

Available evidence and ongoing studies on the Endeavor Resolute drug-eluting stent

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Innovations in Cardiovascular Interventions

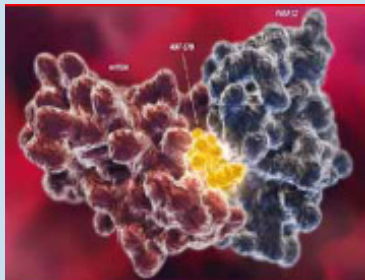
Disclosures

I have the following financial relationships to disclose:

Lecture fees: Medtronic

(level of remuneration: modest)

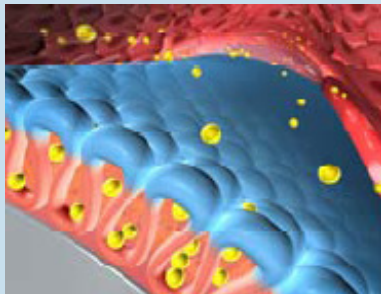
Endeavor Resolute



Zotarolimus



Driver BMS platform



BioLinx Polymer



Delivery System

Endeavor Resolute

- I. The first-in-man „RESOLUTE“ study
- II. Munich Registry
- III. Upcoming clinical trials

I. RESOLUTE

Design: First-in human, feasibility
prospective, non-randomized, single-arm, multicenter

Inclusion: 130 patients with
single, de novo, native coronary artery lesions
vessel size: 2.5-3.5 mm, lesion length: 14-27 mm

Primary Endpoint: LLL at 9 months

Follow-up: Angiographic und IVUS Follow-up
4 months: 30/130 pts
9 months: 100/130 pts
Clinical Follow-up up to 3 years

Meredith et al

Baseline characteristics

	<i>n = 130 pts</i>	
Age – years \pm SD	61 \pm 10	
Women – no. (%)	32 (25)	
Diabetes – no. (%)	23 (18)	
Current smoker – no. (%)	29 (22)	
Hypercholesterolemia– no. (%)	123 (95)	
Prior myocardial infarction – no. (%)	59 (46)	
Prior PCI – no. (%)	24 (19)	
Unstable angina – no. (%)	38 (30)	Meredith <i>et al</i>

Lesion and procedural characteristics

n = 130 pts, 131 lesions

B2/C lesions – no. (%)	107 (82)
LAD – no. (%)	45 (34)
Reference vessel diameter – mm \pm SD	2.8 \pm 0.4
Lesion length – mm \pm SD	15.5 \pm 6.2
MLD, pre PCI – mm \pm SD	0.8 \pm 0.3
DS, pre PCI – % \pm SD	70.5 \pm 11.4
Device success – no. (%)	130 (99)
Procedure success – no. (%)	125 (96)

Meredith et al

Angiographic Results

	In-Stent	In-Segment
Late Lumen Loss, mm \pmSD		
at 4 months (n = 30)	0.12 \pm 0.26	0.05 \pm 0.20
at 9 months (n = 96)	0.22 \pm 0.27	0.12 \pm 0.27
Binary Restenosis, no. (%)		
at 4 months (n = 30)	0	0
at 9 months (n = 96)	1 (1.0)	2 (2.1)

Meredith *et al*

Clinical Results

	12 months	24 months	36 months
Death – no. (%)	3 (2.3)	4 (3.1)	6 (4.6)
- Cardiac death no. (%)	1 (0.8)	1 (0.8)	1 (0.8)
MI – no. (%)	7 (5.4)	7 (5.4)	7 (5.4)
- Q wave MI - no. (%)	0	0	0
Stent Thrombosis – (%)	0	0	0
TLR – no. (%)	1 (0.8)	2 (1.5)	2 (1.5)
MACE – no. (%)	11(8.5)	13 (10)	15 (11.5)

Leon, TCT 2009

RESOLUTE Summary

The RESOLUTE first-in man trial showed stable clinical efficacy and a low rate of MACE with no cases of stent thrombosis out to 36 months

- I. The first-in-man „Resolute“ study
- II. Munich Registry
- III. Upcoming clinical trials

Endeavor Resolute

II.

