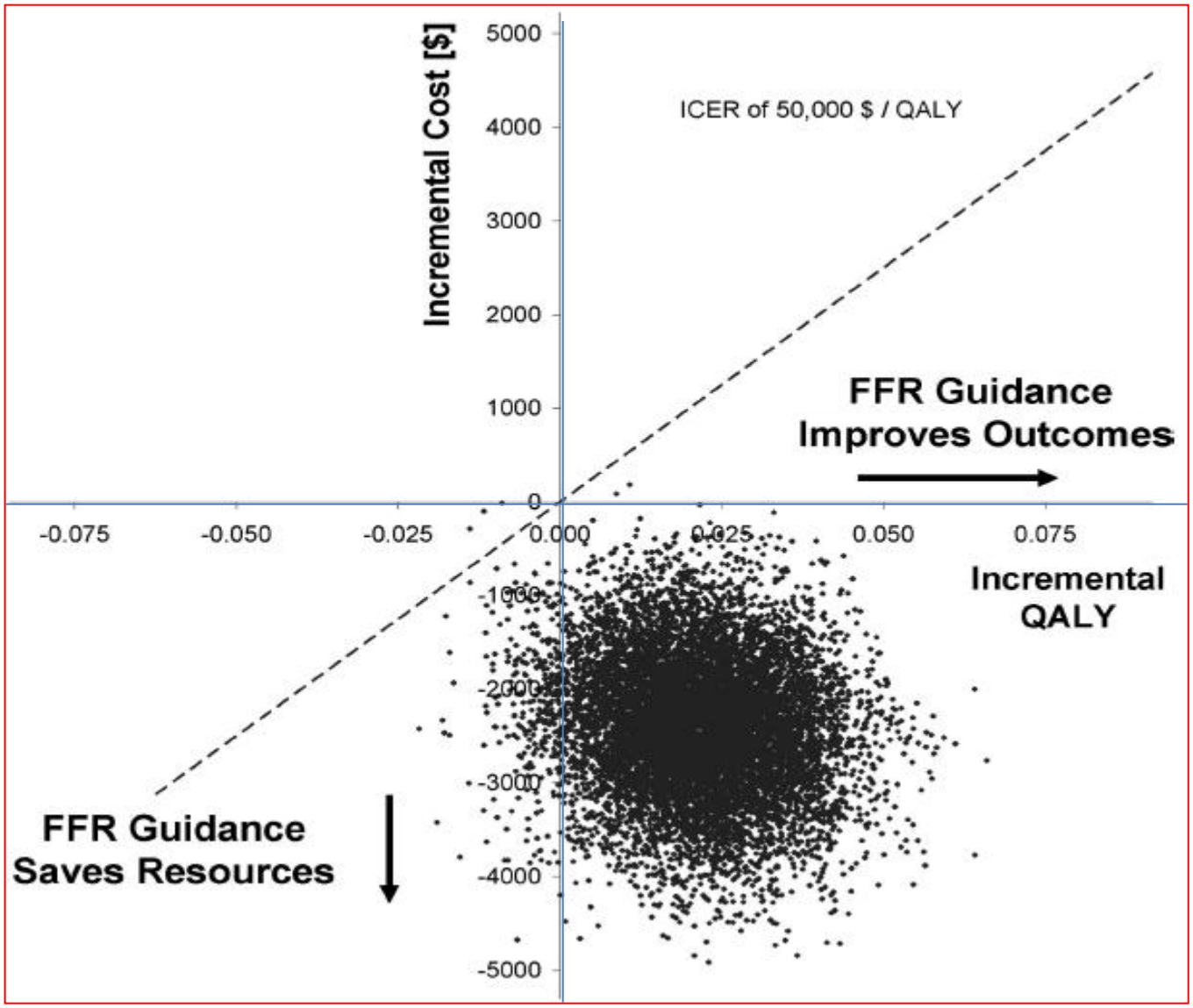
OCT

Clinically relevant =
with demonstrated impact on clinical outcome
(hards events, by evidence-based standards)

