

ENDEAVOR I & II Clinical Program Long Term Follow-Up

**Ian Meredith
and**

William Wijns

For the ENDEAVOR I and II investigators

ENDEAVOR I

Professor Ian Meredith

MBBS, Ph.D, FACC, FRACP

Director of Cardiology

Monash Medical Center, Monash University

and Southern Health Melbourne, Australia

Principal Investigator

On behalf of the ENDEAVOR I Investigators

No conflicts of interest to declare

ENDEAVOR DES System

Key Components

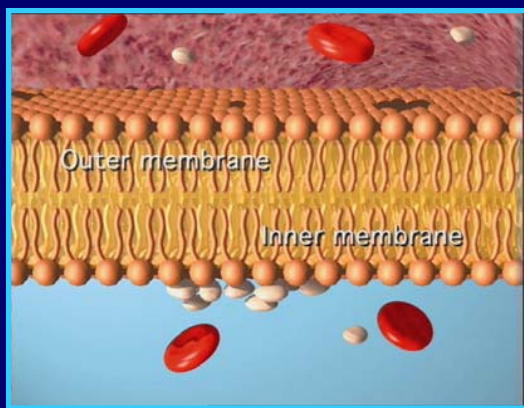
Driver Cobalt Alloy Stent



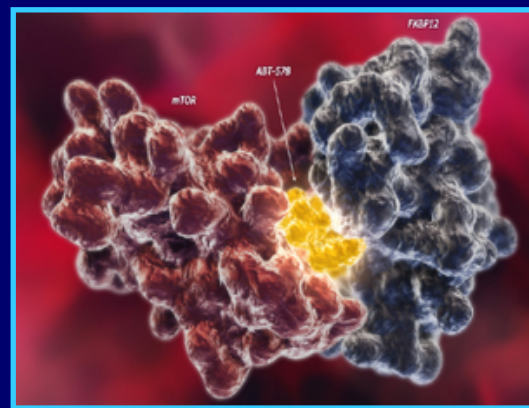
Stent Delivery System



PC Technology



Drug: ABT-578



ENDEAVOR

Clinical Program Update



All ENDEAVOR trials are analyzed in the same independent core laboratory

ENDEAVOR I

Phase I FIM Trial

Single *De Novo* Native
Coronary Artery Lesions (Type A-B2)
Stent Diameter: 3.0-3.5 mm
Stent Length: 18 mm
Lesion Length: <15 mm
Pre-dilatation required

N = 100 patients
8 sites
Australia and New Zealand

Clinical / MACE



Angiography / IVUS



Primary Endpoints: MACE at 30 days and late loss (QCA) at 4 months
Secondary Endpoints: TVF and TLR at 9 months, late loss at 12 months
Antiplatelet therapy for 3 months 10 μ g ABT-578 per mm stent length

ENDEAVOR I

Clinical, QCA and IVUS results to 12 months

	30 Days n=100	4 Months n=98	12 Months n=98
MACE	1%	2%	2%
TLR	1%	2%	2%
TVF	1%	2%	2%
In stent LL	n/a	0.33mm	0.61mm
In segment LL	n/a	0.21mm	0.43mm
In stent ABR	n/a	2.1%	5.4%
Diameter stenosis	n/a	14.6%	22.4%
Neointimal volume	n/a	6.1mm ³	14.2 mm ³

