BIOSOLVE-IV

24-month follow-up of first cohort with 1,075 patients[1]

Conclusions

- The Magmaris® Resorbable Magnesium Scaffold (RMS) shows a very good safety profile of the scaffold in a real-world setting up to 24 months.
- The BIOSOLVE-IV Target Lesion Failure (TLF)[2] rate of 6.6% at 24 months confirms the low TLF[2] rates of the pooled outcomes of BIOSOLVE-II and -III studies up to 24 months.
- No additional Scaffold Thrombosis (ST) is observed at 24 months for BIOSOLVE-IV when compared to 12-month data (0.5%)[3].

Study design

Prospective, multi-center, real-world setting registry.

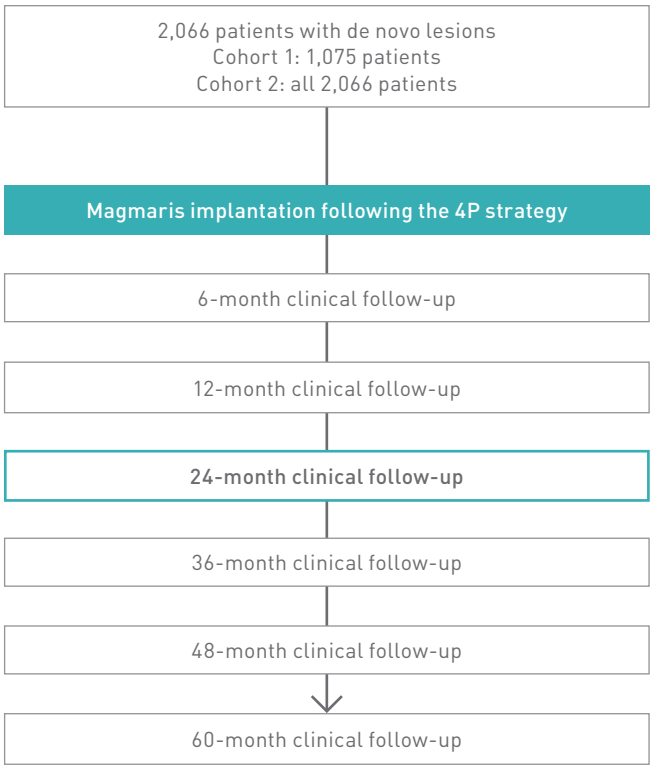
Endpoints

Primary endpoint

- TLF at 12 months defined as a composite of Cardiac Death, Target-Vessel Myocardial Infarction (TV-MI), emergent Coronary Artery Bypass Grafting (CABG), and Clinically-Driven Target Lesion Revascularization (CD-TLR)

Secondary endpoints

- CD-TLR and Target Vessel Revascularization (TVR)
- Cardiac death
- TV-MI
- ST
- Procedure and device success



Patient characteristics	n	
Age, yrs*	61.3 ± 10.5	
Male	806	75.0%
Hypertension	724	67.3%
Hyperlipidemia	713	66.3%
Smoking history	654	61.1%
Diabetes mellitus	**228**	**21.2%**
Insulin dependent	45	19.7%
Non-insulin dependent	183	80.3%
History of MI	219	20.4%
Previous percutaneous intervention	287	26.7%
NSTEMI	**206**	**19.2%**

Lesion location	n	
LAD	561	50.0%
LCx	213	19.0%
RCA	333	29.7%
RI	14	1.2%

Lesion characteristics	n	
Lesion length (mm)*	14.9 ± 4.2	
Reference vessel diameter (mm)*	3.2 ± 0.3	
AHA/ ACC lesion class B2/C	**170**	**15.2%**
Calcification moderate/severe	82	7.3%
Bifurcation lesions	**57**	**5.1%**

