Randomised comparison of a novel, ultrathin strut biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent for percutaneous coronary revascularization

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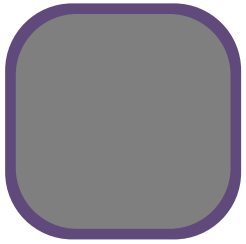
☒ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s): travel expenses supported by Biotronik

☐ **I do not have any potential conflict of interest**

STENT PLATFORMS

	ORSIRO	XIENCE PRIME/XPEDITION
Platform material	Cobalt-Chromium, L-605	Cobalt-Chromium, L-605
		
Strut thickness	60 µm	81 µm
Passive coating	Silicon carbide layer	
Polymer material	Biodegradable	Durable
	PLLA: poly-L-lactic acid	PBMA/PVDF-HFP
Antiproliferative drug	Sirolimus (1.4 µg/mm^2)	Everolimus (1.0 µg/mm^2)

TRIAL DESIGN AND PATIENT FLOW

Non-inferiority trial with minimal exclusion criteria

2119 patients with stable coronary artery disease or acute coronary syndromes undergoing percutaneous coronary intervention

1:1 Randomisation

Stratified according to centre and ST-segment elevation MI

Biodegradable polymer sirolimus-eluting stent n = 1,063

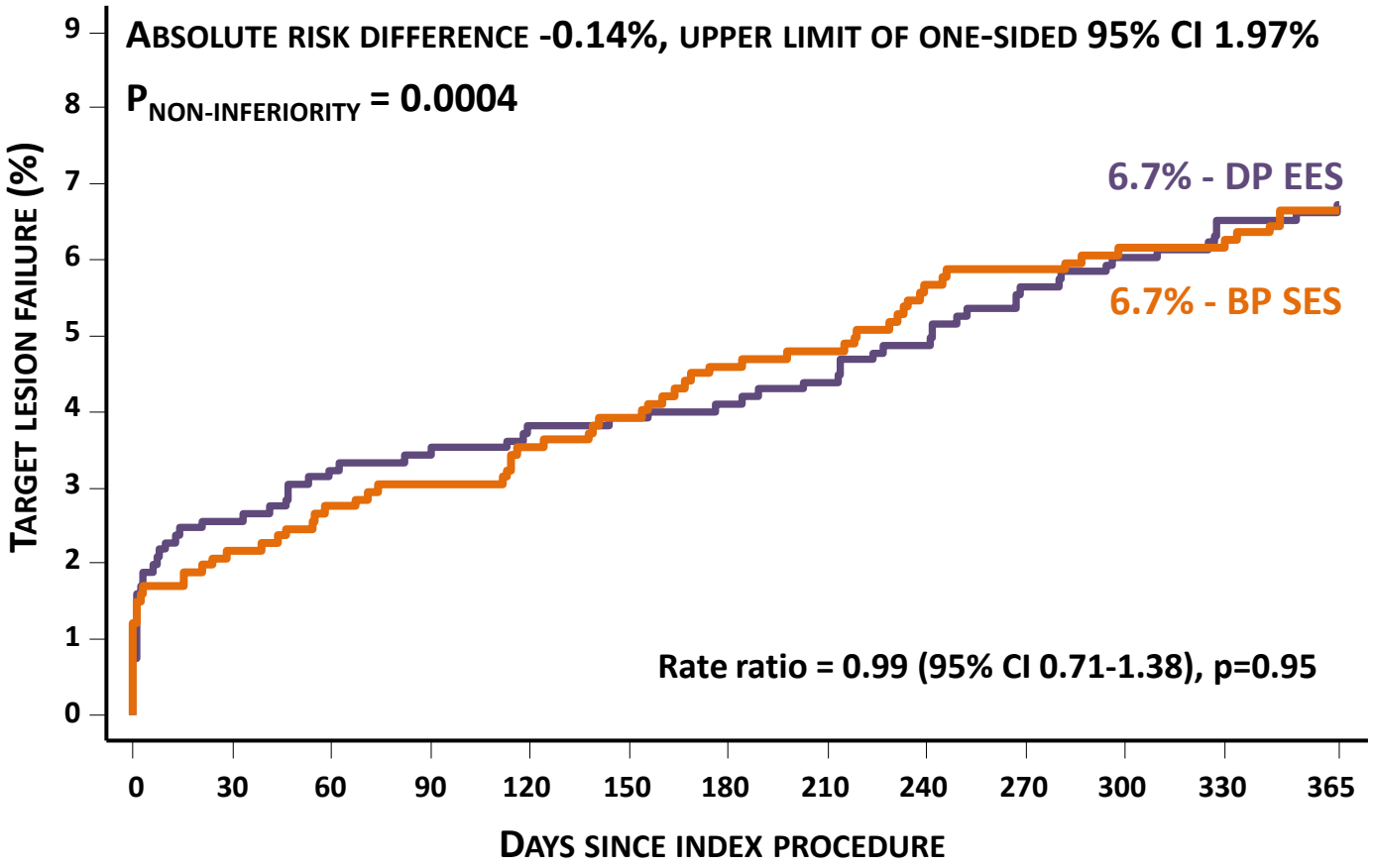
Durable polymer everolimus-eluting stent n = 1,056

PRIMARY ENDPOINT: TARGET LESION FAILURE

Composite of cardiac death, target vessel myocardial infarction, and clinically-indicated target lesion revascularization at 12 months

PRIMARY ENDPOINT

TARGET LESION FAILURE

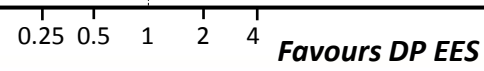


NUMBER AT RISK

DP EES	1056	1021	1004	1002	998	996	994	991	985	975	971	966	945
BP SES	1063	1025	1004	1000	993	988	980	977	967	964	960	958	941

STRATIFIED ANALYSIS OF PRIMARY ENDPOINT

	BP SES	DP EES	RR (95% CI)	p	$p_{interaction}$
Diabetes					**0.41**
Yes	27/257	21/229	1.19 (0.67-2.10)	0.56	
No	42/806	49/827	0.88 (0.58-1.33)	0.55	
Acute Coronary Syndrome					**0.24**
Yes	32/577	38/554	0.81 (0.51-1.30)	0.39	
No	37/486	32/502	1.21 (0.75-1.95)	0.43	
ST-elevation MI					**0.014**
Yes	7/211	17/196	0.38 (0.16-0.91)	0.024	
No	62/852	53/860	1.20 (0.83-1.73)	0.33	
Off-label use					**0.35**
Yes	43/629	51/646	0.87 (0.58-1.31)	0.50	
No	24/427	19/407	1.23 (0.67-2.24)	0.51	
Sex					**0.104**
Female	12/245	20/240	0.59 (0.29-1.21)	0.15	
Male	57/818	50/816	1.15 (0.79-1.68)	0.47	
Renal failure					**0.44**
Yes	18/151	18/130	0.88 (0.45-1.70)	0.70	
No	50/857	43/865	1.19 (0.79-1.79)	0.40	



CONCLUSIONS

- **Ultrathin strut biodegradable polymer sirolimus-eluting stents were non-inferior to durable polymer everolimus-eluting stents for the primary endpoint target lesion failure at 1 year in a population with minimal exclusion criteria.**
- **The observed benefit in the subgroup of patients with ST-segment elevation myocardial infarction warrants confirmation in appropriately designed studies.**