



# BIOFLOW-II

Results for total population out to 5 years

## Conclusions

- Target Lesion Failure (TLF) comparable to Xience Prime\* although separating over time in favor of Orsiro® out to 5 years
- Absence of definite or probable Stent Thrombosis (ST) also in high risk populations such as diabetic and small vessel subgroups out to 5 years
- The results of this prospective, randomized study confirm the long term safety and efficacy profile of Orsiro

## Study design

A prospective, multi-center, randomized, controlled trial comparing Orsiro to Xience Prime.

### Patients

Inclusion of up to two de novo lesions with a maximal length of 26 mm each.

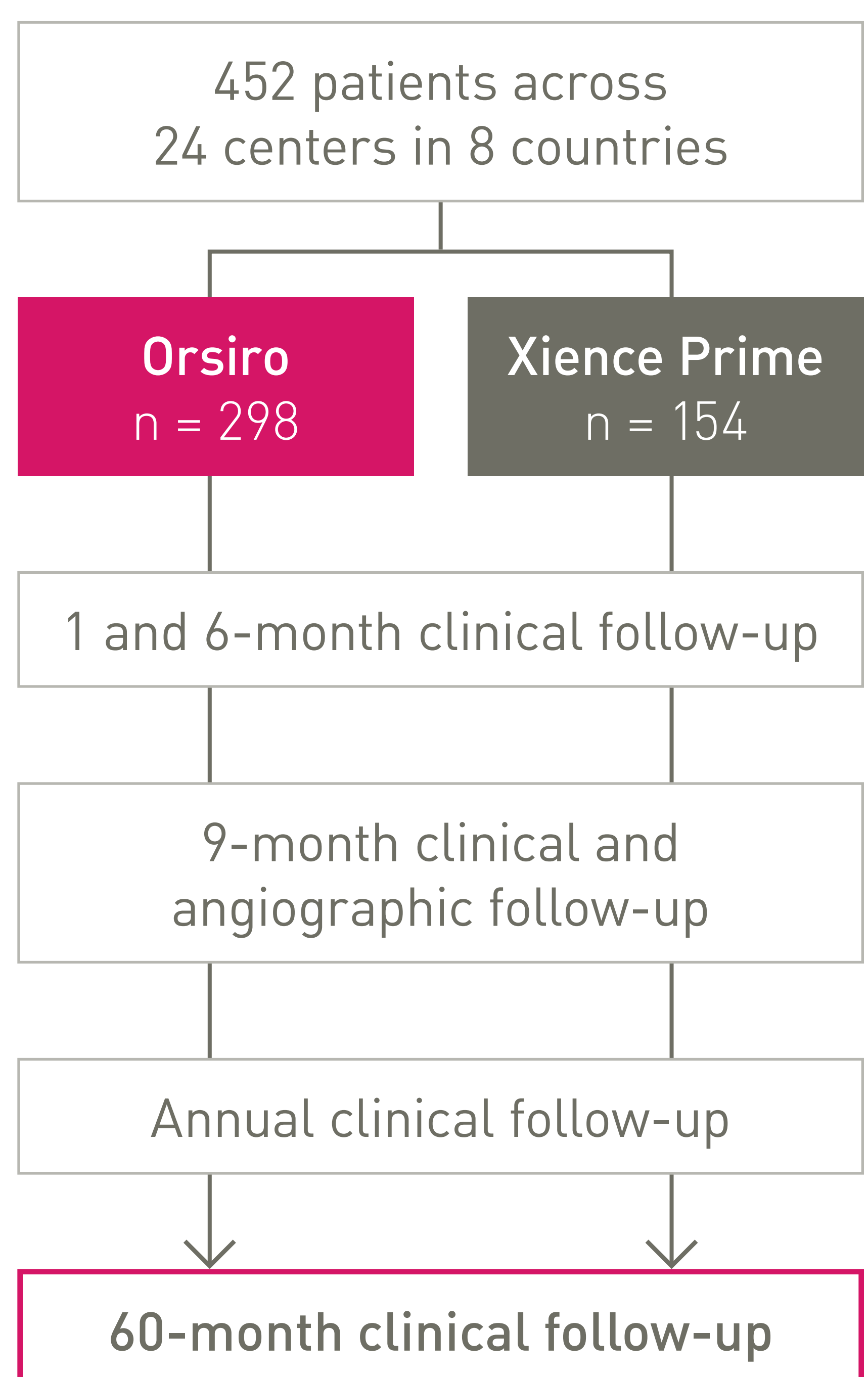
## Endpoints

### Primary endpoint

- In-Stent Late Lumen Loss (LLL) at 9 months

### Secondary endpoints (selected)

- TLF<sup>Δ</sup>
- Definite ST<sup>§</sup>



## Patient and lesion characteristics<sup>1</sup>

	Orsiro n = 298	Xience Prime n = 154
Age, yrs <sup>**†</sup>	62.7 ± 10.4	64.8 ± 9.2
Male	78.2%	74.7%
Hypertension	77.5%	77.3%
Hypercholesterolaemia	67.8%	73.4%
History of MI	30.2%	20.1%
Diabetes	28.2%	28.6%
Insulin dependent	21.4%	34.1%
Non-insulin dependent	78.6%	65.9%
Average number of lesions per patient <sup>**</sup>	13.36 ± 6.82	13.65 ± 5.58

\* Xience and Xience Prime are registered trademarks of Abbott Cardiovascular Systems

