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3-year clinical outcome following treatment with thin, very thin or ultrathin strut drug-eluting stents in *small* coronary vessels in BIO-RESORT

Clemens von Birgelen, MD PhD FESC

on behalf of the

BIO-RESORT trial investigators

Potential conflicts of interest

Speaker's name : Clemens von Birgelen

☑ I have the following potential conflicts of interest to declare:

Institutional research support of Thoraxcentrum Twente by Abbott Vascular, Biotronik, Boston Scientific and Medtronic

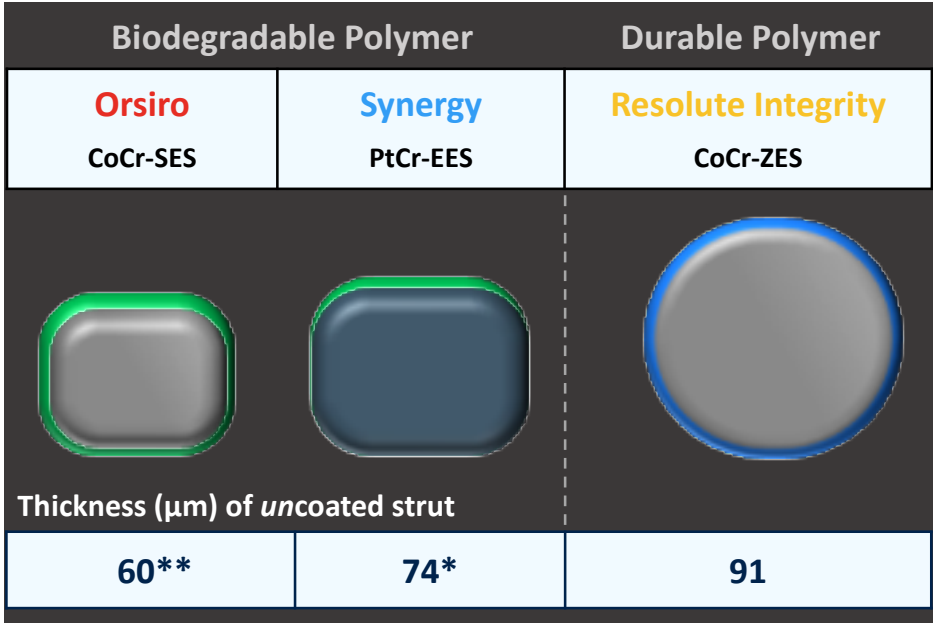
Background

- *Small* coronary vessel PCI has an increased adverse event risk but is performed in many patients.
- Newer DES, such as *ultrathin* strut Orsiro and *very thin* strut Synergy, have substantially thinner struts than earlier DES.
- This may be particularly advantageous in small vessels, due to the greater relative impact of strut size on lumen obstruction.

Aim of the Study

To assess in all-comers with small coronary target lesions the 3-year clinical outcome after treatment with

