DUTCH PEERS (TWENTE II):
A Prospective, Randomized, "All-Comers" Trial of Third-Generation Zotarolimus-Eluting *vs.* Everolimus-Eluting Coronary Stents

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Disclosure Statement

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- ✓ Institutional Research Grant: *Abbott Vascular, Biotronik, Boston Scientific, Medtronic*
- ✓ Consultancy: *Abbott Vascular, Boston Scientific, Medtronic*
- ✓ Travelling Expenses: *Biotronik*
- ✓ Speakers Honorarium: *Biotronik and MSD*
- ❑ Major Stock Shareholder / Equity
- ❑ Royalty Income
- ❑ Ownership / Founder
- ❑ Intellectual Property Rights
- ❑ Other Financial Benefit

Background

- Second-generation drug-eluting stents (DES) with biocompatible durable coatings are efficacious and safe.
- Third-generation durable coating DES use the same coatings but have novel stent platforms with more flexible designs. They may be delivered more easily in complex lesions but might be longitudinally less stable.
- Outcome data for Promus Element were published, but no such data were available for Resolute Integrity.
- We investigated in all-comers whether clinical outcome is similar following randomized use of both DES.

Study Devices

	 RESOLUTE INTEGRITY	 PROMUS ELEMENT
Polymer component	BioLinx®, a blend of hydrophobic C10 polymer, hydrophilic C19 polymer & poly-vinyl pyrrolidone	Fluoropolymer coating
Thickness of coating layer	5.6 µm	7 µm
Antiproliferative drug	Zotarolimus	Everolimus
Drug release period	180 days	120 days
Material of metal stent platform	Cobalt-chromium	Platinum-chromium
Strut thickness of metal stent platform	91 µm	81 µm
Stent manufacturer	Medtronic	Boston Scientific

Tandjung *et al*. DUTCH PEERS: Study design and rationale. *Am Heart J* 2012; 163: 557-62

DUTCH PEERS

(TWENTE II)

- Any patient requiring DES (stable angina, any ACS, including STEMI)
- No limit of number of lesions or vessels treated, lesion length, vessel size, or lesion type (de novo lesion, restenosis, CTO, graft lesion)

- **Inclusion criteria:** Age ≥ 18 yrs; patient requires PCI with DES implantation and is able and willing to comply with study procedures and follow-up procedures; signed informed consent
- **Exclusion criteria:** Participation in another randomized drug or device trial before reaching its primary endpoint; life expectancy < 1yr; planned surgery < 6 mo's of PCI unless DAPT is maintained; known pregnancy; intolerance to heparin, ASA, clopidogrel, or DES components

Zotarolimus-eluting
RESOLUTE INTEGRITY
(n=906)

1811 All-comer patients were enrolled in this single-blinded, investigator-initiated, randomized (1:1) trial in Arnhem, Emmen, Alkmaar & Enschede

Everolimus-eluting
PROMUS ELEMENT
(n=905)

30 days | **1 year** | **2 years**

Primary endpoint	**Target vessel failure at one year** (composite of cardiac death, target vessel-related MI, and clinically driven target vessel revascularization; **non-inferiority hypothesis**)
Secondary endpoints	**Components of primary endpoint; stent thrombosis; patient oriented composite endpoint**

Enrollment: November 25, 2010 to May 24, 2012. Systematic (serial) assessment of cardiac markers and ECG. Monitoring of informed consent and key demographic data in all patients; monitoring of data on potential clinical events in patients with event triggers; in-depth monitoring of all data in 10% of randomly chosen patients. Monitoring performed by CRO Diagram, Zwolle, NL. Processing of clinical outcome data and independent external adjudication of clinical events (CEC) by CRO Cardialysis, Rotterdam, NL. Control angiography only if clinically indicated. Analyses based on intention-to-treat.

Tandjung *et al*. DUTCH PEERS: Study design and rationale. *Am Heart J* 2012;163:557-62.
von Birgelen *et al*. DUTCH PEERS. *Lancet* – in press.

Investigator-initiated study, equally funded by Boston Scientific and Medtronic

Eligibility of Patients

Inclusion Criteria

- Indication for DES use
- Age ≥ 18 years
- Signed informed consent
- Willing to comply with study and follow-up procedures

Exclusion Criteria

- Participation in drug or device RCT
- Life expectancy < 1 year
- Planned surgery < 6 months of PCI unless DAPT was maintained
- Known pregnancy
- Intolerance to heparin, ASA, clopidogrel, or DES components

Power Calculation of Primary Clinical Endpoint

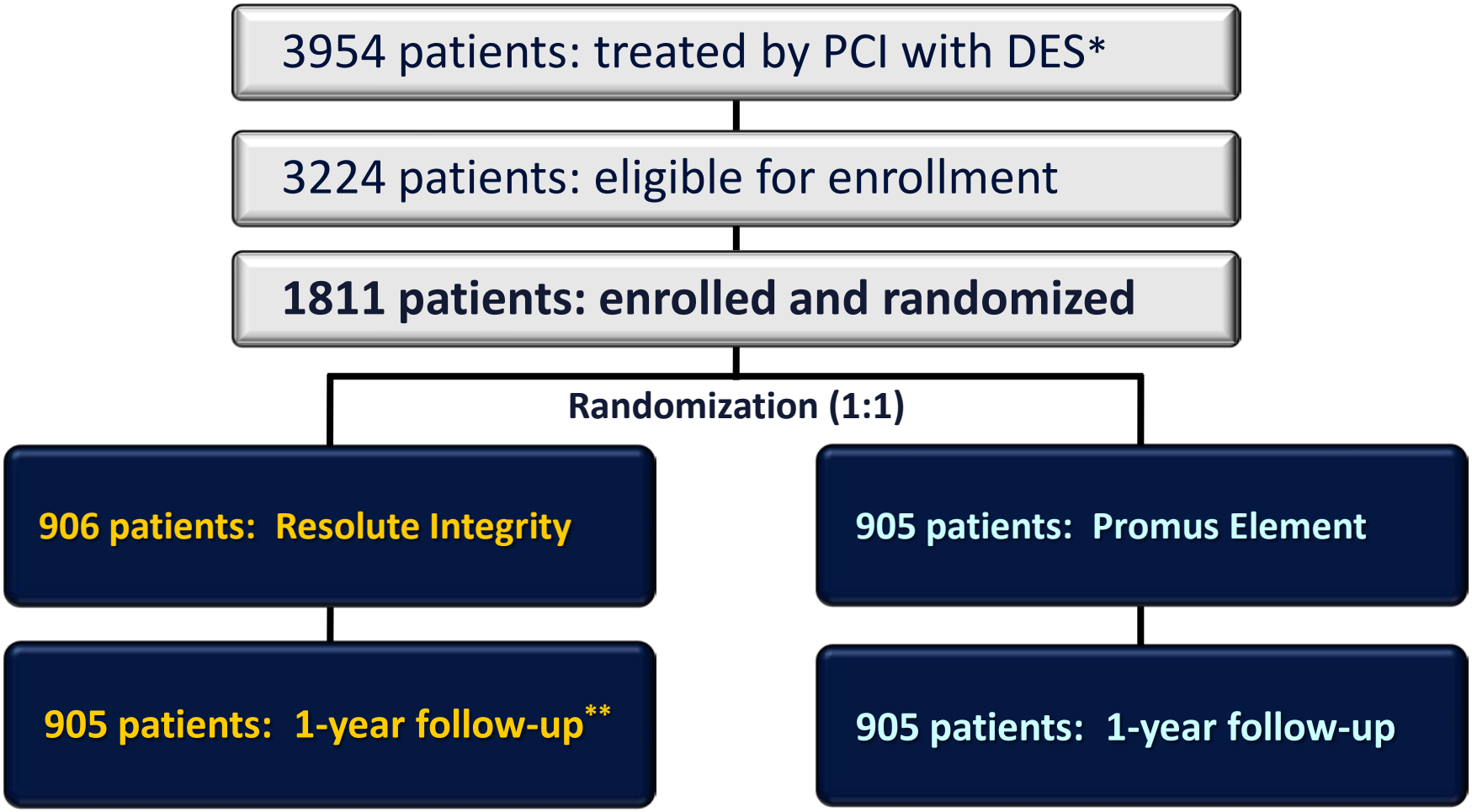
Target Vessel Failure at 12 Months

A composite of cardiac death, target vessel-related MI, and clinically driven target vessel revascularization