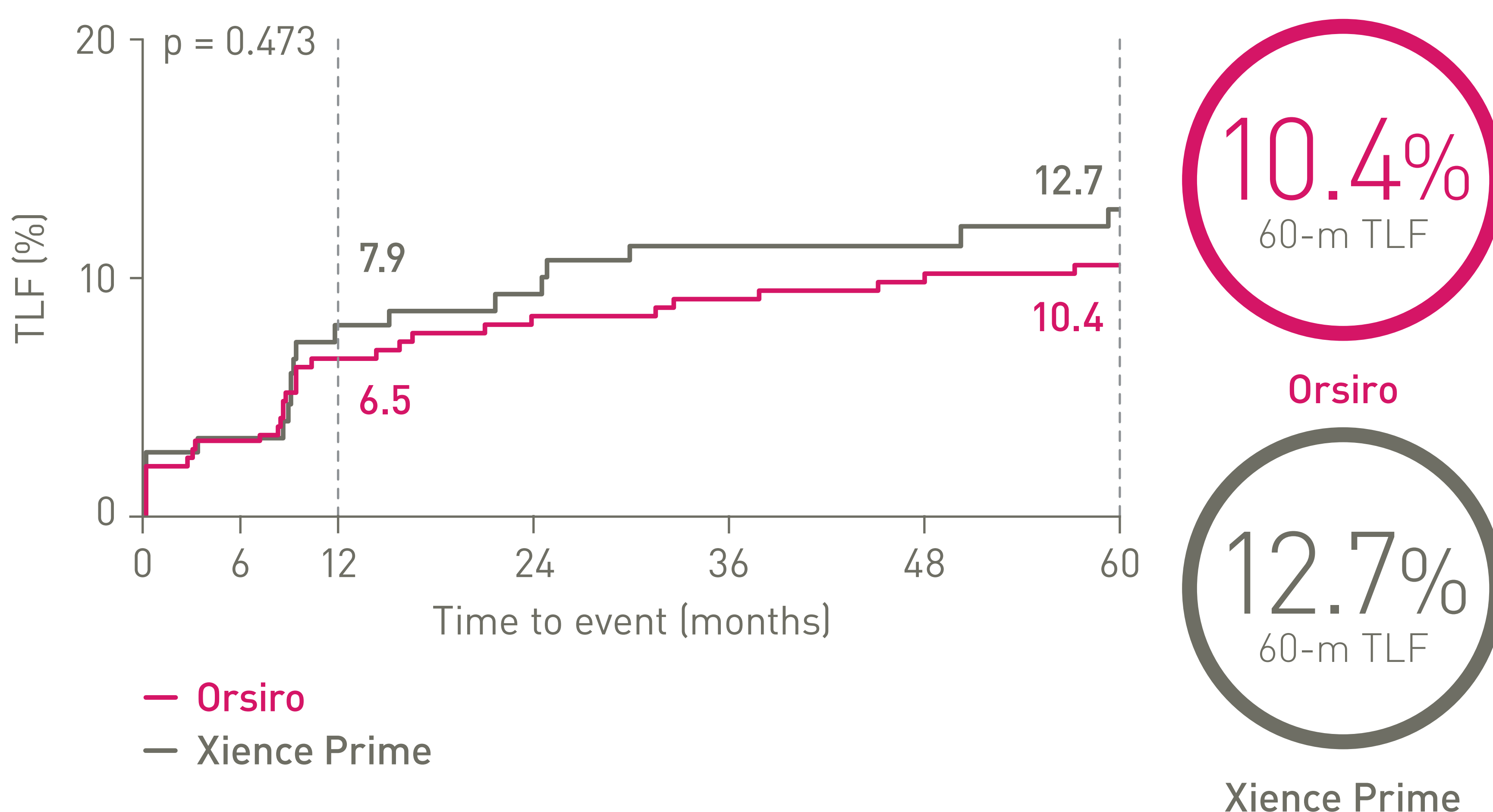
\*\*Data shown as mean ± SD

† p=0.0344

Δ Composite of cardiac death, target vessel Q-wave or non-Q wave Myocardial Infarction (MI), Emergent Coronary Artery Bypass