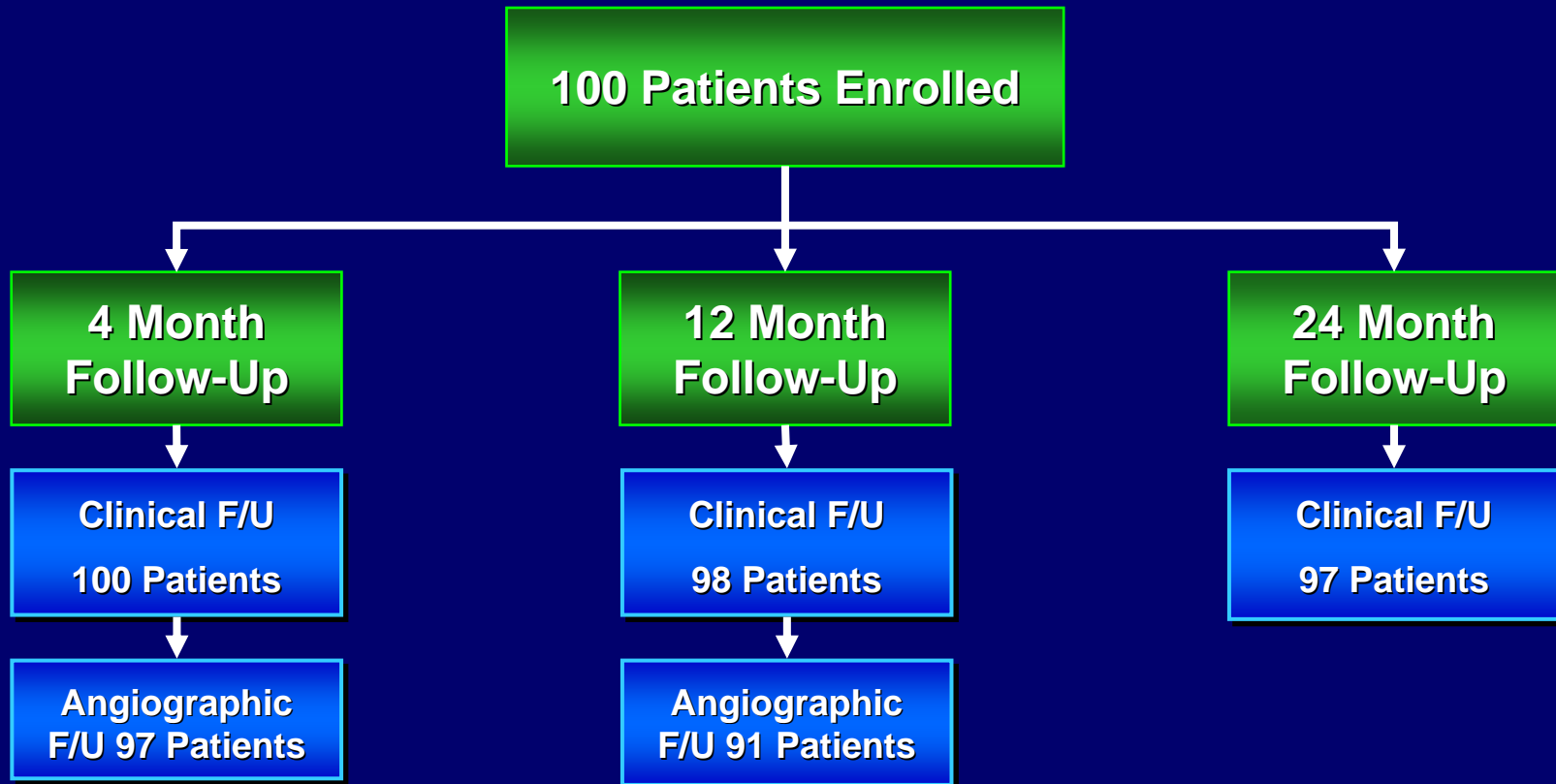
ENDEAVOR I

Clinical outcomes at 24 months

- With the observed increase in late loss from 4 to 12 months would clinical efficacy be preserved at 2 years ?
- Would the safety profile of the ENDEAVOR DES alter with this longer term follow-up ?

ENDEAVOR I

Patient Flowchart



ENDEAVOR I

Clinical Events to 2 Years

	0 - 30 Days n=100	1 - 12 Months n=98	12 - 24 Months n=97	0 - 24 Months n=97
MACE	1%	2%	1%	3%
Death	0	0	1%#	1%#
MI (all)	1%	0	0	1%
Q-wave	0	0	0	0
Non Q-wave	1%*	0%	0	1%*
TLR	1%	2%	0	2%
TVR (non-TL)	0	0	2%	2%
TVF	1%	2%	2%	4%