- **Event rates at 12 months would be equal in both groups**
- **Non-inferiority margin of 3.6%, expecting 10% events based on data of Resolute All-Comers, at a one-sided type-I error of 0.05**

1788 patients would yield 80% power to detect non-inferiority

Study Flow Diagram



- 56% of eligible patients enrolled
- Follow-up data obtained in 99.9% of patients

* Patients treated during study enrollment; ** One patient withdrew consent. Monitoring was performed by CRO Diagram, Zwolle, NL. Data entry by CRO CardioResearch Enschede, Enschede, NL. Independent clinical event adjudication (CEC) was performed by CRO Cardialysis, Rotterdam, NL. Analyses were based on intention-to-treat.

Patient Characteristics

	Resolute Integrity n = 906 pts.	Promus Element n = 905 pts.	*P*
Age (yrs)	64 (56-72)	65 (57-72)	0.86
Men	665 (73.4)	657 (72.6)	0.70
BMI (kg/m²)	27.1 (25.0-30.0)	27.2 (24.9-30.5)	0.48
Diabetes mellitus	167 (18.4)	157 (17.3)	0.55
Chronic renal failure*	35 (3.9)	28 (3.1)	0.37
Arterial hypertension	500 (55.2)	484 (53.5)	0.47
Hypercholesterolemia	418 (46.1)	430 (47.5)	0.56
Current smoker	213 (23.6)	231 (25.5)	0.61
Family history of CAD	452 (50.1)	451 (49.9)	0.98
Previous MI	207 (22.8)	190 (21.0)	0.34
Previous PCI	182 (20.1)	167 (18.5)	0.38
Previous CABG	84 (9.3)	89 (9.8)	0.68
Clinical indication			0.07
Stable angina	372 (41.1)	377 (41.7)	
Unstable angina	113 (12.5)	132 (14.6)	
Non-ST-elevation MI (NSTEMI)	246 (27.2)	201 (22.2)	
ST-elevation MI (STEMI)	175 (19.3)	195 (21.5)	
Left ventricular ejection fraction < 30%	15 (1.7)	13 (1.4)	0.70

Data are frequencies (%) or mean (SD). No significant difference between study groups.
* Serum creatinine level ≥ 130 µmol/L.

Lesion Characteristics

	Resolute Integrity n = 1205 lesions	Promus Element n = 1166 lesions	*P*
Target lesion coronary artery			
Left main	19 (1.6)	21 (1.8)	0.67
Left anterior descending	493 (40.9)	469 (40.2)	0.73
Left circumflex	304 (25.2)	280 (24.0)	0.49
Right coronary artery	378 (31.4)	379 (32.5)	0.55
Bypass graft	30 (2.5)	35 (3.0)	0.45
ACC-AHA lesion class			0.99
A/B1	412 (34.2)	401 (34.4)	
B2/C	793 (65.8)	765 (65.6)	
De novo lesion	1147 (95.2)	1103 (94.6)	0.51
Chronic total occlusion	38 (3.2)	39 (3.3)	0.79
In stent restenosis	28 (2.3)	28 (2.4)	0.90
Aorta ostial lesion	59 (4.9)	65 (5.6)	0.46
Severe calcification	221 (18.3)	251 (21.5)	0.052
Bifurcated lesion	282 (23.4)	249 (21.4)	0.23
Thrombus present	165 (13.7)	174 (14.9)	0.40
Total occlusion	167 (13.9)	153 (13.1)	0.60
Pre-procedural TIMI flow grade			0.86
0	175 (14.5)	155 (13.3)	
1	40 (3.3)	39 (3.3)	
2	128 (10.6)	125 (10.7)	
3	862 (71.5)	847 (72.6)	

Data are frequencies (%) or mean (SD). No significant difference between study groups.
* Thrombus triggering use of thrombus aspiration catheter.

Procedural Data (Patient-based)

	Resolute Integrity n = 906 pts.	Promus Element n = 905 pts.	*P*
Total number of lesions treated per patient			0.32
1 lesion treated	668 (73.7)	688 (76.0)	
2 lesions treated	191 (21.1)	182 (20.1)	
3 or more lesions treated	47 (5.2)	35 (3.9)	
Only de novo coronary lesions treated*	817 (90.2)	810 (89.5)	0.64
At least one chronic total occlusion treated	38 (4.2)	38 (4.2)	1.00
At least one bifurcation lesion treated	244 (26.9)	221 (24.4)	0.22
At least one in-stent restenosis treated	27 (3.0)	28 (3.1)	0.89
At least one small-vessel (RVD < 2.75 mm) tr.	551 (60.8)	517 (57.1)	0.11
At least one long lesion (> 27 mm) treated	161 (17.8)	157 (17.3)	0.81
Glycoprotein IIb/IIIa antagonist administered	262 (28.9)	259 (28.6)	0.89

Data are frequencies (%). No significant difference between study groups.
* Including chronic total occlusion, but not grafts or in-stent restenosis.

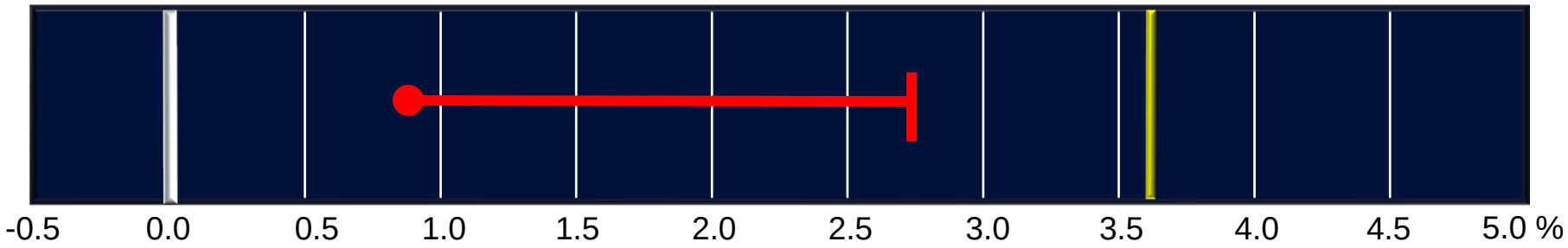
Procedural Data (Lesion-based)

	Resolute Integrity n = 1205 lesions	Promus Element n = 1166 lesions	*P*
Lesion length (mm)	13.63 (9.58-20.41)	13.46 (9.56-20.68)	0.74
Diameter of reference vessel (mm)	2.64 (2.25-3.06)	2.66 (2.27-3.07)	0.28
Minimum lumen diameter (mm)	0.88 (0.63-1.18)	0.88 (0.61-1.23)	0.77
Stenosis (lumen diameter, %)	65.25 (53.83-75.84)	64.48 (53.92-76.17)	0.91
Postprocedure minimum lumen diameter (mm)	2.22 (1.80-2.64)	2.15(1.78-2.58)	0.06
Postprocedure stenosis (lumen diameter, %)	15.07 (10.58-21.17)	15.73 (10.86-21.63)	0.24
Acute gain in segment (mm)	1.27 (0.85-1.78)	1.24(0.79-1.77)	0.38
Number of stents implanted per patient	1.80 (1.08)	1.76 (1.10)	0.41
Number of stents implanted per lesion	1.35 (0.68)	1.36 (0.70)	0.70
Total stent length (mm) per patient	30 (18-50)	28 (20-48)	0.64
Total stent length (mm) per lesion	22 (18-36)	24 (16-38)	0.10
Direct stenting	352 (29.2)	326 (28.0)	0.50
Postdilatation	887 (73.6)	920 (78.9)	*0.002*
Maximum stent diameter per lesion (mm)	3.00 (2.50-3.50)	3.00 (2.50-3.50)	0.09
Implantation of study stents only	1195 (99.2)	1161 (99.6)	0.22
Device success	1194 (99.1)	1158 (99.3)	0.54
Lesion success	1203 (99.8)	1162 (99.7)	0.39
Procedure success	884 (97.6)	890 (98.3)	0.25

Data are frequencies (%) or median (IQR).