Consecutive series of
171 patients treated with the
Endeavor Resolute drug-eluting stent

Methods

- Design:** Consecutive series of 171 patients
- Setting:** Two high volume, tertiary referral PCI centers in Germany
- Patients:** Exclusion criteria:
- acute ST-elevation myocardial infarction
 - PCI in venous bypass grafts
- Follow-up:** 9 months

Baseline characteristics

	<i>n = 171 pts</i>
Age – years \pm SD	68 \pm 11
Women – no. (%)	47 (28)
BMI – kg/m ² \pm SD	27 \pm 4
Diabetes – no. (%)	49 (29)
Arterial hypertension – no. (%)	125 (73)
Current smoker – no. (%)	21 (12)
Hypercholesterolemia– no. (%)	115 (67)

Baseline characteristics *(cont`d)*

n = 171 pts

Prior myocardial infarction – no. (%)	55 (32)
Prior CABG surgery – no. (%)	22 (13)
Clinical presentation	
– Stable angina – no. (%)	105 (61)
– NSTEMI-ACS – no. (%)	66 (39)

Angiographic characteristics

n= 171 pts, n=245 lesions

Multivessel disease – no. (%)	155 (91)
Target vessel – no. (%)	
– LAD	99 (40)
– LCX	61 (25)
– RCA	56 (23)
– LM	29 (12)
LV-EF – %	56 ± 10
Complex (B2/C) lesions – no. (%)	187 (76)
Ostial lesions – no. (%)	71 (29)
Bifurcation lesions – no. (%)	98 (40)

Angiographic characteristics *(cont'd)*

n = 245 lesions

Reference vessel diameter – mm ± SD	2.8 ± 0.6
Lesion length – mm ± SD	16.4 ± 10.6
MLD, pre PCI – mm ± SD	1.0 ± 0.5
DS, pre PCI – % ± SD	66.2 ± 15.2
Lesions per patient – mean ± SD	1.4 ± 0.7
Stents per lesion, mean ± SD	1.3 ± 0.6
Total stent length – mm ± SD	26.5 ± 11.8

Endeavor Resolute

Diameter (mm)	2.25	2.5	2.75	3.0	3.5	4.0	4.5
Length (mm)	8	12	18	24	30		

Procedural Characteristics

n = 245 lesions

Balloon diameter – mm±SD	3.2 ± 0.6
Balloon to vessel ratio	1.1 ± 0.1
Maximal balloon pressure – atm±SD	15.9 ± 3.1
Successful PCI – no. (%)	244 (99.6)
MLD post – mm±SD	2.6 ± 0.5
DS after procedure – %±SD	11.8 ± 6.8

Clinical Endpoints

30 days

n= 171 pts, 245 lesions

Death – no. (%)	1 (0.6%)
Myocardial infarction (CK-MB > 3x ULN)	8 (4.7%)
– Q wave MI – no. (%)	0
Death or MI – no. (%)	8 (4.7%)
Target lesion revascularization (TLR) – no. (%)	1 (0.4%)
– PCI	1 (0.4%)
– CABG	0
MACE (Death, MI, TLR) – no. (%)	8 (4.7%)

Clinical Endpoints

9 months

n= 171 pts, 245 lesions

Death – no. (%)	5 (2.9%)
Myocardial infarction (CK-MB > 3x ULN)	9 (5.3%)
– Q wave MI – no. (%)	0
Death or MI – no. (%)	11 (6.4%)
Target lesion revascularization (TLR) – no. (%)	10 (4.1%)
– PCI	10 (4.1%)
– CABG	0
MACE (Death, MI, TLR) – no. (%)	19 (11%)

Stent Thrombosis

9 months

n = 171

ARC criteria – no. (%)

– definite	1 (0.6)
– probable	0
– possible	2 (1.2)