* Data shown as mean ± SD

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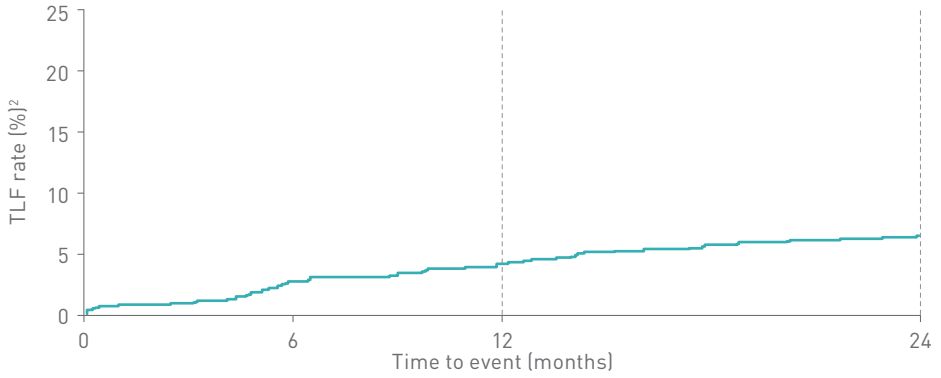
TLF rates[2] up to 24 months



6.6%
24m TLF[2]

Primary and selected secondary endpoints	12 months[4] n = 1,071		24 months[1] n = 1,071	
TLF[2]	**45**	**4.3%**	**70**	**6.6%**
Cardiac death	2	0.2%	5	0.5%
TV-MI	12	1.1%	16	1.5%
CD-TLR	41	3.9%	62	5.9%
CABG	0	0.0%	0	0.0%
Definite or probable ST	**5**	**0.5%[3]**	**5**	**0.5%[3]**

0.5%[3]
def./prob. ST at 12m and 24m

n-values are based on BIOTRONIK data on file.

The rate of very late scaffold thrombosis at 24 months is 0.0%. Therefore, Magmaris RMS shows **consistently low scaffold thrombosis rates** beyond resorption time.

Clinical outcomes at 24 months in comparison

Primary and selected secondary endpoints	BIOSOLVE-II and -III[5] n = 180	BIOSOLVE-IV[1] n = 1,071
TLF[2]	**5.5%**	**6.6%**
Cardiac death	2.2%	0.5%
TV-MI	0.6%	1.5%
CD-TLR	2.7%	5.9%
CABG	0.0%	0.0%
Definite or probable ST	**0.0%**	**0.5%[3]**

The 6.6% TLF[2] rate of BIOSOLVE-IV at 24 months confirms the low TLF[2] rates of the pooled outcomes of BIOSOLVE-II and -III studies up to 24 months.

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1. Torzewski J. Safety and performance of Magmaris at 24 month follow up of BIOSOLVE IV. Presented at: eEuroPCR; 2021; virtual congress. ClinicalTrials.gov: NCT02817802; 2. TLF defined as a composite of Cardiac Death, Target-Vessel Myocardial Infarction (TV-MI), emergent Coronary Artery Bypass Grafting (CABG), and Clinically-Driven Target Lesion Revascularization (CD-TLR); Peri-procedural MI according to SCAI definition and spontaneous MI according to the Extended Historical definition; 3 . Four out of five cases (0.1%) having early antiplatelet or anticoagulant interruption at post procedure; 4. Verheye S, Wlodarczak A, Montorsi P, et al. BIOSOLVE-IV-registry: Safety and performance of the Magmaris scaffold: 12-month outcomes of the first cohort of 1,075 patients. Catheter Cardiovasc Interv. 2020; 1–8. doi.org/10.1002/ccd.29260; 5. 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.

BIOSOLVE-IV based on Kaplan-Meier failure estimate analysis including censored observations. BIOSOLVE-II and -III based on frequency analysis. At 24 months: BIOSOLVE-II and -III reflecting a period up to 760 days and BIOSOLVE-IV reflecting a period up to 730 days.

All events have been adjudicated by a clinical event committee.

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