Outcome based validation studies for FFR

1.	**Intermediate stenoses**	*Pijls*	*New Engl J Med 1996*
		Bech	*Circulation 2001*
		Pijls	*JACC 2010*
2.	**Post-myocardial setting**	*De Bruyne*	*Circulation 2001*
		Ntalianis	*JACCInterv 2010*
3.	**Multivessel disease**	*Tonino*	*New Engl J Med 2009*
		Berger	*JACC 2005*
		Botman	*CCI 2004*
		De Bruyne	*The Lancet 2012*
4.	**Left main stenosis**	*Hamilos*	*Circulation 2009*
5.	**Proximal LAD stenosis**	*Muller*	*JACCInterv 2011*
6.	**Bifurcation lesions**	*Koo*	*Eur Heart J 2010*
7.	**Hybrid Revascularization**	*Davidavicius*	*Circulation 2005*
8.	**Post CABG**	*Botman*	*Ann Thor Surg 2007*

FFR is disruptive by HTA standards (FAME trial)



www.cardio-aalst.be

FDA, Washington, Sept 12, 2011

Fearon WJ et al Circulation 2010

Invasive coronary diagnostics:
research tools or clinically relevant ?

FFR I A

IVUS IIb C (left main)

OCT

Clinically relevant =
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Why did IVUS fail to become a clinically useful tool?

- Used as an add-on technology, when only disruptive new invasive diagnostic tools eventually succeed
- Studies were shooting for the wrong endpoint, restenosis reduction, without offering a solution to this non naturally occuring disease
- IVUS studies are typically poor, small sized, observational, “cheap”
- Images are difficult to read & interpret (expert reading required)
- No robust link between IVUS information and practice nor outcome
- High cost, low return

Should the value of IVUS be upgraded?

New meta-analysis favors IVUS-guidance over angiography-guidance for PCI with DES

	Hazard ratio	95% CI
Death	0.59	0.48 - 0.73
Stent thrombosis	0.58	0.44 - 0.77
MACE	0.87	0.78 - 0.96

11 studies (10 observational, 1 randomised trial of 210 patients)
19.517 patients (8.102 IVUS guidance, 11.517 angiography)
Baseline differences for relevant variables (age, gender, CKD, …)
Variable event definitions and follow-up duration (12-48 months)

Zgang et al EuroIntervention 2012;8.855-65

Invasive coronary diagnostics: **clinically relevant ?**

FFR	**++**	**I**	**A**
IVUS	no, with exceptions	**IIb**	**C**
OCT	still to be determined	**?**	

