Orsiro – BIOSCIENCE

Conclusions

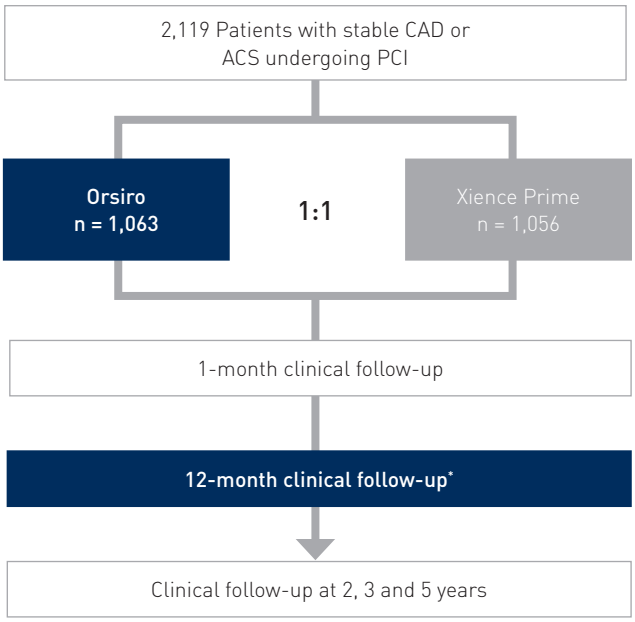
- In this 2,119 patient, randomized, all-comers trial, Orsiro demonstrated **non-inferiority** to Xience Prime for the primary endpoint at 12 months. A similar trend was shown throughout 24 months
- Orsiro, with its **ultrathin** struts and bioabsorbable polymer additionally presents superior results in the high-risk subgroup of patients presenting with ST-elevation myocardial infarction (STEMI) out to 24 months

Study design

Prospective, all-comers, multi-center, randomized, non-inferiority design

Principal Investigator

- Prof. Stephan Windecker, Bern, Switzerland



* Primary endpoint

Patient characteristics[1]

Patients	Orsiro n = 1,063	Xience Prime n = 1,056
Diabetes – n (%)	257 (24 %)	229 (22 %)
Indication – n (%)		
Unstable angina	78 (7 %)	74 (7 %)
NSTEMI	288 (27 %)	284 (27 %)
STEMI	211 (20 %)	196 (19 %)
Stable angina	325 (31 %)	332 (31 %)
Silent ischemia	161 (15 %)	171 (16 %)

Lesion characteristics[1]

Lesions	Orsiro n = 1,063	Xience Prime n = 1,056
LM – n (%)	29 (2 %)	27 (2 %)
LAD – n (%)	649 (41 %)	679 (44 %)
LCx – n (%)	370 (23 %)	341 (22 %)
RCA – n (%)	505 (32 %)	452 (29 %)
CABG – n (%)	41 (2.2 %)	46 (3.4 %)
Long lesion (>20 mm)	826 (54 %)	839 (57 %)
Small vessel (<2.75 mm)	439 (29 %)	468 (32 %)

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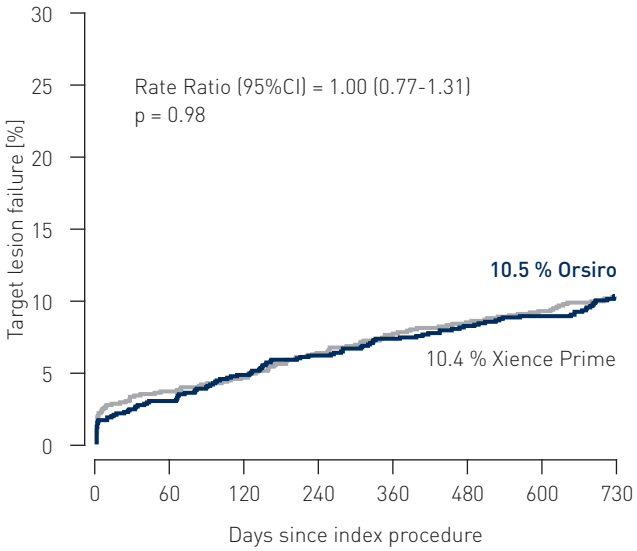
Clinical results up to 24 months[2]