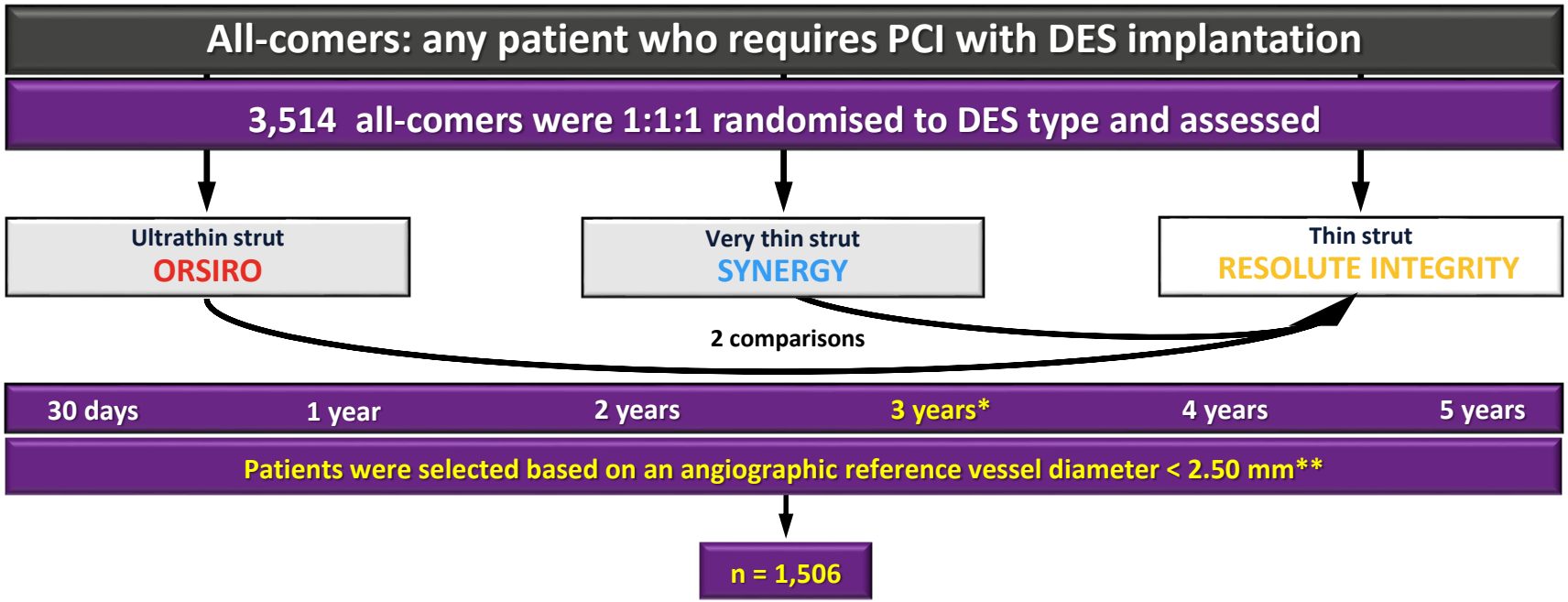
***ultrathin* strut** sirolimus-eluting **Orsiro or *very thin* strut** everolimus-eluting **Synergy versus *thin* strut** zotarolimus-eluting **Resolute Integrity** stents



BIO-RESORT Study Devices

	ORSIRO	SYNERGY	RESOLUTE INTEGRITY
Coating characteristics	Biodegradable Circumferential Asymmetrical	Biodegradable Abluminal	Durable Circumferential Symmetrical
Bare strut thickness, µm	60 (≥ 3.5 mm stents: 80)	74 (3.0 – 3.5 mm: 79, 4.0 mm stent: 81)	91
Coating thickness, µm	7.4 / 3.5 (ab-/luminal)	4	5.6
Coated strut thickness, µm *(of smallest stent)*	71	78	102
Metal	Cobalt-chromium	Platinum-chromium	Cobalt-chromium
Polymer	PLLA (poly [L-lactide] acid) (BIOlute®), on thin amorphous silicon carbide (proBIO®)	PLGA (poly [lactic-co-glycolic acid] polymer) coating	BioLinx®, a blend of hydrophobic C10, hydrophilic C19, and poly-vinyl pyrrolidone
Drug	Sirolimus	Everolimus	Zotarolimus
Drug release time, mo.	3.3	3	6
Degradation time, mo.	24	4	---

