BIOSOLVE-II BIOSOLVE-III

36-month pooled analysis[1]

Conclusions

- Target Lesion Failure (TLF) and Clinically-Driven Target Lesion Revascularization (CD-TLR) rates in BIOSOLVE-II and III remain low for Magmaris® Resorbable Magnesium Scaffold and are comparable to 2nd generation drug-eluting stents out to 36 months.
- No definite or probable Scaffold Thrombosis (ST) were reported up to 36 months.

Study design

Pooled analysis of BIOSOLVE-II and BIOSOLVE-III

Endpoints

Primary endpoint

- BIOSOLVE-II: In-segment LLL at 6-month follow-up
- BIOSOLVE-III: Procedure success

Secondary endpoints (selected)

- TLF rate is defined as a composite of Cardiac Death, Target-Vessel Myocardial Infarction (TV-MI) and Clinically-Driven Target Lesion Revascularization (CD-TLR)
- Definite/probable ST

BIOSOLVE-II

Prospective FIM enrolling 123 patients with de novo coronary artery lesion

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1-month clinical follow-up

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6-month
- Clinical follow-up (mandatory)
- **Angiographic follow-up (mandatory) (PE)**
- IVUS/OCT (Subgroup only)
- Vasomotion (Subgroup only)

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12-month
- Clinical follow-up (mandatory)
- Angiographic, IVUS, OCT, Vasomotion (voluntary)

↓

24-month clinical follow-up

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36-month
- **Clinical follow-up**
- **Angiographic, IVUS, OCT, Vasomotion (voluntary)**

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60-month clinical follow-up (voluntary)

BIOSOLVE-III

Pivotal trial enrolling 61 patients with de novo coronary artery lesion

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Procedure success (PE)

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1-month clinical follow-up

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6-month clinical follow-up

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12-month
- Clinical follow-up (mandatory)
- Angiographic follow-up (mandatory)

↓

24-month clinical follow-up

↓

36-month clinical follow-up

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Patient characteristics	BIOSOLVE-II n = 123		BIOSOLVE-III n = 61		Overall n = 184	
Age, yrs*	65.2 ± 10.3		66.3 ± 11.8		65.5 ± 10.8	
Male	78	63.4%	39	63.9%	117	63.6%
Hypertension	101	82.1%	45	73.8%	146	79.3%
Hyperlipidemia	74	60.2%	40	65.6%	114	62.0%
Smoking	67	54.5%	35	57.4%	102	55.4%
Diabetes mellitus	36	29.3%	10	16.4%	46	25.0%
Insulin dependent	11	30.6%	1	10.0%	12	26.1%
Non-insulin dependent	25	69.4%	9	90.0%	34	73.9%
History of MI	29	23.6%	14	23.0%	43	23.4%
Previous percutaneous intervention	52	42.3%	24	39.3%	76	41.3%

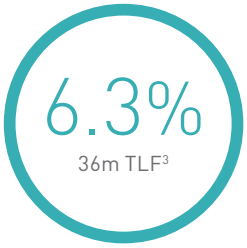
Lesion location n = 187	BIOSOLVE-II n = 123		BIOSOLVE-III n = 64		Overall n = 187	
LAD	47	38.2%	31	48.4%	78	41.7%
LCx	29	23.6%	16	25.0%	45	24.1%
RCA	45	36.6%	16	25.0%	61	32.6%
Intermediate branch	2	1.6%	1	1.6%	3	1.6%

Lesion characteristics n = 187	BIOSOLVE-II		BIOSOLVE-III		Overall	
Lesion length (mm)*	12.6 ± 4.5		11.2 ± 4.3		12.1 ± 4.5	
Reference vessel diameter (mm)*	2.7 ± 0.40		2.7 ± 0.50		2.7 ± 0.43	
AHA/ ACC lesion class B2/C**	53	43.4%	52	81.3%	105	56.4%
Calcification moderate/severe**	13	10.7%	15	23.4%	28	15.1%

* Data shown as mean ± SD; ** Statistical Significant differences between BIOSOLVE-II and BIOSOLVE-III population.

Clinical results[1,2]

TLF[3] rates	6 months n = 180	12 months n = 180	24 months n = 180	36 months n = 174
TLF[3]	3.3%	3.3%	5.5%	6.3%
Cardiac death[4]	1.1%	1.1%	2.2%	2.3%
TV-MI[5]	0.5%	0.5%	0.6%	0.6%
CD-TLR	1.7%	1.7%	2.7%	3.4%
CABG	0.0%	0.0%	0.0%	0.0%
Definite/probable ST	0.0%	0.0%	0.0%	0.0%



Principal investigator

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1. Haude M, Ince H, Kische S, et al. Sustained safety and performance of the second-generation sirolimus-eluting absorbable metal scaffold: Pooled outcomes of the BIOSOLVE-II and -III trials at 3 years. Cardiovascular Revascularization Medicine. 2020. doi: 10.1016/j.carrev.2020.04.006; 2. Haude M, Ince H, Kische S, et al. Safety and clinical performance of a drug eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries: Pooled 12-month outcomes of BIOSOLVE-II and BIOSOLVE-III. Catheter Cardiovasc Interv. 2018; 00:1–10. doi: 10.1002/ccd.27680; 3. TLF rate is defined as a composite of Cardiac death, Target Vessel Myocardial Infarction (TV-MI) and Clinically-Driven Target Lesion Revascularization (CD-TLR) and Coronary Artery Bypass Graft (CABG); 4. Cardiac Death due to ventricular arrhythmia, chronic heart failure and two unknown causes; 5. Peri-procedural MI according to SCAI definition and spontaneous MI according to the Extended Historical definition. Outcomes are based on frequency analysis.

All events have been adjudicated by a clinical events committee. The pooled analysis of BIOSOLVE-II and -III based on frequency analysis.

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