Primary Endpoint

Target Vessel Failure at 1-Year Follow-up



Non-inferiority margin = 3.6 %

Resolute Integrity	Promus Element
6.1 %	5.2 %

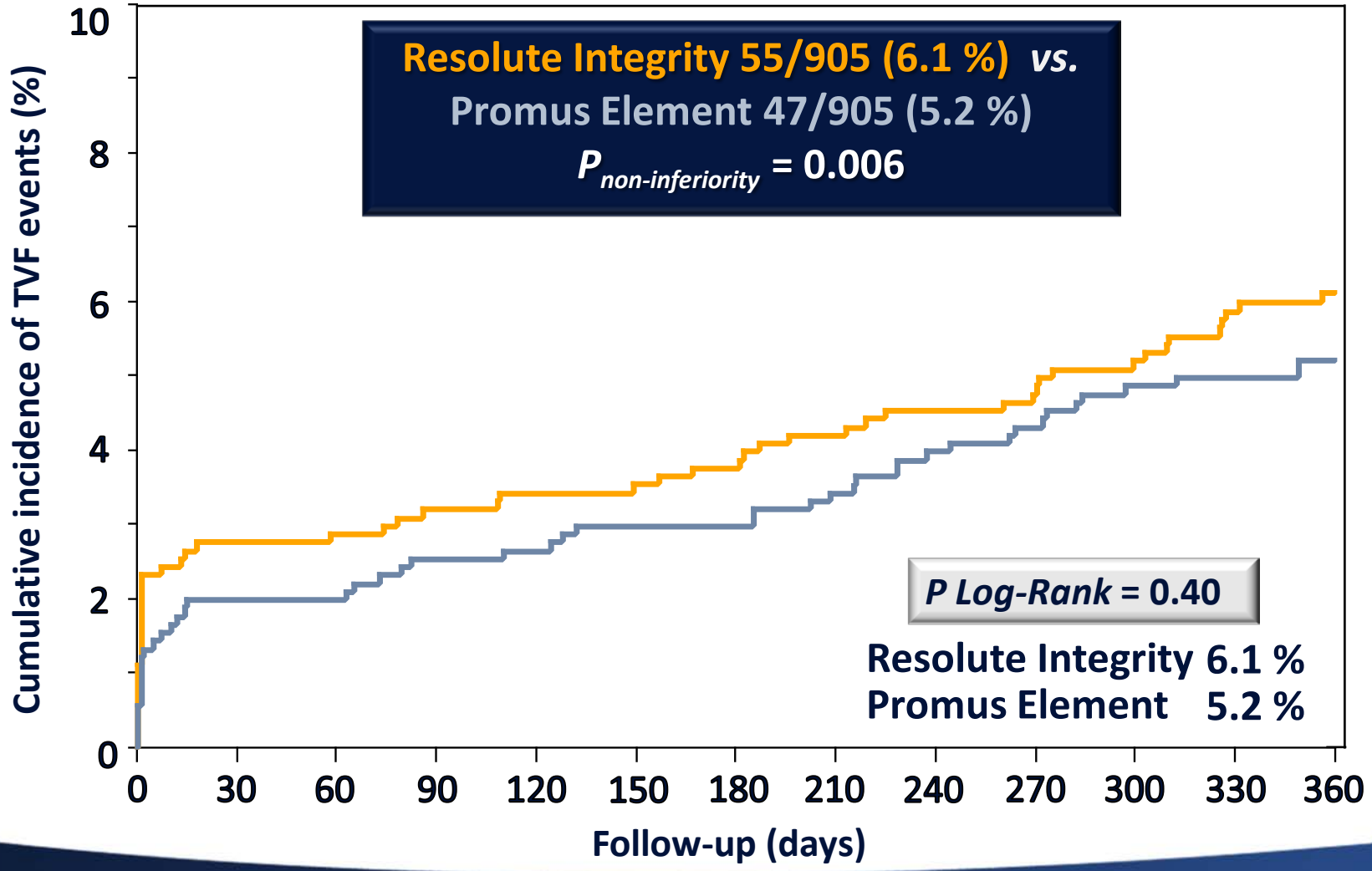
Absolute difference = 0.88 %

Upper 1-sided 95% CI = 2.69 %

$P_{non\text{-}inferiority}$ = 0.006

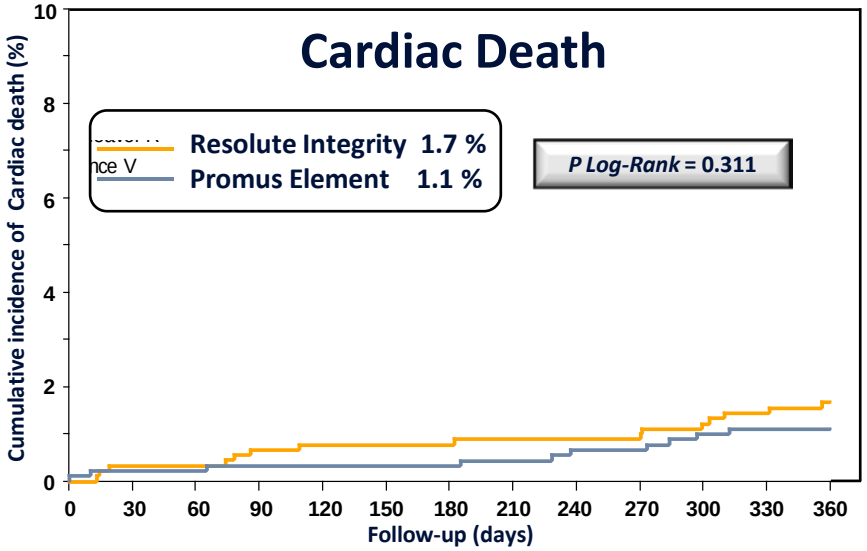
Primary Endpoint

Target Vessel Failure at 1-Year Follow-up

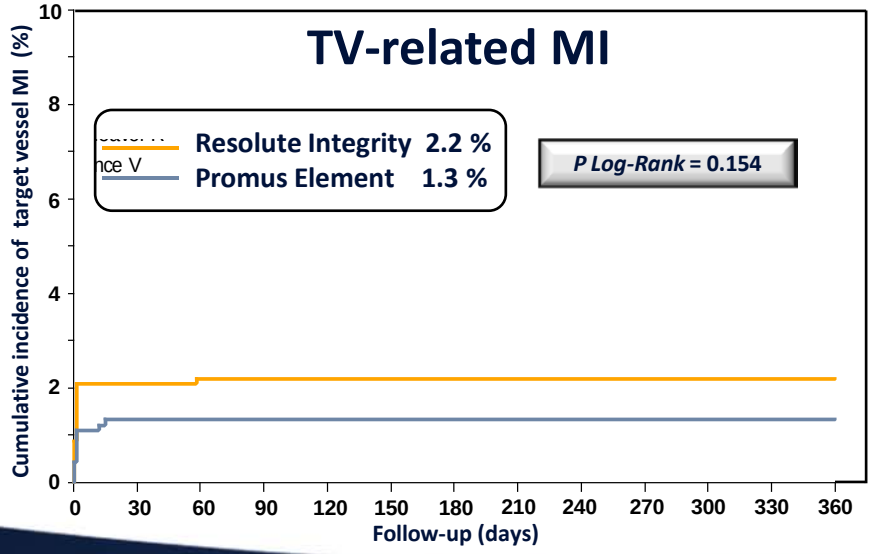


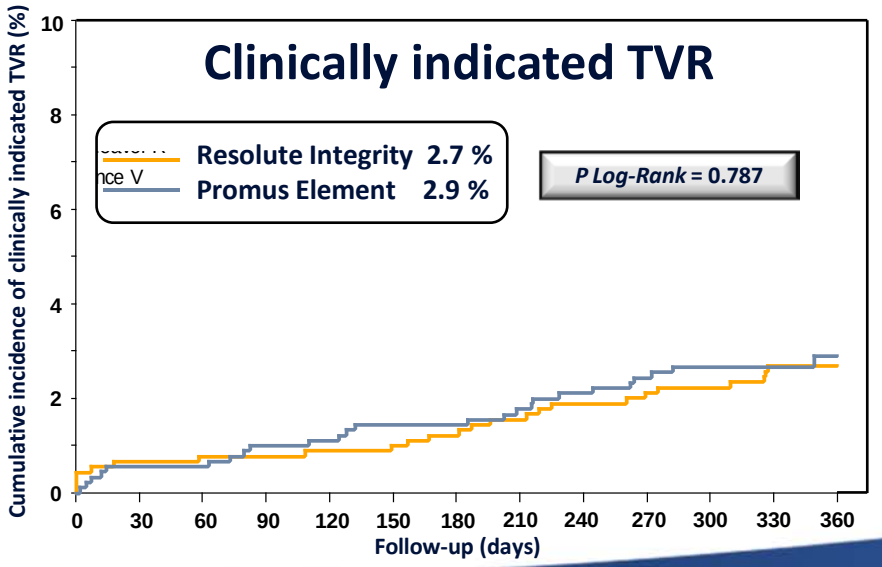
Events displayed in the graph (right lower corner) were calculated by Kaplan-Meier methods and compared