FAME Study

FFR vs **A**ngiography for **M**ultivessel **E**valuation

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Does measuring FFR really make a difference?

FAME is a large, randomized, controlled, multicenter trial comparing stent treatment guided by FFR versus angiographic guidance alone

The FAME study was designed to reflect the daily practice of performing PCI in patients with multivessel disease

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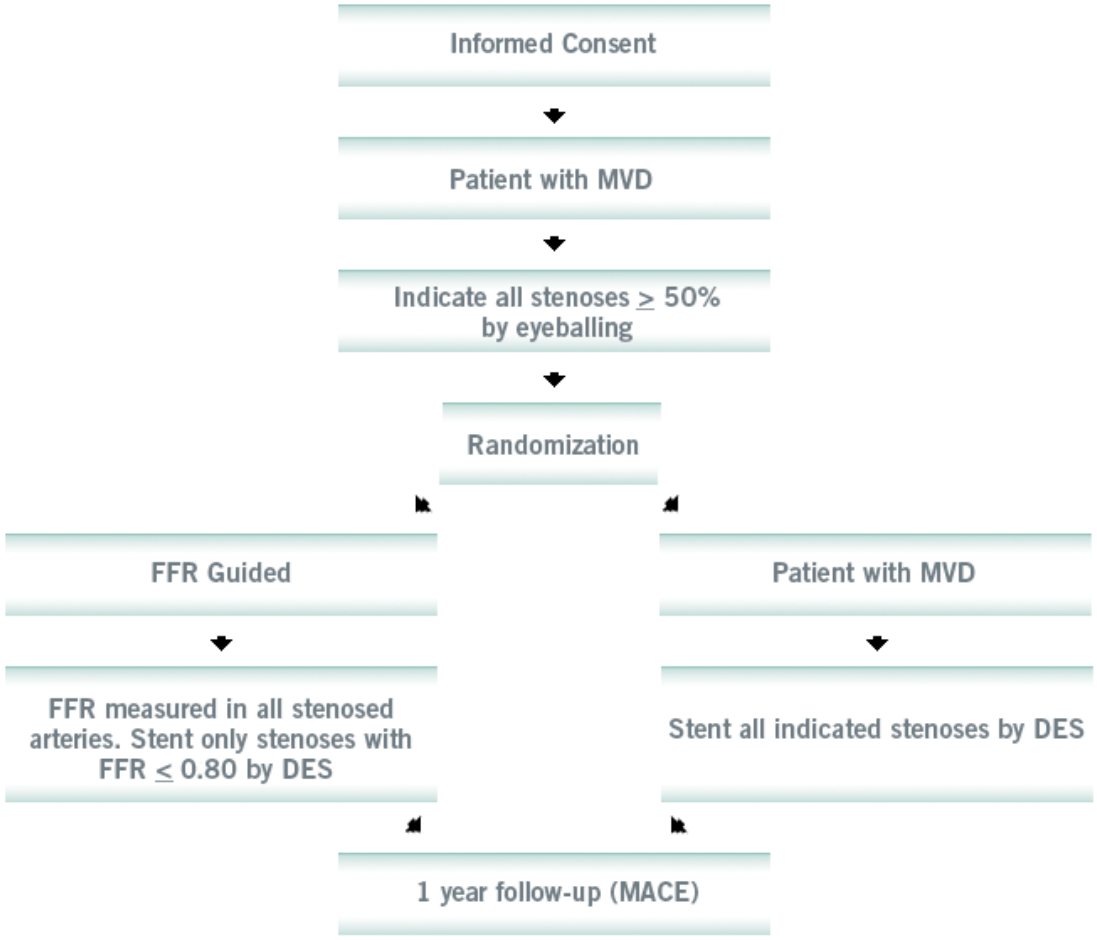
Study Design



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Key Inclusion and Exclusion criteria

Inclusion criteria:

- Patients with multivessel disease
- At least 2 stenoses greater than or equal to 50% in 2 or 3 major epicardial coronary artery vessels, amenable to stenting

Exclusion criteria:

- Left main disease or previous bypass surgery
- ST-elevation MI with CK greater then 1000 U/l within last 5 days
- Extremely tortuous or calcified coronary arteries