BIO-RESORT Small Vessel Analysis

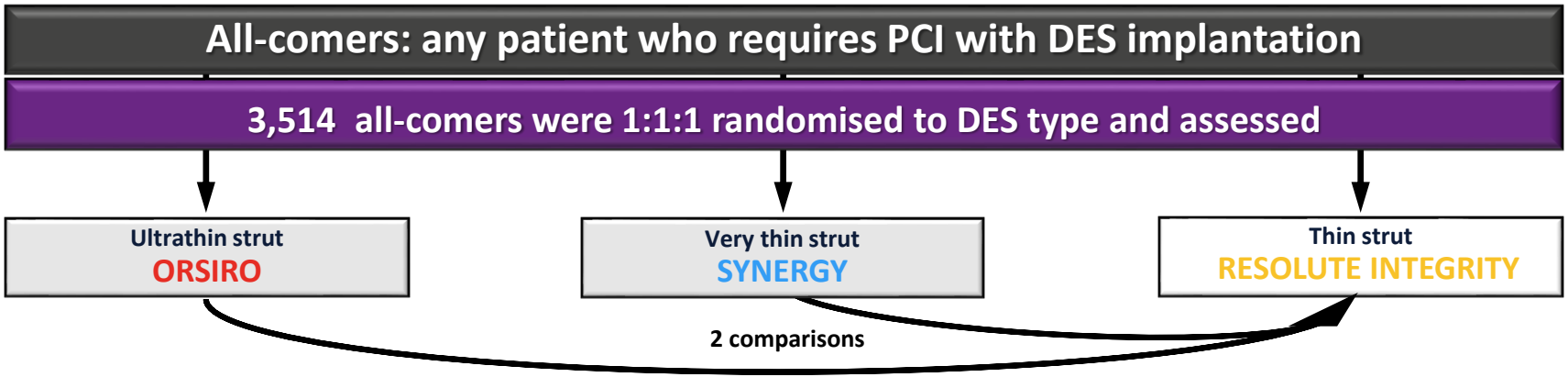


Investigator-initiated, multicenter, assessor and patient-blinded, three-arm, randomized, non-inferiority trial · Visits to outpatient clinic, questionnaire or telephone follow-up · No routine angiographic follow-up · Independent monitoring and clinical event adjudication (CEC) · Supervision by DSMB

BIO-RESORT Study Sites: Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede · Rijnstate Hospital, Arnhem · Haga Hospital, The Hague · Albert Schweitzer Hospital, Dordrecht; all in the Netherlands · Enrollment from December 21, 2012 to August 24, 2015 · PI: C. von Birgelen, MD PhD

* 3-Year BIO-RESORT Trial: Buiten RA, Ploumen EH, Zocca P, et al. JACC Cardiovasc Interv. – *In press.* ** Based on quantitative coronary analysis (QCA) by experienced core lab analysts.

BIO-RESORT Small Vessel Analysis



- Target Lesion Failure (TLF): composite of cardiac death, target vessel-related myocardial infarction, or target lesion revascularisation
- Cardiac Death; Target Vessel-related MI; Target Lesion Revascularisation; Stent Thrombosis

1,452 patients (96.4%) completed 3-year follow-up or had died.
24 patients were lost to follow-up; 30 patients withdrew consent