with the log-rank test. Non-inferiority testing was based on chi-squared analysis (blue panel).

Components of TVF at 1-Year Follow-up



At 1-year follow-up, there was no statistically significant difference between Resolute Integrity and Promus Element stent groups in the components of Target Vessel Failure (TVF).

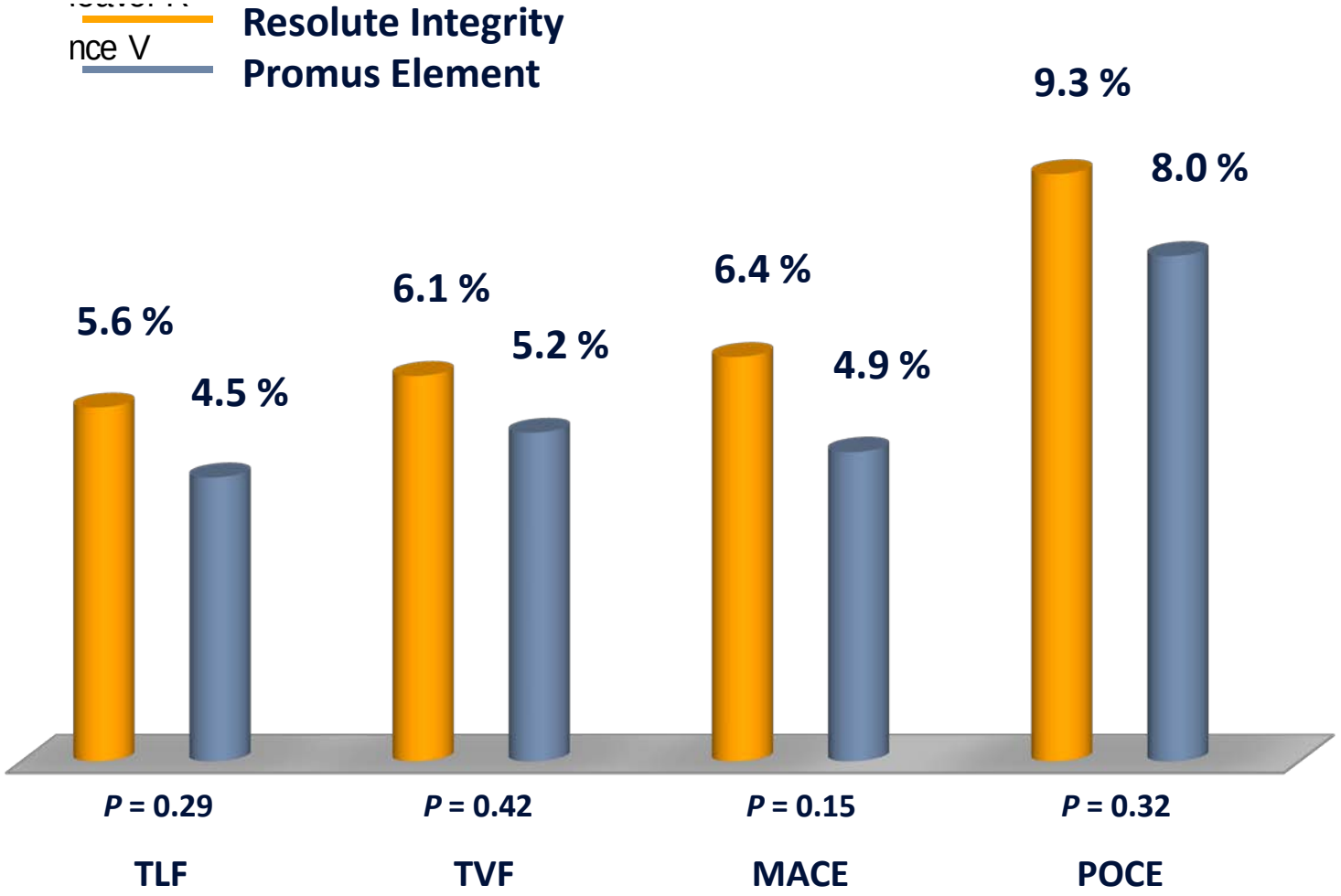




TV-related MI: In each study group (Resolute Integrity and Promus Element), 3 patients (0.3%) developed a periprocedural MI (PMI) with max. CK levels ≥ 5x the ULN; all other PMI had max. CK levels < 5x the ULN.