Note: patients with previous PCI were not excluded

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Endpoints

- **Primary Endpoint**

  Composite of death, myocardial infarction, or repeat revascularization ("MACE") at 1-year

  Secondary Endpoints

  - individual components of MACE at 1-year
  - functional class
  - use of anti-anginal drugs
  - health-related quality of life (EuroQOL-5D)
  - procedure time
  - amount of contrast agent used during procedure
  - cost of the procedure

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Participating Sites

Fourteen European centers and six United States centers enrolled more than 1,000 patients in the FAME Study

September 25, 2007

Total Enrollment Concluded

1005

Inclusion Completed

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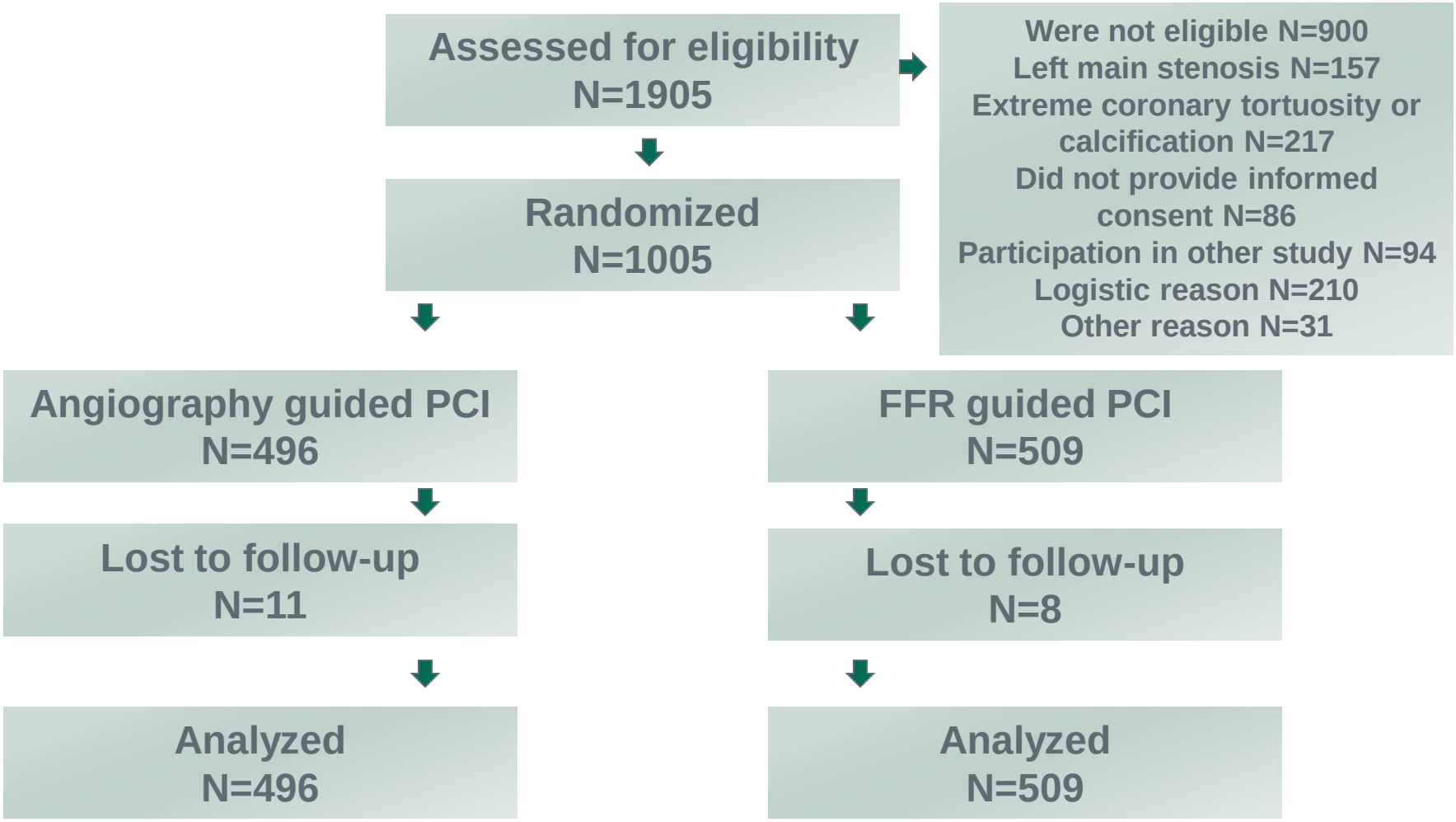
Study Enrollment and Randomization



