BIOFLOW-I

Clinical & angiographic follow-up at 9 months

Conclusions

- Orsiro showed excellent Late Lumen Loss (LLL) results in the overall patient population
- BIOFLOW-I has a high rate of diabetic patients and complex lesions, atypical for a FIM study
- There was no late catch-up in LLL values at 9-month follow-up. This combined with a narrow standard deviation suggests robust study results

Study design

Prospective, multi-center, non-randomized, first-in-man trial

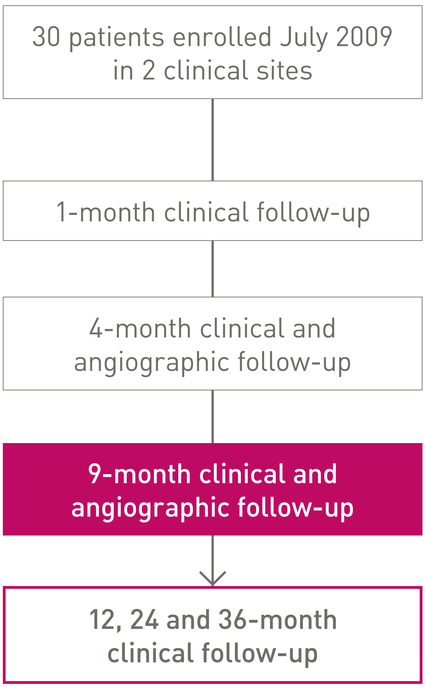
Objective

To assess the safety and clinical performance of the Orsiro in patients with single de novo coronary artery lesions

Endpoints

Primary endpoint

- In-stent LLL at 9 months by QCA



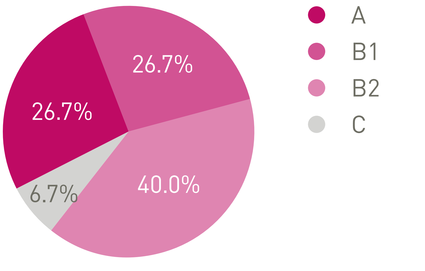
Patient characteristics[1]

	n = 30
Age. yrs*	58.1 ± 9.8
Male	60.0%
Hyperlipidemia	93.3%
History of MI	73.3%
Hypertension	66.6%
Smoker	53.3%
Diabetes	23.3%
Chronic heart failure	20.0%

Lesion characteristics[2]

	n = 30
Pre-procedure	
Diameter stenosis (%)*	65.52 ± 9.47
Mean lesion length (mm)*	11.71 ± 4.40
Procedural	
Stent length per lesion (mm)*	19.93 ± 5.33
Stent diameter per lesion (mm)*	3.08 ± 0.37
Direct stenting	20.0%
Device success**	100.0%

