2-year outcomes of the randomized SORT OUT IX Trial

Polymer-free biolimus-coated stent versus the ultrathin strut biodegradable polymer sirolimus-eluting stent in an all-comers population treated with percutaneous coronary intervention

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Why this study?

- The Scandinavian Organization for Randomized Trials with Clinical Outcome (SORT OUT) IX was the first study to demonstrate that the polymer-free drug-coated BioFreedom stent was not non-inferior to the ultrathin strut biodegradable polymer Orsiro in a population-based all-comers setting in unselected patients for target lesion failure at 1-year

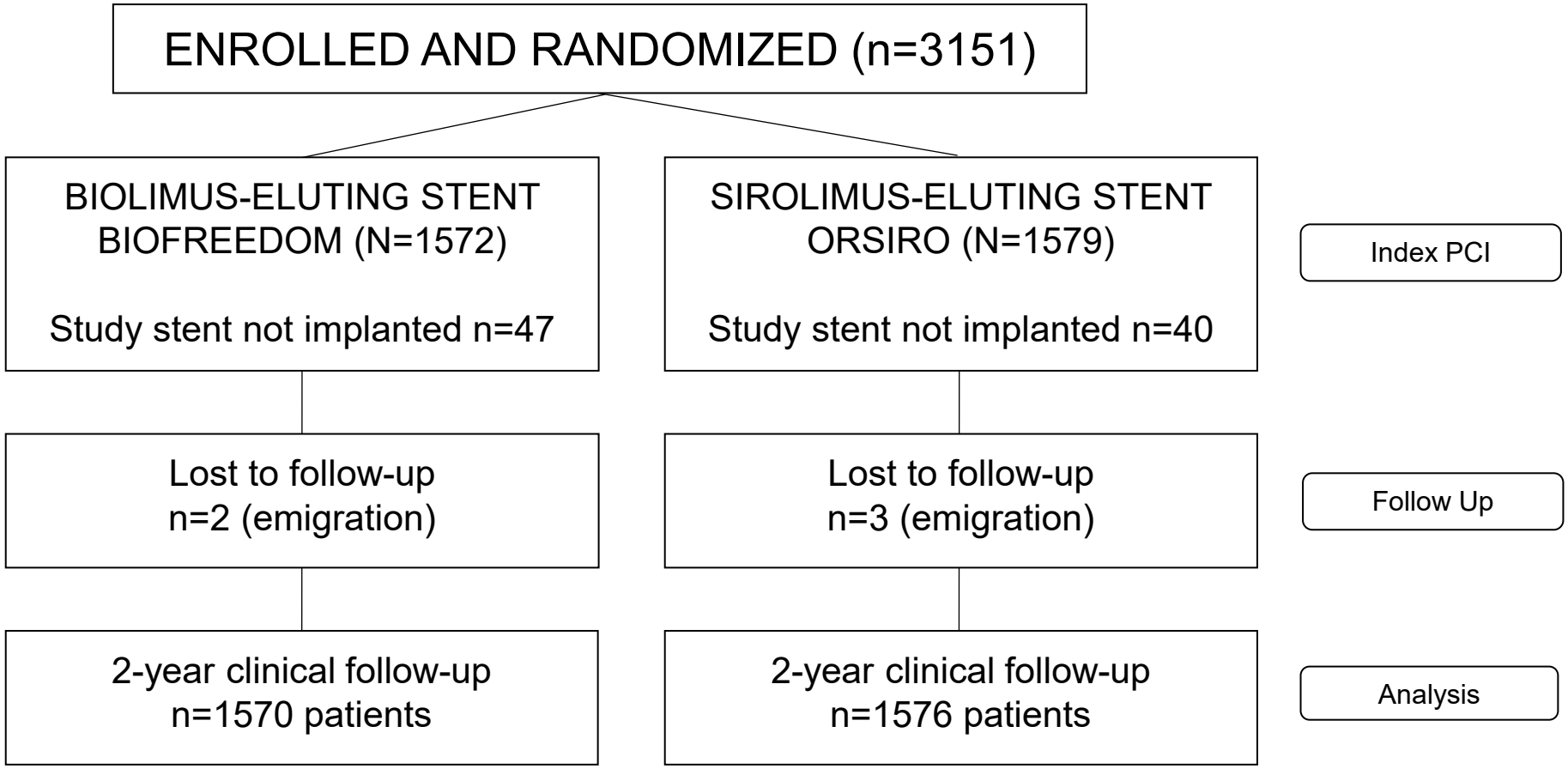
- Safety did not differ significantly however, the biolimus-eluting BioFreedom stent was associated with an increased risk of target lesion revascularization

Primary endpoint TLF 1Y Circulation 2020;141(25):2052-2063

What did we study?