Summary

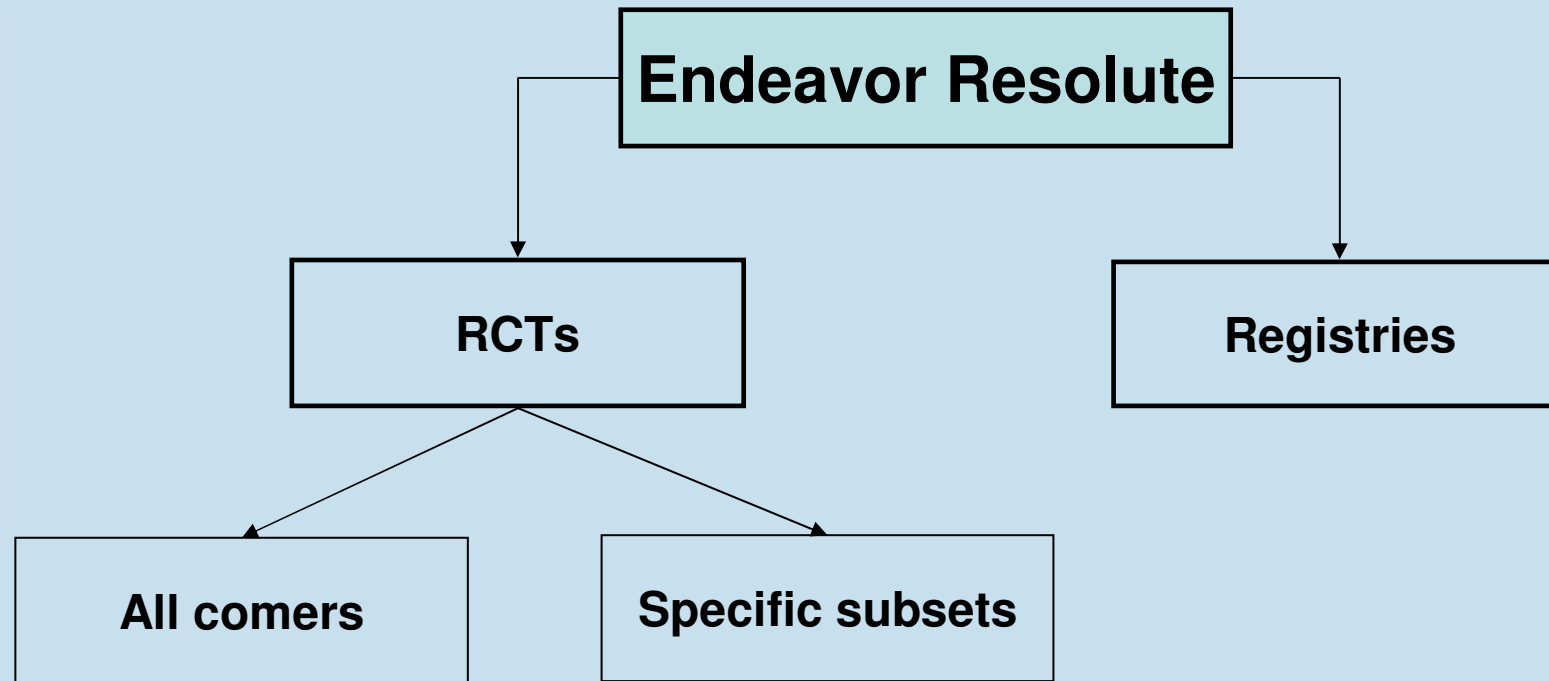
This study cohort comprised consecutive patients with high risk features for coronary restenosis

The Endeavor Resolute stent showed a high procedural success rate, a favorable safety profile and a low rate of TLR at 9 months

Randomized clinical trials are needed to assess its relative merits in comparison with other available DES