* Stent Thrombosis at 10-days

#Non cardiac death – metastatic melanoma

ENDEAVOR I

Summary of Clinical Events

1 Non-Q wave MI, Subacute Closure/Stent Thrombosis

10 days post-procedure

- TLR – PTCA 11 days post-procedure; TLR-CABG 17 days post-procedure

1 non-cardiac death @ 379 days post-procedure

- Cause of death: metastatic melanoma

1 TVR 409 days post-procedure

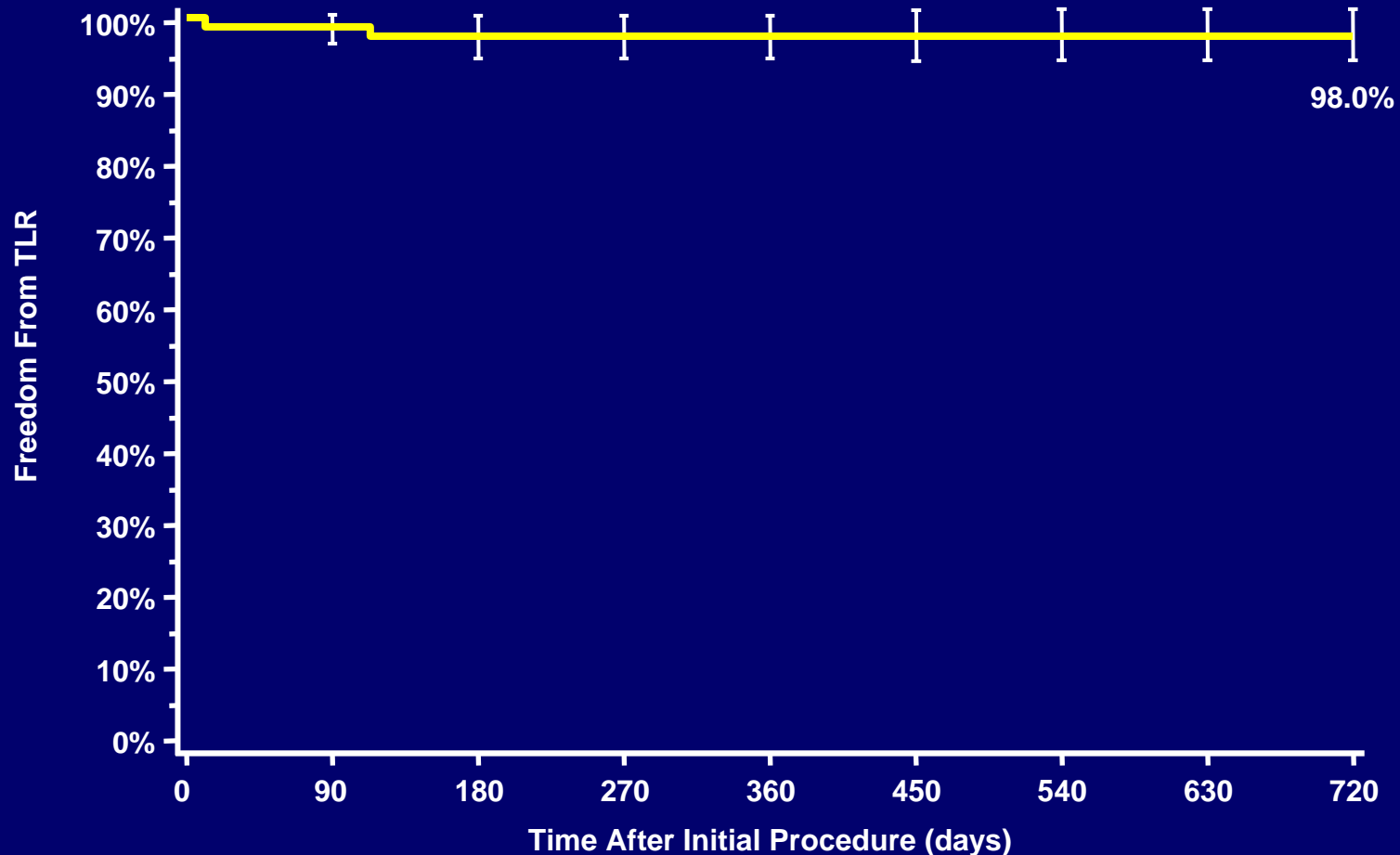
- PCI for mid LAD lesion, remote target vessel revascularization, study stent patent

1 TVR – CABG 515 days post-procedure

- Study stent patent mid LAD, 80% ostial lesion required CABG with a LIMA on the proximal LAD