- Enrollment at 4 hospitals in Denmark December 2015 to April 2017
- Clinically driven event detection based on Danish registries
- Dual antiplatelet treatment (stable angina pectoris 6 months and acute coronary syndromes 12 months)
- Primary endpoint: target lesion failure (TLF), was defined as the composite of cardiac death, myocardial infarction not related to any segment other than the target lesion or target lesion revascularization within 1 year, analyzed by intention-to-treat. ClinicalTrials.gov, NCT02623140
- Follow up extended to 2 years

How was the study executed?

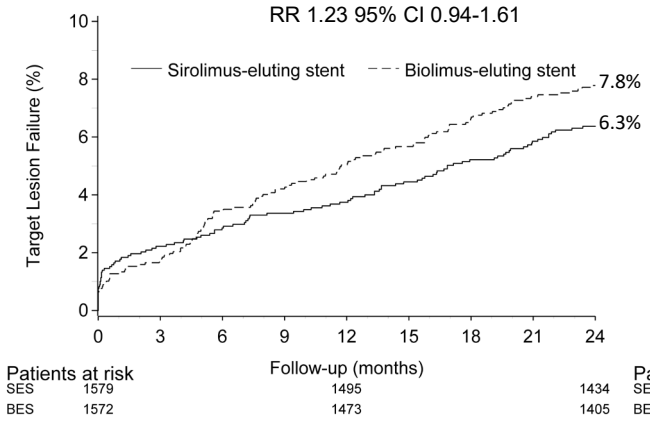


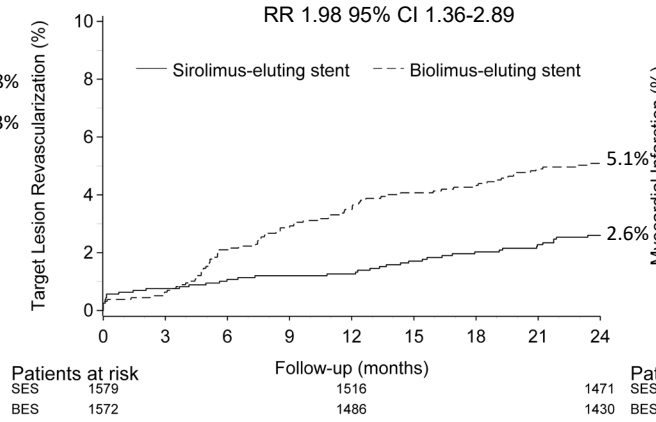
The study was based on clinically driven event detection, and no dedicated follow up was scheduled. At 24-months follow up, data on mortality, hospital admission, coronary angiography, repeat percutaneous coronary intervention, and coronary artery bypass surgery were obtained from national Danish administrative and healthcare registries

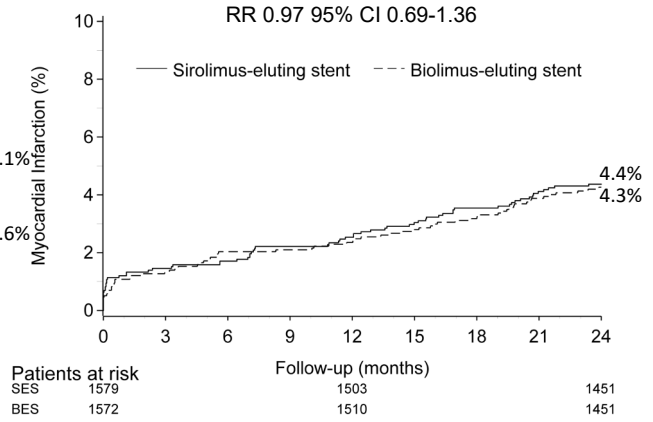
How was the study executed?

