BIONYX

Comparison of Durable Polymer Resolute Onyx to Ultrathin Bioresorbable Polymer **Orsiro®** DES in all-comers patients at 36 Months

Conclusions

- Resolute Onyx shows no advantage over the ultrathin strut Orsiro DES with respect to the primary endpoint of Target Vessel Failure (TVF) (Res. Onyx 9.2 % vs. Orsiro 8.9 %, p = 0.85) at 36 months follow-up in an all-comers population.
- At 36 months, Orsiro showed a numerically lower rate in clinically-indicated Target Vessel Revascularization (TVR) compared to Resolute Onyx.
- At 36 months, ST rates were low and comparable between the two groups, suggesting a favorable safety profile for both stents.

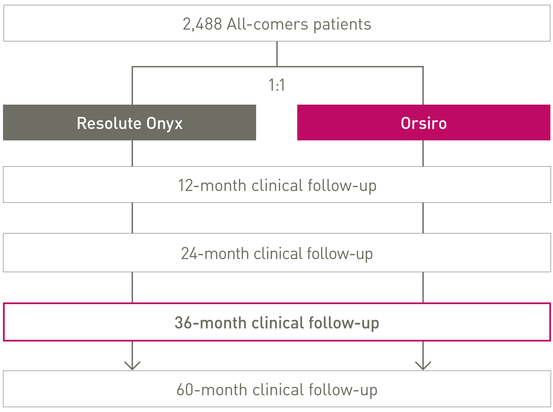
Study design

All-comers, multi-center, assessor and patient blinded, randomized, non-inferiority trial

Endpoints

Primary endpoint
Target Vessel Failure (TVF) at 12 months, defined as the composite of:
- Cardiac Death
- Target vessel Myocardial Infarction (TV-MI)
- Clinically indicated Target vessel Revascularization (TVR)

Selected secondary endpoints
- TVF and individual components beyond 12 months
- Definite/Probable Stent Thrombosis (ST)
- Cardiac death



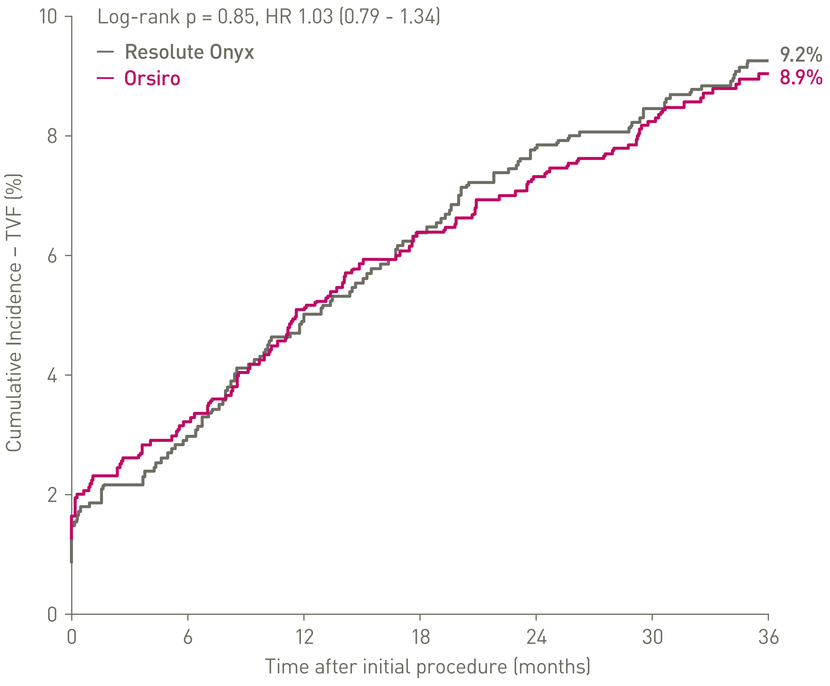
Patient characteristics[1]	Resolute Onyx n = 1,243	Orsiro n = 1,245
Age (years)[¤]	64.1 ± 10.9	63.9 ± 11.2
Female	23.9%	23.9%
Family history of coronary disease	44.7%	42.2%
Diabetes, medically treated	20.9%	20.1%
Hypertension	49.8%	53.2%
Hypercholesterolaemia	45.4%	46.4%
Previous MI	15.6%	16.5%
Acute coronary syndrome	70.8%	71.1%
Acute MI	50.4%	52.1%
ST elevation MI	22.7%	27.2%
Non-ST elevation MI	27.7%	24.9%
Unstable Angina	20.4%	19.0%
Stable Angina or Silent Ischemia	29.2%	28.9%

Lesion characteristics[1]	Resolute Onyx n = 1,646**	Orsiro n = 1,593**
ACC/AHA lesion class	1,644	1,591
A	4.6%	5.3%
B1	25.9%	24.9%
B2	35.3%	33.4%
C	34.3%	36.4%
Bifurcation	31.3%	32.5%
Severe calcification	15.0%	16.0%
In-stent restenosis	2.9%	1.8%
Chronic total occlusion	3.1%	4.0%