Survival Free from Target Lesion Revascularization

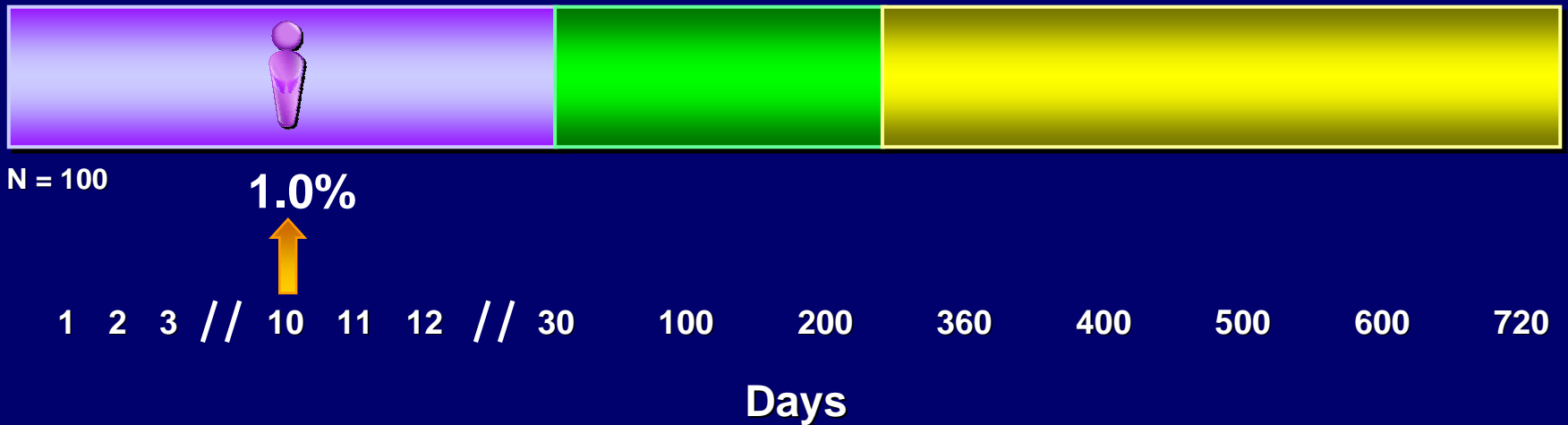
Event-Free Survival ± 1.96 SE



ENDEAVOR I Safety Profile

No Stent Thrombosis After 10 Days

ENDEAVOR I



Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischaemia (chest pain and ECG changes).

Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency.

ENDEAVOR I

Summary

- **97% clinical follow-up to 2 years**
- **Sustained safety and efficacy**
 - ➔ **97% MACE free at 24 months**
 - ➔ **2% TLR by 12 months**
 - ➔ **No further TLR to 24 months**
 - ➔ **No stent thrombosis after 10 days**

ENDEAVOR II

A Randomized Trial to Evaluate the Safety and Efficacy of the
Medtronic AVE ABT-578 Eluting Driver Coronary Stent in De Novo
Native Coronary Artery Lesion

12 month follow-up

J. Fajadet, W. Wijns and R. Kuntz

**Principal Investigators
for the ENDEAVOR II trial**

No conflicts of interest to declare

ENDEAVOR II

Randomized, Double-Blind Trial Design

Single *De Novo* Native Coronary Artery Lesions
Stent Diameters: 2.25-3.5 mm
Stent Lengths: 18-30 mm (8/9 mm bailout)
Lesion Length: 14-27 mm
Pre-dilatation required