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Baseline Characteristics

Characteristic	Angiography Group (N=496)	FFR Group (N=509)	P Value†
Demographic			
Age — yr	64.2±10.2	64.6±10.3	0.47
Sex — no. (%)			0.30
Male	360 (72.6)	384 (75.4)	
Female	136 (27.4)	125 (24.6)	
Clinical			
Angina classification — no. (%)†			0.13
I	115 (23.2)	132 (25.9)	
II	165 (33.3)	170 (33.4)	
III	118 (23.8)	132 (25.9)	
IV	98 (19.8)	75 (14.7)	
Previous myocardial infarction — no. (%)	180 (36.3)	187 (36.7)	0.84
Previous PCI — no. (%)	129 (26.0)	146 (28.7)	0.34
Diabetes — no. (%)	125 (25.2)	123 (24.2)	0.65
Hypertension — no. (%)	327 (65.9)	312 (61.3)	0.10
Hypercholesterolemia — no. (%)	362 (73.0)	366 (71.9)	0.62
Family history — no. (%)	190 (38.3)	205 (40.3)	0.49
Current smoker — no. (%)	156 (31.5)	138 (27.1)	0.12
Unstable angina — no. (%)			
With dynamic ECG changes	91 (18.3)	73 (14.3)	0.09
Without dynamic ECG changes	87 (17.5)	77 (15.1)	0.29
Left ventricular ejection fraction — %	57.1±12.0	57.2±11.0	0.92
Medication			
Beta-blocker — no. (%)	377 (76.0)	395 (77.6)	0.55
Calcium antagonist — no. (%)	96 (19.4)	121 (23.8)	0.09
Nitrate — no. (%)	179 (36.1)	167 (32.8)	0.27
ACE inhibitor or ARB — no. (%)	255 (51.4)	267 (52.5)	0.74
Statin — no. (%)	397 (80.0)	417 (81.9)	0.45
Aspirin — no. (%)	454 (91.5)	465 (91.4)	0.92
Clopidogrel — no. (%)	292 (58.9)	310 (60.9)	0.51

Similar characteristics in the two groups

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Baseline Characteristics (cont'd)

Characteristic	Angiography Group (N=496)	FFR Group (N=509)	P Value†
Angiographic Findings			
Indicated lesions per patient — no.§	2.7±0.9	2.8±1.0	0.34
Extent of occlusion — no. of lesions/total no. (%)			
50–70% narrowing	550/1350 (40.7)	624/1414 (44.1)	
71–90% narrowing	553/1350 (41.0)	530/1414 (37.5)	
91–99% narrowing	207/1350 (15.3)	202/1414 (14.3)	
Total occlusion	40/1350 (3.0)	58/1414 (4.1)	
Patients with total occlusion — no. (%)	37 (7.5)	54 (10.6)	
Quantitative coronary analysis			
Extent of stenosis — %	61.2±16.6	60.4±17.6	0.24
Minimal luminal diameter — mm	1.0±0.4	1.0±0.5	0.35
Reference diameter — mm	2.5±0.6	2.5±0.7	0.81
Lesion length — mm	12.6±6.9	12.5±6.5	0.42
SYNTAX score¶	14.5±8.8	14.5±8.6	0.95
EQ-5D score‖	64.7±19.2	66.5±18.3	0.24