Graft (CABG), clinically driven Target Lesion Revascularization (TLR).

§ ST as per ARC definition

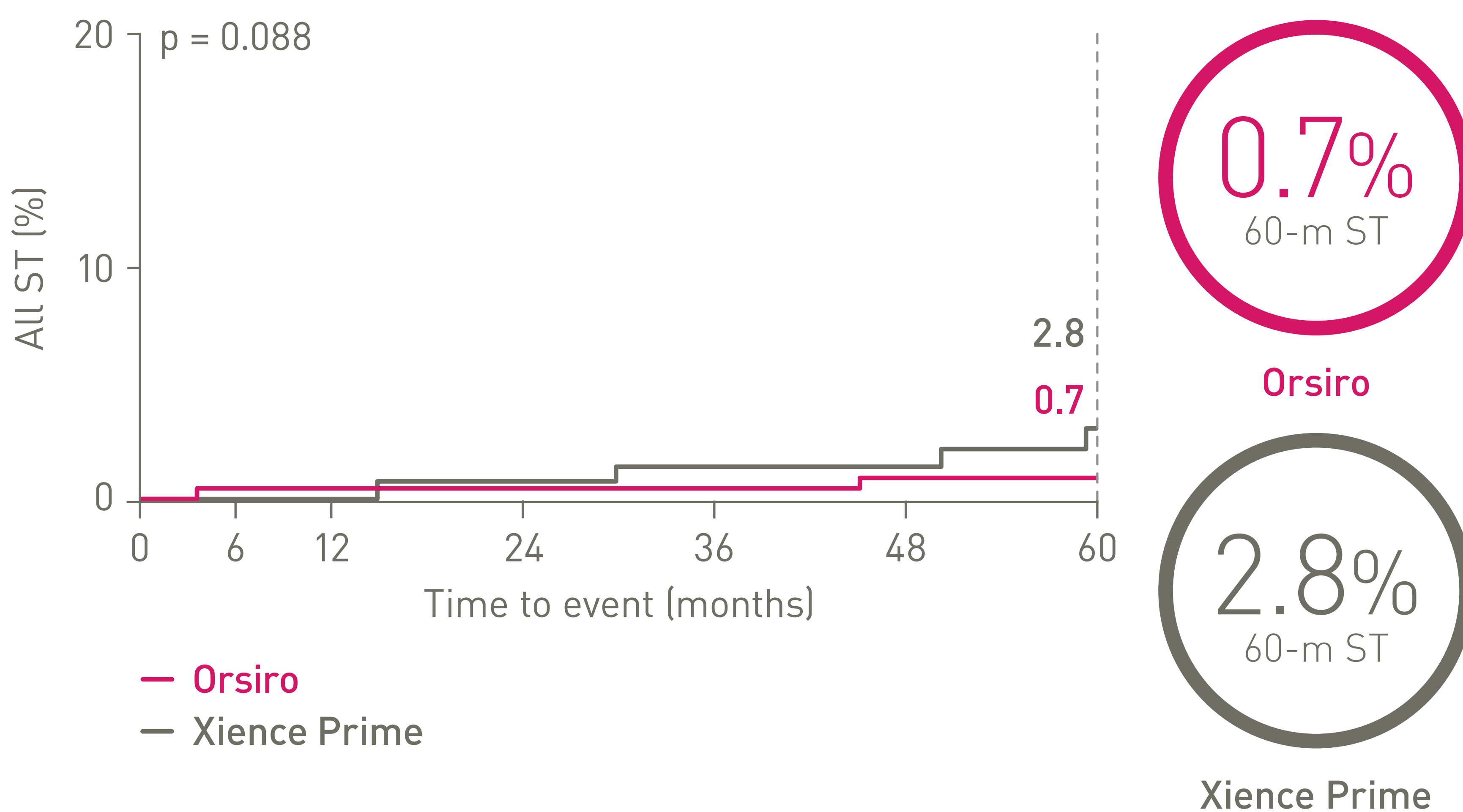
## TLF rates - Total population out to 5 years<sup>1</sup>



