BioMimics 3D
The Swirling Flow® Stent

Veryan

MIMICS 2 Three-Year Results

Summary

MIMICS-2 is a prospective, single-arm, multicentre clinical study conducted under FDA-approved Investigational Device Exemption to evaluate the safety and effectiveness of the BioMimics 3D Vascular Stent System in the treatment of patients with symptomatic atherosclerotic disease of the femoropopliteal artery.

Baseline Demographics & Lesion Characteristics		N=271 Subjects
Age	Mean years ± SD (N)	68.4 ± 9.5 (271)
Risk factor	Diabetes Mellitus	45.4% (123/271)
Rutherford category	2/3/4	99.6% (270/271)
Lesion location	Mid/Distal	88.5% (239/270)
Lesion length	Mean ±SD (mm)	81.2 ± 38.4 (269/271)
Total occlusion	%	30.0 (81/270)
Lesion calcification	Moderate / Severe	45.9 (124/270)
BioMimics 3D Stents*	# Stents / N	305 / 271
Stented Segment**	Mean ± SD (mm)	112.3 ± 36.3 (269/271)

Study Principal Investigators:
Timothy M. Sullivan, MD
Minneapolis, MN, USA

Thomas Zeller, MD
Bad Krozingen, Germany

Masato Nakamura, MD
Tokyo, Japan

43 investigational sites enrolled 271 subjects:
US: 31 sites N =162
Germany: 6 sites N =78
Japan: 6 sites N =31

- **Duration of follow-up:** 3 years.
- **Independent committee adjudication of clinical events.**
- **Core laboratories:** Duplex ultrasound; angiography and X-ray.

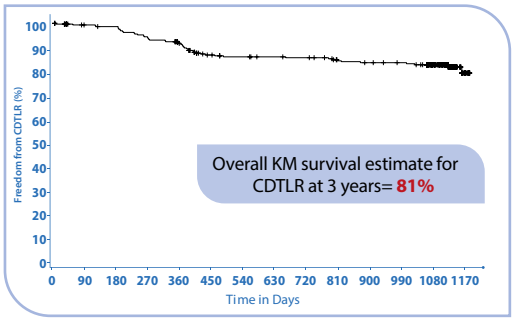
Results

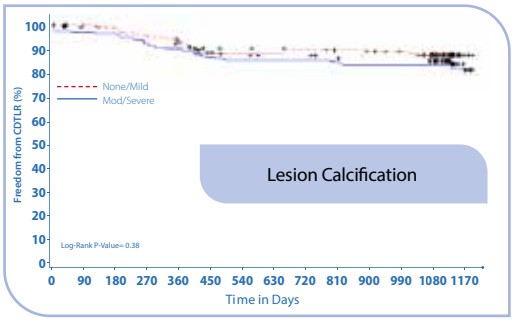
Overview of 3 Year Results from MIMICS-2

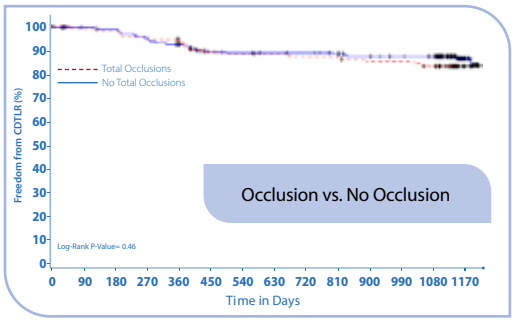
Primary Safety Endpoint***	30 days	99.6%
Primary Effectiveness Endpoint/Primary Stent Patency	12 months	73%
Stent fracture/Core Lab review	Maintained out to 3 years	0%
KM freedom from loss of primary patency	12 months	83%
KM freedom from CDTLR****	12 months	89%
	2 Years	84%
	3 Years	81%

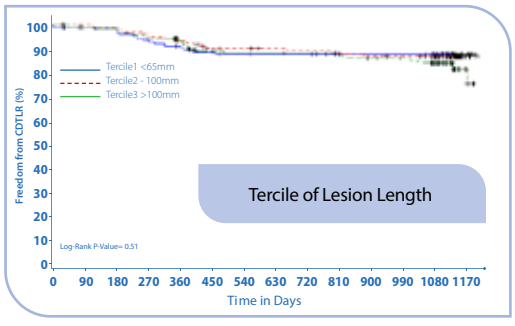
Rigorous, high quality data shows continuing benefit at
3 years

Continuing benefit at 3 years even in challenging cases









* Investigator-reported.

