BIOSOLVE-II
60-month results[1]

Conclusions

- Target Lesion Failure (TLF)* (8.0%) and Clinically-Driven Target Lesion Revascularization (CD-TLR) (5.6%) rates in BIOSOLVE-II remain low and demonstrate an excellent safety and efficacy profile up to 60 months.
- There was no definite or probable Scaffold Thrombosis (ST) at 60-month clinical follow-up.
- BIOSOLVE-II demonstrates favorable safety results with only 1.7% Cardiac Death and 2.1% Target Vessel Myocardial Infarction (TV-MI) rates.
- These are the first long-term results on safety and clinical performance of Magmaris® comparable to 2nd generation drug eluting stents, which will support future generations.

Study design

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

Endpoints

Primary endpoint
- In-segment Late Lumen Loss (LLL) at 6 months

Secondary endpoints (at 1, 6, 12, 60 months)
- TLF* rate
- Scaffold thrombosis rate
- Procedure and device success

123 patients with de novo coronary artery lesions

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Magmaris®

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1-month clinical follow-up

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6-month clinical and angiographic follow-up

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12-month clinical follow-up

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24-month clinical follow-up

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36-month clinical follow-up

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48-month clinical follow-up

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60-month clinical follow-up

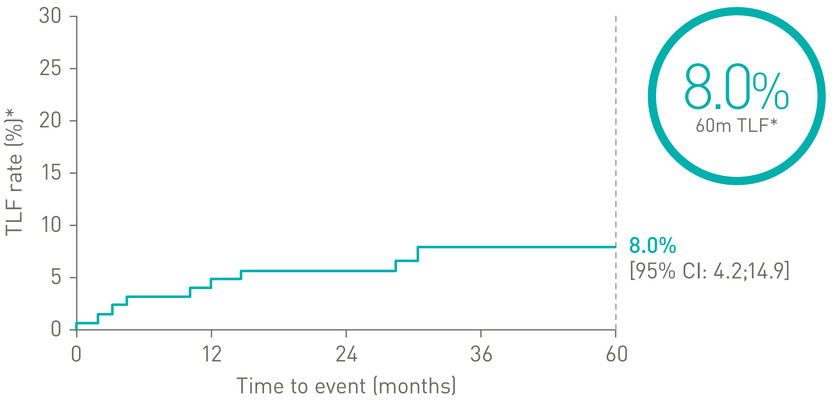
Lesion location	n = 123	
LAD	47	38.2%
LCx	29	23.6%
RCA	45	36.6%
Intermediate branch	2	1.6%

Lesion characteristics	n = 123	
Lesion length (mm)**	12.6 ± 4.5	
Reference vessel diameter (mm)**	2.7 ± 0.40	
AHA/ACC lesion class B2/C	53	43.4%
Calcification moderate/severe	13	10.7%

Patient characteristics	n = 123	
Age, yrs**	65.2 ± 10.3	
Male	78	63.4%
Hypertension	101	82.1%
Hyperlipidemia	74	60.2%
Smoking	67	54.5%
Diabetes mellitus	36	29.3%
Insulin dependent	11	30.6%
Non-insulin dependent	25	69.4%
History of MI	29	23.6%
Previous percutaneous intervention	52	42.3%

* Composite of Cardiac Death, Target Vessel Myocardial Infarction (TV-MI), Clinically-Driven Target Lesion Revascularization (CD-TLR) and CABG.
**Data shown as mean ± SD

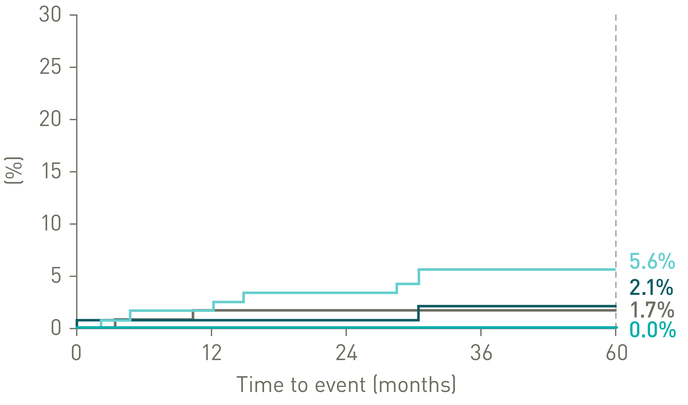
TLF* rate up to 60 months



	6 months[7] n = 120		12 months[8] n = 118		24 months[7] n = 120		36 months[9] n = 117		60 months[1] n = 80	
TLF*	4	3.3%	4	3.4%	7	5.9%	8	6.8%	7	8.0%
TLF* components										
Death	2	1.7%	2	1.7%	4	3.3%	5	4.3%	6	7.5%
Cardiac death	12	0.8%	1[2]	0.8%	2[2,3]	1.7%	2[2,3]	1.7%	2	1.7%
Non-cardiac death	14	0.8%	1[4]	0.8%	2[4,5]	1.7%	3[4,5,6]	2.6%	4	5.0%
TV-MI°	1	0.8%	1	0.8%	1	0.8%	1	0.9%	2	2.1%
CD-TLR	2	1.7%	2	1.7%	4	3.3%	5	4.3%	5	5.6%
CABG	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
ST definite or probable	**0**	**0.0%**	**0**	**0.0%**	**0**	**0.0%**	**0**	**0.0%**	**0**	**0.0%**

Note: 6-, 12-, 24-, 36- month outcomes are based on frequency analysis whereas the 60-month results are based on Kaplan-Meier failure estimate analysis including censored observations.

Selected secondary clinical endpoints up to 60 months



- Target Vessel Myocardial Infarction°
  [95% CI: 0.5;8.6]
- Clinically-Driven Target Lesion Revascularization
  [95% CI: 2.5;12.2]
- Scaffold Thrombosis (definite/probable)
  [95% CI:0.0;0.0]
- Cardiac Death
  [95% CI:0.4;6.5]

* Composite of Cardiac Death, Target Vessel Myocardial Infarction (TV-MI), Clinically-Driven Target Lesion Revascularization (CD-TLR) and CABG.
° Peri-procedural MI according to SCAI definition and spontaneous MI according to the Extended Historical definition.

Principal investigator

Prof. M. Haude, Lukaskrankenhaus, Neuss, Germany

1. Haude M. Long-term clinical data of the BIOSOLVE-II study with the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries - BIOSOLVE-II. Presented at the: e-Course PCR, 25.June 2020, Paris, France; 2. Unwitnessed death 134 days post PCI of distal RCA, no autopsy available; 3. Unwitnessed death 395 days post PCI of the mid RCA, no autopsy available; 4. Patient died of cancer; 5. Patient died of pulmonary infection leading to septic shock; 6. Patient died of intracerebral hemorrhage. 7. Haude M et al. Sustained safety and clinical performance of a drug-eluting absorbable metal scaffold up to 24 months: pooled outcomes of BIOSOLVE-II and BIOSOLVE-III. EuroIntervention. 2017;13-online publish-ahead-of-print May 2017; 8. Haude M et al. Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. European Heart Journal. 2016; 37, 2701–2709; doi:10.1093/eurheartj/ehw196; 9. Haude M. Long-term clinical data and multimodality imaging analysis of the BIOSOLVE-II study with the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries BIOSOLVE-II. presented at EuroPCR 2018, Paris, France. All events have been adjudicated by a clinical event committee.

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