

SORT OUT IX

A randomized trial comparing BioFreedom with **Orsiro**[®] in an all-comers patient population

Conclusions

- BioFreedom* was not non-inferior to Orsiro in the primary endpoint of Target Lesion Failure (TLF) at 12-month follow-up (5.2% vs. 4.0%, p-non inferiority = 0.123)¹, and no significant difference was found at 24-month follow-up (6.3% vs. 7.8%, RR 1.23 95% CI 0.94 – 1.61)².
- At 2 years, Target Lesion Revascularization (TLR) rate was significantly lower in the Orsiro stent group compared to the BioFreedom stent group (2.6% vs. 5.1%, RR 1.98 95% CI 1.36 – 2.89)².
- BioFreedom and Orsiro both had similar safety and risk profile for definite Stent Thrombosis (ST) up to 2 years.²

Study design

Randomized, multi-center, single blind, all-comers, two-arm, non-inferiority trial comparing BioFreedom to Orsiro stent in patients treated with PCI at 4 hospitals in Denmark.

Endpoints

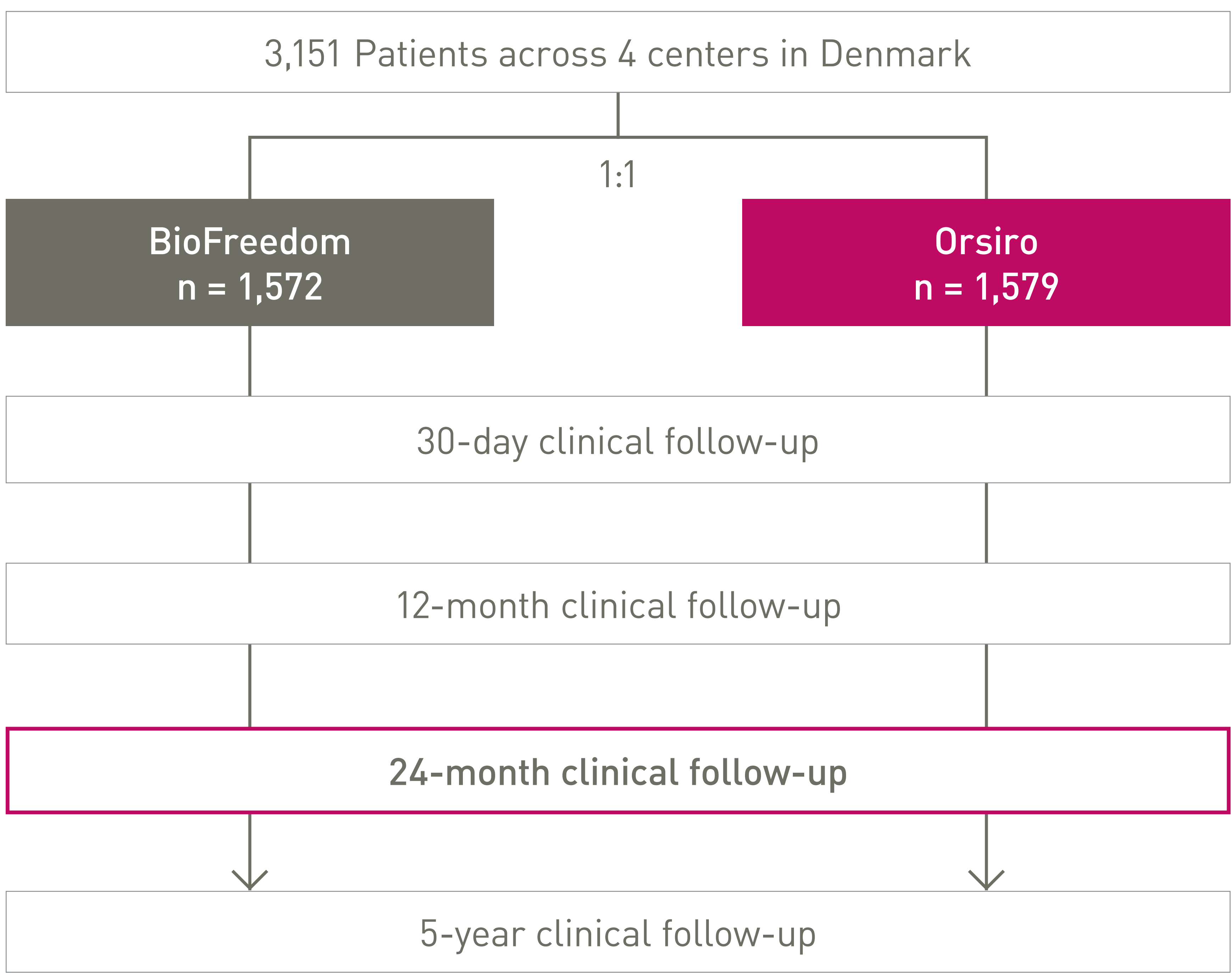
Primary endpoint

Target Lesion Failure (TLF) defined as the composite of:

- Cardiac Death
- Myocardial Infarction (MI) not related to any segment other than the target lesion
- Target Lesion Revascularization (TLR)

Secondary endpoints

- Individual components of the primary endpoint
- Stent Thrombosis (ST) rate according to the ARC definition^Δ