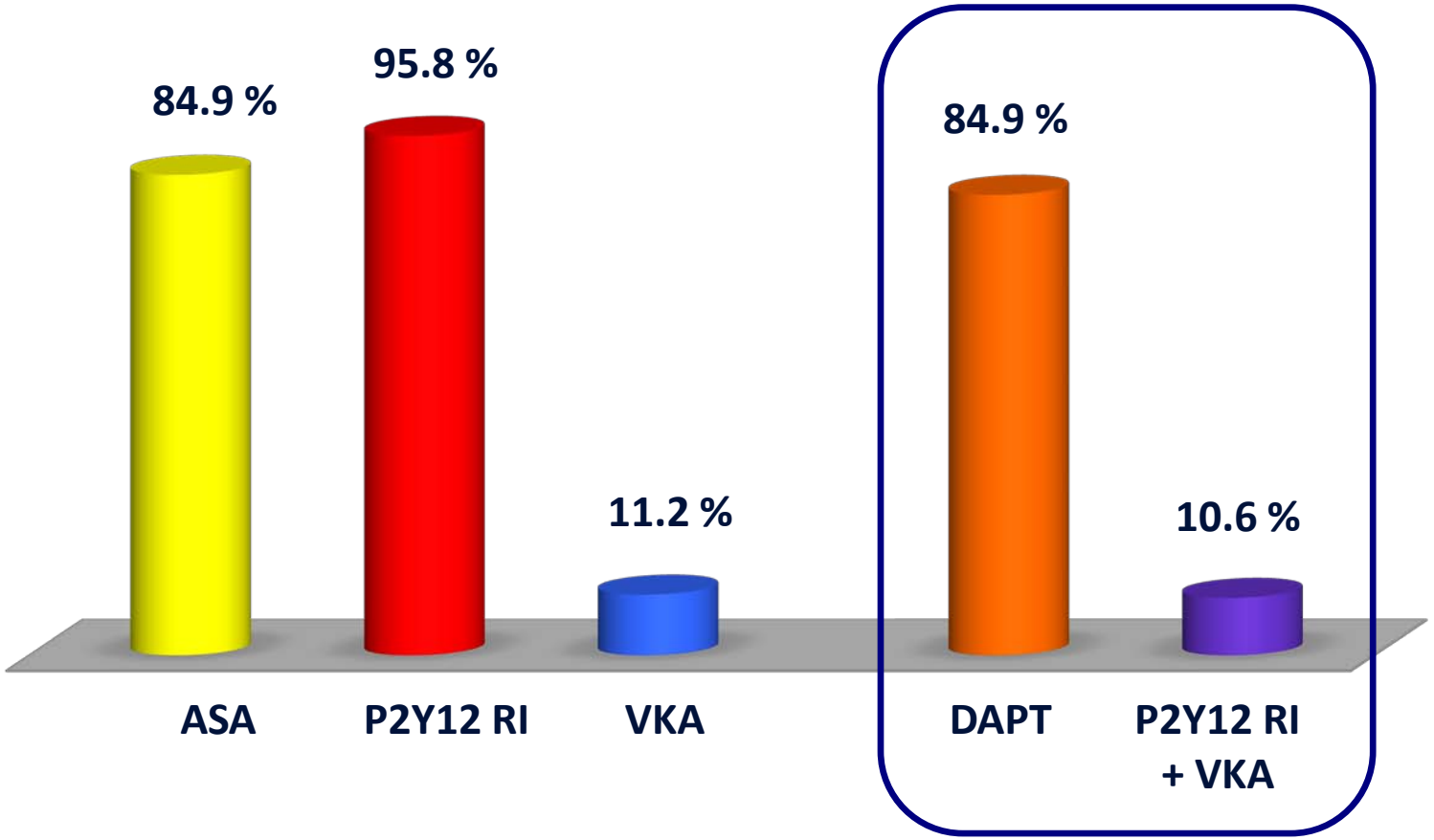
Events displayed in the graph were calculated by Kaplan-Meier methods and compared with the log-rank test.
TV-related MI was defined by the extended historical definition (Vranckx et al. (ARC), EuroIntervention 2010;5:871-4).

Composite Clinical Endpoints at 1-Year



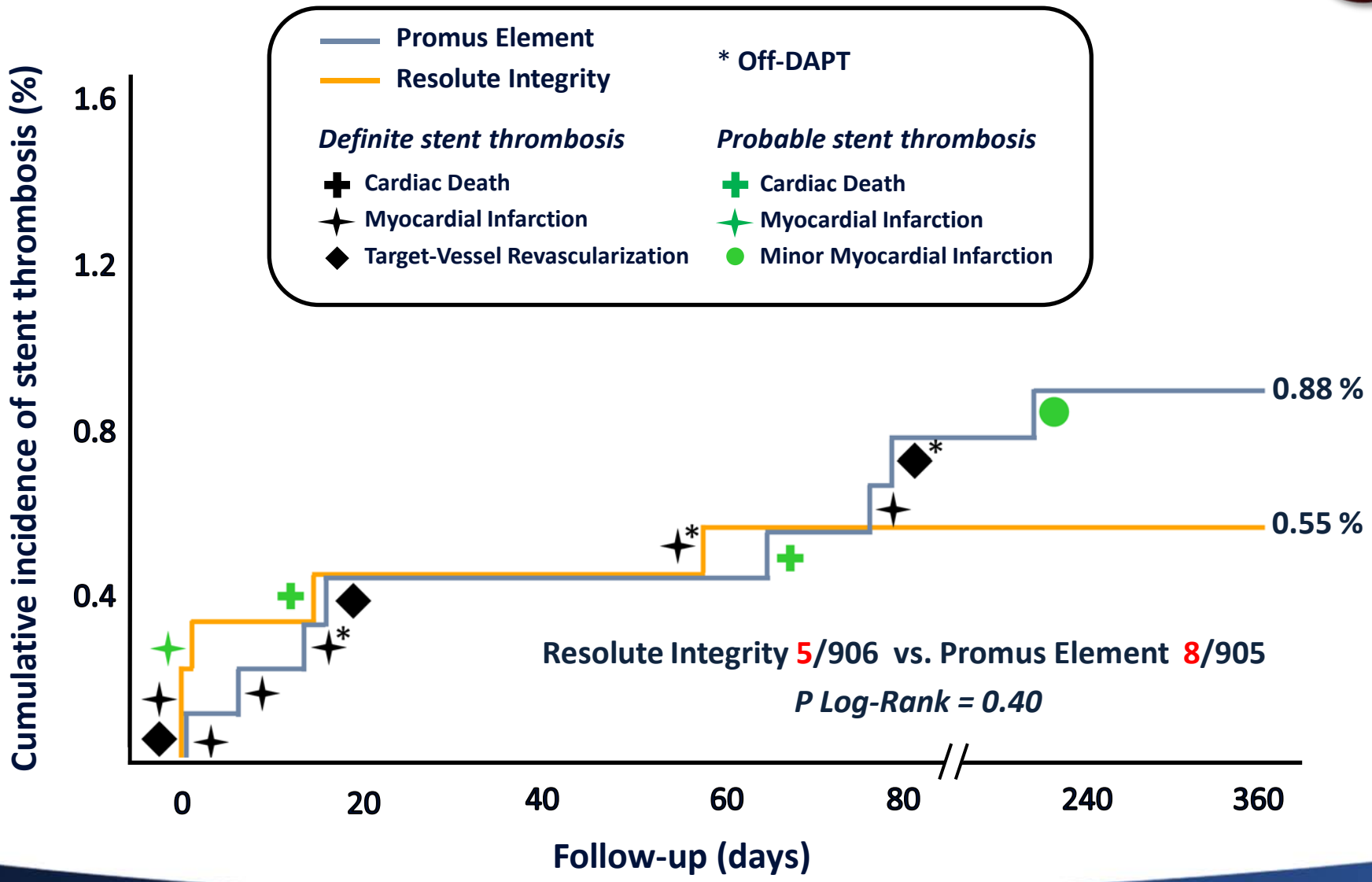
Target Lesion Failure (TLF): cardiac death, target lesion-related MI & clinically indicated target lesion revascularization. Target Vessel Failure (TVF, the primary endpoint of the trial): cardiac death , target vessel related MI & clinically indicated target vessel revascularization. Major Adverse Cardiac Events (MACE): any death, any MI, clinically indicated TLR & emergent CABG. Patient-Oriented Composite Endpoint (POCE): any death, any MI, any PCI & any CABG.

Medication at 1-Year



Between stent arms, there was no significant difference in medication. Data on the use of antiplatelet drugs and/or oral anticoagulation were available in 1810 patients. ASA=acetylsalicylic acid; P2Y12 RI=P2Y12 receptor inhibitor; VKA=vitamin K antagonist; DAPT=dual antiplatelet therapy.