n=1,200 patients

72 sites

Europe, Asia Pacific, Israel,
New Zealand and Australia

ENDEAVOR Stent
Active Arm
n=600

Driver Stent
Control Arm
n=600

Clinical / MACE

30d

6mo

8mo

9mo

12mo

2yr

3yr

4yr

5yr

Angiography / IVUS

Angio N = first 600

IVUS N = first 300

IVUS for overlapping stents

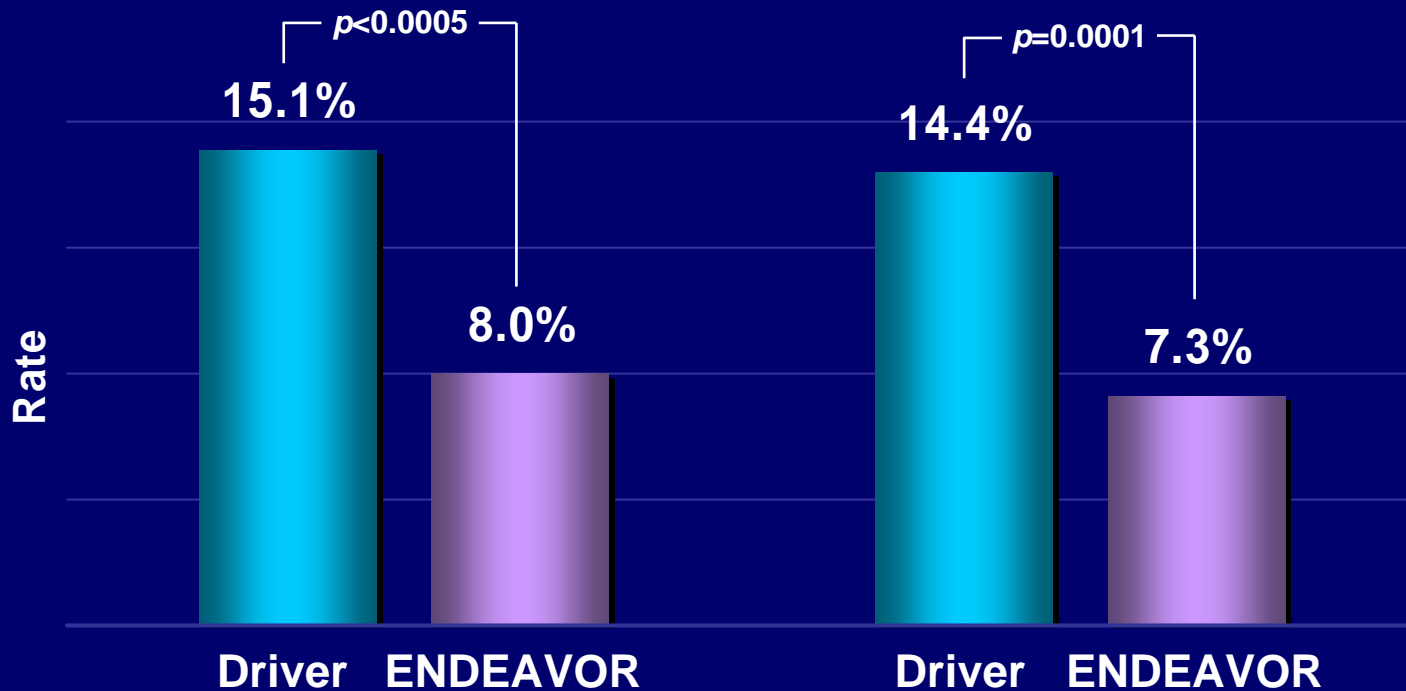
Primary Endpoint: TVF (cardiac death, MI, TVR) at 9 months
Dual antiplatelet therapy for 3 months
10 μ g ABT-578 per mm stent length

ENDEAVOR II

Clinical Outcome

TVF*

MACE



TVF * = Primary Endpoint at 9 Month Follow-Up

Pivotal DES Trials

DES arm (1:1)	SIRIUS	TAXUS	ENDEAVOR
Number of patients	533	662	598
Clinical Outcome			
Target Vessel Failure [%]	8.6	7.6	8.0
MACE [%]	7.1	8.5	7.3

Pivotal DES Trials

DES arm (1:1)	SIRIUS	TAXUS	ENDEAVOR
Number of patients	533	662	598
Clinical Outcome			
Target Vessel Failure [%]	8.6	7.6	8.1
MACE [%]	7.1	8.5	7.4
Angiographic Metrics			
In-stent Late Loss [mm]	0.17	0.39	0.62
In segment Late Loss [mm]	0.24	0.23	0.36