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STATE-OF-THE-ART PAPER

Intracoronary Optical Coherence Tomography: A Comprehensive Review

Clinical and Research Applications

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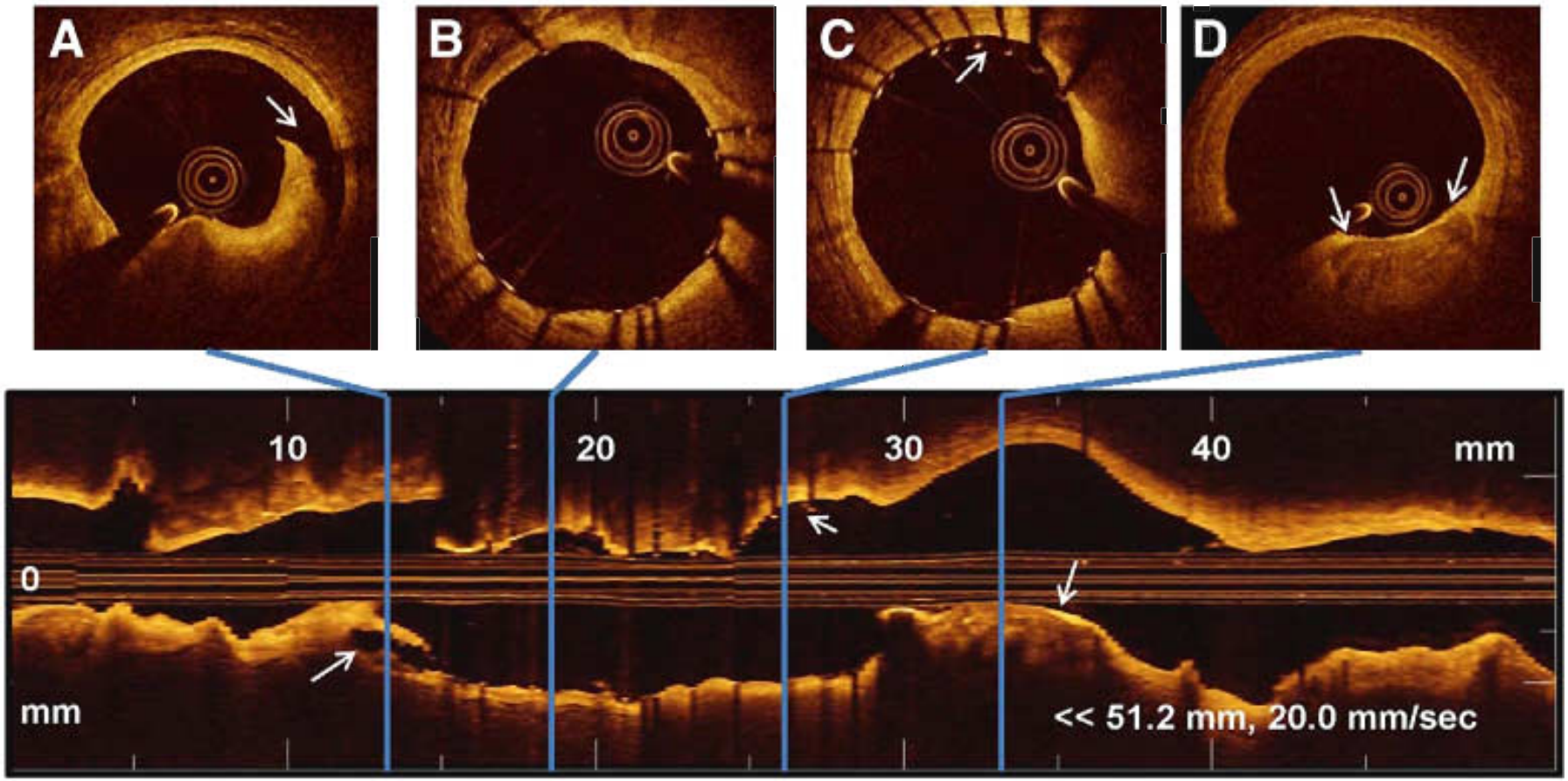


Will OCT become another IVUS: a great research tool with limited clinical relevance ?

- OCT imaging provides high resolution information regarding coronary anatomy and the effects of mechanical and pharmacological therapies

- Are abnormal OCT findings
  - Unique ?
  - Frequent ?
  - Potentially relevant ?

CLI-OPCI Study: OCT findings

	Angiographic plus optical coherence tomography guidance group (N=335)
Number of vessels assessed with OCT	
1	**79.4 %**
2	**19.4 %**
3	**1.2 %**
OCT on left anterior descending	**50.7 %**
OCT pullbacks	**3.8 ±1.7**
OCT findings	
Edge dissection	**14.2 %**
Lumen narrowing	**2.8 %**
Stent malapposition	**29.7 %**
Stent underexpansion	**11.4 %**
Thrombus	**22.0 %**
Further intervention after OCT	**34.7 %**

Prati et al EuroIntervention 2012;8:823-9

CLI-OPCI Study

- Angiography alone versus angiography + OCT to guide decision-making during PCI: impact on 1 year outcome
- A total of 670 patients were included: 335 in the OCT group and 335 in the angiography group (matched from database)

