BIOFLOW-VI

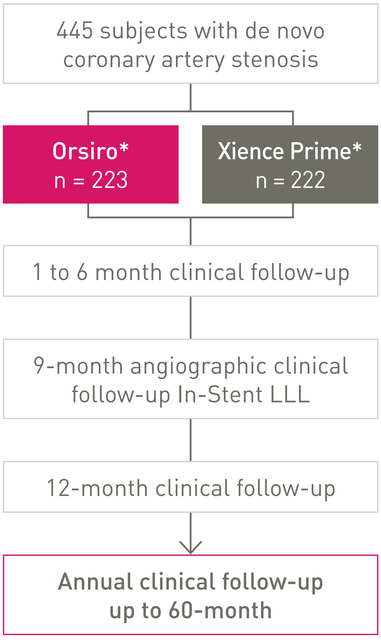
9-month angiographic and 1 year clinical follow-up for Orsiro in China

Conclusions

- The non-inferiority of Orsiro to Xience Prime was confirmed concerning In-Stent Late Lumen Loss (LLL) at 9 months[1]
- Low Target Lesion Failure[2] (TLF) rates at 12 months in both arms with no statistically significant differences between the individual composites[1]
- No definite/probable Stent Thrombosis[3] (ST) was reported up to 12 months
- The TLF rates are comparable to other clinical trials in Western and Asian populations[1]

Study design

Prospective, multi-center, non-inferiority, 1:1 randomized controlled trial comparing Orsiro to Xience in 445 patients with de novo lesions



Endpoints

Primary endpoint
- In-Stent LLL at 9 months

Secondary endpoints
- TLF at 12 months
- ST

Patient characteristics	Orsiro n = 220	Xience Prime n = 220	p-value
Age, yrs††	59.1 ± 8.5	58.4 ± 8.6	0.41
Female	27.3%	35.5%	0.06
Hypertension	54.5%	56.8%	0.63
Hypercholesterolemia	38.2%	42.3%	0.38
Diabetes mellitus (insulin-dep. & non-insulin-dep.)	27.2%	26.3%	0.98
Stroke or TIA	9.1%	9.5%	0.87
Renal disease	3.2%	0.9%	0.18
Smoking (current & ex)	57.3%	55.4%	0.50

Lesion characteristics	Orsiro n = 257	Xience Prime n = 259	p-value
Moderate/severe tortuosity	43.4%	43.6%	1.00
Bifurcation lesion	18.4%	20.1%	0.90
Thrombus	0.4%	0.4%	1.00
ACC-AHA Lesion Class B2/C	77.4%	78.8%	0.85

Procedural results	Orsiro	Xience Prime	p-value
Lesion success**	98.8%	99.2%	1.00
Device success†	98.9%	98.9%	1.00
Procedural success§	96.8%	97.7%	0.56

* 3 withdrawal of consent in Orsiro group, 2 withdrawal of consent in Xience group; did not receive device treatment

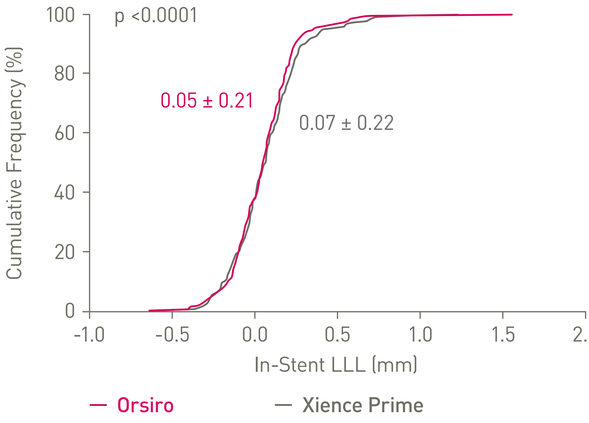
** Lesion Success: ⩽30% residual stenosis of target lesion using any percutaneous method

