BIOSOLVE-II
12-month results

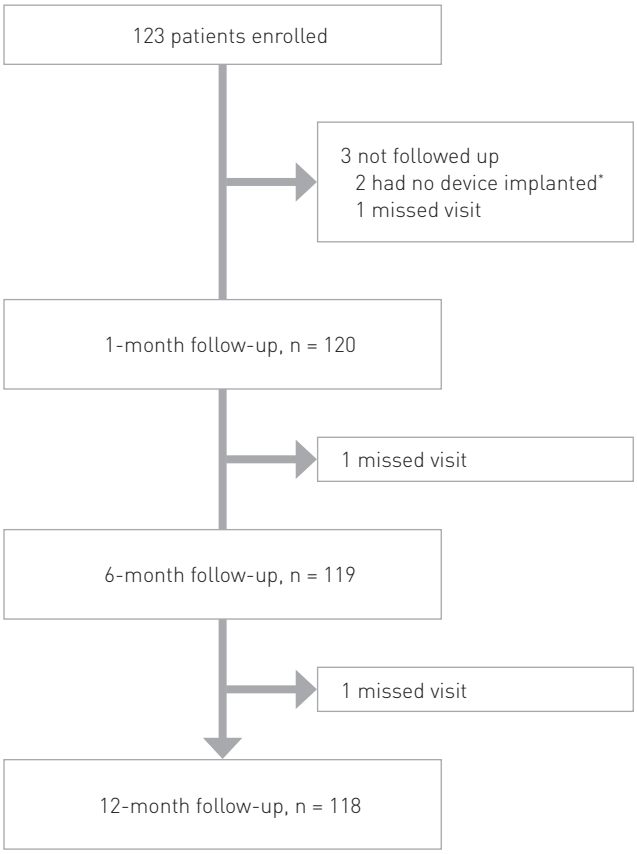
Conclusions
- No additional TLF after 6 months
- The rates of scaffold thrombosis remained at 0 % at 12 months follow-up
- 80 % of the patients tested demonstrated vasomotion at 6 and 12 months

Study design
Prospective, multi-center, first-in-man trial to evaluate the safety and performance of Magmaris in 123 patients with a maximum of 2 de novo lesions in 2 separate coronary arteries

Principal investigator
- Prof. Michael Haude, Neuss, Germany

Endpoints
Primary endpoint
- In-segment late lumen loss (LLL) at 6-month follow-up

Secondary endpoints (selected)
- Target Lesion Failure (TLF) defined as a composite of cardiac death, target-vessel myocardial infarction and clinically-driven target lesion revascularization at 12 months
- Scaffold thrombosis at 12 months



	6 month	12 months**
In-segment LLL (mean ± SD, in mm)	0.27 ± 0.37	0.25 ± 0.22

* Two patients did not receive an implant were included in calculation of device and procedural success only