N events at 1 y (%)	Angio guidance	Angio + OCT
Death	23 (6.9)	11 (3.3)
Cardiac death	15 (4.5)	4 (1.2)
Cardiac death or MI	43 (13.0)	22 (6.6)

Prati et al EuroIntervention 2012;8:823-9

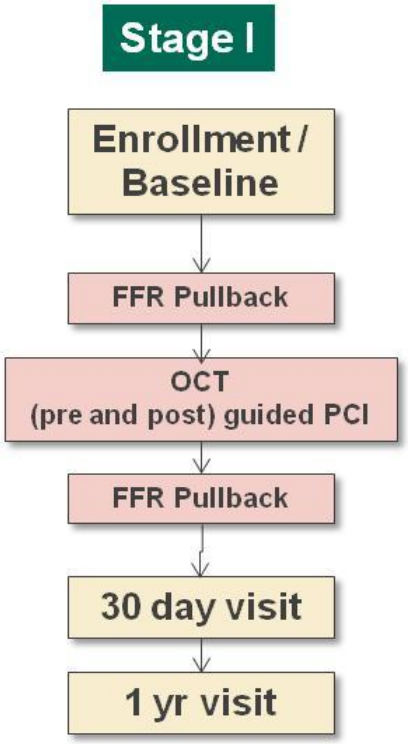
Will OCT become another IVUS: a great research tool with limited clinical relevance ?

- OCT imaging provides high resolution information regarding coronary anatomy and the effects of mechanical and pharmacological therapies with suggested clinical impact
- FFR identifies appropriate targets with improved outcomes and cost savings
- HYPOTHESIS: Use of FFR and OCT in synergy during PCI will lead to optimised care of CAD pts

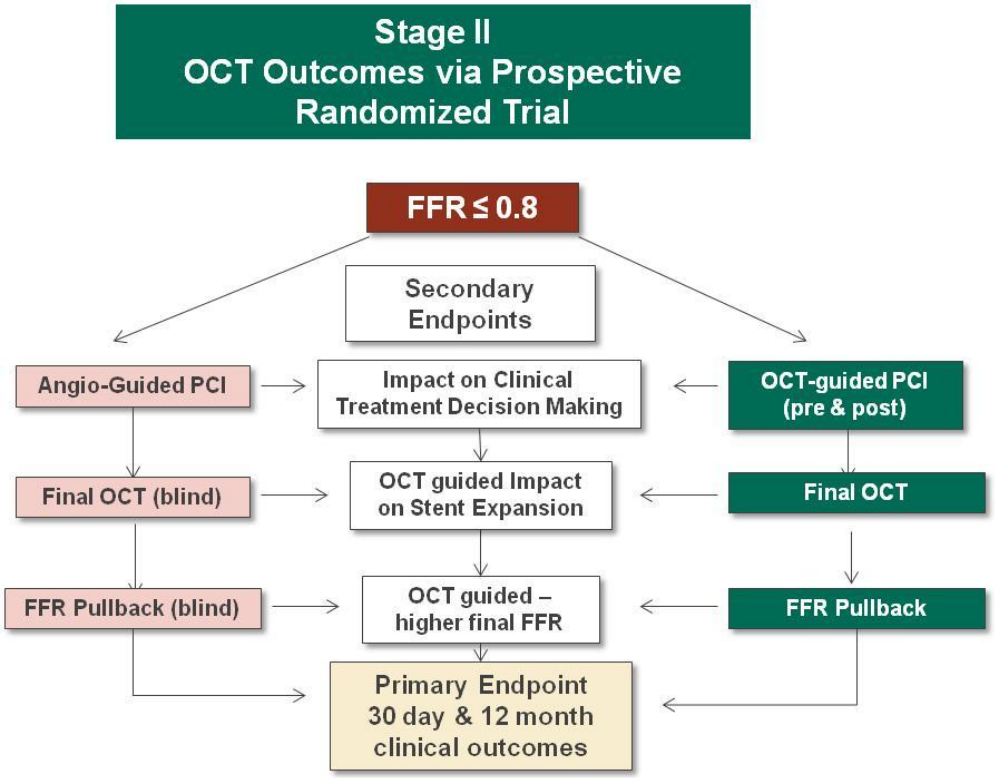
ILUMIEN I Protocol Synopsis	
Title	Observational Study of OCT in Patients Undergoing FFR and PCI: Stage I
Purpose	To define and evaluate OCT stent guidance parameters through the prospective data collection of PCI procedures of de novo lesions
Primary Objective	To identify OCT peri-procedural guidance parameters for stent implantation that relate with patient outcomes in the hospital, at 30 days, and 12 months
Secondary Objectives	1. Assessment of OCT impact on physician decision-making post PCI 2. Correlation / relationship of OCT parameters, as defined by OCT volumetric analysis, on pre- and post- intervention FFR values 3. Assess health economic and resource utilization impact
Design	Multi-center, prospective, global observational evaluation • Approximately 40 centers (EU, Asia, US) • Up to 500 subjects (max 50 subjects per site)
Follow-up	Hospitalization / Discharge, 30 days, 6 months, 12 months • In geographies where longitudinal OCT imaging is routinely performed, the data from that visit will also be collected.