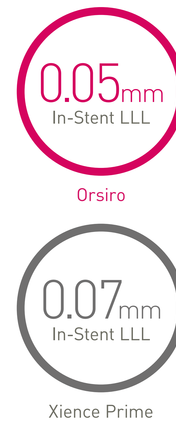
† Device Success: ⩽30% residual stenosis of target lesion using the assigned study stent only

†† Data shown as mean ± SD

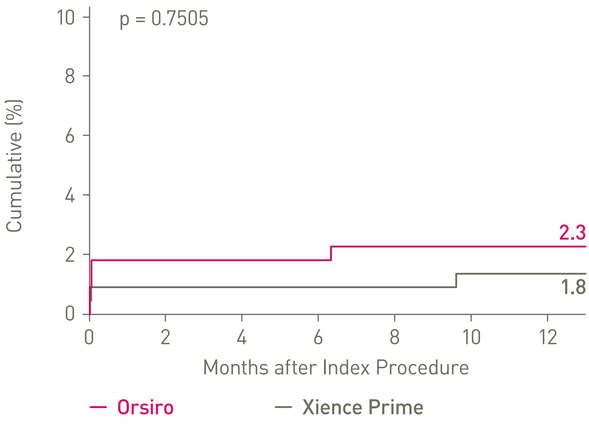
§ Procedural Success: ⩽30% residual stenosis of target lesion using the assigned study stent only without occurrence of in hospital major adverse cardiac event (composite of all death, Q-wave or non-Q-wave MI and clinically-driven TLR)

In-Stent LLL out to 9 months[1]



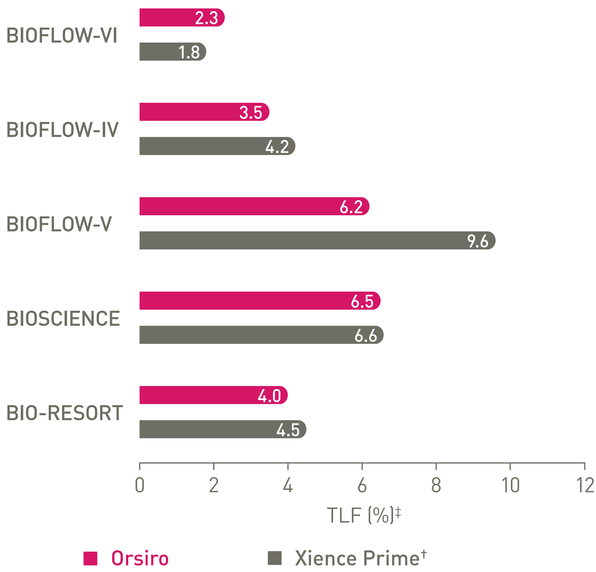


TLF rates at 12 months[1]



TLF components	Orsiro	Xience Prime	p-value
Cardiac death	0.5%	0.0%	0.50
TV MI	1.8%	0.9%	0.45
CD-TLR	0.0%	0.9%	0.50
CABG	0.0%	0.5%	1.00

TLF rates[4] out to 12 months[1]



† Xience was the comparator for all the trials except for BIO-RESORT in which Resolute Integrity was the comparator
‡ TLF components as per respective definitions in trials

Principal investigator

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1. Yang Y, et al. BIOFLOW VI : BIOTRONIK-Safety and Clinical PerFormance of the Drug ELuting Orsiro Stent in the Treatment of Subjects with de novo Coronary Artery Lesions – VI, Presented at: CIT 2018; March 23, 2018; Suzhou, China; ClinicalTrials.gov: NCT02870985; 2. Composite of cardiac death, target vessel Q-wave or non-Q wave Myocardial Infarction (MI), Emergent Coronary Artery Bypass Graft (CABG), clinically driven Target Lesion Revascularization (TLR); 3. ST as per ARC definition; 4. Numbers represented are Kaplan–Meier estimates.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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