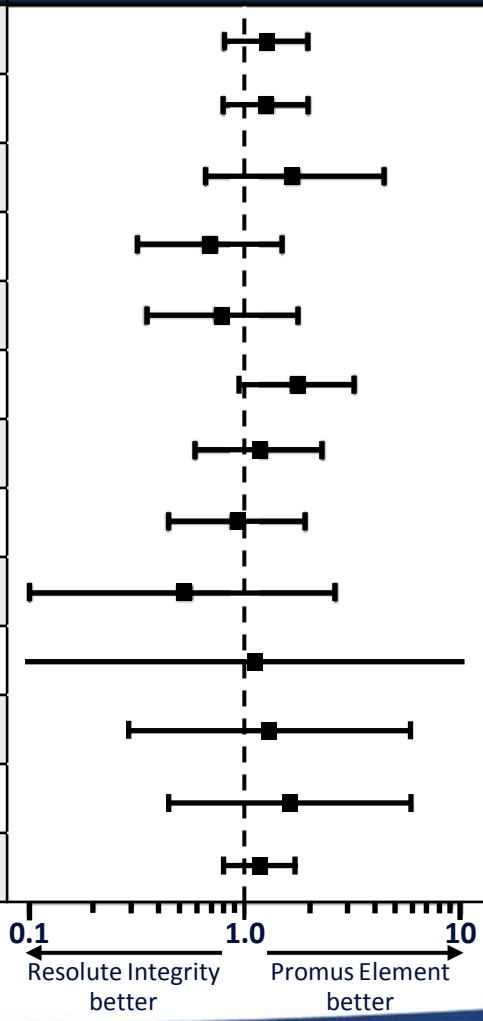
Stent Thrombosis at 1-Year



Definite stent thrombosis occurred in 3 patients (0.33 %) of the Resolute Integrity stent group and in 6 patients (0.66 %) of the Promus Element stent group (P = 0.51). There was no definitive stent thrombosis beyond 3 months.
Events displayed in the graph were calculated by Kaplan-Meier methods and compared with the log-rank test. Stent thrombosis was defined according to the Academic Research Consortium (ARC).

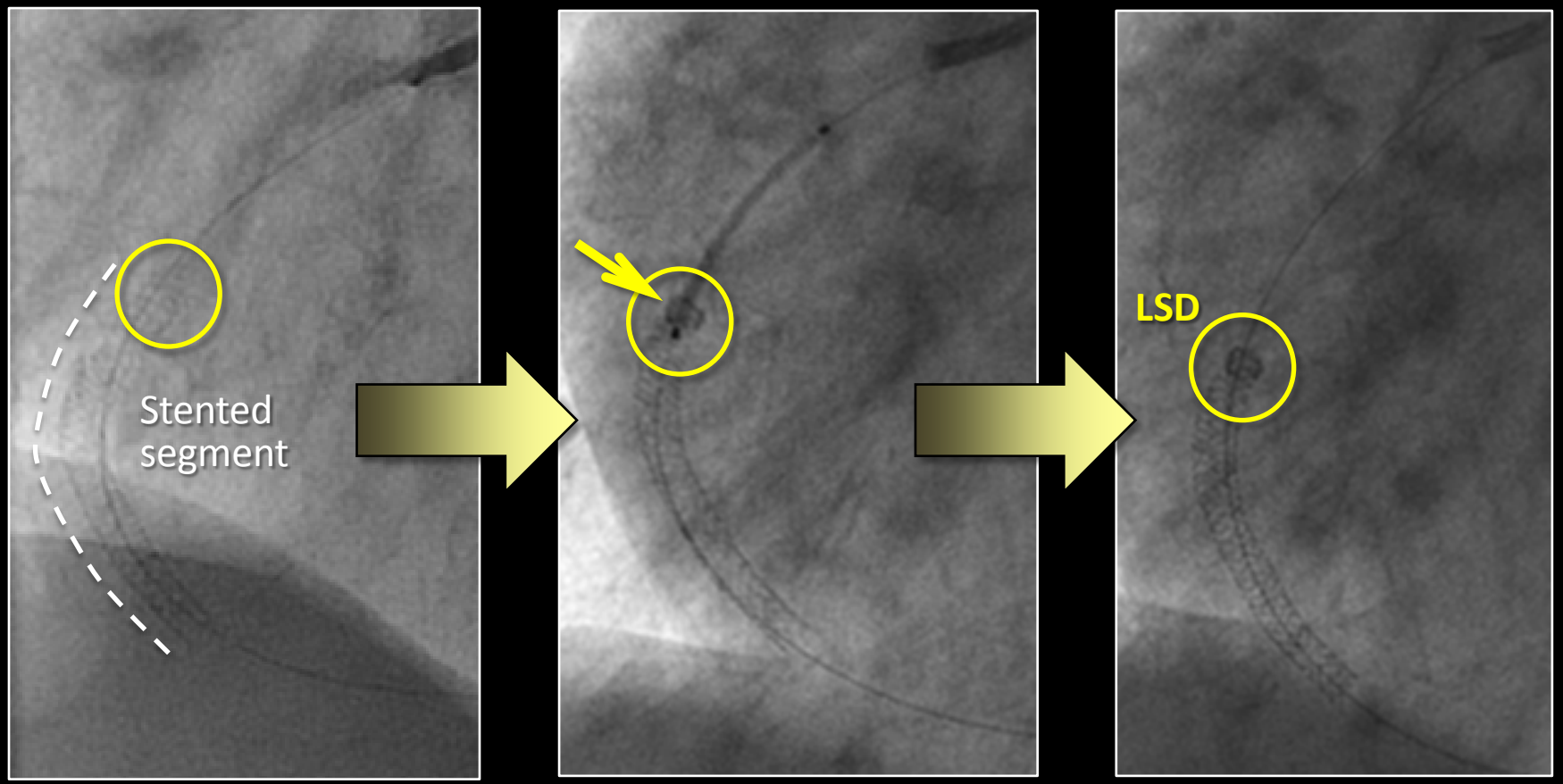
TVF Subgroup Analysis at 1-Year

	Resolute Integrity n = 906	Promus Element n = 905	Relative Risk (95% CI)	*P*
Off-label indication	42/648 (6.5)	32/617 (5.2)	1.25 (0.80-1.95)	0.33
RVD < 2.75mm	41/550 (7.5)	31/517 (6.0)	1.24 (0.79-1.95)	0.34
Acute MI < 72 hr	11/285 (3.9)	6/258 (2.3)	1.66 (0.62-4.42)	0.31
Multivessel PCI	11/163 (6.7)	13/133 (9.8)	0.69 (0.32-1.49)	0.34
Diabetes	10/167 (6.0)	12/157 (7.6)	0.78 (0.35-1.76)	0.55
Overlapping stents	27/299 (9.0)	15/287 (5.2)	1.73 (0.94-3.18)	0.07
Bifurcation lesion	18/244 (7.4)	14/221 (6.3)	1.17 (0.59-2.29)	0.66
Lesion length > 27 mm	13/160 (8.1)	14/157 (8.9)	0.91 (0.44-1.88)	0.80
In-stent restenosis	2/27 (7.4)	4/28 (14.3)	0.52 (0.10-2.60)	0.67
Left main treated	1/19 (5.3)	1/21 (4.8)	1.11 (0.07-16.47)	1.00
Bypass graft treated	3/24 (12.5)	3/31 (9.7)	1.29 (0.29-5.84)	1.00
Renal insufficiency	6/35 (17.1)	3/28 (10.7)	1.60 (0.44-5.83)	0.47
All	55/905 (6.1)	47/905 (5.2)	1.17 (0.80-1.71)	0.47



RVD=reference vessel diameter.
Subgroup analysis was non-prespecified.

Longitudinal Stent Deformation



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Longitudinal Stent Deformation

- Angiograms of all patients were reviewed for stent deformation (LSD).
- LSD was defined as distortion or shortening of an implanted stent in the longitudinal axis following successful initial deployment.
- LSD was noted on angiograms of 9 patients of the Promus Element group and none of the Resolute Integrity group (9/905 vs. 0/906; p=0.002).
- In the Promus Element group, LSD was seen in 1/100 patients treated (1%) and in 0.6/100 Promus Element stents implanted (0.6%).
- LSD often triggered postdilation and implantation of additional stents, but was not associated with any adverse events.