TLF components <sup>1</sup>	Orsiro n = 298	Xience Prime n = 154	p-value
Cardiac death	1.7%	2.8%	0.504
TV-MI	3.4%	3.3%	0.953
CD-TLR	6.3%	6.7%	0.850

## No definite or probable ST occurred in the Orsiro arm out to 5 years<sup>1</sup>

	Orsiro	Xience Prime	p-value
ST	0.7%	2.8%	0.088
Definite ST	0.0%	0.7%	0.341
Probable ST	0.0%	0.0%	-



## Coordinating clinical investigators

Prof. Stephan Windecker, Bern, Switzerland

Dr. Thierry Lefèvre, Massy, France

1. Lefèvre T et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: 5-year outcomes of the randomized BIOFLOW-II trial. JACC: Cardiovascular Interventions 2018;11(10):995-1002; ClinicalTrials.gov: NCT01356888.

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Vascular Intervention // Coronary // **Orsiro**


# BIOFLOW-II

## Diabetic subgroup

### Conclusions

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### Diabetic subgroup demographics and lesion characteristics<sup>1</sup>

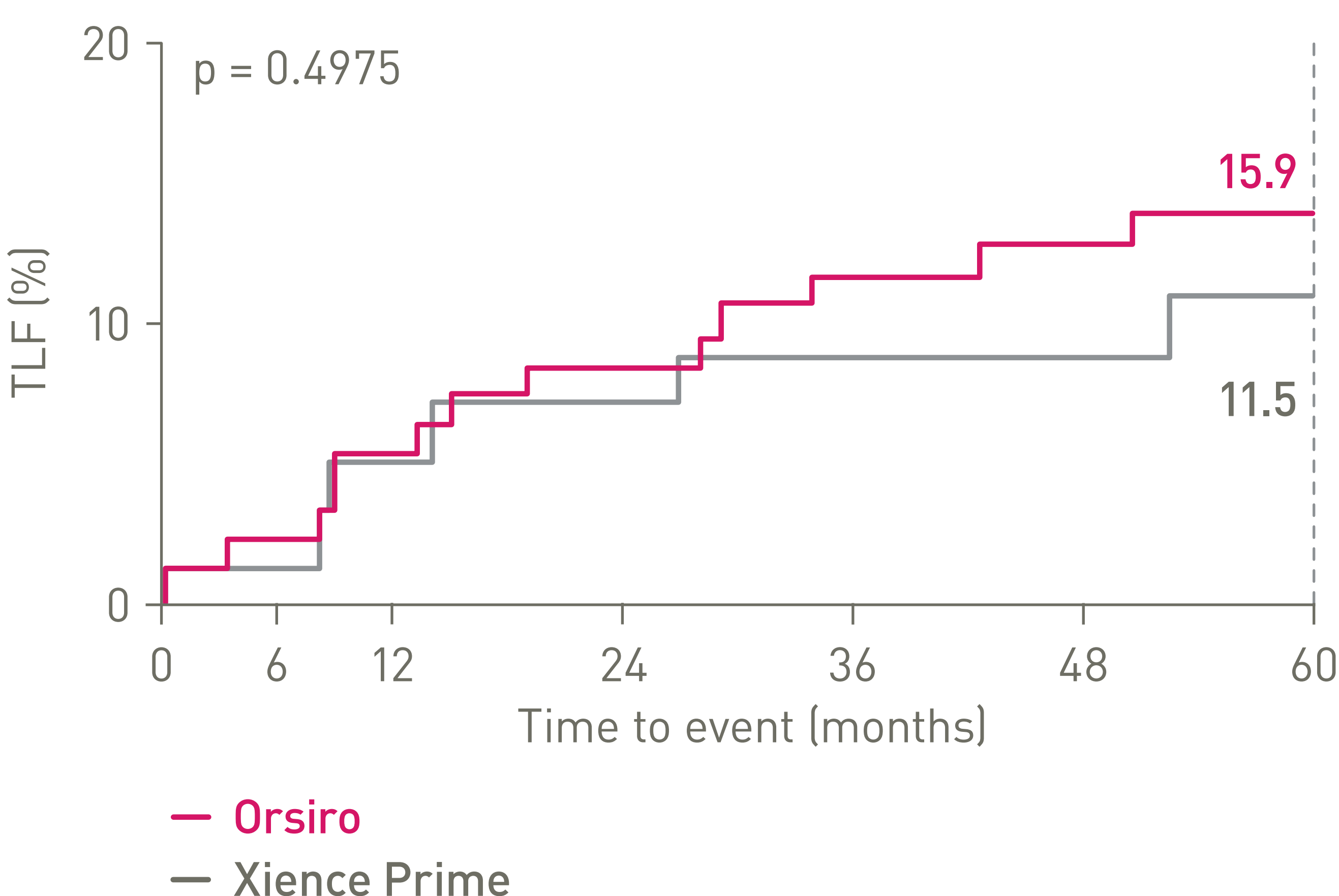
Subjects	Orsiro n = 84	Xience Prime n = 44
Age, yrs**	63.7 ± 9.2	64.8 ± 7.5
Hypertension	91.7%	88.6%
Hyperlipidemia	76.2%	77.3%
History of MI	28.6%	15.9%
Congestive heart failure <sup>‡</sup>	13.1%	27.3%
Insulin dependent	21.4%	34.1%
Non-insulin dependent	78.6%	65.9%
Lesions	n = 93	n = 49
Lesion length (mm)**	12.58 ± 5.22	14.37 ± 6.21
Reference vessel diameter (mm)**	2.71 ± 0.53	2.73 ± 0.51
Diameter stenosis (%)	67.6 ± 14.36	67.83 ± 14.45

