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

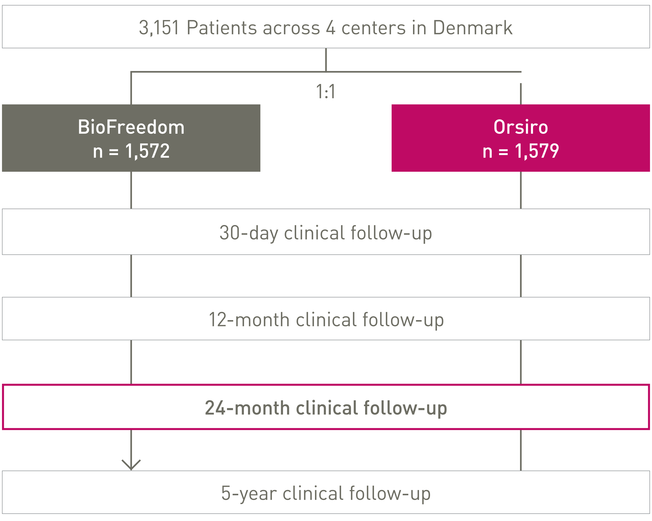
Primary endpoint

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$^{\Delta}$
- All-case death
- Target Vessel Revascularization (TVR)
- POCE (Death, MI, or any revascularization)

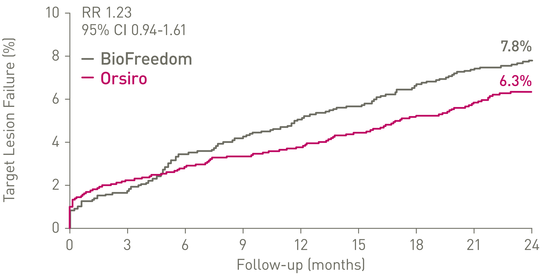


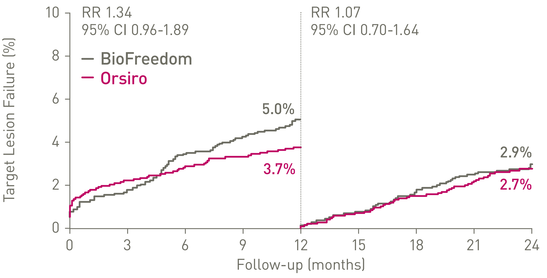
Patient characteristics[1]	BioFreedom n = 1,572	Orsiro n = 1,579
Age (years)**	66.4 ± 10.7	66.1 ± 11.1
Male	77.5%	77.3%
Diabetes	19.3%	19.2%
Current smoker	29.8%	29.3%
Prior PCI	20.9%	20.9%
Prior CABG	8.4%	7.0%
Prior MI	14.7%	15.2%
Stable angina	42.7%	40.8%
NSTEMI / Unstable Angina	28.9%	28.7%
STEMI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

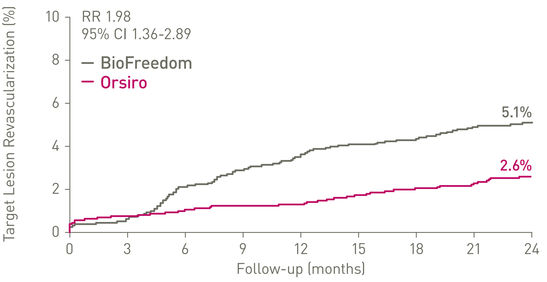
TLF at 12- and 24-month[2]





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-month[2]



ST 24-month[2]

RR 0.80
95% CI 0.47-1.37

BioFreedom

Orsiro

Subgroup[2]

		Rate of TLF events BioFreedom	Orsiro	Rate Ratio (95% BCI**)	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)	

Principal investigator

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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-Comers 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 outocmes 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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