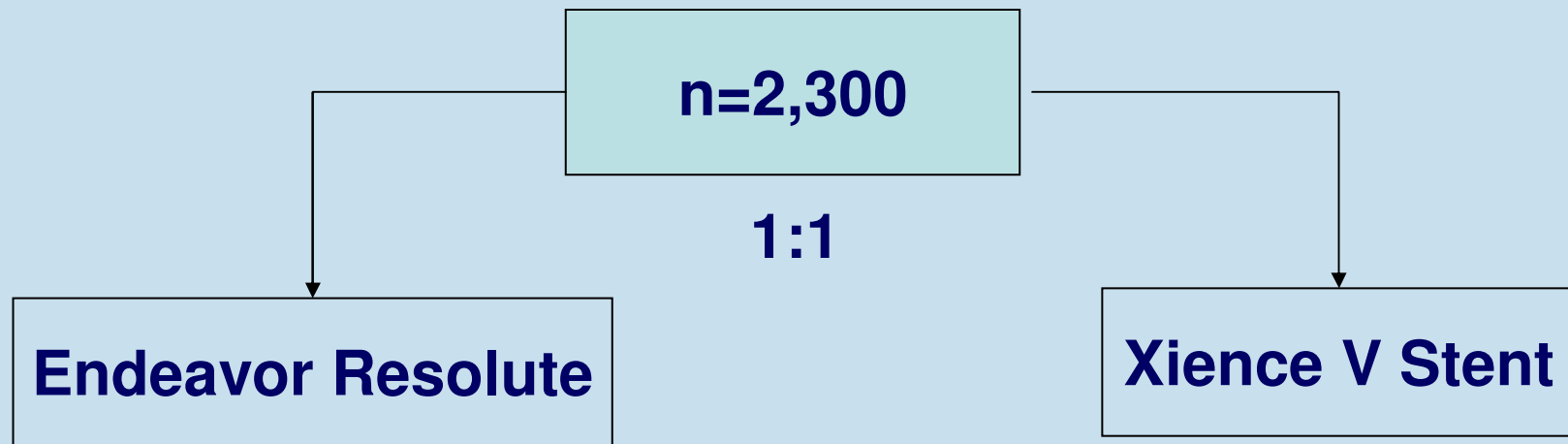
- I. The first-in-man „Resolute“ study
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Upcoming clinical trials