‡ p = 0.047

### TLF<sup>Δ</sup> components<sup>2</sup>

	Orsiro n = 84	Xience Prime n = 44	p-value
Cardiac death	1.3%	6.9%	0.089
TV-MI	2.5%	0.0%	0.545
CD-TLR	13.5%	4.5%	0.138

### Diabetic subgroup TLF rates out to 5 years<sup>2</sup>



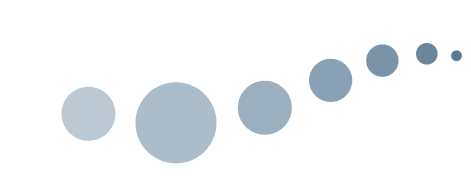
1. Sabaté M et al. BIOFLOW-II – 1 year substudy results of the diabetic and small vessel cohorts; Presented at: EuroPCR 2014; May 20, 2014; Paris, France; ClinicalTrials.gov: NCT01356888; 2. Lefèvre T et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: 5-year outcomes of the randomized BIOFLOW-II trial. JACC: Cardiovascular Interventions. 2018 May 21;11(10):995-1002.

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## Small vessel subgroup

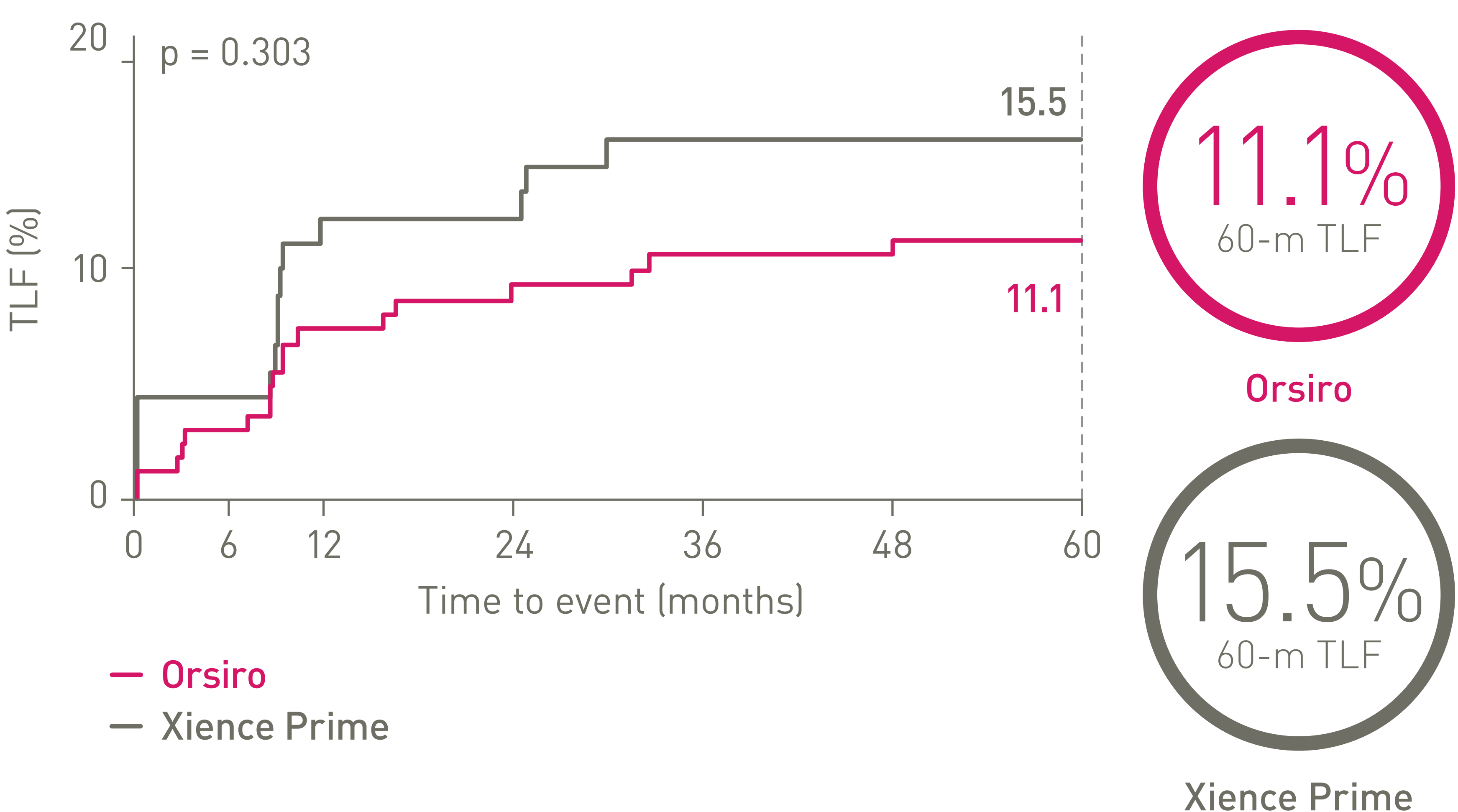
**Conclusions**

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**Small vessel subgroup demographics and lesion characteristics<sup>1</sup>**

Subjects	Orsiro n = 168	Xience Prime n = 91