** Angiographic follow-up at 12-month has been voluntary. LLL are based on unpaired data.

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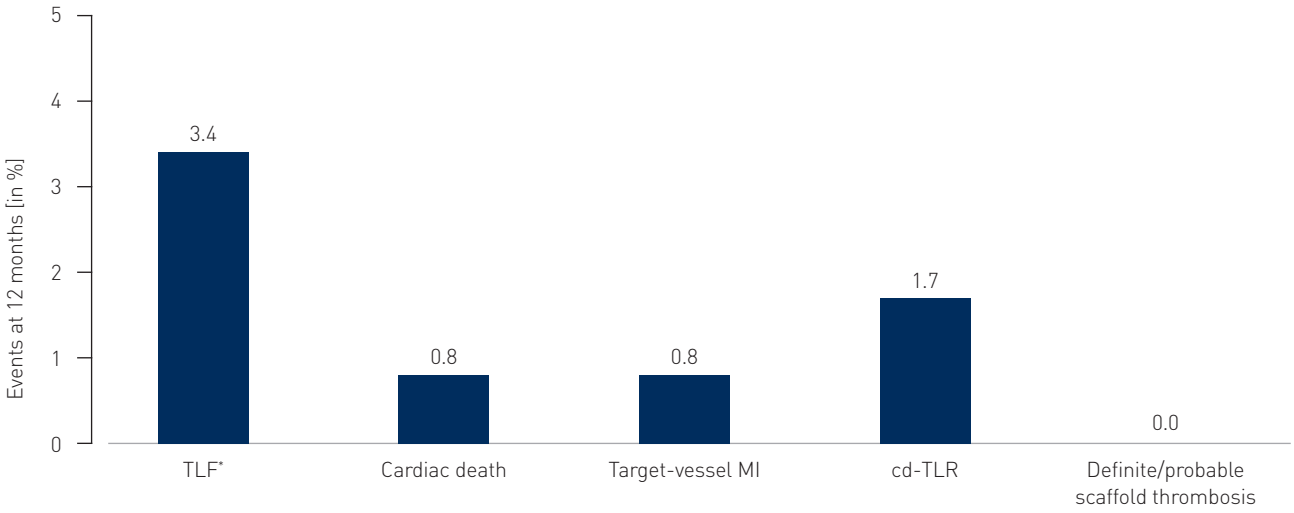
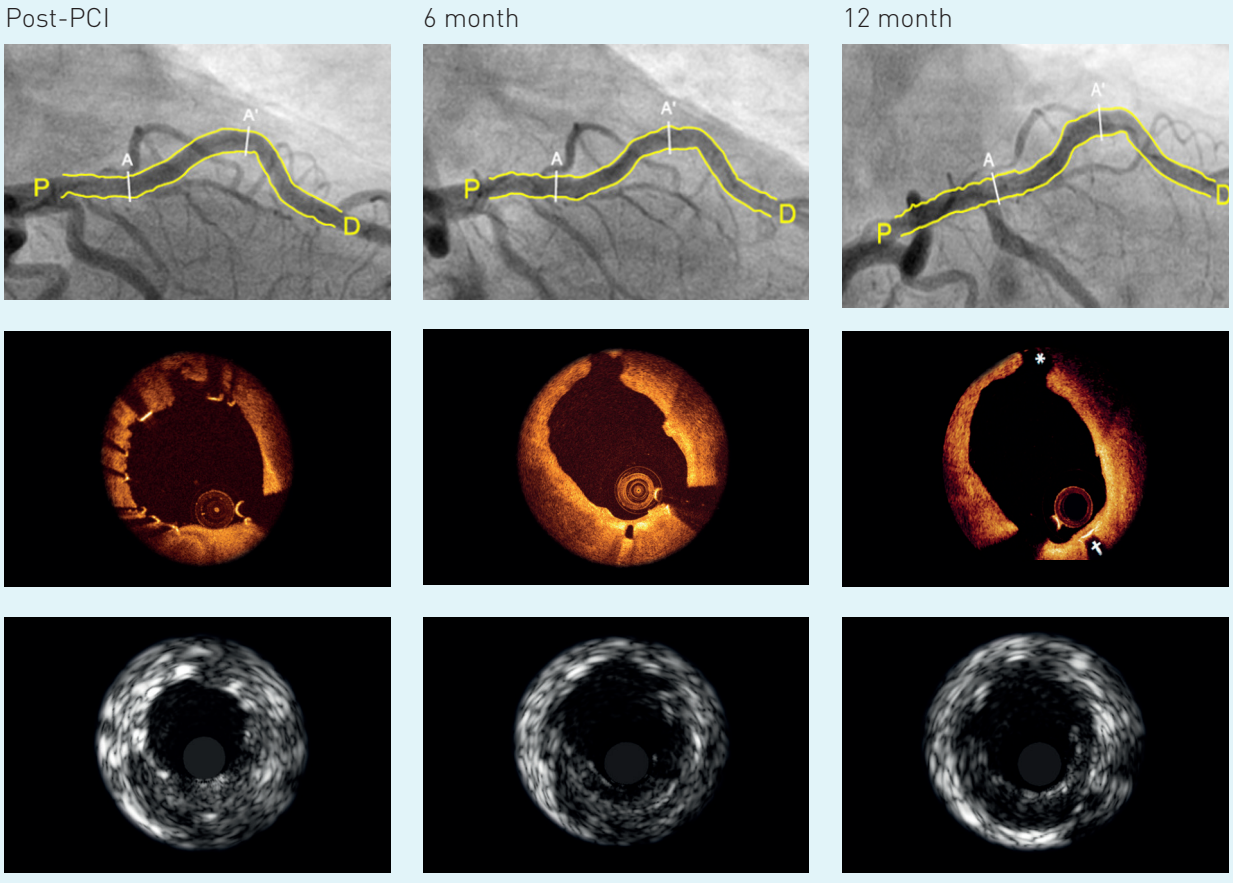
Clinical results



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

Serial angiographic, OCT and IVUS of a patient implanted with Magmaris



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