BIOFLOW-V

Comparison of Ultrathin strut Orsiro® Bioresorbable Polymer DES to Xience Durable Polymer DES at 60 Months[1]

Conclusions

- **Orsiro** ultrathin strut DES outperformed Xience DP-EES at 1-year and sustained performance up to 5 years:
  - 20% lower Target Lesion Failure (p = 0.136)
  - 36% significantly lower Target Vessel Myocardial Infarction (p = 0.021)
  - 23% lower Ischemia-driven Target Lesion Revascularization (p = 0.223)
  - 22% lower Cardiac Death/Myocardial Infarction (p = 0.121)
- **Orsiro** showed a 0.7% definite/probable Stent Thrombosis rate overall through 5 years: 64% lower compared to Xience.
  - 83% significantly lower late/very late definite/probable Stent Thrombosis (p = 0.021)

Study design

Prospective, multi-center, 2:1 randomized controlled IDE trial to assess the safety and effectiveness of **Orsiro** in the treatment of patients with up to three de novo or restenotic lesions (standard PTCA only).

Endpoints

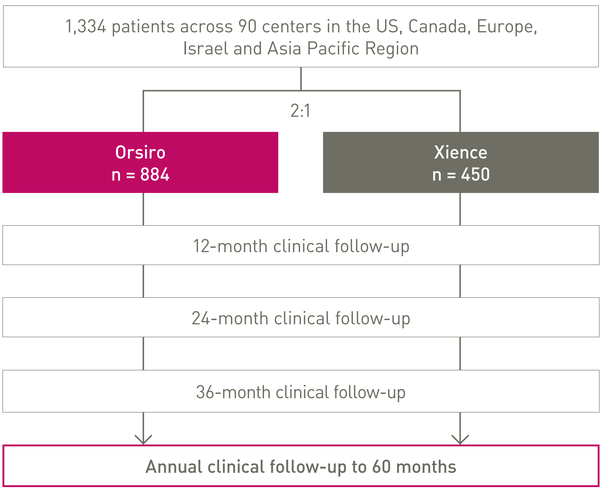
Primary Endpoints

Target Lesion Failure (TLF) at 12 months follow-up defined as the composite of:

- Cardiac Death
- Target Vessel-Myocardial Infarction (TV-MI)
- Ischemia-driven Target Lesion Revascularization (TLR)

Secondary Endpoints

- Components of the primary endpoint
- MACE as a composite of all-cause death, MI or ischemia driven TLR
- Target Vessel Failure (TVF) and individual TVF components
- Stent thrombosis (all, definite, definite/probable, probable, possible ST)[Δ]



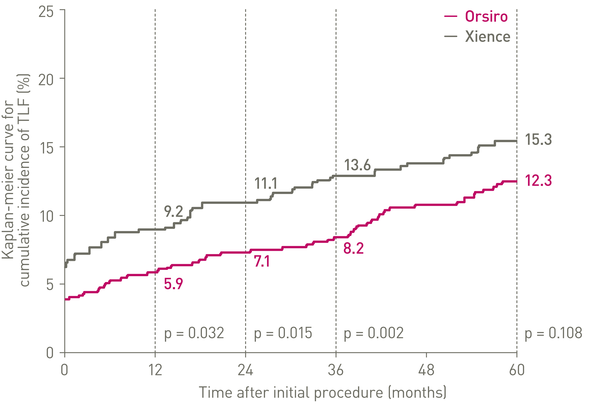
Patient characteristics	Orsiro n = 884	Xience n = 450
Age, yrs*	64.5 ± 10.3	64.6 ± 10.7
Female	25.3%	27.1%
Hypertension	79.7%	80.5%
Diabetes	34.0%	37.0%
Stable Angina	48.4%	47.4%
Unstable Angina	39.3%	39.0%
Acute Coronary Syndrome◊	51.4%	49.6%
Previous PCI	36.8%	33.0%
Previous CABG	7.1%	5.2%

Lesion characteristics	Orsiro n = 1,051	Xience n = 561
Lesion length (mm)*	13.3 ± 7.6	13.2 ± 7.7
Bifurcation lesion	14.8%	15.0%
Calcification, moderate/severe	24.0%	26.7%
Lesion Class B2/C	72.6%	75.9%
Number of target lesion/patient*§	1.2 ± 0.4	1.3 ± 0.5
Number of stents/patient*§	1.3 ± 0.7	1.5 ± 0.9
Total stent length (mm)*§	26.8 ± 14.7	29.5 ± 17.5
Reference vessel diameter (mm)*	2.59 ± 0.54	2.60 ± 0.58