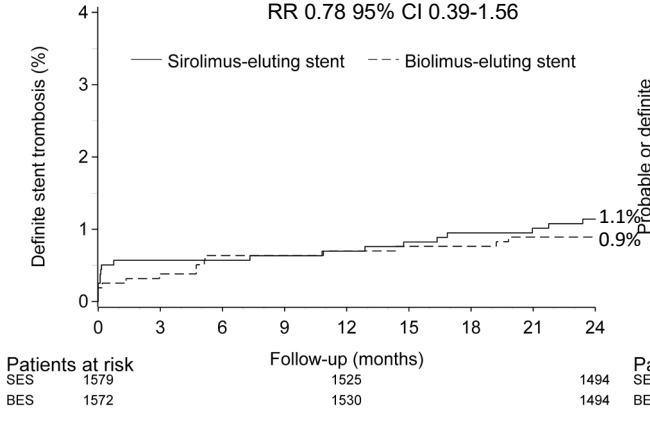
	BIOFREEDOM STENT	ORSIRO STENT	p
No. of patients	1,572	1,579	
Age (years)	66.4 ± 10.7	66.1 ± 11.1	0.35
Male gender	77.5 %	77.3 %	0.88
Diabetes	19.3 %	19.2 %	0.92
Hypertension	59.0 %	56.0 %	0.21
Current smoker	29.8 %	29.3 %	0.78
Prior CABG	8.4 %	7.0 %	0.13
Prior PCI	20.9 %	20.1 %	0.59
Prior myocardial infarction	14.7 %	15.2 %	0.53
Body mass Index (kg/m^2)	27.8 ± 7.5	27.6 ± 8.0	0.47
Indication for PCI			0.62
Stable angina pectoris	42.7 %	40.8 %	
NSTEMI / Unstable angina pectoris	28.9 %	28.7 %	
STEMI	23.3 %	25.1 %	
Other	5.1 %	5.3 %	

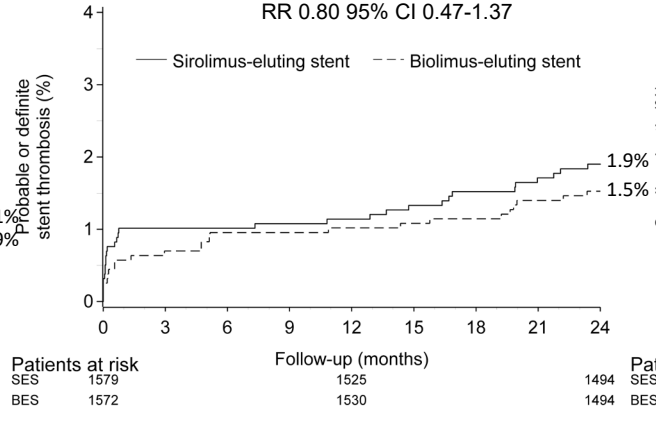
What are the essential results?

