9-month primary endpoint results of the Orient trial, RCT Orsiro vs. Resolute Integrity

Conclusions

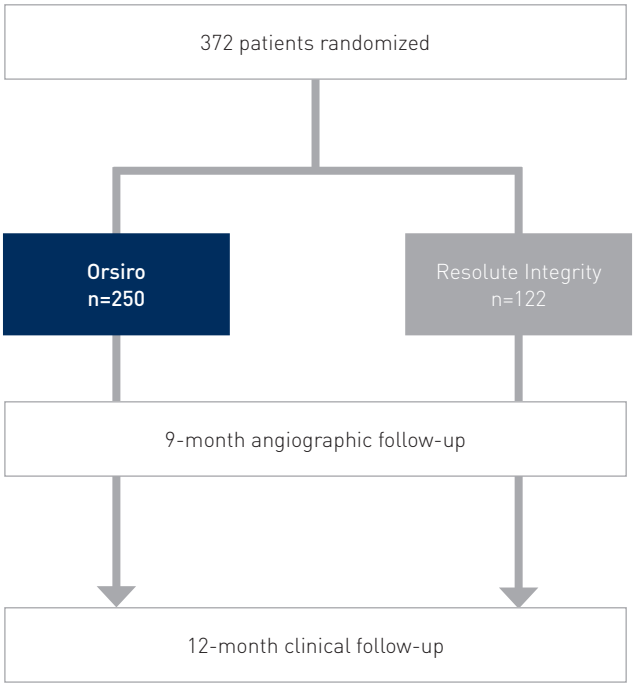
- In this 375 patient randomized trial with an angiographic primary endpoint of late lumen loss (LLL) at 9 months, Orsiro demonstrated non-inferiority to Resolute Integrity. (Orsiro 0.10 ± 0.35 mm, Resolute Integrity 0.16 ± 0.39 mm, p for non-inferiority <0.001)
- Orsiro, with its ultrathin struts and bioabsorbable polymer, additionally showed numerically better results for the secondary clinical endpoint, target lesion failure (TLF) out to 12 months. (Orsiro 2.4 %, Resolute Integrity 3.3 %, p = 0.0623)
- These highly encouraging results reconfirm those of previous Orsiro trials and adds to the solid foundation of clinical evidence that supports the use of Orsiro across a broad range of indications

Study design

A prospective, multi-center, randomized, controlled trial comparing the Orsiro hybrid DES to Resolute Integrity

Principal Investigator

- Prof. Tae-Jin Youn, Seoul National University Bundang Hospital, South Korea



Endpoints

Primary endpoint

- In-stent LLL at 9 months

Secondary endpoints (selected)

- TLF defined as composite of cardiac death, TLR and target vessel-related MI
- All-cause and cardiac deaths
- Clinically-driven TLR
- MI (target or non-target vessel-related)
- Definite or probable stent thrombosis (ST)

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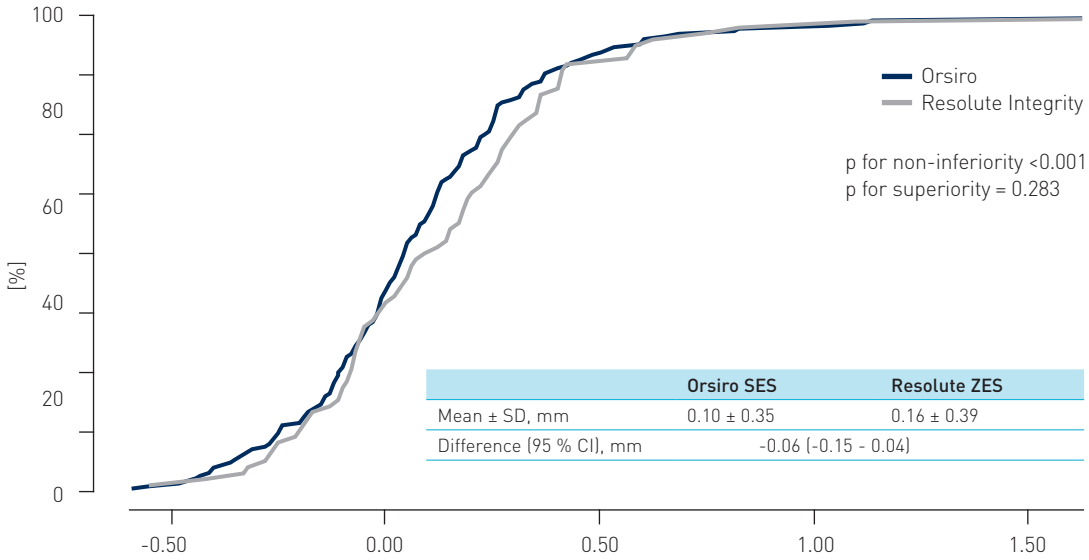
Primary endpoint

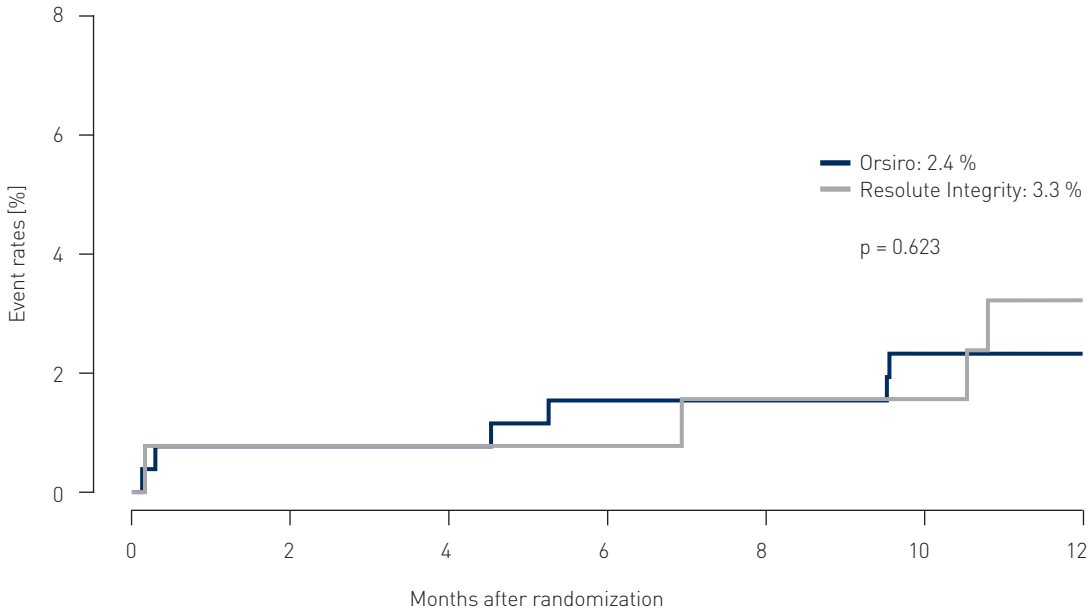
In-stent Late Lumen Loss



	Orsiro SES	Resolute ZES
Mean ± SD, mm	0.10 ± 0.35	0.16 ± 0.39
Difference (95 % CI), mm	-0.06 (-0.15 - 0.04)	

Secondary endpoint

Target Lesion Failure



Source: Kang S. EuroPCR 2016. Oral presentation.

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