ORIENT

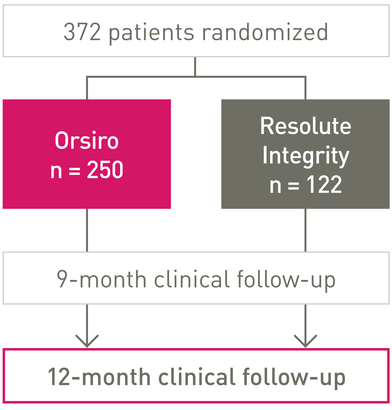
A prospective, randomized, multi-center, controlled trial comparing the Orsiro to Resolute Integrity

Conclusions

- In this 372 patient randomized trial with an angiographic primary endpoint of Late Lumen Loss (LLL) at 9 months, Orsiro demonstrated non-inferiority to Resolute Integrity
- Orsiro, with its ultrathin struts and bioabsorbable polymer, showed numerically better results for the secondary clinical endpoint, Target Lesion Failure (TLF) out to 12 months
- These highly encouraging results reconfirm those of previous Orsiro trials and add to the solid foundation of clinical evidence that supports the use of Orsiro across a broad range of patients population

Study design

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



Endpoints

Primary endpoint
- In-stent LLL at 9 months

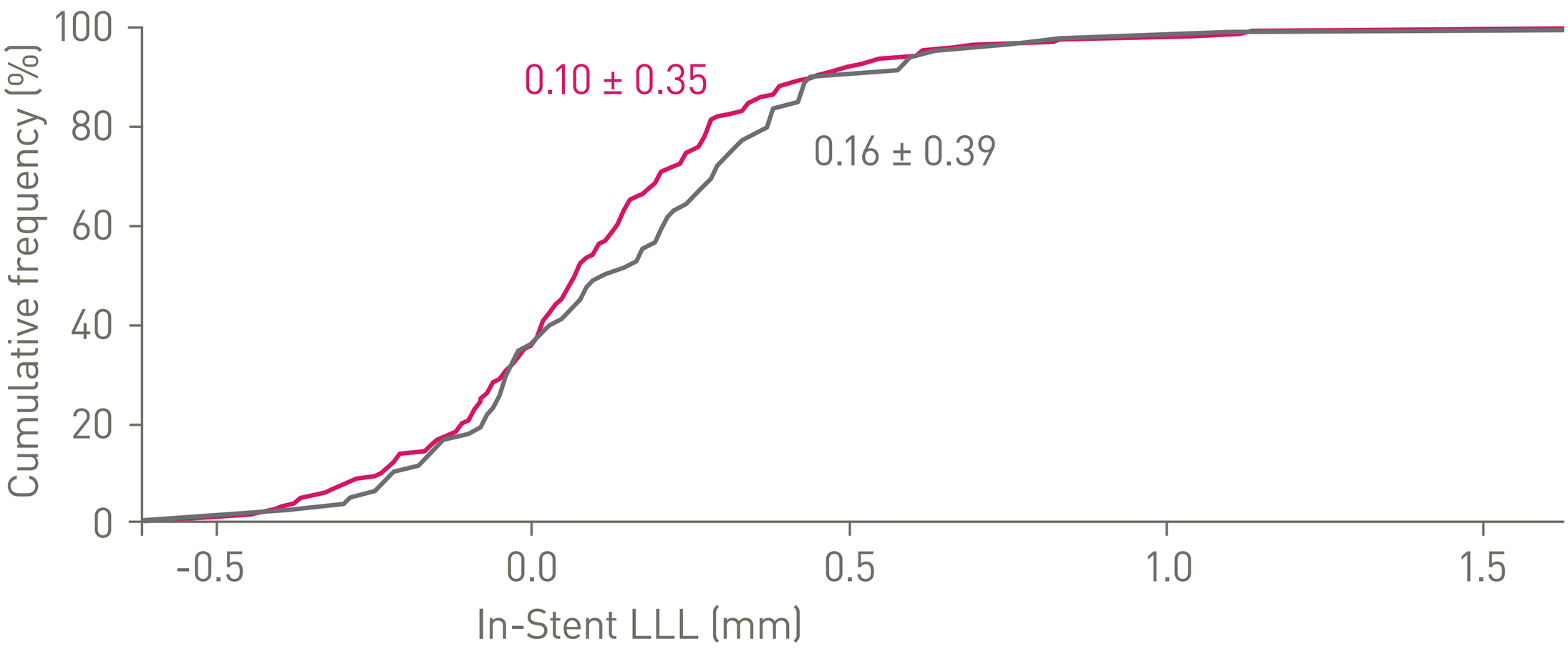
Secondary endpoints (selected)
- TLF defined as composite of cardiac death
- Target Lesion Revascularization (TLR) and target vessel-related Myocardial Infarction (MI)
- All-cause and cardiac death
- Clinically-driven TLR
- MI (target or non-target vessel-related)
- Definite or probable Stent Thrombosis (ST)

Patient characteristics[1]	Orsiro n = 250	Resolute Integrity n = 122
Age, yrs*‡	65.2 ± 11.9	64.8 ± 11.0
Male	72.0%	70.5%
Diabetes	25.2%	27.0%
Hypertension	64.8%	66.4%
Previous PCI	13.6%	14.8%
Previous CABG	0.8%	0.0%
Indication		
Stable Angina	53.3%	55.1%
Unstable Angina	24.3%	19.7%
STEMI	9.4%	8.7%
NSTEMI	12.9%	16.5%

