SORT OUT IX

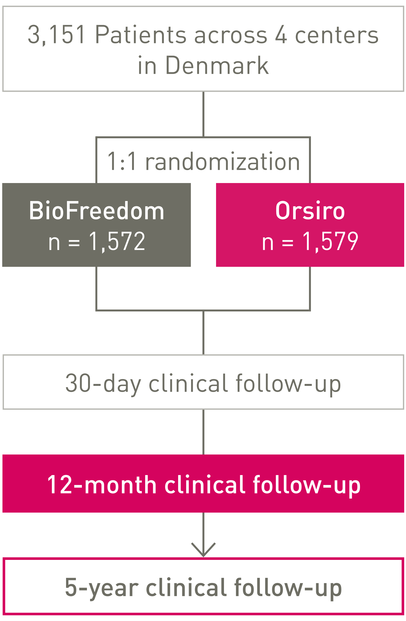
A randomized trial comparing BioFreedom with Orsiro® in an all-comers patient population

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% $p_{non\text{-}inferiority}$=0.123).
- Target Lesion Revascularization (TLR) rate for BioFreedom (3.5%) demonstrated significantly lower efficacy (p<0.0001) than Orsiro (1.3%)
- BioFreedom and Orsiro both had similar safety and risk profile for definite Stent Thrombosis (ST)

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

- TLF defined as a composite of cardiac death, target lesion Myocardial Infarction (MI) or TLR at 12 months

Secondary endpoints

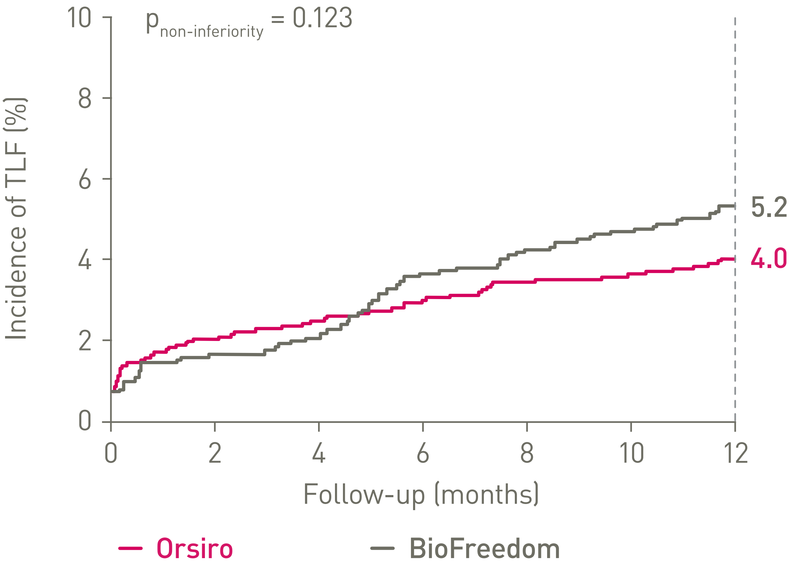
- Individual components of the primary endpoint and ST rate according to the ARC definition[Δ]

Patient characteristics[1]	BioFreedom n = 1,572	Orsiro n = 1,579
Age, yrs**	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 characteristics[1]	BioFreedom n = 1,966[◊]	Orsiro n = 1,985[◊]
Lesions 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

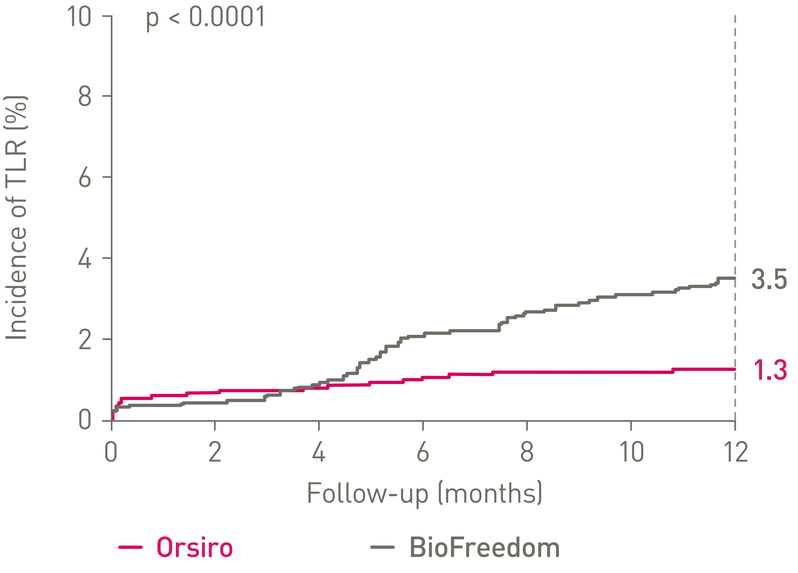
TLF at 12 months[1]



p=0.123
BioFreedom not non-inferior to Orsiro

TLF components[1]	BioFreedom	Orsiro	p-value
Cardiac death	1.2%	2.1%	0.055
MI	2.4%	2.5%	0.81
TLR	3.5%	1.3%	<0.0001

TLR at 12 months[1]



p<0.0001
Significantly lower TLR
Orsiro

ST at 12 months[1]	BioFreedom	Orsiro	p-value
Definite ST	0.7%	0.7%	0.99
Definite/probable ST	1.0%	1.1%	0.73

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.

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