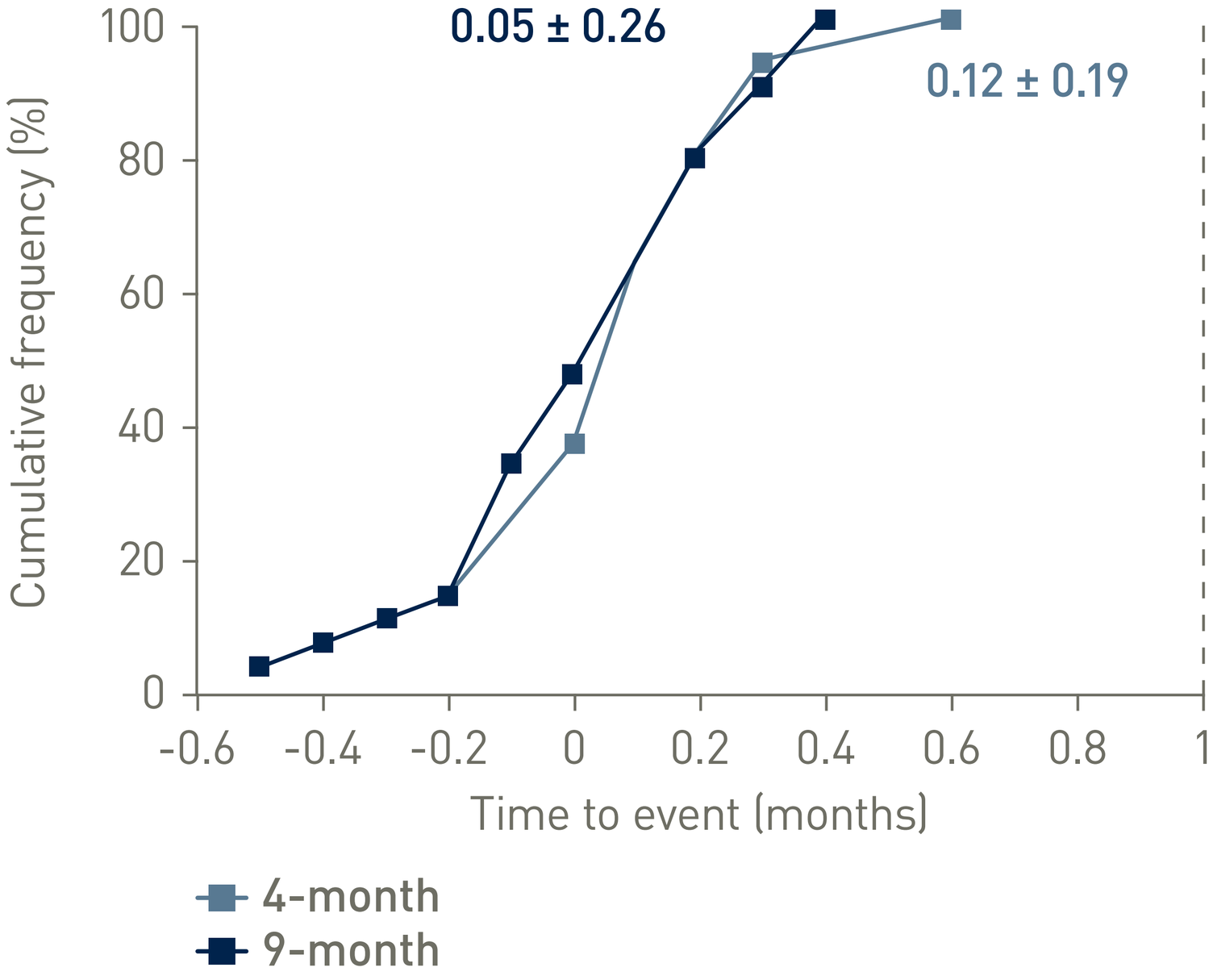
AHA / ACC‡ lesion classification[1]

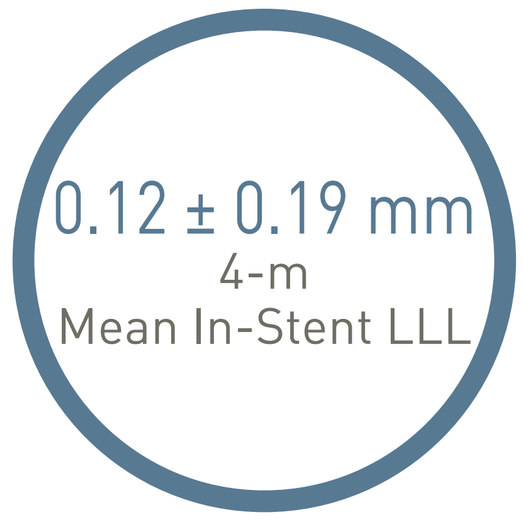


* Data shown as mean ± SD
** Defined as in-stent < 30% residual stenosis by offline QCA
‡ AHA/ACC: American Heart Association/American College of Cardiology classification of coronary artery lesion complexity.

Primary endpoint[2]

Cumulative frequency of in-stent Late Lumen Loss at 4 and 9 months





Secondary endpoint[1] MACE rate at 12 months

12-month clinical results	n	%
MACE†	3	10.0
Cardiac death	1	3.3
MI	0	0.0
Stent thrombosis	0	0.0
TLR (clinically driven)	2	6.7

† MACE defined as composite of cardiac death, MI attributed to the target vessel, stent thrombosis and clinically driven target lesion revascularization. Stent thrombosis was defined according to the Academic Research Consortium definitions.

Coordinating clinical investigator

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1. Hamon M, Niculescu R, Deleanu D, et al. Clinical and angiographic experience with a third-generation drug-eluting Orsiro stent in the treatment of single de novo coronary artery lesions (BIOFLOW-I): a prospective, first-in-man study. EuroIntervention. 2013 Jan 22;8(9):1006-11; 2. Hammon M et al. First in Man Experience With a Drug Eluting Stent in De Novo Coronary Artery Lesions (BIOFLOW-I); Presentation; Presented at: EUROPCR 2011; May, 2011; Paris, France; ClinicalTrials.gov: NCT01214148.

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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