The FAME Study

Two-year Results

St. Jude Medical™

More control. Less risk.

We Aspire to Have Fractional Flow Reserve (FFR) Measurement Become the Standard of Care in Cath Labs Around the World.

Radi Medical Systems, now a part of St. Jude Medical, Inc., pioneered the development of FFR, which resulted in the market-leading device PressureWire™ and put us at the forefront of FFR Technology. It is our commitment to build on this foundation and develop solutions that reduce risk and improve patient outcomes.

St. Jude Medical's PressureWire™ Certus was the exclusive FFR measurement system used in the FAME[1] (Fractional flow reserve vs. Angiography in Multivessel Evaluation) Clinical Study. The one-year results, published in *The New England Journal of Medicine* in January 2009, validated PressureWire's clinical benefits by establishing that, compared to angiography alone, FFR measurement significantly reduces major adverse coronary events, is cost-saving and does not increase procedure time.

FAME Study Methods

- *Randomized, prospective study – angiography only or angiography plus FFR*
- *20 centers in Europe and U.S.*
- *1,005 PCI patients undergoing DES stenting for multivessel disease*

PressureWire™

The PressureWire FFR measurement systems provide reliable and complete FFR measurements for improved diagnostic accuracy compared to image-based techniques such as angiography or IVUS.

PressureWire is currently available in a stand-alone configuration or integrated with selected hemodynamic recording systems.

PressureWire Aeris
Wireless FFR Measurement System

PressureWire Certus
FFR Measurement System

FAME STUDY TWO-YEAR RESULTS

The FAME two-year results, presented at TCT 2009, affirm the advantages of using FFR to guide multivessel intervention. FFR-guided PCI significantly improves patient outcomes and results in reduced procedural and healthcare costs, without prolonging the cath lab procedure, compared to angiography alone.

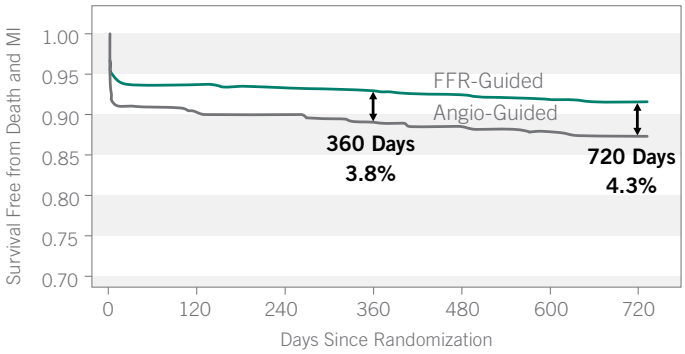
Outcomes

- reduced mortality and myocardial infarction at two years by 34%
- reduced MI at two years by 37%
- cost-saving and does not prolong procedure time
- decreased amount of contrast agent used

Improved Outcomes at Lower Costs

Bootstrap simulation indicated that the FFR-guided strategy was cost-saving in 99.8% and cost-effective in all 1,000 scenarios.

Two-year Survival Free of Death/MI



Procedural Characteristics

	ANGIO-Group N=496	FFR-Group N=509	P-Value
DES per Patient, No.	2.7 ± 1.2	1.9 ± 1.3	< 0.001
Procedure Time, Min.	70 ± 44	71 ± 43	0.51
Contrast Agent Used, ML	302 ± 127	272 ± 133	< 0.001
Materials Used at Procedure, Mean USD	6007 ± 2819	5332 ± 3261	< 0.001
Length of Hospital Stay, Days	3.7 ± 3.5	3.4 ± 3.3	0.05

One-year Results

	ANGIO-Group N=496	FFR-Group N=509
Incremental Health Costs, USD[2]	14357	12291

Two-year Results, No. (%)

	ANGIO-Group N=496	FFR-Group N=509	P-Value
Death, MI and Repeat Vascularization	110 (22.2)	90 (17.7)	0.07
Death or Myocardial Infarction	63 (12.7)	43 (8.4)	0.03
Death	19 (3.8)	13 (2.6)	0.25
Myocardial Infarction	48 (9.7)	31 (6.1)	0.03
Freedom from Angina	(75.8)	(79.9)	0.14
Follow-up	(92.7)	(94.5)	0.34

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

1. Tonino PA, De Bruyne B, Pijls NH, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. *N Engl J Med.* 2009;360(3):213-24

2. ESC (European Society of Cardiology) 2009 Clinical Trials Update III presentation slides (PDF) and Webcast available at: www.escardio.org

3. TCT (Transcatheter Cardivascular Therapeutics) 2009, Late Breaking Clinical Trials

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ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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