BIOSOLVE-II 6-month follow-up

BIOSOLVE-II

Conclusions

- In-segment Late Lumen Loss of 0.27 mm.
- BIOSOLVE-II demonstrates excellent clinical results with a low TLF rate of 3.3 %.
- No definite nor probable scaffold thrombosis occurred up to 6 months.
- BIOSOLVE-II shows a significant improvement in In-segment Late Lumen Loss compared to BIOSOLVE-I and PROGRESS.

Study design

Prospective, multi-center, First-in-Man, patients with single de novo coronary artery lesions in up to two coronary arteries and a Reference Vessel Diamater (RVD) between 2.2-3.7 mm and ⩽ 21 mm length

Principal investigator

- Prof. Michael Haude, Neuss, Germany

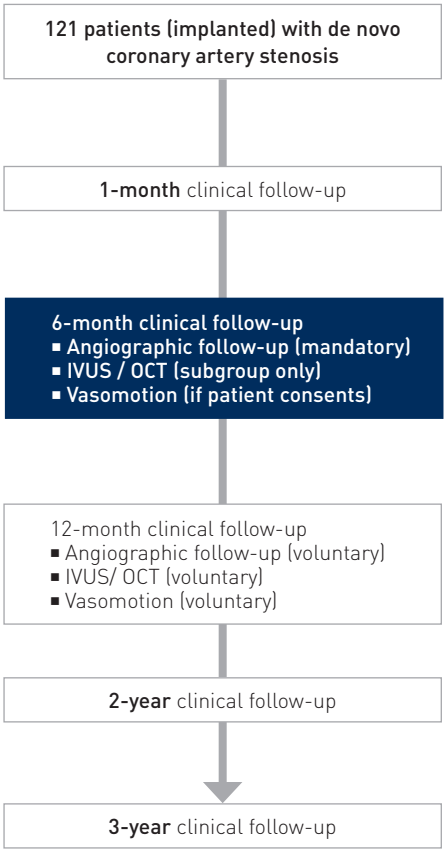
Endpoints

Primary endpoint

- In-segment Late Lumen Loss (LLL) at 6-month

Secondary endpoints (selected)

- Target Lesion Failure (TLF*) defined as a composite of
  - Cardiac death
  - Target vessel myocardial infarction (MI)
  - Clinically driven Target Lesion Revascularization (TLR)
  - Coronary Artery Bypass Surgery (CABG)



* Society of Cardiovascular Angiography and Interventions (SCAI) definition

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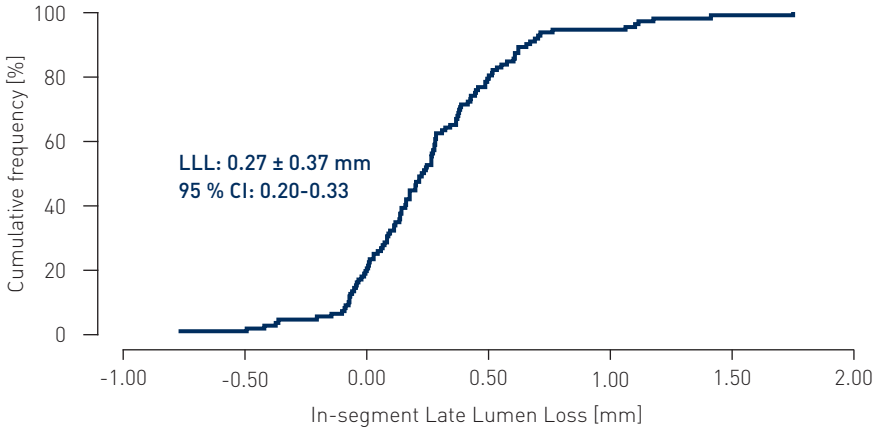
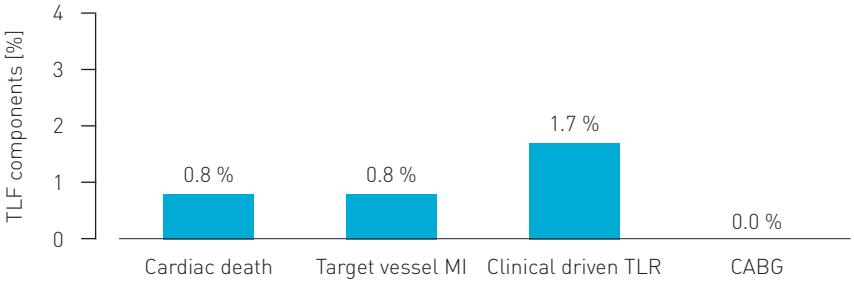
Primary endpoint results

6-month follow-up



TLF components



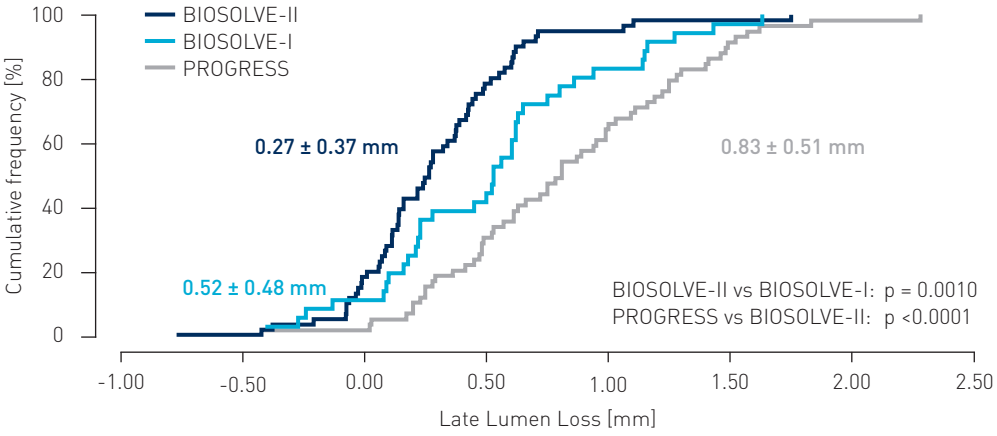
Scaffold thrombosis (definite or probable)

	%	95 % confidence interval
Scaffold thrombosis	0.0	0.0-3.1

There was no definite nor probable scaffold thrombosis up to 6 months.

In-segment Late Lumen Loss comparison BIOSOLVE-II, BIOSOLVE-I and PROGRESS

BIOSOLVE-II shows a significant decrease in in-segment LLL compared to BIOSOLVE-I (6-month follow-up) and PROGRESS (4-month follow-up).



Not currently available in the United States.

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