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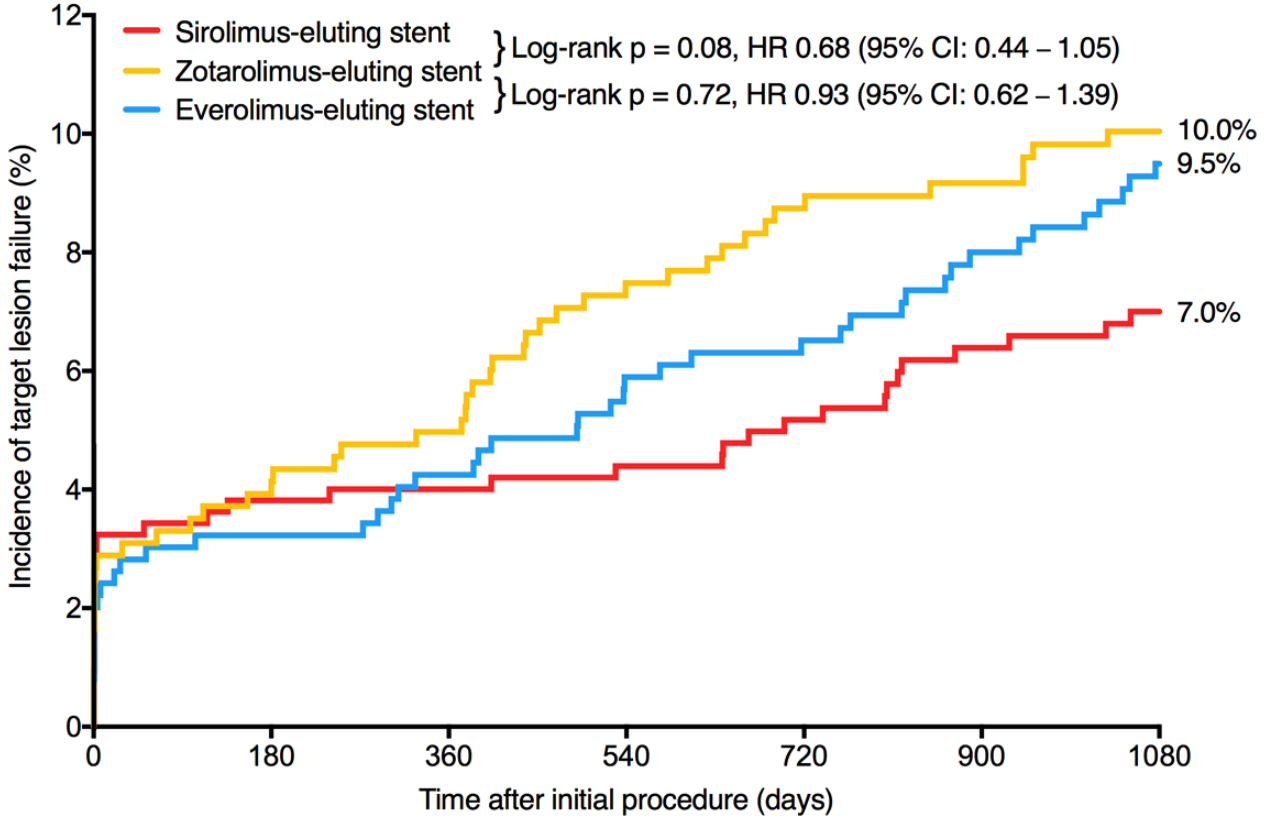
Small vessel analysis: **Baseline data**

Patients	Orsiro n = 525	Synergy n = 496	Resolute Integrity n = 485
Mean age, years	64.9 ± 10.2	64.0 ± 10.6	64.0 ± 10.3
Female sex	30.1 %	28.6 %	30.7 %
Diabetes mellitus	19.2 %	21.4 %	21.0 %
Clinical syndrome at index PCI			
Acute myocardial infarction	49.7 %	48.2 %	46.2 %
Unstable angina	19.4 %	17.3%	19.2%
Stable angina	30.9 %	34.5 %	34.6 %
Previous myocardial infarction	18.1 %	17.5 %	22.5 %

Procedures	Orsiro n = 525	Synergy n = 496	Resolute Integrity n = 485
Multiple vessels treated	29.3 %	28.4 %	32.4 %
At least one complex (type B2 or C) target lesion	81.7 %	76.8 %	77.5 %
At least one bifurcation target lesion	44.8 %	44.0 %	44.7 %
At least one severely calcified target lesion	23.0 %	23.6 %	25.6 %
At least one in-stent restenosis treated	1.3 %	2.4 %	2.9%

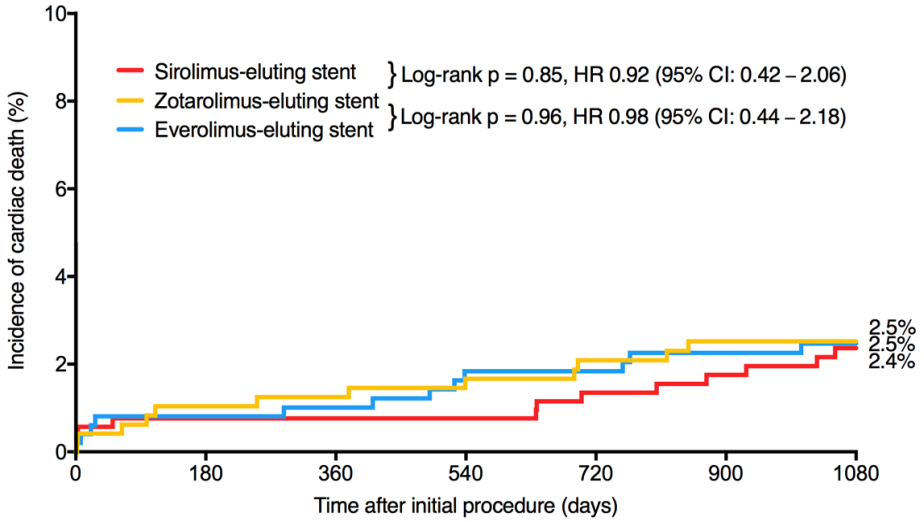
Results of 3-yr. small vessel analysis: **Target Lesion Failure**