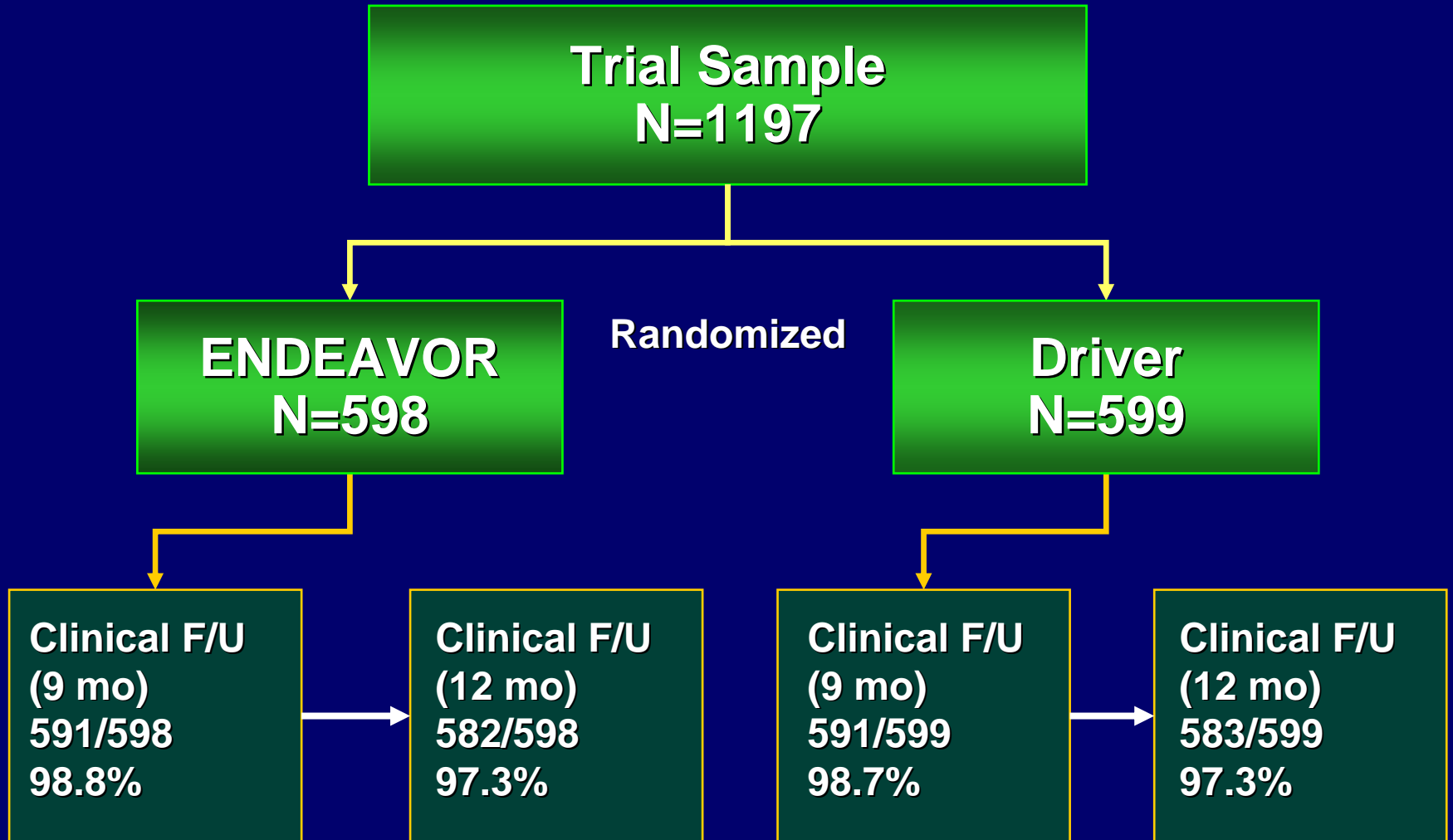
ENDEAVOR II

Clinical outcome at 12 months

- **Given the observed late loss, will these safety and efficacy results be maintained at 1 year?**