ILUMIEN TRIAL PROGRAMME (world wide)

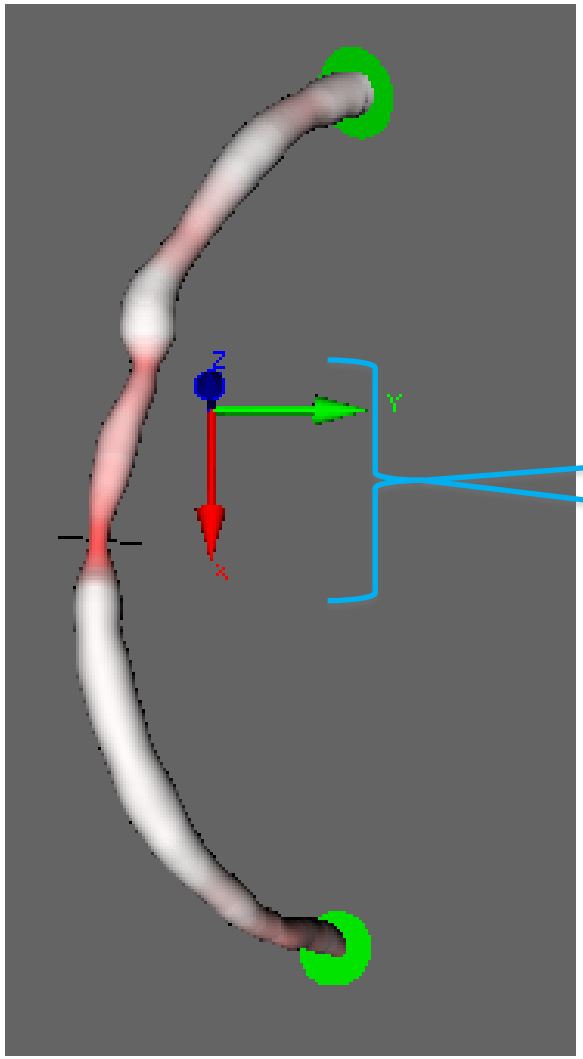
Stage 1 Observational: 2012
To determine *acute, OCT guidance parameters* through a prospective, multi-center study