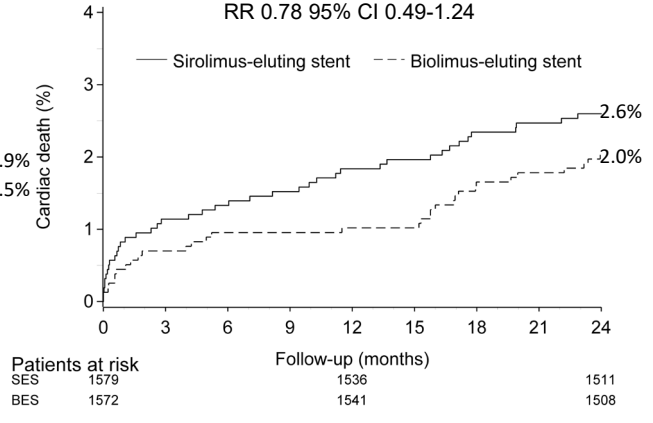












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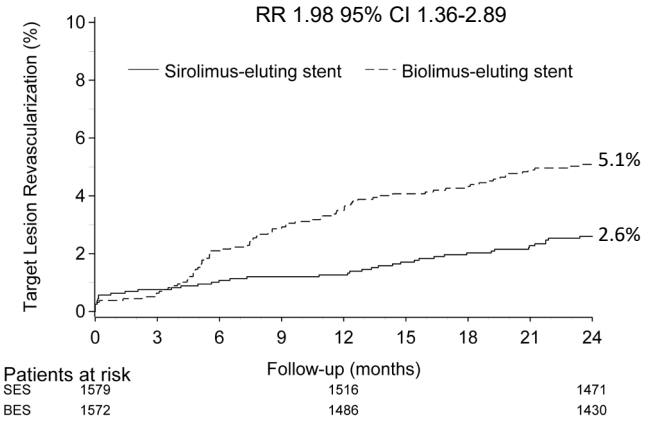
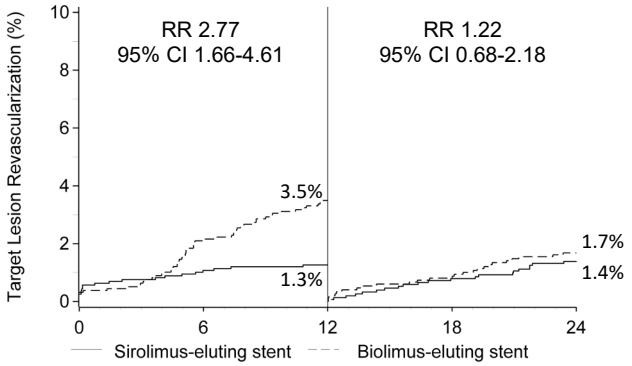
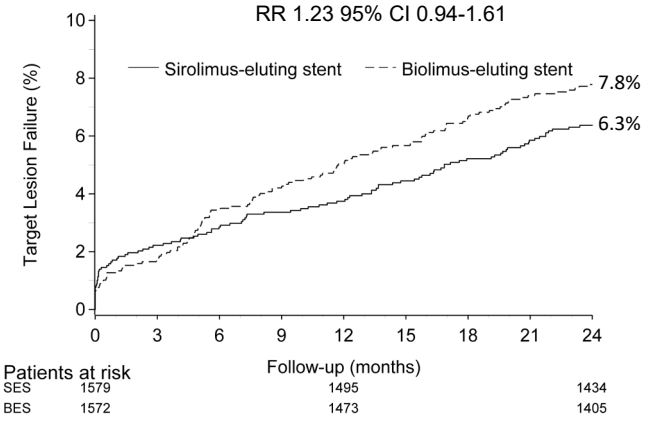
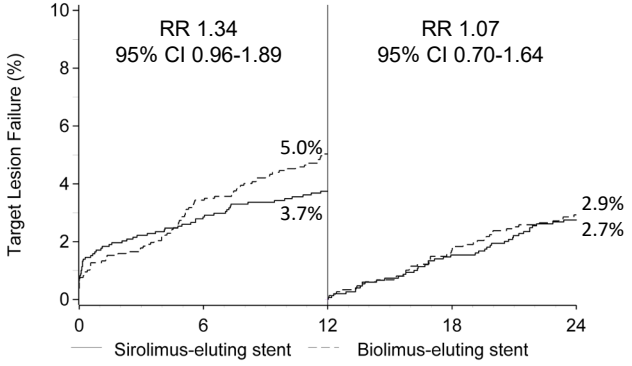


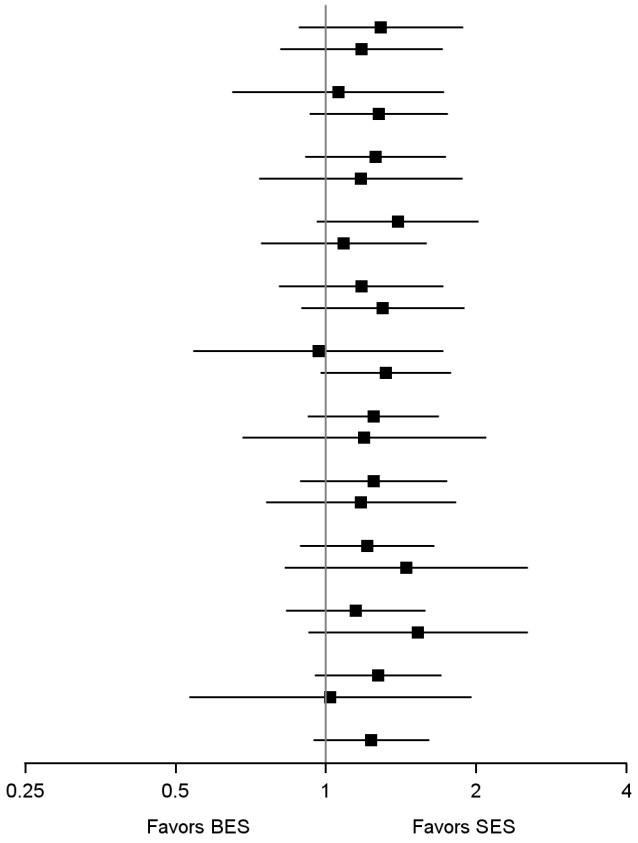






What are the essential results?