- RESOLUTE All Comers
- ISAR-Test 5
- ISAR-Left main 2

RESOLUTE All Comers

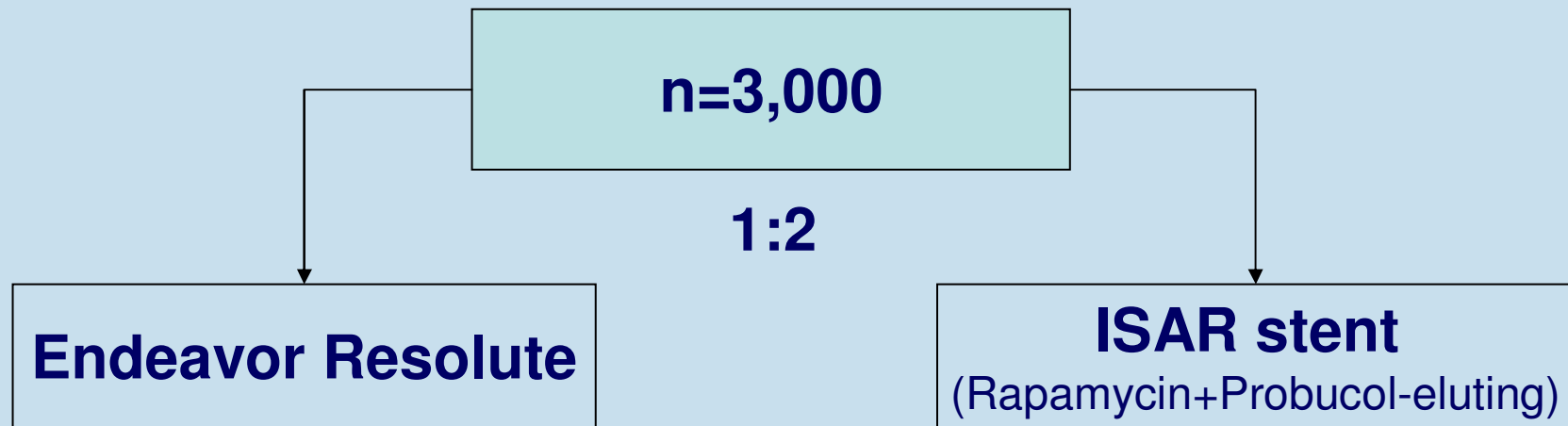


Primary endpoint: Composite of cardiac death, target vessel MI, TLR at 12 months

Secondary endpoints: Composite at 30 d, 6 months, 2-5 years

Angiographic and OCT parameters at 13 months

ISAR-Test 5

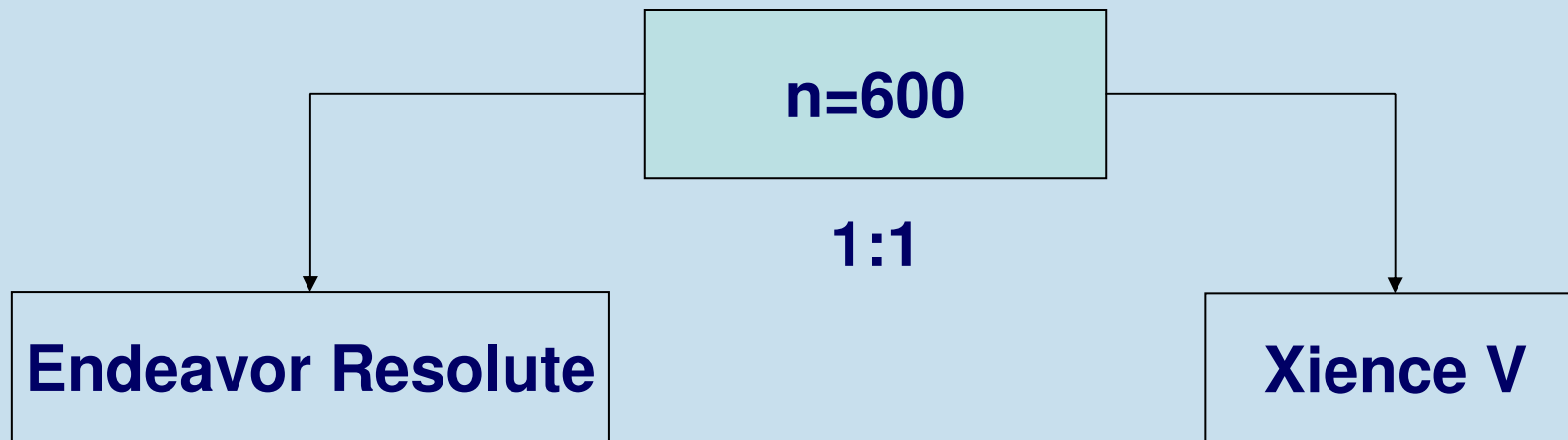


Primary endpoint: Composite of cardiac death, target vessel MI, TLR at 12 months

Secondary endpoints: LLL

Stent thrombosis

ISAR-Left main 2



Primary endpoint: Composite of death, MI + TLR at 12 months

Secondary endpoints: Angiographic restenosis

Registries



RESOLUTE Intl

Non-RCT Observational (n=2,200) **enrolled**



RESOLUTE US

2.25 Angio Non-RCT (n=129)

2.5-3.5 Clinical Non-RCT vs. Hx Control (n=1,112)

2.5-3.5 Angio/IVUS Non-RCT vs. Hx Control (n =100)

38 mm-Long Lesion Non-RCT (n=TBD)

4.0 Angio Non-RCT (n=58)



RESOLUTE Japan

Non-RCT (n~100) **enrolled**



RESOLUTE Asia-Pacific

Non-RCT (n=1400)

Summary

- **Clinical experience for the Endeavor Resolute stent is very favorable but still limited**
- **Large ongoing clinical trials are expected to provide results in the near future**