Age, yrs**	62.9 ± 10.2	65.5 ± 9.0
Hypertension	80.4%	76.9%
Hyperlipidemia	69.6%	68.1%
History of MI	33.9%	26.4%
Diabetes	33.9%	28.6%
Insulin dependent	29.8%	30.8%
Non-insulin dependent	70.2%	69.2%
Lesions	n = 195	n = 109
Lesion length (mm)**	13.93 ± 6.88	13.08 ± 5.22
Reference vessel diameter (mm)**	2.49 ± 0.37	2.49 ± 0.33
Diameter stenosis (%)	67.55 ± 13.70	65.56 ± 14.47

TLF components <sup>2</sup>	Orsiro n = 168	Xience Prime n = 91	p-value
Cardiac death	0.6%	2.2%	0.265
TV-MI	3.7%	4.4%	0.738
CD-TLR	8.7%	8.9%	0.948

**Small vessel subgroup TLF rates out to 5 years<sup>2</sup>**

1. Sabaté M et al. BIOFLOW-II – 1 year substudy results of the diabetic and small vessel cohorts; Presented at: EuroPCR 2014; May 20, 2014; Paris, France; ClinicalTrials.gov: NCT01356888; 2. Lefèvre T et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: 5-year outcomes of the randomized BIOFLOW-II trial. JACC: Cardiovascular Interventions 2018 May 21;11(10):995-1002.