Target lesion failure

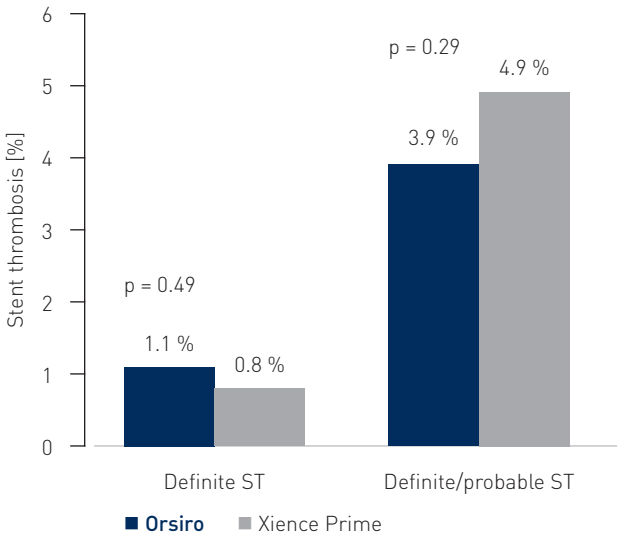


Components of target lesion failure

Target lesion failure composites (%)		Orsiro n = 1,063	Xience Prime n = 1,056	p-value
12 m	Cardiac death	1.9	2.1	non-significant
	Target vessel MI	2.9	3.0	non-significant
	Clinically-indicated TLR	3.4	2.4	non-significant
24 m	Cardiac death	3.2	3.2	non-significant
	Target vessel MI	4.1	4.5	non-significant
	Clinically-indicated TLR	6.0	5.1	non-significant

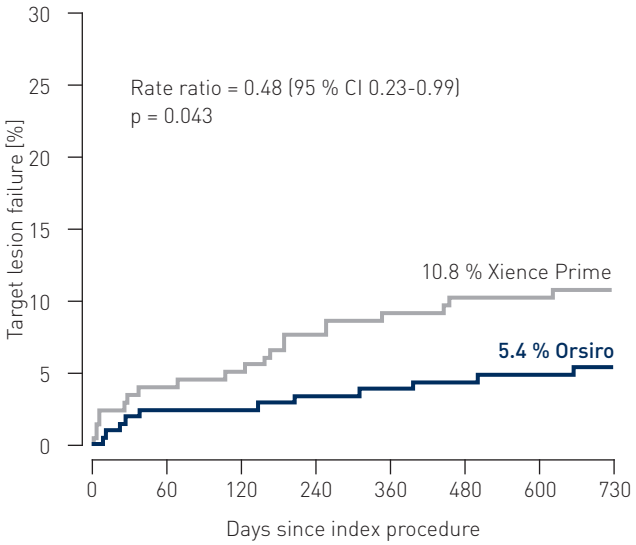
Stent thrombosis up to 24 months[2]

Definite ST / Definite or probable ST*



STEMI subgroup up to 24 months[3]

Target lesion failure rates in STEMI patients



[1] Pilgrim T. et al. Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial, Lancet. 2014 Sept 1 (Online publication).

[2] Iglesias J. How the Orsiro DES performs in high-risk subgroups. EuroPCR 2015. Oral presentation.

[3] Piccolo R. Biodegradable polymer Sirolimus-eluting stents vs. durable polymer Everolimus-eluting stents in patients with STEMI: Two-year follow-up of the BIOSCIENCE. EuroPCR 2016. Oral presentation.

* Definite and probable stent thrombosis according to ARC definition and adjudicated by independent clinical events committee.

Not currently available in the United States.

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