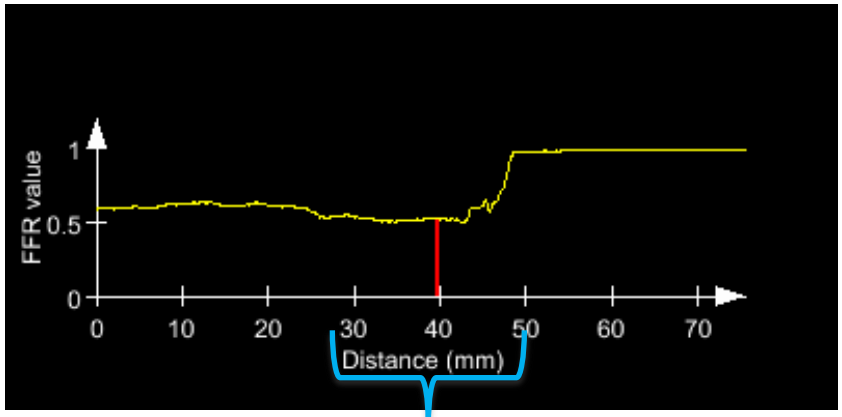


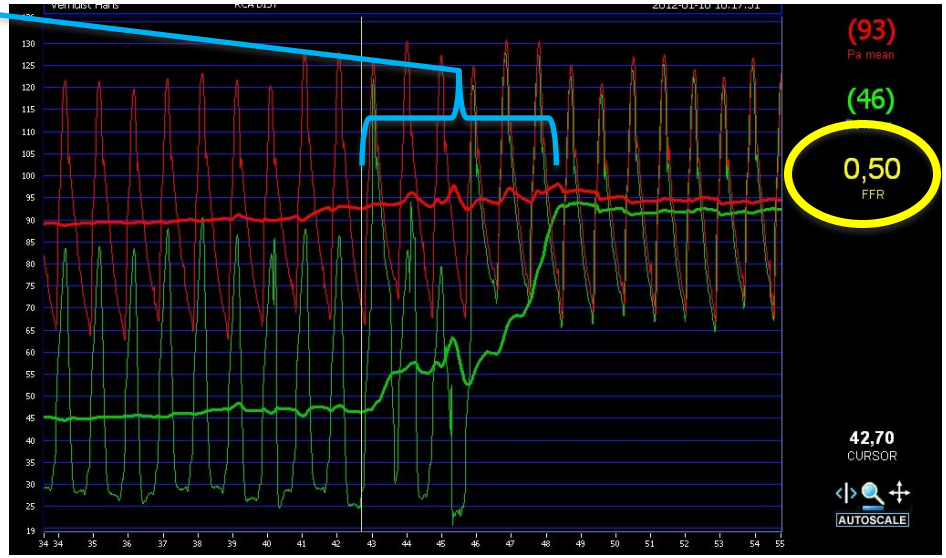
Stage 2 RCT: 2014
To test findings from stage 1 through a randomized, clinical trial, both acutely and at 12 month follow-up