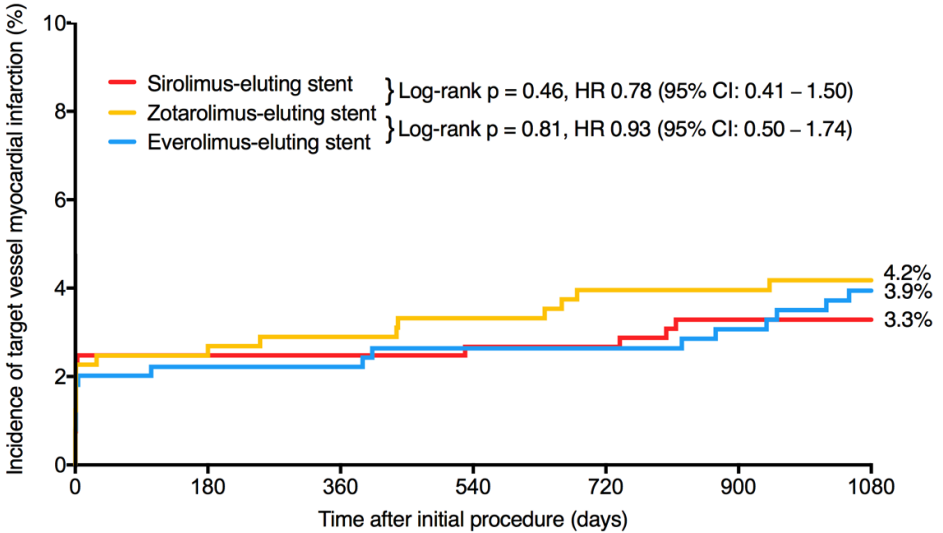
Sirolimus-eluting stent: Orsiro; Zotarolimus-eluting stent: Resolute Integrity; Everolimus-eluting stent: Synergy.