ENDEAVOR II

Patient Flowchart



ENDEAVOR II

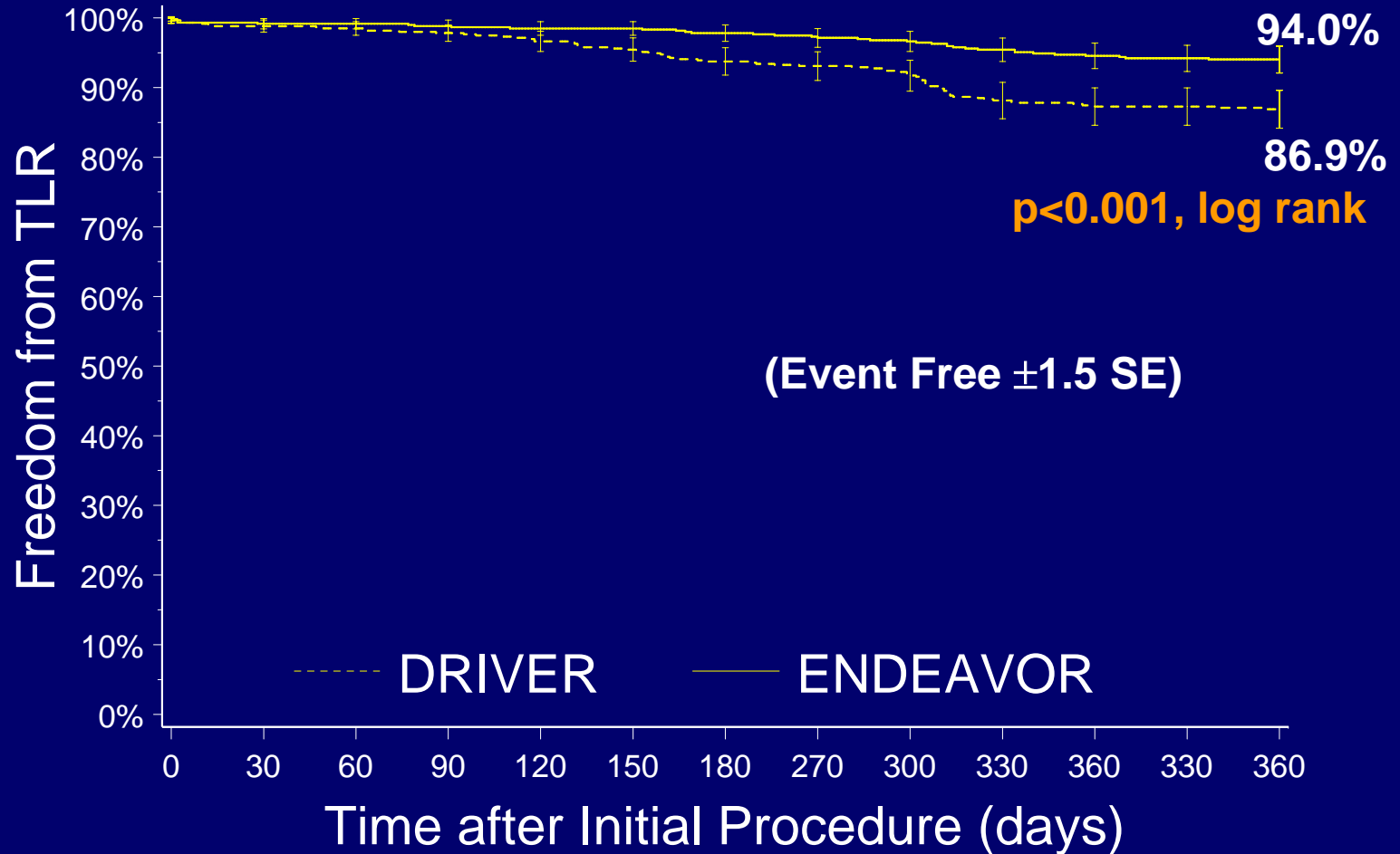
Clinical Events to 12 months

	0 - 9 Months ENDEAVOR	9 - 12 Months ENDEAVOR	0 - 9 Months Driver	9 - 12 Months Driver
MACE	7.3%	1.5%	14.4%	1.5%
Death	1.2% [7*]	0.2% [1]	0.5% [3]	0.2% [1]
MI (all)	2.7%	0%	4.0%	0%
Q-wave	0.3%	0%	0.9%	0%
Non Q-wave	2.4%	0%	3.1%	0%
TLR	4.6%	1.4%	11.8%	1.4%
TVR (non-TL)	1.5%	0.3%	2.2%	0.3%
TVF	8.0%	1.9%	15.1%	1.9%

* 2 of 7 deaths non-cardiac (1 lung cancer, 1 cerebral hemorrhage)

