BIOMAG-I

A new resorbable magnesium scaffold for de novo coronary lesions (DREAMS 3G): 12-month results of the BIOMAG-I first-in-human study[1]

Conclusions

- DREAMS 3G has an improved angiographic in-scaffold LLL compared to its precursor DREAMS 2G[2] at 12-month follow-up, making DREAMS 3G a potential alternative to permanent DES.[3]
- At 12-month follow-up, DREAMS 3G shows low TLF (2.6%) and clinically-driven TLR rate (2.6%), no myocardial infarction and no definite or probable scaffold thrombosis.
- Furthermore, at 12-month follow-up, patients treated with DREAMS 3G demonstrated a return of vasomotion.[4]
- OCT analysis revealed that 99.3% of struts were no longer visible at 12 months confirming the preclinical data.[5]

Study design

- Prospective, multi-center, single arm
- Subjects with single de novo coronary artery lesions in up to two coronary arteries
- Reference Vessel Diameter (RVD) between 2.5-4.2 mm and lesion length ⩽ 28 mm long

Patients

20.7% of NSTEMI patients included

Endpoints

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

Angiographic Endpoints (at 6 and 12 months)
- In-Segment LLL
- Binary restenosis rate
- % In-Scaffold and In-Segment Diameter Stenosis
- In-Scaffold LLL (powered for both time points)

Clinical Endpoints
- Target Lesion Failure* (TLF)
- Definite or Probable Scaffold Thrombosis

Imaging and Physiological Endpoint
- Procedure and device success
- Descriptive analysis of vessel morphology, lesion composition and scaffold strut data (IVUS and OCT)
- Descriptive analysis of vasomotion

116 subjects with de novo coronary artery stenosis

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1-month clinical follow-up

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6-month
- Clinical and angiographic FUP (mandatory)
- IVUS & OCT (mandatory)

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12-month
- Clinical and angiographic FUP (mandatory)
- IVUS & OCT (mandatory)
- Vasomotion (if subject consents)

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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

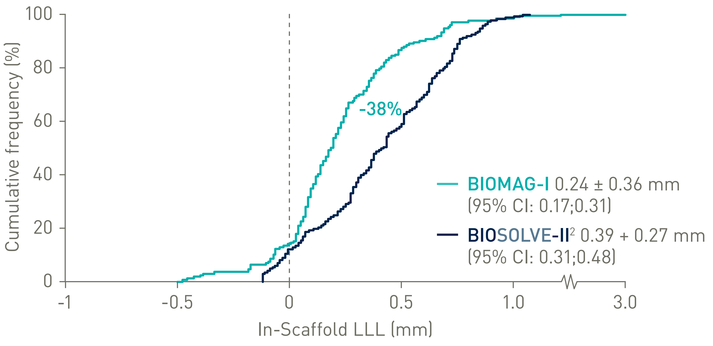
Patient characteristics	n = 116	%
Age, years	61.0 ± 9	
Male	90	77.6%
Hypertension	86	74.1%
Hypercholesterolemia	72	62.1%
Diabetes	32	27.6%
History of smoking	75	64.7%
History of myocardial infarction	39	33.6%
NSTEMI	**24**	**20.7%**

Lesion location	n	
LAD	53	45.3%
LCx	22	18.8%
RCA	40	34.2%
Ramus intermedius	2	1.7%

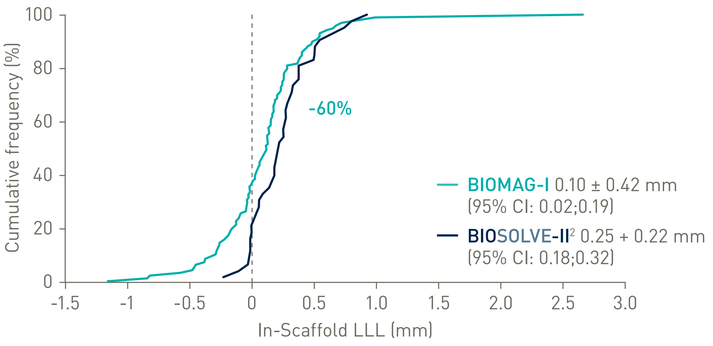
Lesion characteristics	n	
Lesion length (mm)	12.3 ± 5.1	
Reference vessel diameter (mm)	2.72 ± 0.46	
AHA/ACC lesion class B2/C	**90**	**76.9%**
Side branch involvement	25	21.4%

Lesion characteristics are estimated by core lab.

In-Scaffold Late Lumen Loss at 12 months[1] (n = 100)



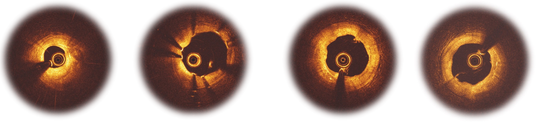
In-Segment Late Lumen Loss at 12 months[1] (n = 100)



Comparison of the clinical outcomes at 6 and 12 months

	BIOMAG-I 6m n = 116	BIOMAG-I 12m n = 116	BIOSOLVE-II[2] 12m n = 121
Target lesion failure*	0.9%	2.6%°	3.4%
Cardiac death	0.0%	0.0%	0.8%
TV-MI**	0.0%	0.0%	0.8%
CD-TLR	0.9%	2.6%	1.7%
Definite or probable ST	0.0%	0.0%	0.0%

Serial OCT and IVUS Data Analysis



Pre-procedure	Post-procedure	6m follow-up	12m follow-up
	• Malapposed† struts %: 4.62 ± 4.69 • Total incomplete strut apposition area mm²: 0.08 ± 0.11	Struts hardly discernable	Struts were not discernable anymore

	Baseline	Post-procedure	6-month	12-month
Mean lumen area (mm²)	5.96 ± 2.25	7.65 ± 2.23	7.00 ± 2.42	7.09 ± 2.73
				Δ Post-procedure – 12m
				-0.56 ± 1.45‡

Coordinating investigator

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*TLF is defined as Composite of Cardiac Death, TV-MI, CD-TLR (Kaplan-Meyer estimate); **peri-procedural target vessel MI according to SCAI definition and non-peri-procedural target vessel MI according to Universal MI Definition; °driven by three clinically-driven target lesion revascularization; †Definition of malapposition: if the distance between outer contour of the strut and vessel wall is more than the individual strut thickness; ‡p < 0.05 for 12-month vs post-procedure. 1. Haude, M ¨1-Year Clinical Outcomes of the new resorbable Magnesium scaffold DREAMS 3G, from the first in-human BIOMAG-I study¨ presented at EuroPCR May 2024; 2. 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. Eur Heart J 2016;37:2701-2709; 3. Byrne RA, et al., Report of a European Society of Cardiology-European Association of Percutaneous Cardiovascular Interventions task force on the evaluation of coronary stents in Europe: executive summary. Eur Heart J 2015;36:2608-262; 4. Haude, M ¨First in human study BIOMAG-I: 12 months results of the sirolimus eluting resorbable coronary magnesium scaffold system (DREAMS 3G) in the treatment of subjects with de novo coronary artery lesions¨ presented at ESC August 2023; 5. Seguchi, M ¨Twelve-months vessel healing profile following the novel resorbable magnesium scaffold implantation: an intravascular OCT analysis of the BIOMAG-I trial¨ presented at ESC August 2023.

All endpoint related events have been adjudicated by an independent clinical event committee. BIOMAG-I and BIOSOLVE-II are based on Kaplan-Meier failure estimate analysis including censored observations. DREAMS 3G next generation Resorbable Magnesium Scaffold is not CE or FDA approved and not commercially available.

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