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## BIOFLOW-II

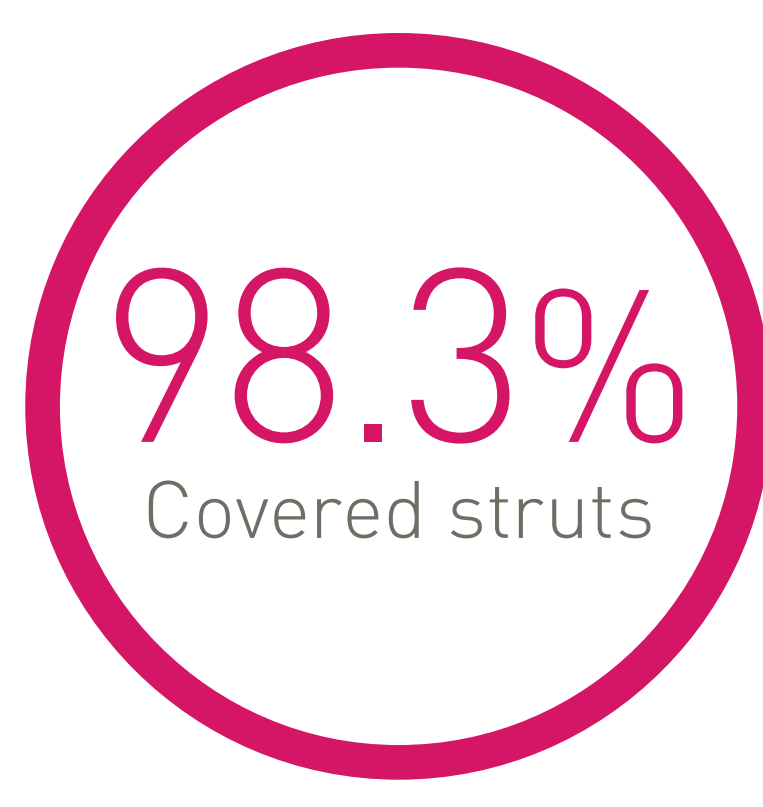
Imaging data

### Conclusions

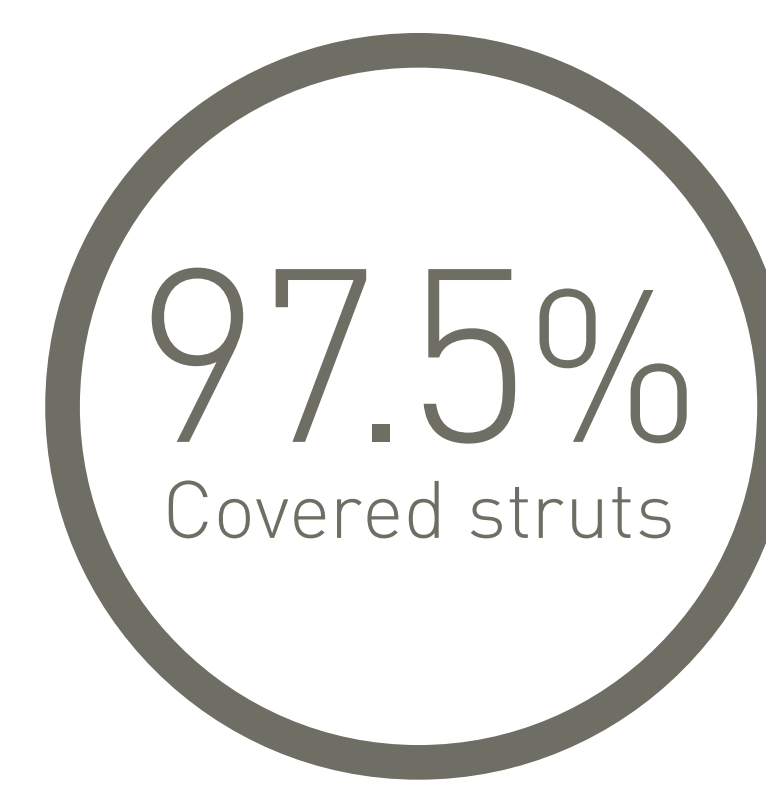
- The BIOFLOW-II OCT/IVUS subgroup analysis showed similar results between the Orsiro<sup>®</sup> and Xience Prime\*
- Safe inhibition of neointimal hyperplasia was seen in both arms at 9 months with struts well covered with a thin, uniform neointima
- Orsiro was associated with a significantly lower area of neointimal hyperplasia than Xience Prime and achieved excellent strut coverage

### Intravascular imaging subgroups<sup>1</sup>

OCT imaging was performed in a pre-specified subgroup to assess strut coverage at 9 months.



Orsiro



Xience Prime

	Orsiro	Xience Prime	p-value
Apposed struts	98.9%	99.2%	0.43
Covered struts	98.0%	97.29%	0.48
Neointimal area (mm <sup>2</sup> )**	0.75 ± 0.40	1.00 ± 0.44	0.03
Neointimal thickness (mm)**	0.10 ± 0.04	0.11 ± 0.04	0.37

### Neointimal hyperplasia at 9-month follow-up<sup>1</sup>

IVUS imaging was performed in a pre-specified subgroup to evaluate potential neointimal hyperplasia at 9 months.