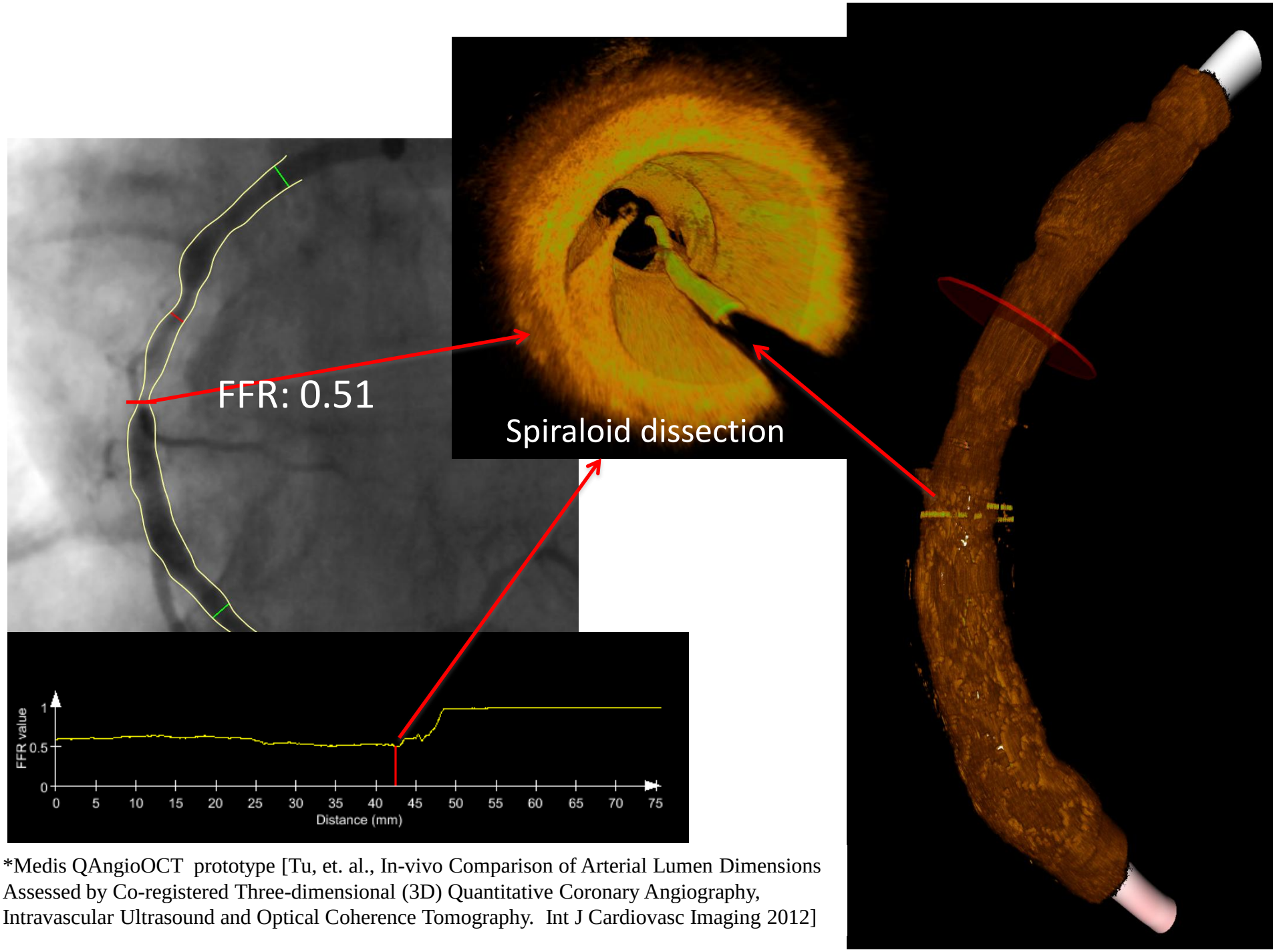


Exact localisation of the site where FFR jumps



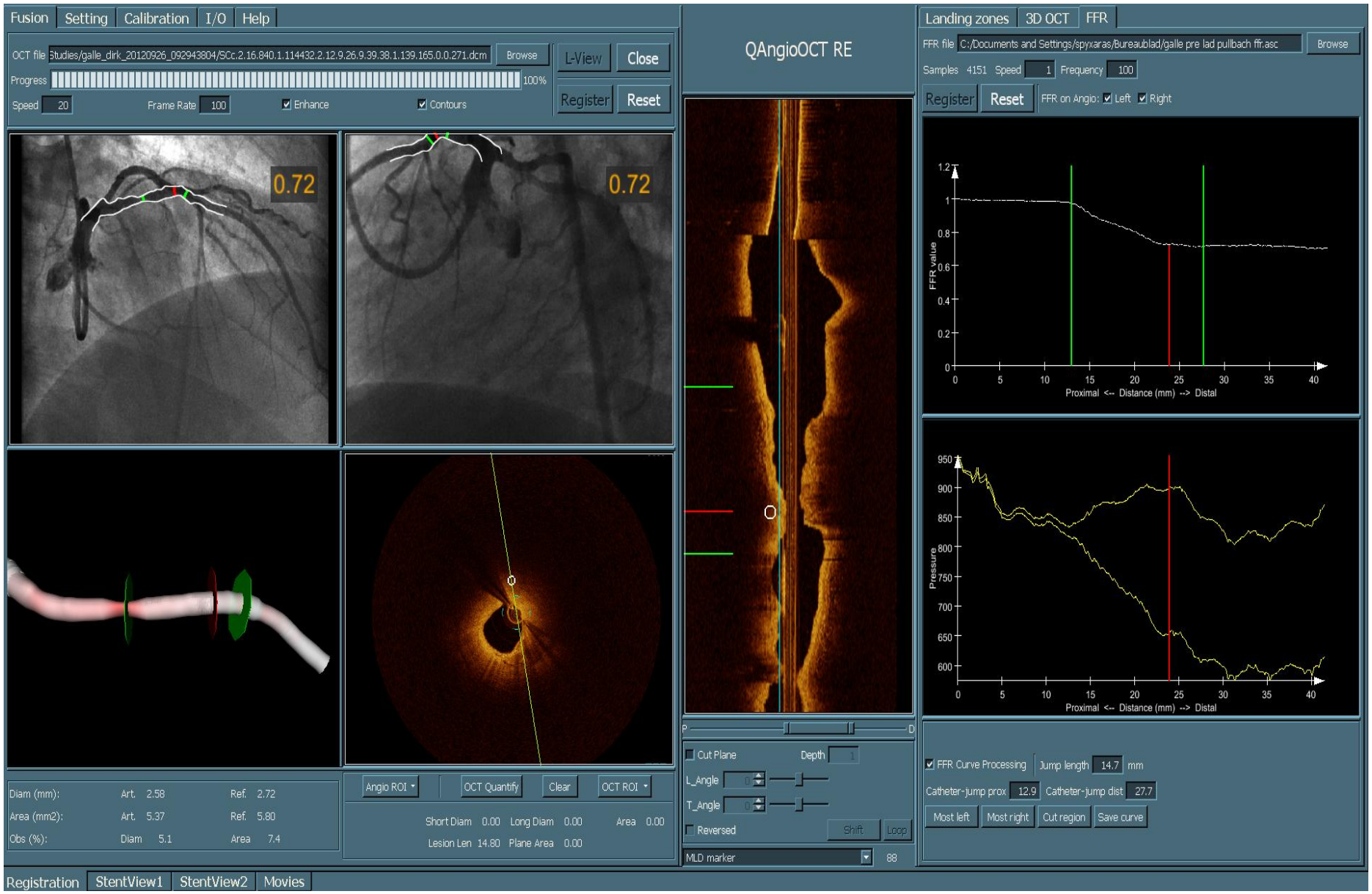






*Medis QAngioOCT prototype [Tu, et. al., In-vivo Comparison of Arterial Lumen Dimensions Assessed by Co-registered Three-dimensional (3D) Quantitative Coronary Angiography, Intravascular Ultrasound and Optical Coherence Tomography. Int J Cardiovasc Imaging 2012]

Co-registration prior to bioerodable scaffold implant



Take-Home Message

- OCT, a superior invasive imaging tool, is being tested for clinical relevance
- We hypothesize that PCI outcome in complex lesions and high-risk patients can be further optimised with integrated FFR and OCT (the former pays for the latter)
- Adoption of novel invasive imaging will likely be highly variable depending on local health care systems and regulatory environments

Potential conflicts of interest

Speaker's name: William Wijns, Cardiovascular Center Aalst, B

☐ **I have the following** potential conflicts of interest to report:

- ☐ Institutional research contracts with several device and pharmaceutical companies including St Jude Medical
- ☐ Cardiovascular Center Aalst founded Cardio^{3}Biosciences
- ☐ Other(s): Chairman of (Euro)PCR