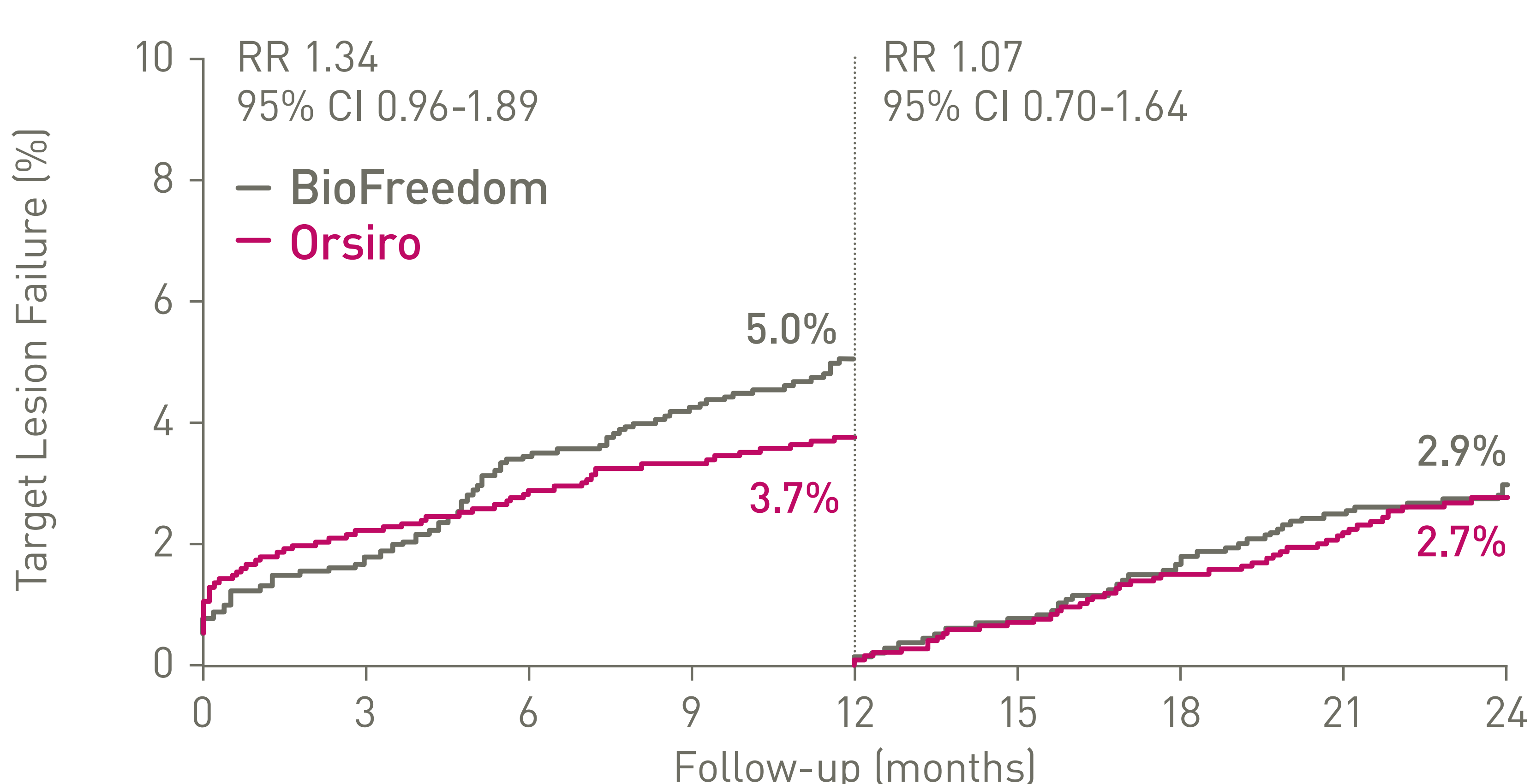
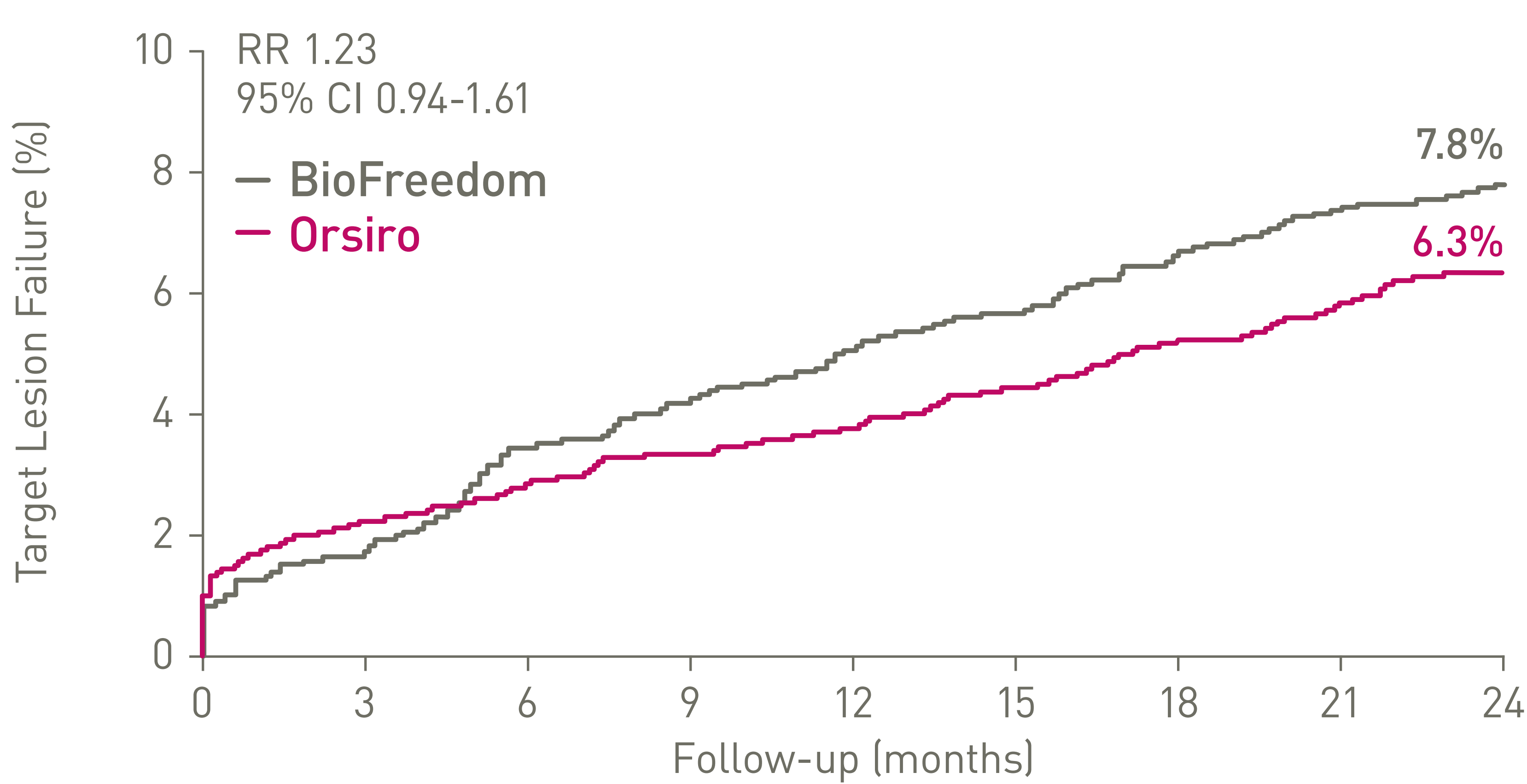
Patient characteristics ¹	BioFreedom n = 1,572	Orsiro n = 1,579
Age (years)**	66.4 ± 10.7	66.1 ± 11.1
Male	77.5%	77.3%
Diabetes	19.3%	19.2%
Current smoker	29.8%	29.3%
Prior PCI	20.9%	20.9%
Prior CABG	8.4%	7.0%
Prior MI	14.7%	15.2%
Stable angina	42.7%	40.8%
NSTEMI / Unstable Angina	28.9%	28.7%
STEMI	23.3%	25.1%
Other	5.1%	5.3%

