BIONYX

Comparison of Durable Polymer Resolute Onyx to Ultrathin Bioresorbable Polymer **Orsiro®** DES in all-comers patients at 24 Months

Conclusions

- Resolute Onyx shows no advantage in Target Vessel Failure (TVF) over the ultrathin strut Orsiro DES (Resolute Onyx 7.6% vs. Orsiro 7.1%, p = 0.66) at 24 months follow-up in an all-comers population.
- At 24 months, Orsiro showed numerically lower rates in Target Vessel-Myocardial Infarction (TV-MI) and clinically-indicated Target Vessel Revascularization (TVR) compared to Resolute Onyx.
- ST rates were low and comparable between the two groups, suggesting a positive safety signal for both stents.

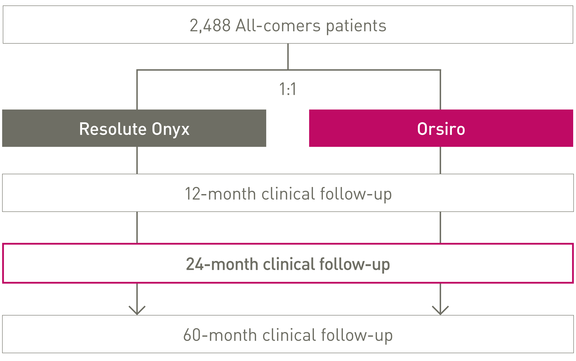
Study design

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) or Target Vessel Revascularization (TVR)

Secondary endpoints
- Individual components of the primary endpoint
- Stent Thrombosis (ST)



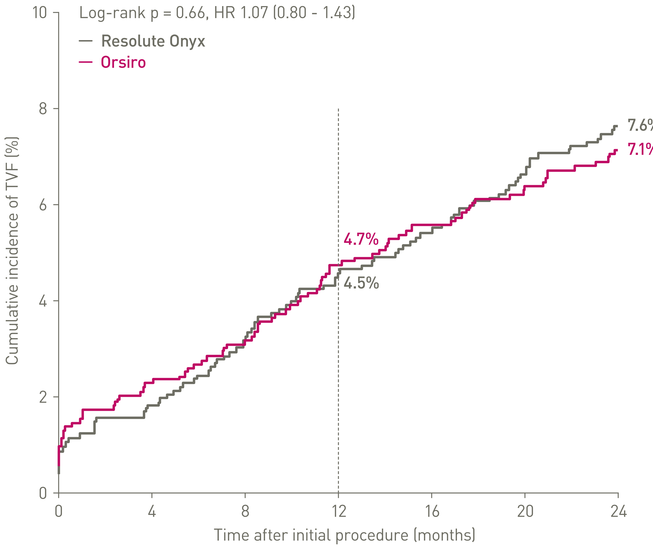
Patient characteristics[1]	Resolute Onyx n = 1,243	Orsiro n = 1,245
Age (years)[¤]	64.1 ± 10.9	63.9 ± 11.2
Female	23.9%	23.9%
Family history of coronary disease	44.7%	42.2%
Diabetes, medically treated	20.9%	20.1%
Hypertension	49.8%	53.2%
Hypercholesterolaemia	45.4%	46.4%
Previous MI	15.6%	16.5%
Acute 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%

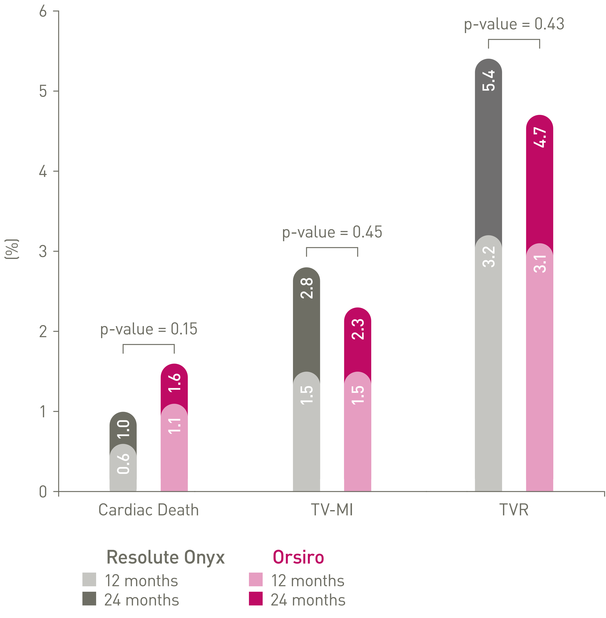
Procedural characteristics[1]	Resolute Onyx n = 1,243	Orsiro n = 1,245
Radial approach	73.5%	72.6%
Pre procedural[§]		
Lesion length (mm)[+]	15.3 (10.9 - 22.9)	15.6 (11.2 - 23.7)
Minimum lumen diameter (mm)[+]	0.75 (0.48 - 1.04)	0.74 (0.43 - 1.06)
Post procedural[Δ]		
Minimum lumen diameter (mm)[¤]	2.41 ± 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.

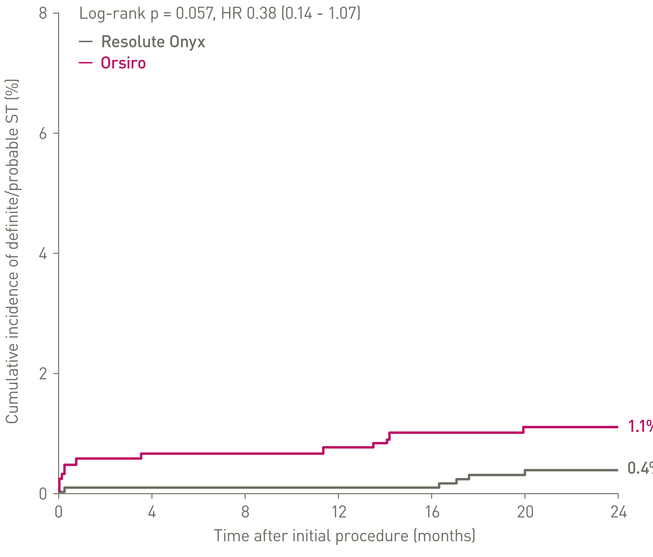
Primary Endpoint – TVF at 12 and 24 Months[1,2]



Selected Secondary Endpoints at 12 and 24 Months[1,2]



Definite/Probable ST at 24 Months[2]



Principal investigator

Prof. Clemens von Birgelen, Enschede, the Netherlands

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 polymer-coated (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.

Nov_2020/MI336

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach,
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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