Thank you for your attention



ISAR-Test 2

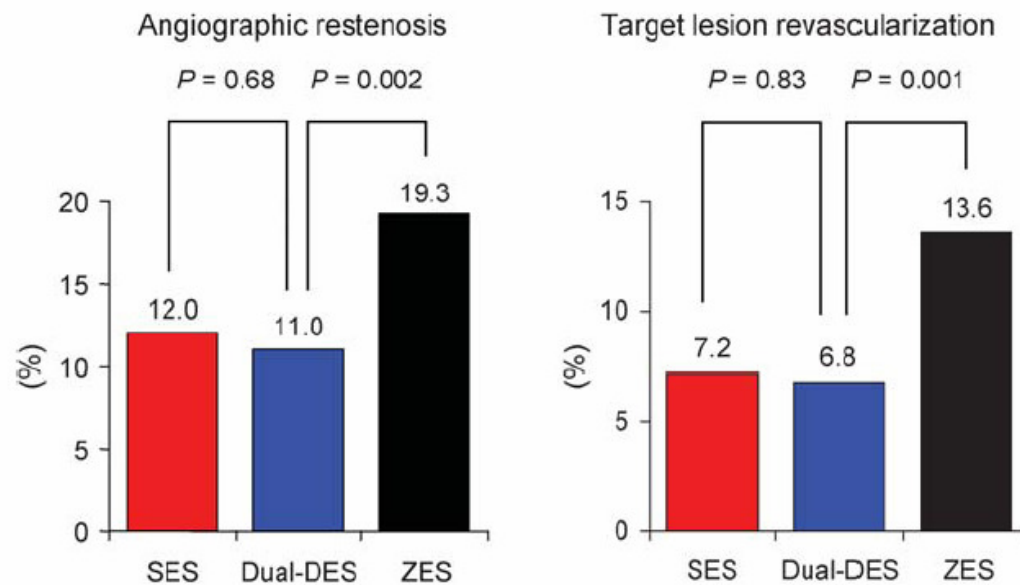


Figure 3 Angiographic restenosis and target lesion revascularization. Dual-DES, rapamycin- and probucol-eluting stent; SES, sirolimus eluting stent; ZES, zotarolimus-eluting stent.

ISAR-Test 2

Table 4 Clinical follow-up data at 1 year

	SES (n = 335)	Dual-DES (n = 333)	ZES (n = 339)	P-value
Death or myocardial infarction, n (%)	20 (6.0)	20 (6.0)	21 (6.2)	0.99
Death, n (%)	9 (2.7)	8 (2.4)	12 (3.5)	0.66
Cardiac death, n (%)	8 (2.4)	7 (2.1)	6 (1.8)	0.85
Myocardial infarction, n (%)	12 (3.6)	14 (4.2)	11 (3.2)	0.80
Q wave	3 (0.9)	4 (1.2)	4 (1.2)	0.83
Definite stent thrombosis, n (%)	3 (0.9)	3 (0.9)	2 (0.6)	0.87
Of which acute or subacute, n (%)	1 (0.3)	3 (0.9)	2 (0.6)	0.60
Probable stent thrombosis, n (%)	0	0	1 (0.3)	0.37
Definite or probable stent thrombosis, n (%)	3 (0.9)	3 (0.9)	3 (0.9)	>0.99
Possible stent thrombosis, n (%)	2 (0.6)	3 (0.9)	1 (0.3)	0.59
TLR ^a , n (%)	30 (7.2)	29 (6.8)	57 (13.6)	<0.001
Repeat PCI	28 (6.7)	29 (6.8)	57 (13.6)	<0.001
Repeat CABG	2 (0.5)	0	0	0.13
Remote target vessel revascularization, n (%)	15 (4.5)	14 (4.2)	12 (3.5)	0.82

Dual-DES, rapamycin- and probucol-eluting stent; SES, sirolimus eluting stent; ZES, zotarolimus-eluting stent.

^aPer lesion analysis.

ISAR-Test 2

In-stent late luminal loss was significantly different across the treatment groups ($P < 0.001$). The rate of late loss observed with Dual-DES (0.23 ± 0.50 mm) was significantly lower than that observed with the ZES (0.58 ± 0.55 mm; $P < 0.001$) and similar to that of the SES (0.24 ± 0.51 mm; $P = 0.78$). We also per-