Case	PDSL	Stent type	Diameter	Vessel	Lesion	Characteristics	Post-dilation	Additional prox. stent	Association with clinical event
Following attempts to re-cross stent									
1	0.94	Pr. Element	3.0 mm	LAD	C	bifurcation	+	+	**none**
2	0.83	Pr. Element	2.5 mm	RCA	C	severe calcification	+	+	**none**
3	0.74	Pr. Element	3.5 mm	LAD	C	bifurcation	+	+	**none**
4	0.79	Pr. Element	2.25 mm	LAD	C	bifurcation	–	+	**none**
Following very oversized postdilatation									
5	0.94	Pr. Element	2.25 mm	LAD	C	severe calcification	+	+	**none**
6	0.87	Pr. Element	3.5 mm	Left main	B2	bifurcation	+	–	**none**
Following contact with guiding or balloon catheter									
7	0.81	Pr. Element	2.5 mm	RCA	C	bifurcation	+	+	**none**
8	0.91	Pr. Element	3.0 mm	LAD	C	moderate calcification	+	+	**none**
9	0.84	Pr. Element	3.0 mm	RCA	C	severe calcification	+	–	**none**

PDSL means post-deployment stent length ratio, defined as final stent length divided by stent length immediately after deployment. Cases 2 and 4 are female patients. Lesion types were assigned according to ACC/AHA lesion classification. LAD=left anterior descending artery. LSD=longitudinal stent deformation. Pr.=Promus. RCA=right coronary artery.

Conclusion

Use of third-generation zotarolimus-eluting Resolute Integrity stents and everolimus-eluting Promus Element stents in an “all-comers” population resulted in excellent clinical outcomes, especially in view of the large number of patients treated for acute myocardial infarction.

Efficacy and safety of the Resolute Integrity stent were similar to that of the Promus Element stent.

DUTCH PEERS
(TWENTE II)

Third-generation zotarolimus-eluting and everolimus-eluting stents in all-comer patients requiring a percutaneous coronary intervention (DUTCH PEERS): a randomised, single-blind, multicentre, non-inferiority trial

Clemens von Birgelen, Hanim Sen, Ming Kai Lam, Peter W Danse, Gillian A J Jessurun, Raymond W M Hautvast, Gert K van Houwelingen, Alexander R Schramm, R Melvyn Tjon Joe Gin, Johannes W Louwerenburg, Frits H A F de Man, Martin G Stoel, Marije M Löwik, Gerard C M Linssen, Salah A M Saïd, Mark B Nienhuis, Patrick M J Verhorst, Mounir W Z Basalus, Carine J M Doggen, Kenneth Tandjung

Simultaneous publication online in The Lancet

DUTCH PEERS

Trial Organization

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- P. Danse, MD PhD
- G.A.J. Jessurun, MD PhD

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- Scheper Hospital, Emmen
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  - R.E. van der Leest
  - J. van Es, MD
  - J.W. Louwerenburg, MD

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  - J.C. Jonge Poerink, RN

Clinical Event Adjudication
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  - P.P. Kint, RN
  - W. Lindeboom, MSc
  - Clinical Event Committee:
  - P. Vranckx, MD PhD (chair)
  - H.M. Garcia-Garcia, MD PhD
  - J. Wykrzykowska, MD PhD

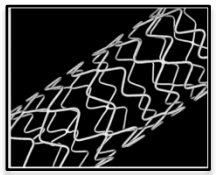
Statistical Analysis
- K. Tandjung, MD
- C.J.M. Doggen, PhD

Investigator-initiated study, equally supported by Boston Scientific and Medtronic

Backup Slides

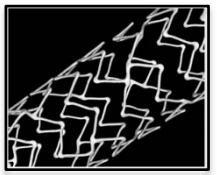
DUTCH PEERS
(TWENTE II)

- Any patient requiring DES (stable angina, any ACS, including STEMI)
- No limit of number of lesions or vessels treated, lesion length, vessel size, or lesion type (de novo lesion, restenosis, CTO, graft lesion)



Zotarolimus eluted within < 180 days from a 5.6 µm BioLinx™ polymer coating on an Integrity stent platform with 91µm $CoCr^2$ struts

- **Inclusion criteria:** Age ≥ 18 yrs; patient requires PCI with DES implantation and is able and willing to comply with study procedures and follow-up procedures; signed informed consent
- **Exclusion criteria:** Participation in another randomized drug or device trial before reaching its primary endpoint; life expectancy < 1yr; planned surgery < 6 mo's of PCI unless DAPT is maintained; known pregnancy; intolerance to heparine, ASA, clopidogrel, or DES components



Everolimus eluted within < 120 days from a 7 µm fluoropolymer coating on an Element stent platform with 81µm $PtCr^2$ struts

Zotarolimus-eluting
RESOLUTE INTEGRITY
(n=906)

1811 All-comer patients were enrolled in this single-blinded, investigator-initiated, randomized (1:1) trial in Arnhem, Emmen, Alkmaar & Enschede

Everolimus-eluting
PROMUS ELEMENT
(n=905)

30 days | **1 year** | **2 years**

Control angiography only if clinically indicated

Primary endpoint	**Target vessel failure at one year** (composite of cardiac death, target vessel-related MI, and clinically driven target vessel revascularization; **non-inferiority hypothesis**)
Secondary endpoints	**Components of primary endpoint; stent thrombosis; patient oriented composite endpoint**

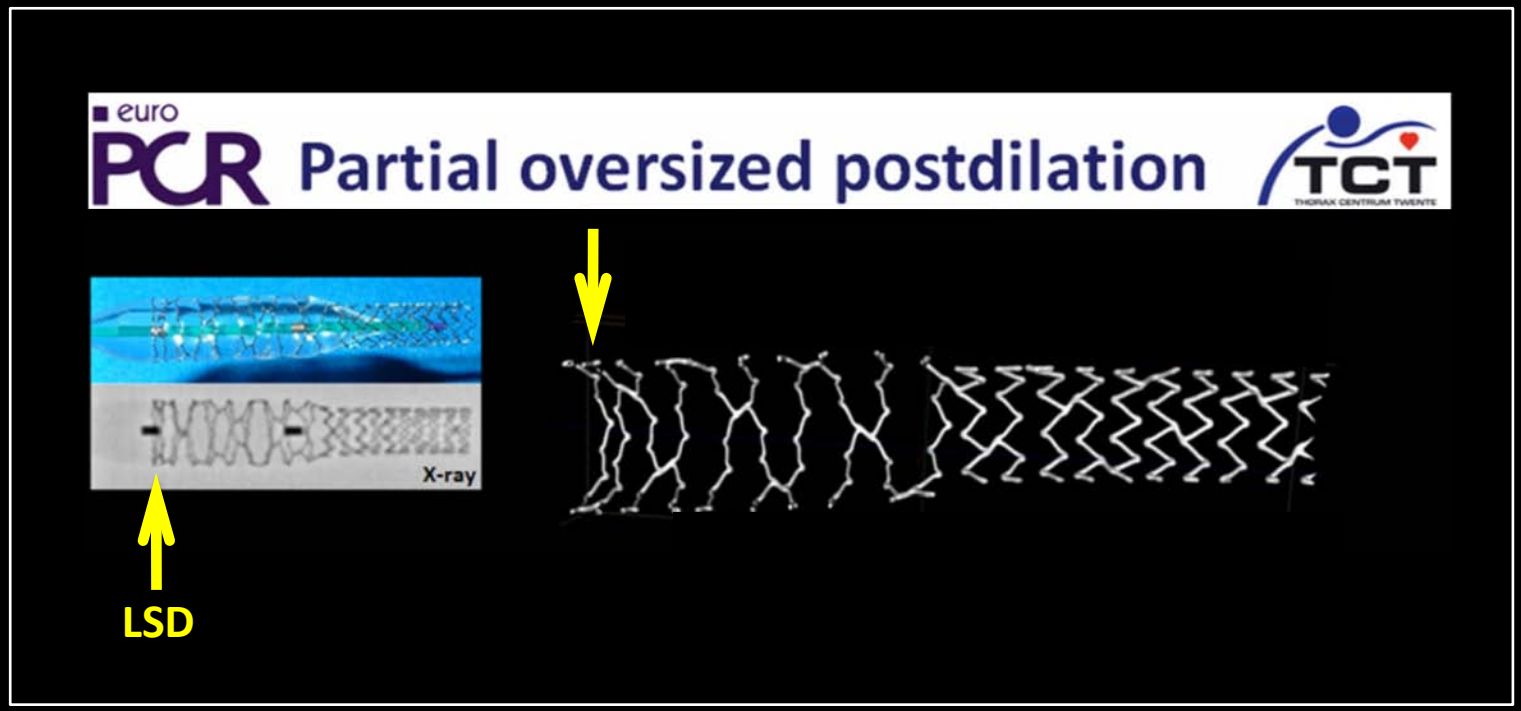
Enrollment: November 25, 2010 to May 24, 2012. Systematic (serial) assessment of cardiac markers and ECG. Monitoring of informed consent and key demographic data in all patients; monitoring of data on potential clinical events in patients with event triggers; in-depth monitoring of all data in 10% of randomly chosen patients. Monitoring performed by CRO Diagram, Zwolle, NL. Processing of clinical outcome data and independent external adjudication of clinical events (CEC) by CRO Cardialysis, Rotterdam, NL.
Analyses based on intention-to-treat. 1-Year follow-up available in 99.9% of patients.

