BIOSOLVE-IV FULL COHORT

Safety and performance of a resorbable magnesium scaffold under real world conditions: NSTEMI, Diabetes and B2/C lesions subgroup analysis at 24 months[1]

Conclusions

- In the high-risk patient populations of the full cohort of BIOSOLVE-IV, the **Magmaris®** Resorbable Magnesium Scaffold showed a very good safety and efficacy profile up to 24 months.
- No significant differences were observed for patients with diabetes versus non-diabetic or with B2/C lesions compared to type A/B1 lesions at 24 months in BIOSOLVE-IV full cohort.
- Patients with NSTEMI (18.5% of the BIOSOLVE-IV full cohort) had significant higher rates of TLF, higher rates of TV-MI, nummerically highe rates of clinically driven TLR and marginally higher rates of definite and probable scaffold thrombosis compared to the rest of the population.

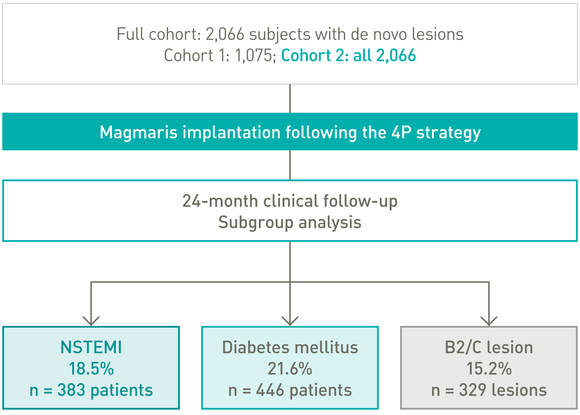
Study design

Prospective, multi-center, real-world setting registry

Endpoints

Primary endpoint
- TLF* at 12 months

Secondary endpoints
- Clinically-driven Target Lesion Revascularization (CD-TLR) and Target Vessel Revascularization (TVR)
- Cardiac death
- Target-Vessel Myocardial Infarction (TV-MI)
- Definite/probable Scaffold Thrombosis (ST) at 12 months powered to show the superiority of Magmaris vs. historical data of Absorb for full cohort based on a one one-sided exact binomial test
- Procedure and device success



Patient characteristics	n = 2,066	
Age, yrs°	61.9 ± 10.5	
Male	1,539	74.5%
Hypertension	1,370	66.3%
Hyperlipidemia	1,347	65.2%
Smoking	1,224	59.2%
Diabetes mellitus	**446**	**21.6%**
Insulin dependent	94	21.2%
Non-insulin dependent	352	78.9%
History of MI	448	21.7%
Previous percutaneous intervention	594	28.8%
NSTEMI	**383**	**18.5%**

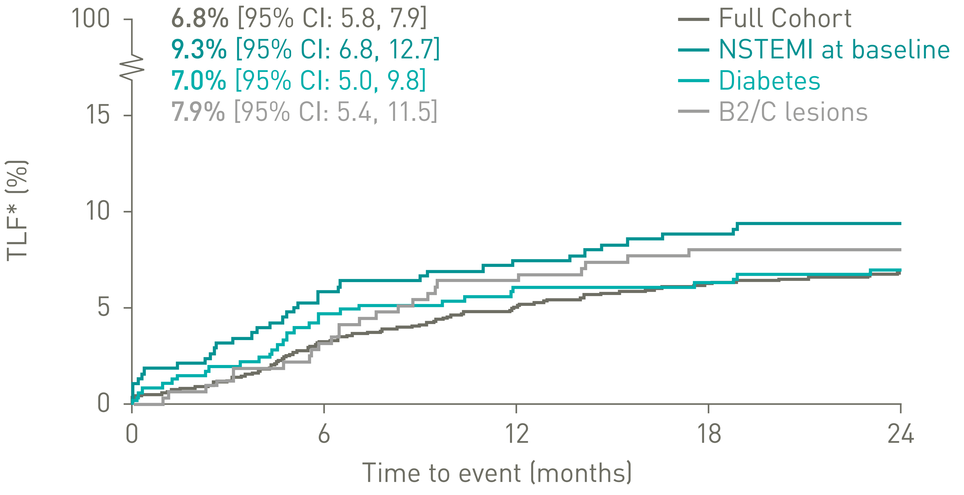
Lesion location	n	
LAD	1,067	49.5%
LCx	441	20.5%
RCA	620	28.8%
Ramus intermedius	26	1.2%