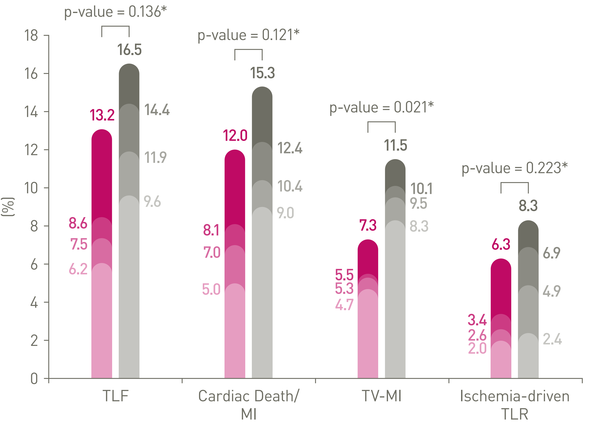
Target-lesion characteristics as assessed by an independent angiographic core laboratory.

Δ According to Academic Research Consortium (ARC) criteria for acute, subacute, late, very late and cumulative stent thrombosis
* Data shown as mean ± SD
◊ Acute coronary syndrome defined as subjects with unstable angina or any elevated cardiac enzymes at baseline (any pre-procedure CK, CK-MB or troponin out of normal range)
§ There were no statistically significant differences between groups except for variable denoted by (§). Multivariable analysis of TLF, TV-MI and TLR confirmed no clinical, angiographic or procedural characteristic that differed between group was identified as a predictor of adverse outcome.

TLF out to 5 years[1-5]



Outcomes out to 5 years[1-5]

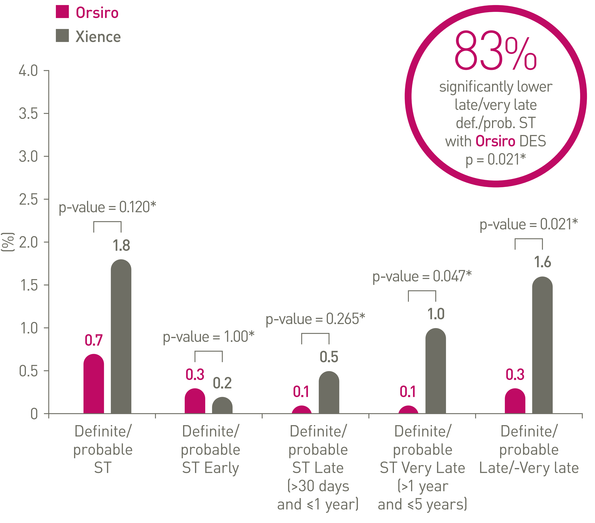


Orsiro
- 12 months
- 24 months
- 36 months
- 60 months

Xience
- 12 months
- 24 months
- 36 months
- 60 months

36%
significantly lower TV-MI with **Orsiro** DES
p = 0.021*

ST events out to 5 years[1]



83%
significantly lower late/very late def./prob. ST with **Orsiro** DES
p = 0.021*

Principal investigators

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*p-values for 60-month frequentist analysis

All figures from submitted manuscript are rounded by Biotronik after the BIOFLOW-V figures presented by D. Kandzari, at CRT 2022, Washington, USA.

PCI: Percutaneous Coronary Intervention, CABG: Coronary Artery Bypass Graft, DES: Drug Eluting Stent, PTCA: Percutaneous Transluminal Coronary Angioplasty, IDE: Investigational Device Exemption, DP-EES: Durable Polymer Everolimus-Eluting Stents.

1. Kandzari D et al. Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents for Coronary Revascularization: Final 5-year Outcomes from the Randomized BIOFLOW V Trial, Submitted manuscript to JACC, 2022: NCT02389946; 2. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020, doi: 10.1016/j. jcin.2020.02.019; 3. Kandzari D et al. Ultrathin bioresorbable polymer sirolimus-eluting stents versus thin durable polymer everolimus-eluting stents. Journal of the American College of Cardiology. 2018 Dec 17;72(25):3287-97; 4. Kandzari D, et al. BIOFLOW-V: A Prospective Randomized Multicenter Study to Assess the Safety and Effectiveness of the Orsiro Sirolimus Eluting Coronary Stent System in the Treatment Of Subjects With up to Three De Novo or Restenotic Coronary Artery Lesions Science. Presentation at ESC 2017; 5. Kandzari D et al. Ultrathin, bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents in patients undergoing coronary revascularisation (BIOFLOW V): a randomised trial. Lancet. 2017 Oct 21; 390(10105):1843-1852.

April_2022

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