Pre-specified subgroups	BES-events (%)	SES-events (%)	Rate ratio (95% CI)	P for interaction
Acute coronary syndrome no	63(8.4)	48(6.6)	1.29 (0.88 - 1.88)	0.75
Acute coronary syndrome yes	59(7.2)	52(6.1)	1.18 (0.81 - 1.71)	
Age <= 65	32(4.8)	33(4.6)	1.06 (0.65 - 1.73)	0.53
Age > 65	90(9.9)	67(7.8)	1.28 (0.93 - 1.76)	
Diabetes melitus no	83(6.5)	67(5.3)	1.26 (0.91 - 1.74)	0.83
Diabetes melitus yes	39(12.8)	33(10.9)	1.17 (0.73 - 1.88)	
LAD no	66(8.4)	48(6.1)	1.39 (0.96 - 2.02)	0.36
LAD yes	56(7.1)	52(6.6)	1.09 (0.74 - 1.59)	
Lesion type C	60(10.1)	50(8.5)	1.18 (0.81 - 1.72)	0.72
Lesion type not C	62(6.4)	49(5.0)	1.30 (0.89 - 1.90)	
Male no	23(6.5)	24(6.7)	0.97 (0.54 - 1.72)	0.35
Male yes	99(8.1)	76(6.2)	1.32 (0.97 - 1.78)	
Multivessel disease no	95(7.3)	77(5.9)	1.25 (0.92 - 1.69)	0.88
Multivessel disease yes	27(10.3)	23(8.6)	1.19 (0.68 - 2.09)	
One stent per patient no	75(7.5)	61(6.1)	1.25 (0.89 - 1.75)	0.83
One stent per patient yes	44(7.8)	38(6.7)	1.18 (0.76 - 1.82)	
Previous MI no	90(6.9)	75(5.8)	1.21 (0.89 - 1.65)	0.45
Previous MI yes	29(12.9)	21(9.0)	1.45 (0.83 - 2.54)	
Previous PCI no	80(6.6)	71(5.7)	1.15 (0.83 - 1.58)	0.66
Previous PCI yes	39(12.1)	25(8.0)	1.53 (0.92 - 2.54)	
STEMI no	104(8.6)	81(6.9)	1.27 (0.95 - 1.70)	0.54
STEMI yes	18(4.9)	19(4.8)	1.02 (0.53 - 1.96)	
Overall	122(7.8)	100(6.3)	1.23 (0.94 - 1.61)	



Why is this important?

ORSIRO		BIOFREEDOM
Cobalt-Chromium	**Stent material**	Stainless steel
60 µm (2.25-3.0 mm stents) 80 µm (>3.0 mm stents)	**Strut thickness**	120µm
Poly-L-lactic acid (PLLA)	**Polymer material**	-
Bioresorbable, circumferential coating, completely degraded in 12-24 months	**Polymer type**	Polymer- and carrier-free
Amourphous silicon carbide	**Passive coating**	-
Sirolimus (1.4µg/mm^2) 3 months	**Antiproliferative drug relase**	Biolimus (A9) (15.6µg/mm^2) 98% released after 28 days

The essentials to remember

- **Why?** Target lesion failure at 1 year may not predict the longer term outcome with safety and efficacy after 2 years
- **What?** 2-year Target lesion failure of 2 drug-eluting stents with different stent technologies
- **How?** SORT OUT IX is the first study to compare the biolimus A9-coated BioFreedom stent with a modern drug-eluting stent in a population-based all-comers setting
- **What are the results?** At 2-year follow-up, Target lesion failure did not differ between the ultrathin strut biodegradable polymer Orsiro and the polymer-free drug-coated BioFreedom stent
- **Why is this important?** Target lesion revascularization was significantly lower in the Orsiro stent group compared to the BioFreedom stent group which largely was attributable to a lower risk of target lesion revascularization within the first year