Results of 3-yr. small vessel analysis: **Safety Endpoints**

Cardiac death



Target vessel myocardial infarction

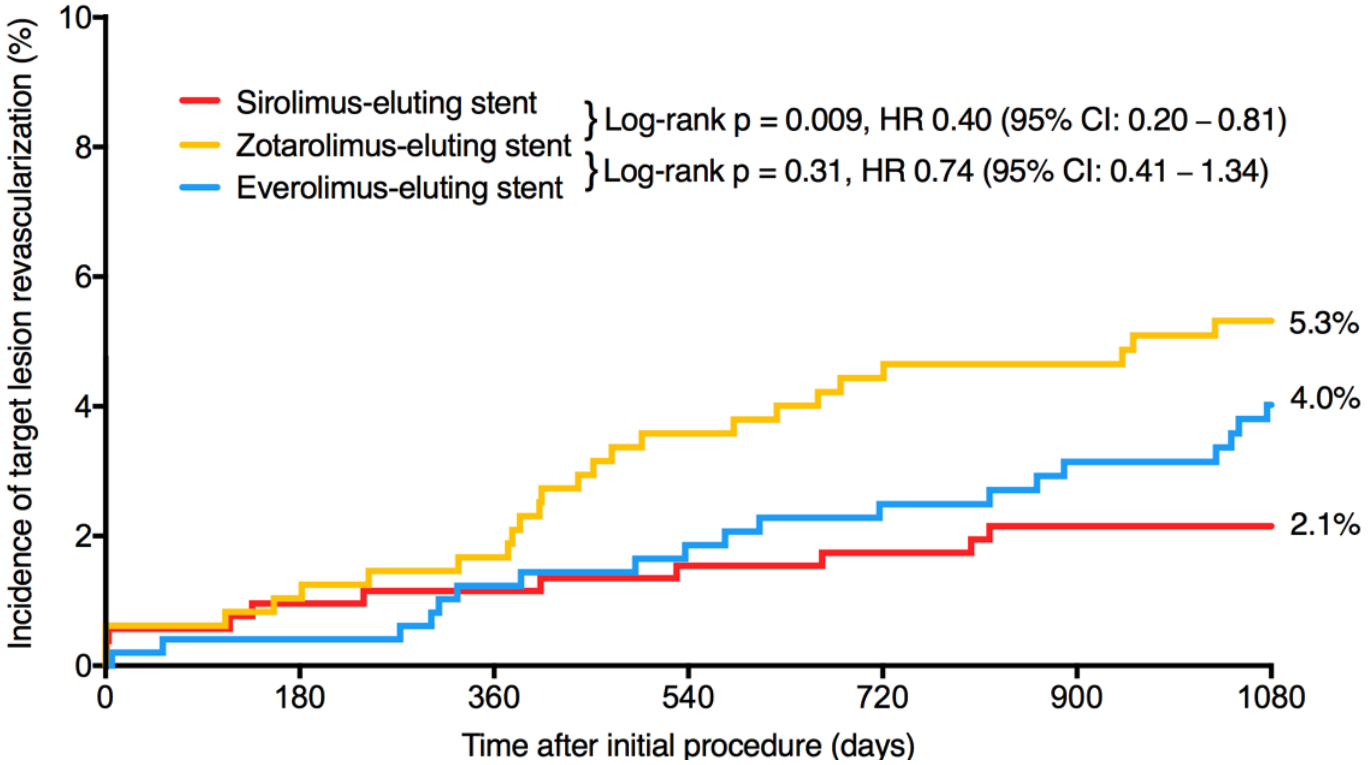


There was no between-stent difference in the incidence of cardiac death or target vessel-related myocardial infarction.

In addition, the *definite* stent thrombosis rate was in ultrathin strut Orsiro 0.4%, in very thin strut Synergy 0.8% and in thin strut Resolute Integrity 1.1% (p=0.21 and p=0.72, respectively).

Sirolimus-eluting stent: Orsiro; Zotarolimus-eluting stent: Resolute Integrity; Everolimus-eluting stent: Synergy.

Results of 3-yr. small vessel analysis: **TLR**

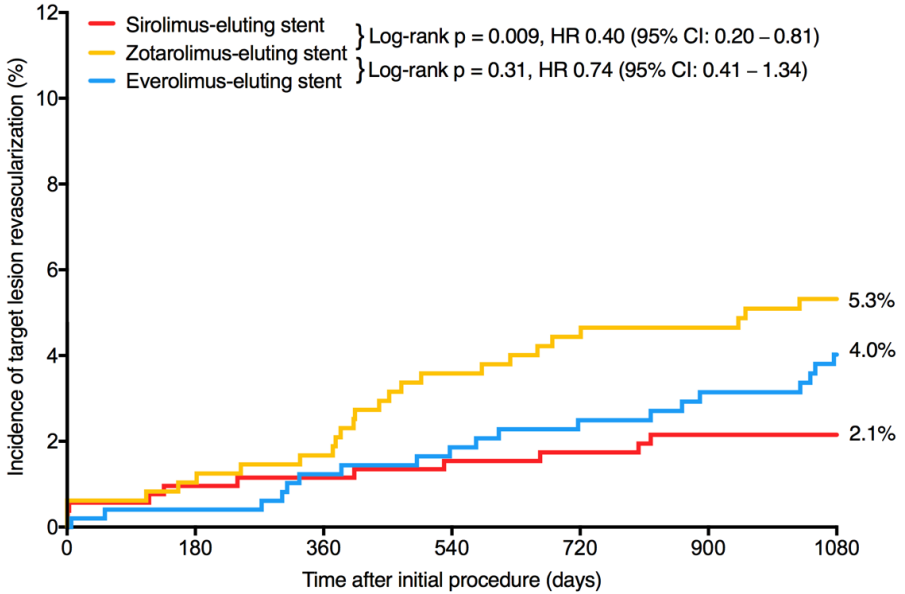


PCI with *ultrathin strut Orsiro* stents resulted in fewer target lesion revascularisations than PCI with *thin strut Resolute Integrity*.