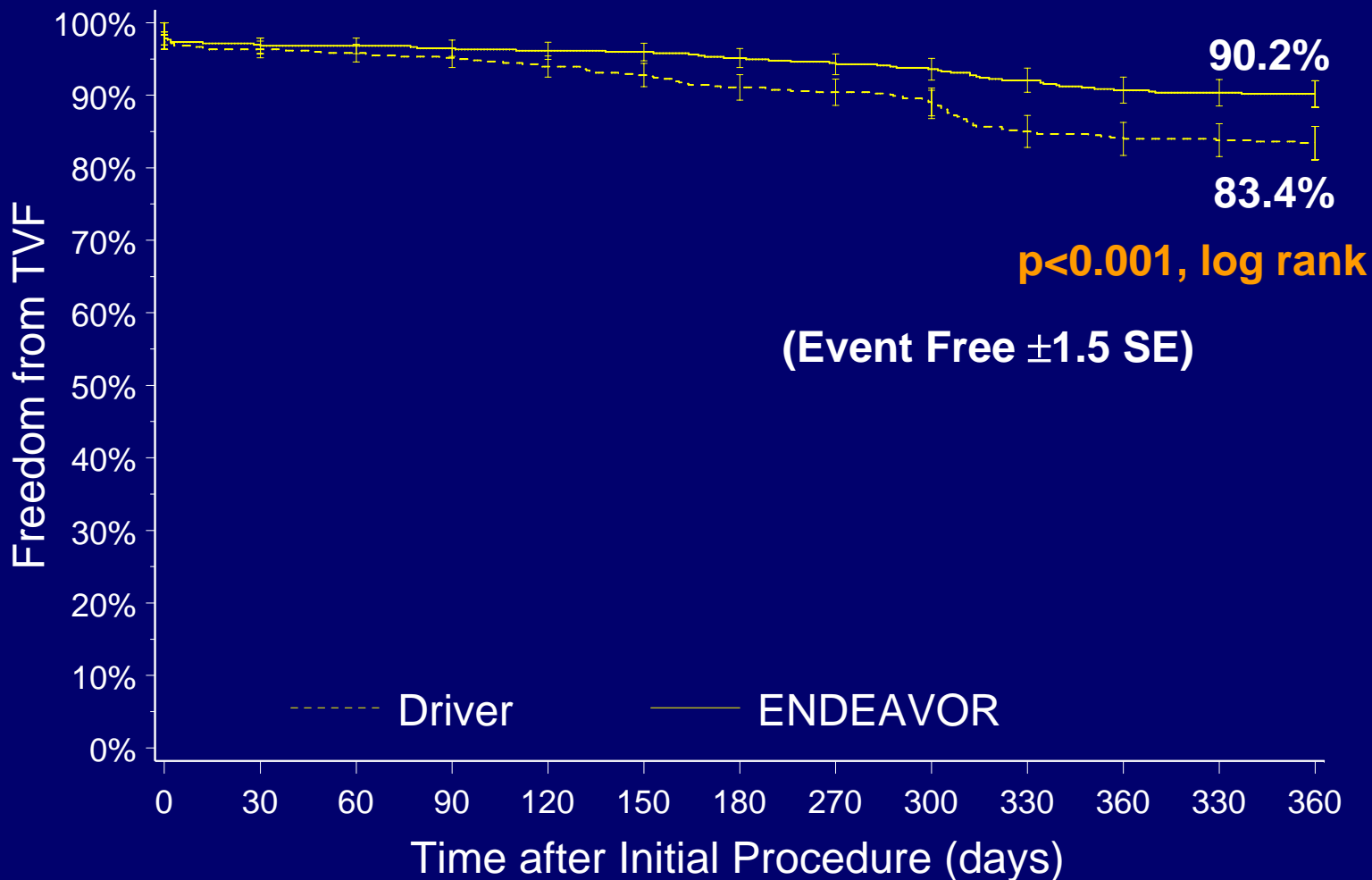
ENDEAVOR II

TLR-Free Survival at 360 Days



ENDEAVOR II

TVF-Free Survival at 360 Days

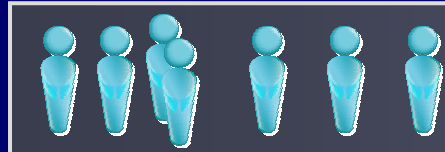


ENDEAVOR II

Stent Thrombosis Timing

*No Stent Thrombosis After 14 Days **

Driver



1.2% (7)

1 2 3 // 12 13 14 // 30 100 150 200 270 300 325 360 Days

ENDEAVOR



0.5% (3)

Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischaemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency.

* Through 12 months of follow-up

Conclusions

ENDEAVOR I and II

- **The ENDEAVOR stent is highly deliverable**
- **The need for repeat intervention is low and maintained**
- **No stent thromboses were observed beyond 10 days**
- **These clinical data confirm that the ENDEAVOR stent is a safe, effective and durable treatment option for patients undergoing PCI in the DES era**