Lesion characteristics[1]	Orsiro n = 345	Resolute Integrity n = 176
Chronic total occlusion	9.0%	6.3%
Ostial lesion	7.0%	5.1%
Bifurcation lesion	22.9%	23.9%
Restenotic lesion	1.2%	2.3%
Calcification	11.0%	12.5%
Lesion Classification		
A	4.3%	5.7%
B1	21.7%	18.8%
B2	31.3%	29.5%
C	42.6%	46.0%

* Data shown as mean ± SD
‡ p=0.759

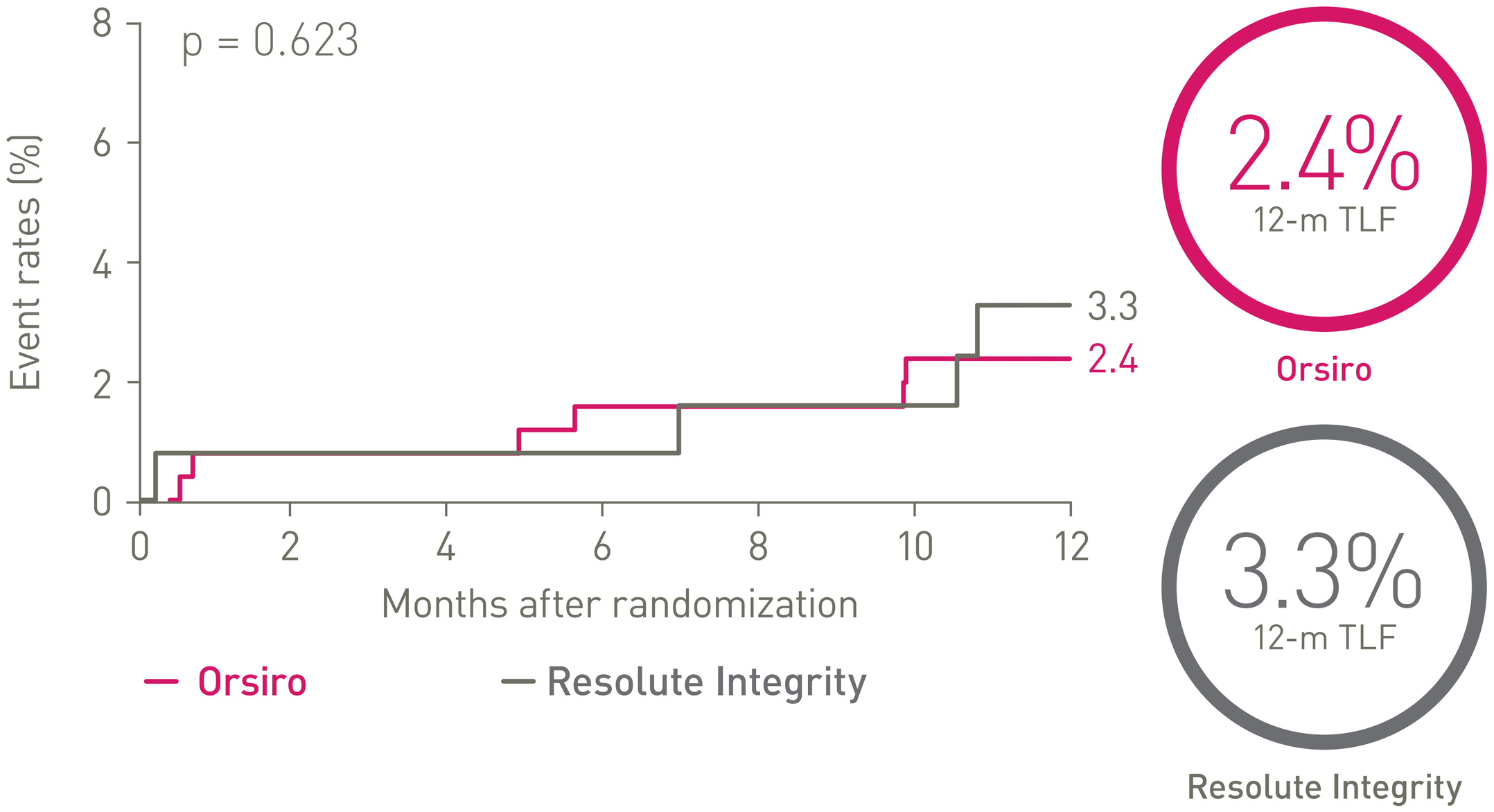
Primary endpoint in-stent LLL[1]



Difference (95% CI), mm -0.06 (-0.15 - 0.04)

p for non-inferiority <0.001
p for superiority = 0.205

Secondary endpoint TLF[1]



Principal investigator

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1. Kang SH, Chung WY, Lee JM, et al. Angiographic outcomes of Orsiro biodegradable polymer sirolimus-eluting stents and Resolute Integrity durable polymer zotarolimus-eluting stents: results of the ORIENT trial. EuroIntervention: journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology. 2017 Jan;12(13):1623-31.

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