Lesion characteristics	n	
Lesion length (mm)°	14.8 ± 4.0	
Reference vessel diameter (mm)°	3.2 ± 0.3	
AHA/ ACC lesion class B2/C	**329**	**15.2%**
Calcification moderate/severe	162	7.5%
Bifurcation lesions	99	4.6%

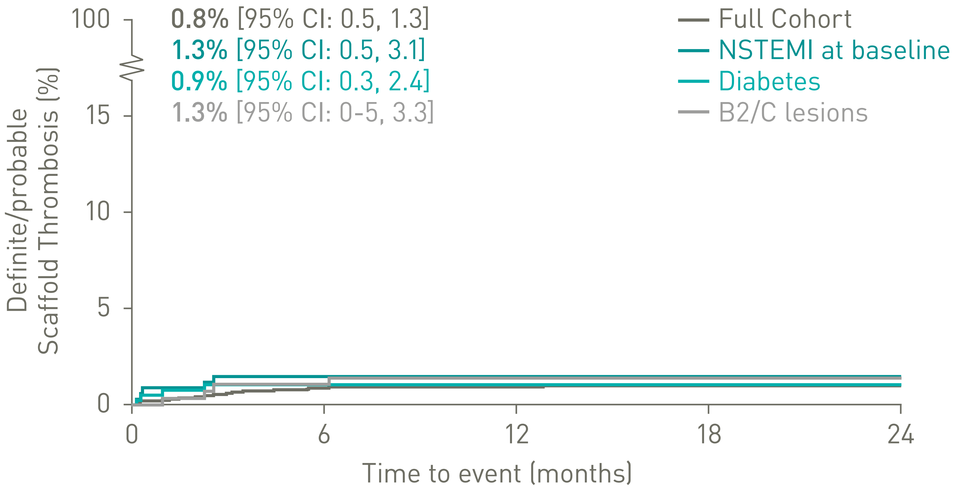
* TLF is defined as a composite of Cardiac Death, TV-MI, emergent Coronary Artery Bypass Grafting (eCABG), and Clinically-driven TLR. Peri-procedural MI according to SCAI definition and spontaneous MI according to the extended historical definition.
° Data shown as mean ± SD

In respect to the NSTEMI and B/C lesion subgroups, please consult IFU for indications and use in special populations.

TLF* of Magmaris at 24 months[1]



Scaffold Thrombosis of Magmaris up to 24 months[1]



TLF* and selected components[1]

24-month follow-up	Full cohort n = 2,057	NSTEMI n = 381	Diabetes n = 444	B2/C lesions n = 316
TLF*	6.8%	9.3%	7.0%	7.9%
Cardiac Death	0.5%	0.3%	0.5%	0.6%
TV-MI	1.6%	3.7%	1.8%	1.9%
Clinically-Driven TLR	6.0%	8.0%	6.1%	7.6%
Definite or probable ST	0.8%§	1.3%	0.9%	1.3%

n-values based on internal Kaplan-Meier statistics which differ from baseline patient and lesion characteristics.

Principal investigator

Adrian Wlodarczak , MD, PhD, Miedziowe Centrum Zdrowia S.A., Lublin, Poland

* TLF is defined as a composite of Cardiac Death, TV-MI, emergent Coronary Artery Bypass Grafting (eCABG), and Clinically-driven TLR. Peri-procedural MI according to SCAI definition and spontaneous MI according to the extended historical definition; § 0.4% scaffold thrombosis rate excluding cases with early antiplatelet or anticoagulant interruption.

1. Wlodarczak A. NSTEMI, diabetes and B2/C lesions subgroups at 24 months: BIOSOLVE-IV full cohort. Presented at: EuroPCR; 2023; ClinicalTrials.gov: NCT02817802.

All events have been adjudicated by an independent clinical event committee. BIOSOLVE-IV registry is based on Kaplan-Meier failure estimate analysis including censored observations. In respect to the NSTEMI and B/C lesion subgroups, please consult IFU for indications and use in special populations.

Jun_2023

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach,
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life