** CoreLab-reported.

*** Major Adverse Events comprising death, major amputation on index limb or CDTLR through Day 30.

****Core Lab adjudicated, clinically-driven TLR with objective evidence. Subjects are censored at their last known follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.[1]

BioMimics 3D
The Swirling Flow® Stent

Conclusions

MIMICS-2 shows continuing benefit of the BioMimics 3D Vascular Stent System at 3 Years, even in challenging cases:

- Reproducible, rigorous, high quality data from US, Japan and Europe.
- 81% freedom from CDTLR at 3 years.
- Comparable outcomes to DES/DCB despite more challenging lesions and without the need for lesion preparation.
- Providing ease-of-use simplicity and long-term benefits.
- Core Lab X-ray imaging review confirmed 0% stent fracture .

The BioMimics 3D Vascular Stent System reduces the burden of re-intervention for the patient and the health care system.[1,2]

The MIMICS Clinical Programme: An evolving database of the safety and effectiveness of the BioMimics 3D Vascular Stent System.

Gathering clinical evidence from a "real world" patient population from single de novo to complex, long and severely calcified lesions.

1750+
patients and growing

MIMICS *FIH*	MIMICS *RCT*	MIMICS *2*	MIMICS 3D	MIMICS 3D *USA*	MIMICS *et seq*
N = 10 1 site Germany	N = 50 8 sites Germany	N = 271 43 sites USA/Japan/Germany	N = 507 23 sites Pan European	N = c. 500 c. 40 sites USA	N = c. 400 Multiple sites Europe
• First in Human • FU - 1 year • Completed	• Randomised controlled trial • FU - 2 years • Completed	• IDE Registry • FU - 3 years • Completed	• Prospective Registry • FU - 3 years • 1 year complete	• Prospective Registry • FU - 3 years • Starting 2020	• Physician initiated prospective and retrospective registries • Enrolment ongoing

MIMICS *RCT*

A randomised study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control. Freedom from loss of primary patency through 2 years for BioMimics 3D Vascular Stent System was superior (P = 0.05) to straight control stents (72% vs 55%). There were no stent fractures at 2 years for patients treated with the BioMimics 3D Vascular Stent System .[3]

MIMICS *2*

A multicentre, international (USA, Japan and Germany) IDE study. At 3 years follow-up BioMimics 3D demonstrated continuing benefit with CDTLR showing comparable outcomes to DES/DCB. Core Lab X-ray imaging review confirmed 0% stent fracture in any MIMICS-2 subject treated with BioMimics. MIMICS-2 represents a more challenging patient population. than in DES/DCB pivotal trials.[4,5]

MIMICS 3D

A prospective observational registry evaluating the BioMimics 3D Vascular Stent System in a real-world clinical population with a dedicated subgroup analysis of device performance as a complementary treatment in procedures involving drug-coated balloons. MIMICS-3D enrolled 507 patients across 23 clinical sites in Europe.

MIMICS 3D *USA*

A prospective, multicentre observational study evaluating the safety, effectiveness and device performance of the BioMimics 3D Vascular Stent System within a real-world clinical population of patients undergoing femoropopliteal intervention. MIMICS-3D-USA will enrol more than 500 patients in 40 clinical sites across the United States.

1. Data on file at Veryan Medical
2. Kearns BMJ 2016
3. Zeller T et al; Circ Cardiovasc Interv. 2016;9
4. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235
5. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

The BioMimics 3D Vascular Stent System has CE Mark approval.

For additional information please contact your local representative.

GERMANY
T +49 3222 999 0027
E veryanmedical@healthlinkeurope.com
W veryanmed.com

ALL OTHER EUROPEAN COUNTRIES
T +31 (0)73 303 5510
E veryanmedical@healthlinkeurope.com
W veryanmed.com

PAM-253-issue-00

Veryan
AN OTSUKA MEDICAL DEVICES COMPANY