von Birgelen *et al*. Third-generation zotarolimus-eluting and everolimus-eluting stents in all-comer patients requiring a PCI (DUTCH PEERS). *Lancet* – in press.

Investigator-initiated study, equally funded by Boston Scientific and Medtronic

Longitudinal Stent Deformation

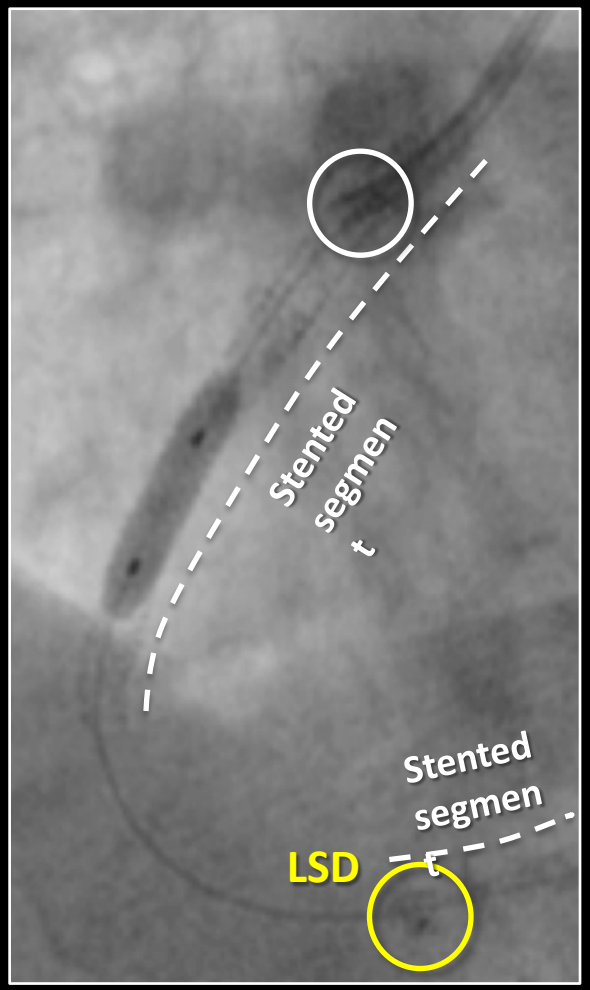
Longitudinal stent deformation (LSD) after very oversized postdilation of stents (bench top, unconstrained model)



C. von Birgelen, Thoraxcentrum Twente, Enschede, Netherlands

Longitudinal Stent Deformation

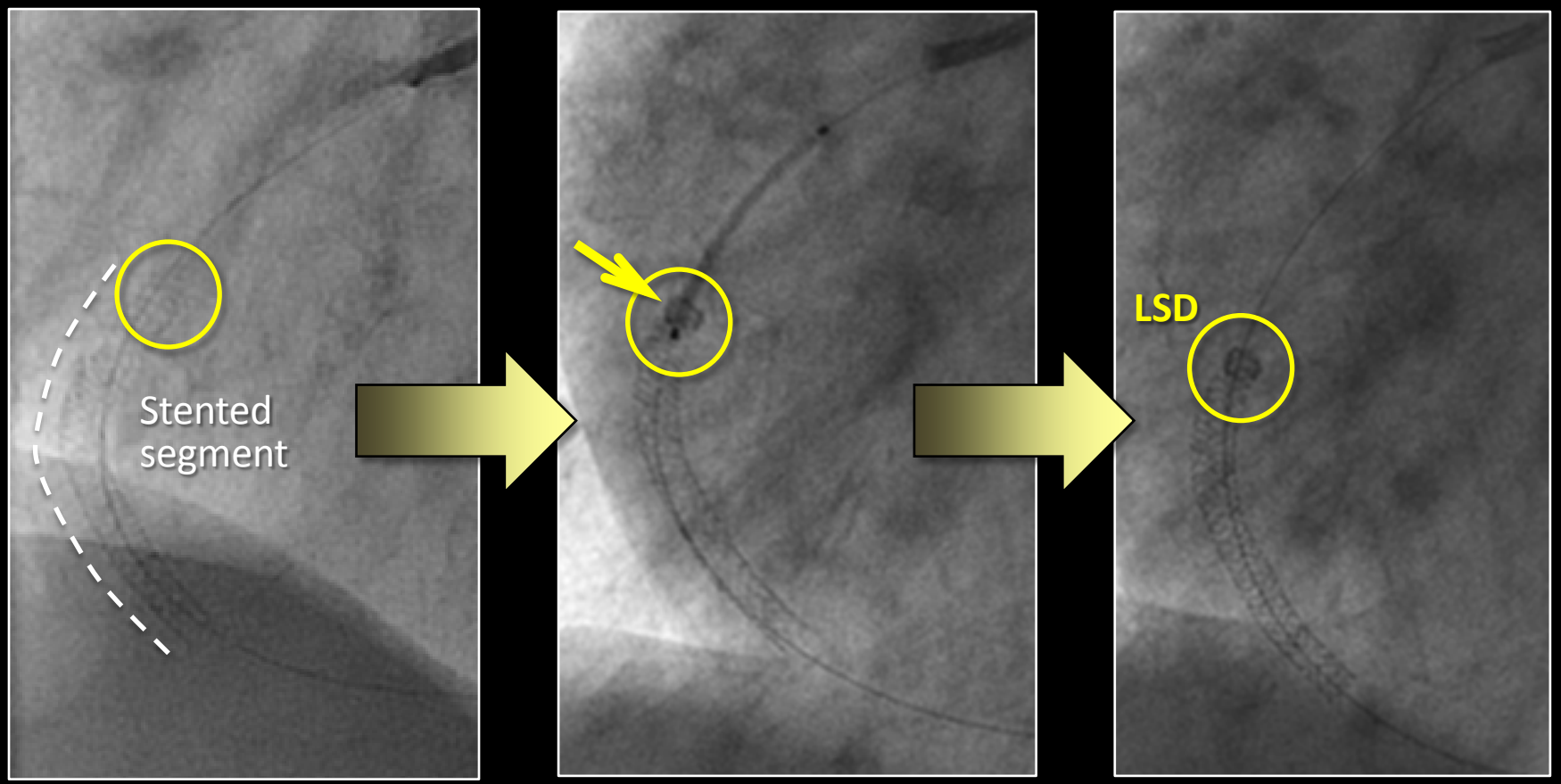
LSD in distal stent + contact between guiding catheter tip and proximal stent



C. von Birgelen, Thoraxcentrum Twente, Enschede, Netherlands

LSD in the distal stent resulted from recrossing the distal stent with a balloon catheter.

Longitudinal Stent Deformation



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