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Results

Variable	Angiography Group (N=496)	FFR Group (N=509)	P Value†
Procedure time — min†	70±44	71±43	0.51
Volume of contrast agent used — ml	302±127	272±133	<0.001
Drug-eluting stents			
No. of stents per patient			
Mean	2.7±1.2	1.9±1.3	<0.001
Median (interquartile range)	3 (2–3)	2 (1–3)	
Total length per patient — mm	51.9±24.6	37.9±27.8	<0.001
Average diameter per patient — mm	2.96±0.33	2.92±0.36	0.13
Total no. of stents	1359	980	
Zotarolimus-eluting — no. (%)	603 (44.4)	403 (41.1)	
Sirolimus-eluting — no. (%)	273 (20.1)	202 (20.6)	
Paclitaxel-eluting — no. (%)	414 (30.5)	316 (32.2)	
Other — no. (%)	69 (5.1)	59 (6.0)	
Lesions in which stents successfully placed — no./total no. (%)§	1237/1350 (91.6)	819/874 (93.7)	
FFR-guided strategy			
Lesions successfully measured for FFR — no./total no. (%)¶	NA	1329/1414 (94.0)	
FFR	NA	0.71±0.18	
Ischemic lesions	NA	0.60±0.14	
Nonischemic lesions	NA	0.88±0.05	
Lesions with FFR ≤0.80 — no./total no. (%)	NA	874/1387 (63.0)	
Lesions with FFR >0.80 — no./total no. (%)	NA	513/1387 (37.0)	
Cost of materials — $‖	6,007±2,819	5,332±3,261	<0.001
Hospital stay at baseline admission — days	3.7±3.5	3.4±3.3	0.05

Significant difference between the two groups

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Endpoints

End Point	Angiography Group (N=496)	FFR Group (N=509)	P Value†	Relative Risk with FFR Guidance (95%CI)
Events at 1 year				
Composite of death, myocardial infarction, and repeat vascularization — no. (%)†	91 (18.3)	67 (13.2)	0.02	0.72 (0.54–0.96)
Death — no. (%)	15 (3.0)	9 (1.8)	0.19	0.58 (0.26–1.32)
Myocardial infarction — no. (%)	43 (8.7)	29 (5.7)	0.07	0.66 (0.42–1.04)
Repeat vascularization — no. (%)	47 (9.5)	33 (6.5)	0.08	0.68 (0.45–1.05)
Death or myocardial infarction — no. (%)	55 (11.1)	37 (7.3)	0.04	0.66 (0.44–0.98)
Total events — no.	113	76		
Events per patient — no.	0.23±0.53	0.15±0.41	0.02	
Functional status at 1 year				
Patients without event and free from angina — no./total no. (%)	326/482 (67.6)	360/493 (73.0)	0.07	
Patients free from angina — no./total no. (%)	374/480 (77.9)	399/491 (81.3)	0.20	
Antianginal medications — no.§	1.23±0.74	1.20±0.76	0.48	
Score on EQ-5D visual-analogue scale¶	73.7±16.0	74.5±15.7	0.65	

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Results One-year Follow-up

FAME:
- proof that measuring FFR during the stenting procedure really does make a difference...

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Results One-year Follow-up

...there is a reduction in MACE: 28%

less risk of dying, having a heart attack or having to come back for more stents or a bypass operation

...there is a reduction in death or MI: 34%

less risk of dying or having a heart attack

Summary:

Better outcomes... AND it significantly SAVES on costs AND it doesn't prolong the procedure.