Lesion and Procedural characteristics ¹	BioFreedom n = 1,966 [◇]	Orsiro n = 1,985 [◇]
Lesion per patient**	1.3 ± 0.6	1.3 ± 0.6
Lesion type B2/C	60.6%	58.1%
Reference vessel size (mm)**	3.3 ± 0.6	3.3 ± 0.6
Number of stents		
Per patient**	1.6 ± 0.9	1.6 ± 0.9
Per lesion**	1.3 ± 0.6	1.2 ± 0.6
Total stent length (mm)		
Per patient**	31.1 ± 21.9	30.6 ± 19.8
Per lesion**	24.7 ± 16.0	24.3 ± 13.6

* BioFreedom is a trademark or registered trademark of Biosensors International Group, Ltd.
 ** Data shown as mean – SD
 ◇ Number of lesions
 Δ According to Academic Research Consortium (ARC) criteria for acute, subacute, late, very late and cumulative stent thrombosis



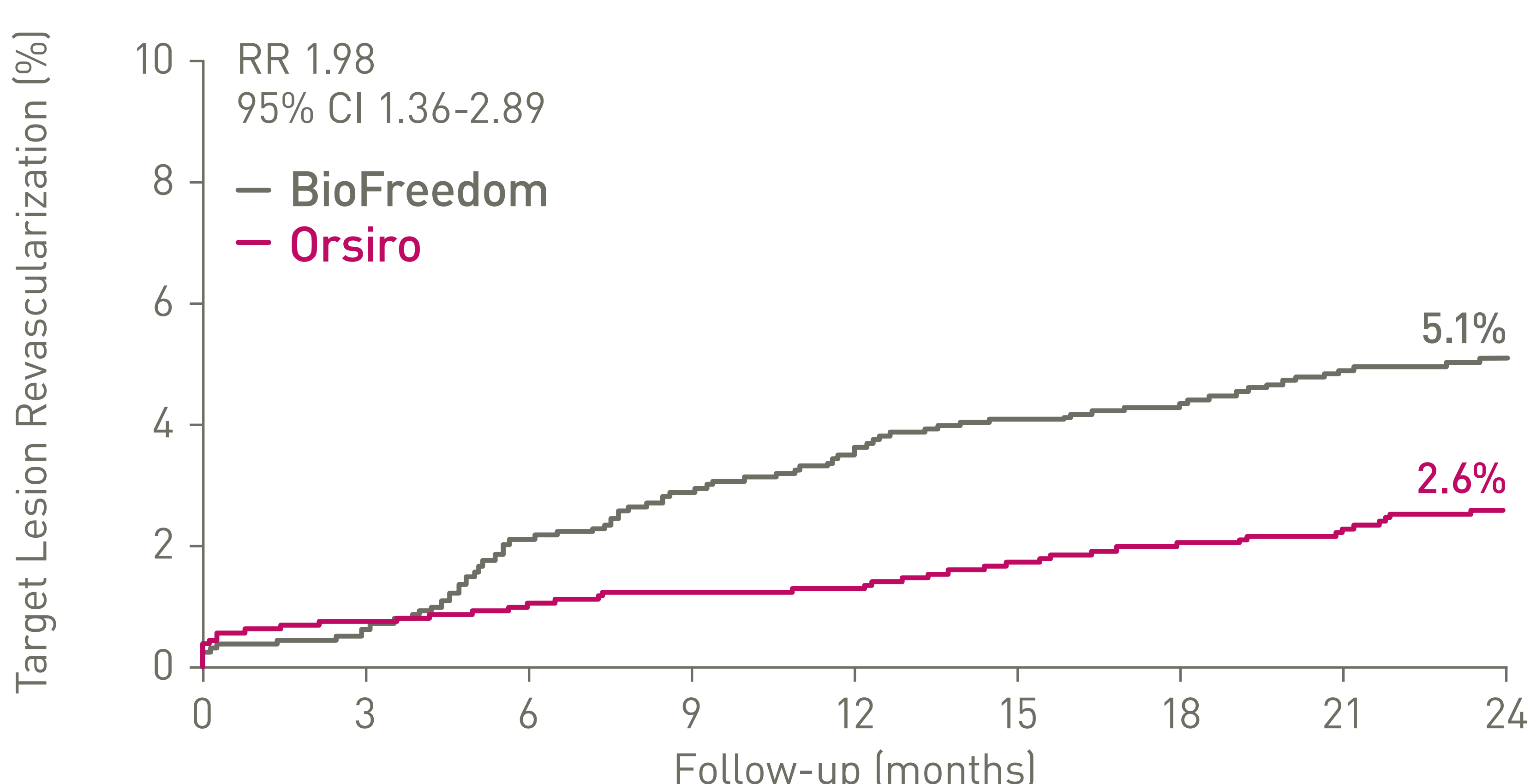
TLF at 12- and 24-month²



TLF Components at 24-month

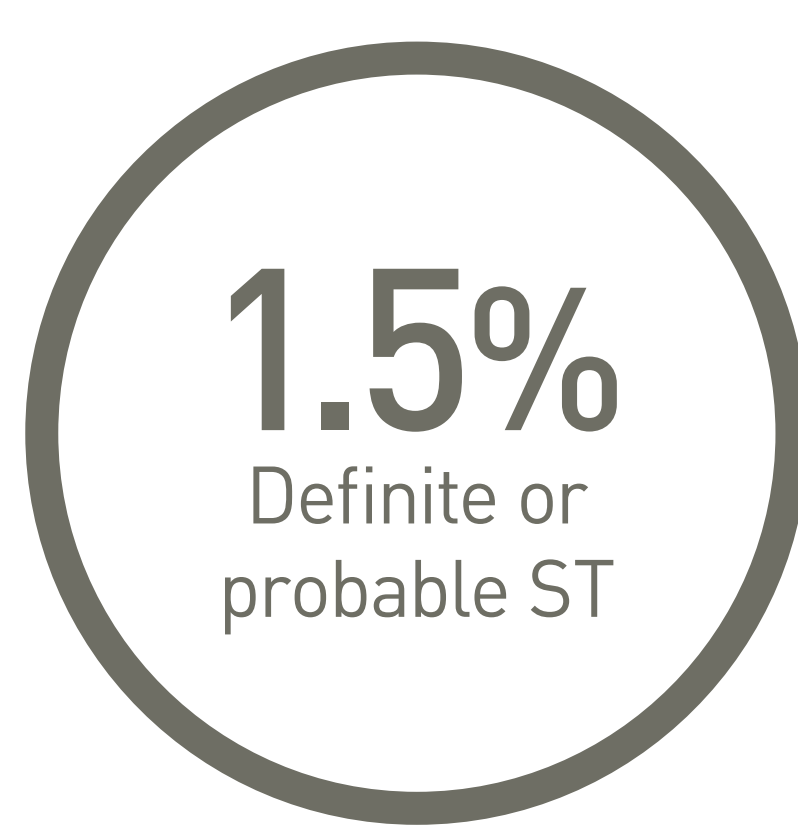
	BioFreedom n = 1,570	Orsiro n = 1,576	Rate ratio (95% CI)
Cardiac Death	2.0%	2.6%	0.78 [0.49 - 1.24]
MI	4.3%	4.4%	0.97 [0.69 - 1.36]
TLR	5.1%	2.6%	1.98 [1.36 - 2.89]

