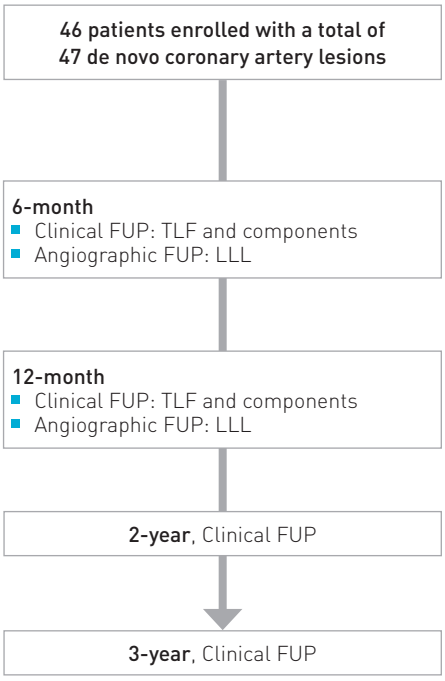
BIOSOLVE-I
12-month results

Conclusions
- No scaffold thrombosis or cardiac death at 12-month follow-up. The only myocardial infarction happened during the 12-month angiography follow-up with subsequent intervention at a non-target-lesion site
- Overall device and procedure success was 100 %
- In-segment Late Lumen Loss decreased from 0.52 mm at 6 months to 0.39 mm at 12 months

Study design
Prospective, multi-center, First-In-Man trial testing DREAMS (Drug-Eluting Absorbable Magnesium Scaffold) in 46 patients with a total of 47 de novo lesions

Principal investigator
- Prof. Michael Haude, Neuss, Germany



Endpoints
Primary endpoint
- Target Lesion Failure (TLF) defined as a composite of cardiac death, target-vessel myocardial infarction (TV-MI) and clinically driven Target Lesion Revascularization (cd-TLR) at 6 and 12 months

Secondary endpoints (selected)
- Late Lumen Loss (LLL) at 6 and 12 months
- Scaffold thrombosis at 1, 24 and 36 months
- Cumulative rates of TLF at 1, 24 and 36 months

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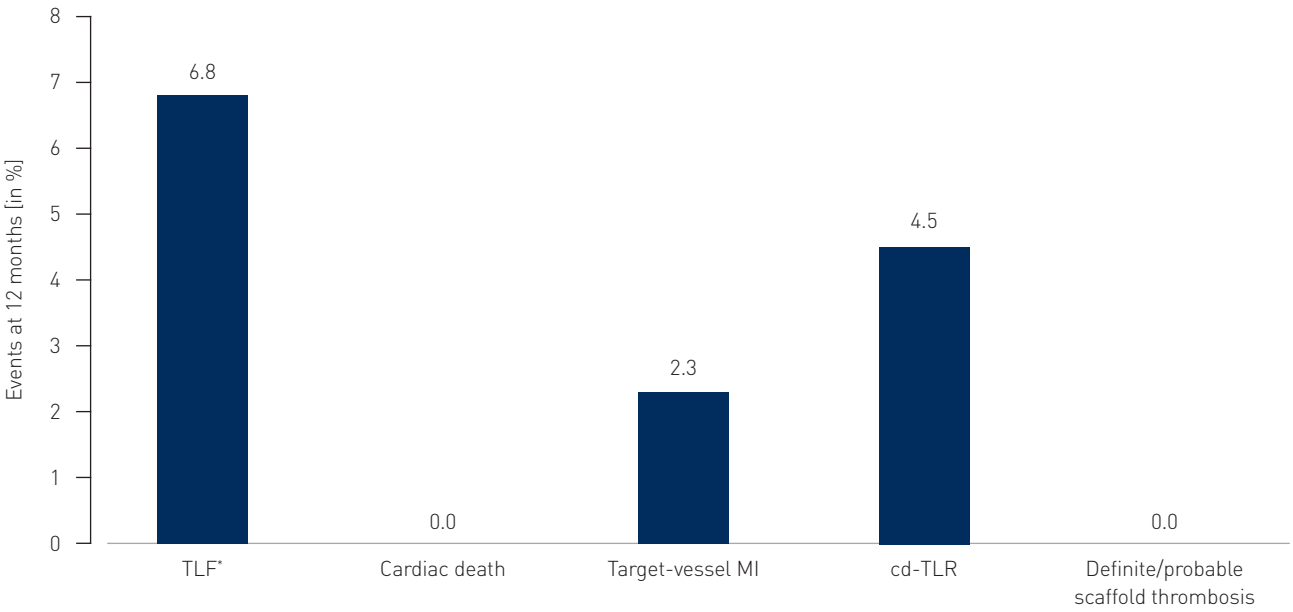
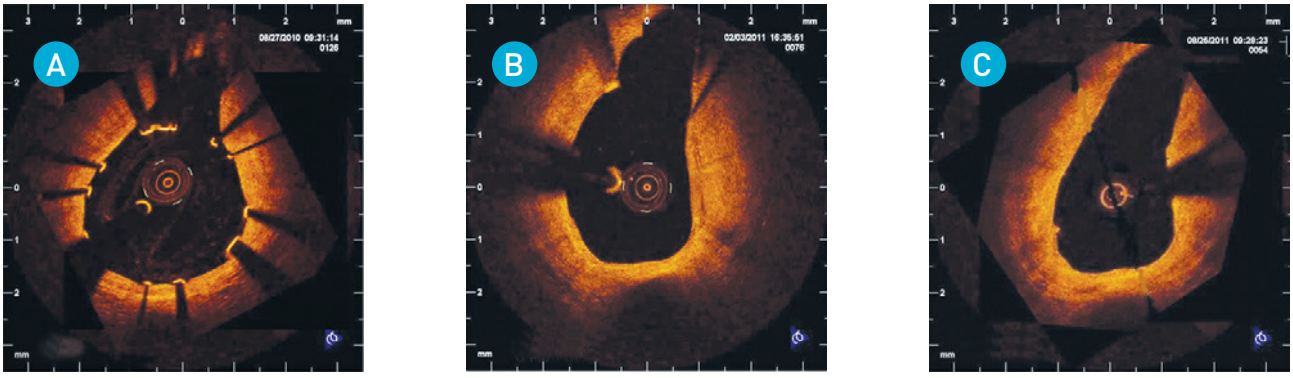
Clinical results



* TLF defined as a composite of cardiac death, target-vessel MI and cd-TLR

Events at 12 months [in %]	BIOSOLVE-I n = 46
TLF	6.8
Cardiac death	0.0
Target-vessel MI	2.3
cd-TLR	4.5
Definite/probable scaffold thrombosis	0.0

Representative optical coherence tomography after implantation of drug-eluting bioresorbable scaffolds (DREAMS) (A) and at 6 months (B) and 12 months (C)



Immediately after implantation strut apposition to the vessel wall is good, with some struts covering the side branch. At 6 months remnants are mostly covered and former struts over the side branch are being resorbed. The change from a metallic stent-like appearance to remnants after magnesium resorption is shown.

Reference: Haude M et al. Safety and performance of the drug-eluting absorbable metal scaffold (DREAMS) in patients with de novo coronary lesions: 12-month results of the prospective, multi-centre, first-in-man BIOSOLVE-I trial. Lancet. 2013; 381: 836-44.

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