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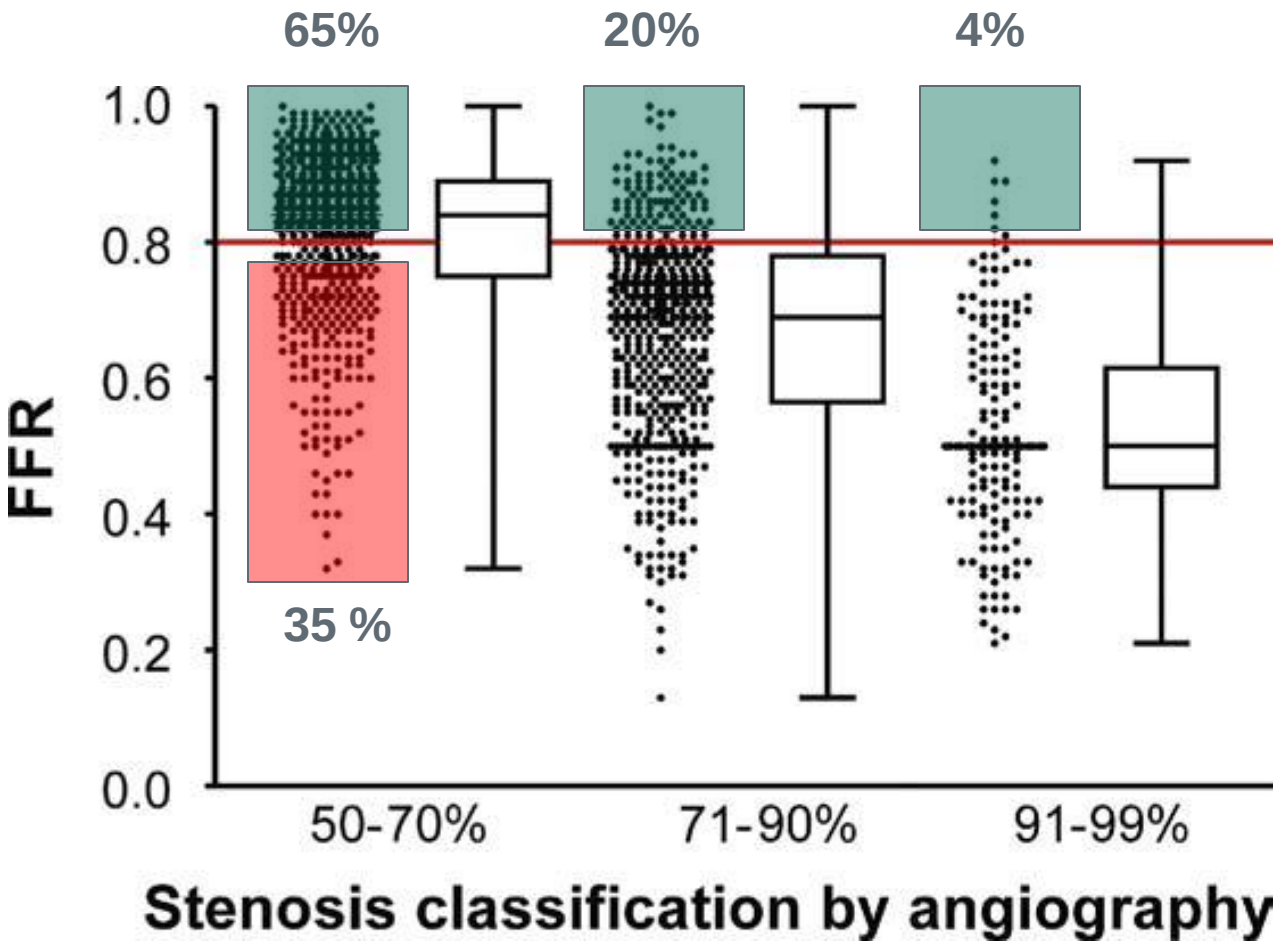
Sub-analysis – Angiographic vs Functional Severity