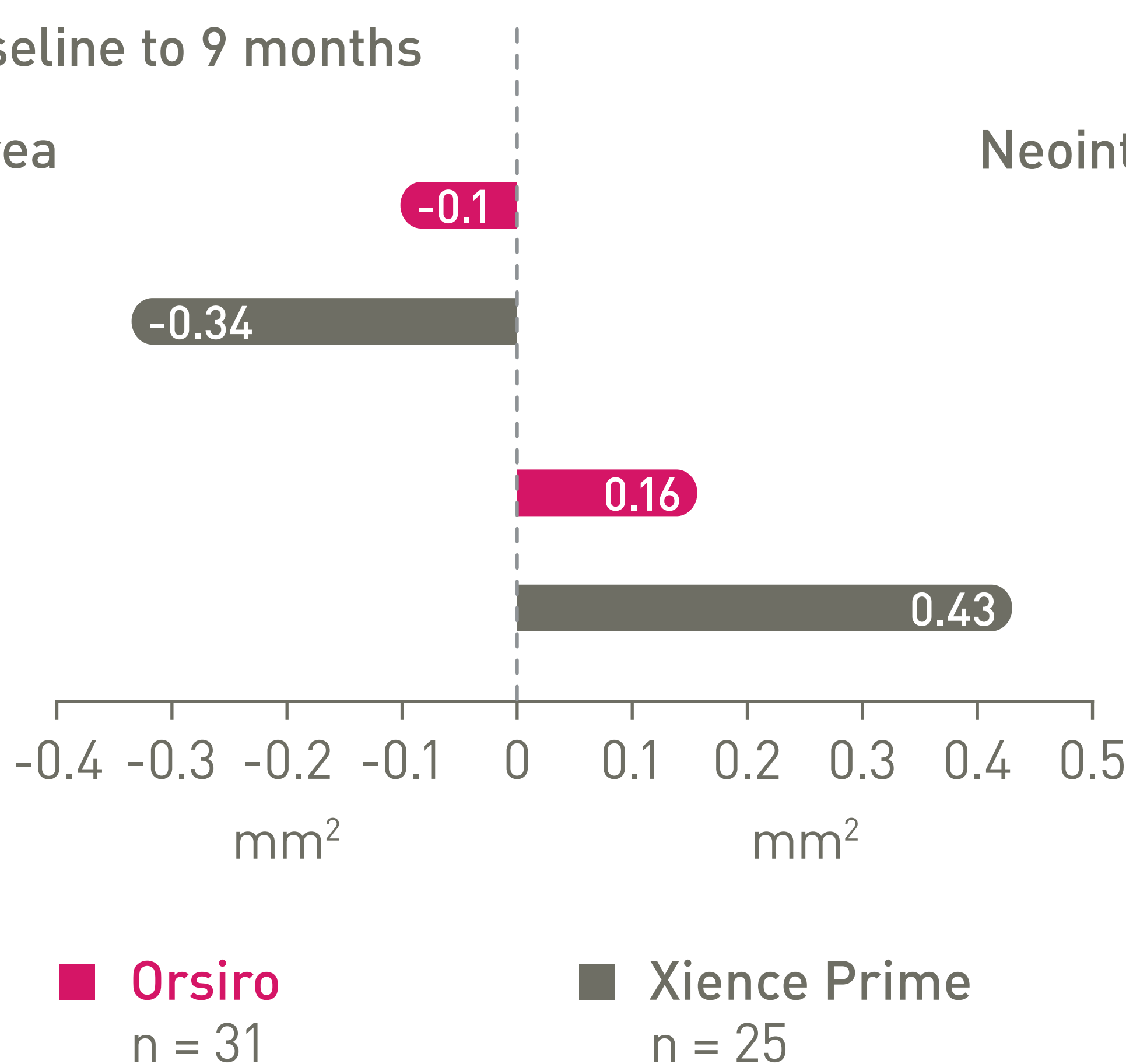
Change from Baseline to 9 months

Δ Mean lumen area

p = 0.34

Neointimal area

p = 0.04



1. Windecker S et al. Comparison of a novel biodegradable polymer sirolimus-eluting stent with a durable polymer everolimus-eluting stent: results of the randomized BIOFLOW-II trial. *Circulation: Cardiovascular Interventions*. 2015 Feb 1;8(2):e001441.

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