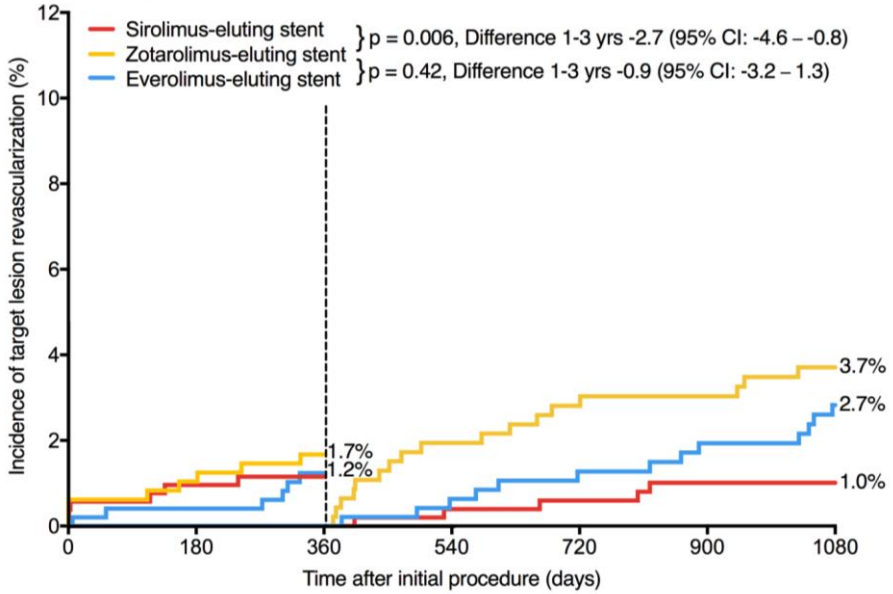
Sirolimus-eluting stent: Orsiro; Zotarolimus-eluting stent: Resolute Integrity; Everolimus-eluting stent: Synergy.

Results of 3-yr. small vessel analysis: **TLR, 1-yr. Landmark**

3-year target lesion revascularisation



Target lesion revascularisation, 1-year landmark



Landmark analysis revealed that this significant between-DES difference in TLR emerged between 1-year and 3-year follow-up.

Sirolimus-eluting stent: Orsiro; Zotarolimus-eluting stent: Resolute Integrity; Everolimus-eluting stent: Synergy.

Discussion & Conclusion

- Stenting of small coronary vessel lesions is *common,* but data on the performance of the *ultrathin* strut Orsiro and *very thin* strut Synergy stents in small coronary vessels are *scarce*.
- DES types differ not only in strut thickness but also in stent geometry, coating and drug.
- Until 3-year follow-up, all-comer patients with small vessel lesions treated with the *ultrathin* strut Orsiro stent experienced *fewer repeat target lesion revascularisations* than patients treated with the *thin* strut Resolute Integrity stent.
- There was no statistically significant between-DES difference in safety endpoints.

Our data suggest a relation between the use of the *ultrathin* strut Orsiro stent and a lower repeat target lesion revascularisation risk in patients with small vessel lesions.

Essentials of 3-yr. BIO-RESORT small vessel analysis

- **Why?** Stenting small vessel lesions increases adverse event risk, but data with contemporary *very thin* and *ultrathin* strut DES are scarce.
- **What?** 3-year clinical outcome in 1,506 patients treated with *thin, very thin or ultrathin* strut DES in small target vessels.
- **How?** Prespecified analysis of data from the randomised BIO-RESORT trial.
- **What are the results?** Patients treated with the *ultrathin* strut Orsiro had fewer repeat target lesion revascularisations than patients treated with *thin strut* Resolute Integrity (2.1% vs. 5.3%).
- **Why is this important?** Our findings suggest a relation between the use of the *ultrathin* strut Orsiro stent and a lower repeat target lesion revascularisation risk in all-comer patients with small vessel lesions.

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