TLR 24-month²



ST 24-month²

RR 0.80
95% CI 0.47-1.37



BioFreedom



Orsiro

Subgroup²

		Rate of TLF events BioFreedom Orsiro	Rate Ratio (95% BC ¹ **)	p for interaction
ACS	no	63 [8.4%] 48 [6.6%]	1.29 [0.88-1.88]	0.75
	yes	59 [7.2%] 52 [6.1%]	1.18 [0.81-1.71]	
Age	≤ 65	32 [4.8%] 33 [4.6%]	1.06 [0.65-1.73]	0.53
	> 65	90 [9.9%] 67 [7.8%]	1.28 [0.93-1.76]	
Diabetes mellitus	no	83 [6.5%] 67 [5.3%]	1.26 [0.91-1.74]	0.83
	yes	39 [12.8%] 33 [10.9%]	1.17 [0.73-1.88]	
LAD	no	66 [8.4%] 48 [6.1%]	1.39 [0.96-2.02]	0.36
	yes	56 [7.1%] 52 [6.6%]	1.09 [0.74-1.59]	
Lesion type C	yes	60 [10.1%] 50 [8.5%]	1.18 [0.81-1.72]	0.72
	no	62 [6.4%] 49 [5.0%]	1.30 [0.89-1.90]	
Male	no	23 [6.5%] 24 [6.7%]	0.97 [0.54-1.72]	0.35
	yes	99 [8.1%] 76 [6.2%]	1.32 [0.97-1.78]	
MVD	no	95 [7.3%] 77 [5.9%]	1.25 [0.92-1.69]	0.88
	yes	27 [10.3%] 23 [8.6%]	1.19 [0.68-2.09]	
One stent per patient	no	75 [7.5%] 61 [6.1%]	1.25 [0.89-1.75]	0.83
	yes	44 [7.8%] 38 [6.7%]	1.18 [0.76-1.82]	
Previous MI	no	90 [6.9%] 75 [5.8%]	1.21 [0.89-1.65]	0.45
	yes	29 [12.9%] 21 [9.0%]	1.45 [0.83-2.54]	
Previous PCI	no	80 [6.6%] 71 [5.7%]	1.15 [0.83-1.58]	0.66
	yes	39 [12.1%] 25 [8.0%]	1.53 [0.92-2.54]	
STEMI	no	104 [8.6%] 81 [6.9%]	1.27 [0.95-1.70]	0.54
	yes	18 [4.9%] 19 [4.8%]	1.02 [0.53-1.96]	
Overall		122 [7.8%] 100 [6.3%]	1.23 [0.94-1.61]	

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Favours BioFreedom Favours Orsiro

Principal investigator

Prof. Lisette Okkels Jensen, Odense University Hospital, Odense, Denmark

1. Okkels L et al. A Randomized Trial Comparing a Polymer-Free Coronary Drug-Eluting Stent With an Ultra-Thin Strut Bioresorbable Polymer-Based Drug-Eluting Stent in an All-Coroner Patient Population; Presentation; Presented at: TCT 2018; September, 2018; San Diego, USA; Corrected slides, published online on tctMD, Nov 5, 2018; ClinicalTrials.gov: NCT02623140; 2. Okkels L et al. 2-year outcomes of the randomized SORT OUT IX trial, Polymer-free biolimus stent versus the ultrathin strut biodegradable polymer sirolimus-eluting stent in an all-comers population treated with percutaneous coronary intervention, Presented at euroPCR 2021, May 2021, Paris, FRANCE, ClinicalTrials.gov NCT02623140.

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