Tonino P. A. L *et al; J. Am. Coll. Cardiol. 2010;55;2816-2821*

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Results 2-year Follow-up

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

Significant difference in MI and MI/death between the two groups

Tonino P. A. L *et al; J. Am. Coll. Cardiol. 2010;55;2816-2821*

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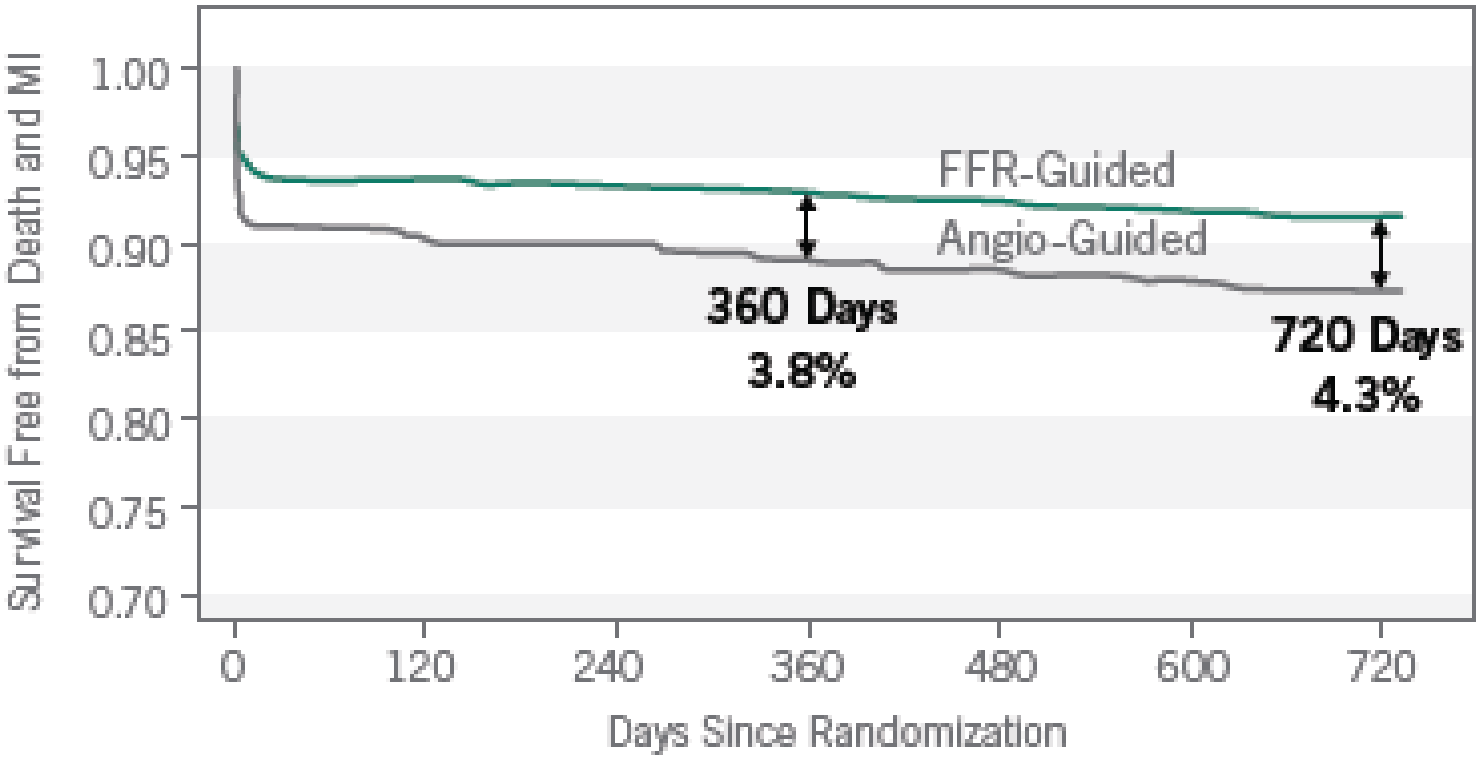
2-year Survival from Death and MI