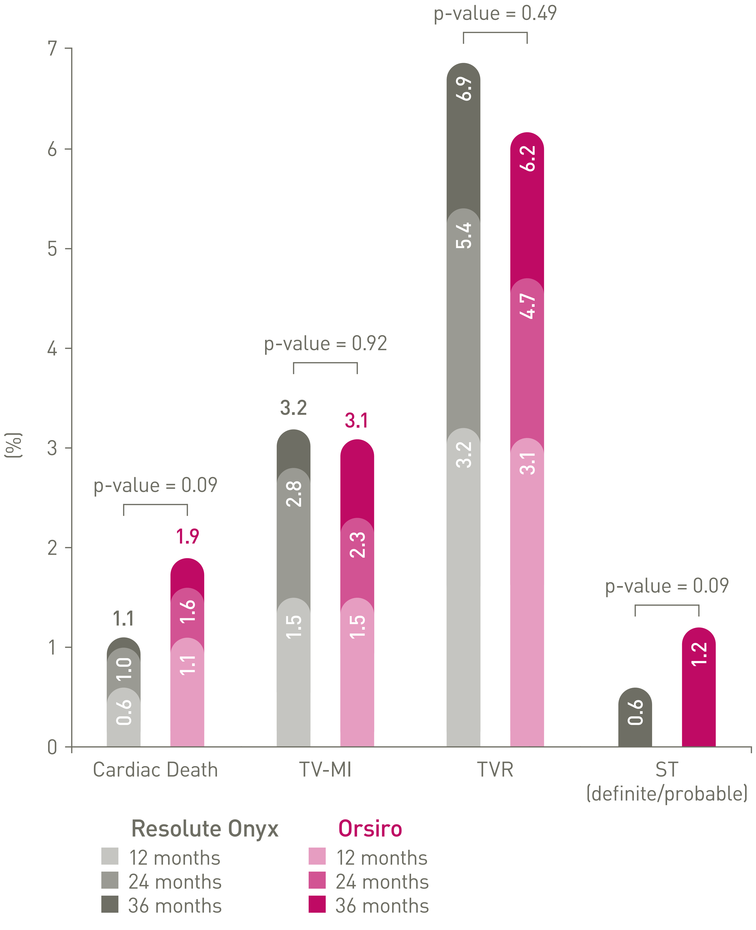
Procedural characteristics[1]	Resolute Onyx n = 1,243	Orsiro n = 1,245
Radial approach	73.5%	72.6%
Pre procedural[§]		
Lesion length (mm)[+]	15.3 (10.9 - 22.9)	15.6 (11.2 - 23.7)
Minimum lumen diameter (mm)[+]	0.75 (0.48 - 1.04)	0.74 (0.43 - 1.06)
Post procedural[Δ]		
Minimum lumen diameter (mm)[¤]	2.41 ± 0.54	2.41 ± 0.52
Number of stents per lesion[¤]	1.27 ± 0.55	1.26 ± 0.57
Lesion success[#]	99.7%	99.6%
Device success[‡]	98.4%	97.8%
Postdilation	63.5%	64.5%

[¤]Data shown as mean ± SD;+Median (IQR or Interquartile Range); §Data for at least 1,638 lesions in the Resolute Onyx group and 1,589 lesions in the Orsiro group;[Δ]Data for at least 1,641 lesions in the Resolute Onyx group and 1,585 lesions in the Orsiro group; [#]Lesion success was defined as <50% residual stenosis post percutaneous coronary intervention; [‡]Device success was defined as <50% residual stenosis post percutaneous coronary intervention by use of assigned stens only; **Number of lesions.

TVF at 36 Months[3]



Selected Secondary Endpoints at 36 Months[3]



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1. von Birgelen C, Zocca P, Buiten RA, et al. Thin composite wire strut, durable polymer-coated (Resolute Onyx) versus ultrathin cobalt–chromium strut, bioresorbable polymercoated (Orsiro) drug-eluting stents in allcomers with coronary artery disease (BIONYX): an international, single-blind, randomised non-inferiority trial. The Lancet. 2018 Sep 22; 2. Buiten R. et al. Thin Composite- Wire- Strut Zotarolimus-Eluting Stents versus Ultrathin-Strut Sirolimus- Eluting Stents in BIONYX at 2 years. JACC: Cardiovascular Interventions. doi.org/10.1016/j.jcin.2020.01.230. 3. Ploumen E.H., et al. Three-year outcome of all-comer patients treated with Resolute Onyx zotarolimus-eluting versus Orsiro sirolimus-eluting stents in the randomized BIONYX trial. Presented at ACC 2021.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes. Orsiro and Orsiro Mission are trademarks or registered trademarks of the BIOTRONIK Group of Companies. Resolute and Resolute Onyx are trademarks or registered trademarks of the Medtronic group of companies.

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