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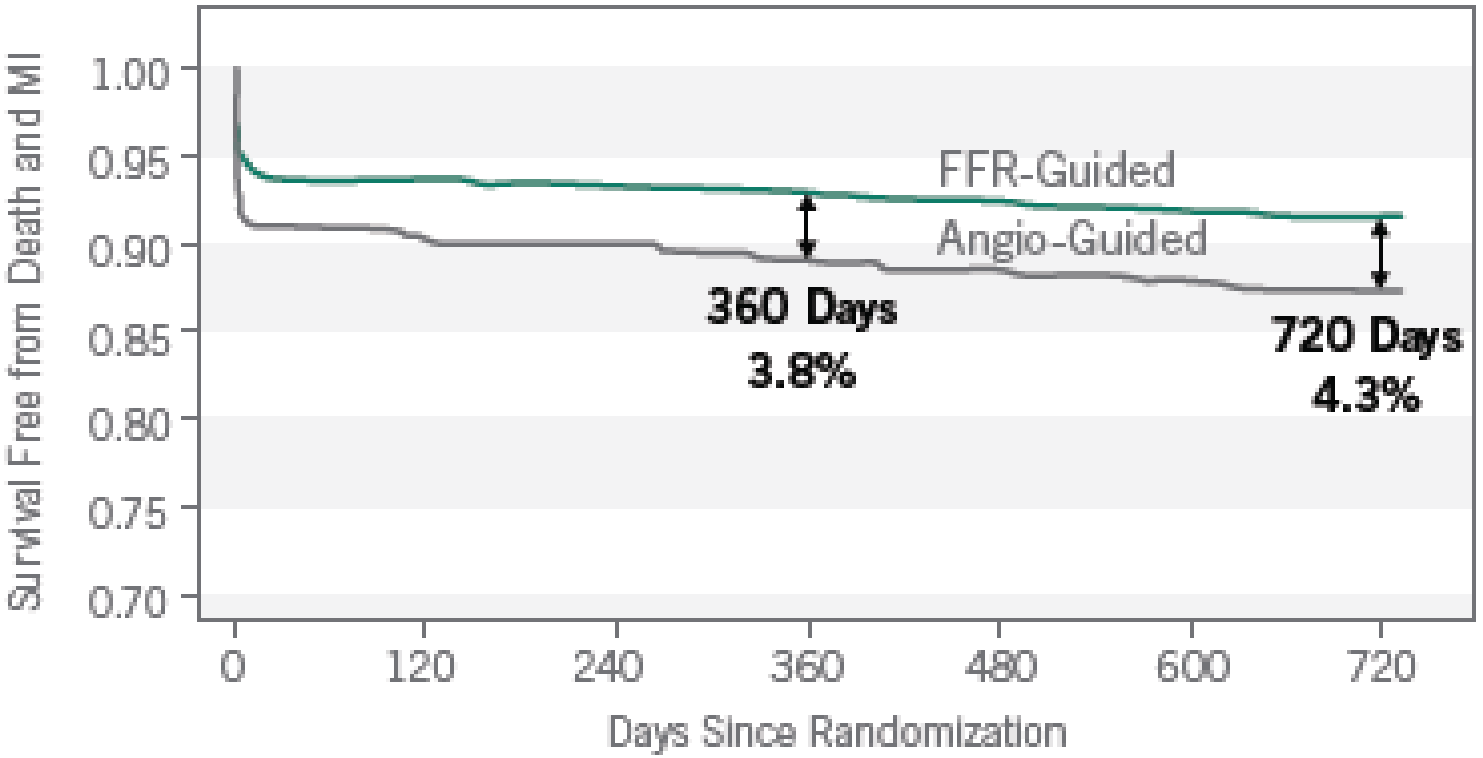
2-year Survival from Death and MI



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Outcome of Deferred Lesions

513 Deferred Lesions in
509 FFR-Guided Patients

↓ **2-years**

53 Repeat Revascularizations → 37
in a New or Restenotic Lesion

↓

16
Originally Deferred Lesions → 6
Without FFR or
Despite an FFR > 0.80

↓

10
Originally Deferred Lesions
with Clear Progression

Only 10/513 or 1.9% of deferred lesions clearly progressed requiring repeat revascularization

William F. Fearon et al, on behalf of the FAME Study Investigators. Presented at TCT "==)

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Outcome of Deferred Lesions

513 Deferred Lesions in
509 FFR-Guided Patients

2-years

31 Myocardial Infarctions → 22 Peri-procedural

9 Late Myocardial Infarctions → 8 Due to a New Lesion or Stent-Related

1 Myocardial Infarction due to an Originally Deferred Lesion

Only 1/513 or 0.2% of deferred lesions resulted in a late myocardial infarction

William F. Fearon et al, on behalf of the FAME Study Investigators. Presented at TCT "==)

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2-year follow-up:
Better 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.

Tonino P. A. L *et al; J. Am. Coll. Cardiol. 2010;55;2816-2821*

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Measuring FFR using St Jude Medical's PressureWire improves patient outcomes up to 2-years post procedure and reduces procedural *and* healthcare costs without prolonging procedure time.

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Results Two-year Follow-up

- At 2-years a significant decrease in the rate of MI in the FFR-guided arm is demonstrated.
- There continues to be a significant decrease in death and MI favoring the FFR-guided approach.
- There is a strong trend toward a lower rate of death, MI or the need for repeat revascularization in the FFR-guided arm.
- There is no sign suggesting that deferred lesions are likely to be responsible for late myocardial infarctions or to progress and require repeat revascularizations.

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Rx Only

Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

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