BioMimics 3D
The Swirling Flow® Stent

Veryan

MIMICS *RCT* Two-Year Results

Summary

A randomised study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control.The study evaluated the performance of the BioMimics 3D Vascular Stent System in the treatment of diseased SFA/proximal popliteal arteries.

Baseline Patient Demographics		BioMimics 3D (N=50)	Control Stent (N=26)	P value
Age	Mean ± SD (N)	68 ± 10.4	67 ± 8.9	0.66
Gender	Male	66%	65%	1.0
Risk Factors	Diabetes Type 2 Insulin-dependent Hypertension Smoking current	26% 14% 88% 42%	42% 19% 85% 50%	0.16 1.00 0.73 0.63
Medical History	Carotid artery disease Iliac disease	10% 18%	8% 15%	1.00 1.00
Previous Interventions	Previous PTA Previous Stent	16% 2%	12% 8%	0.74 0.27
Rutherford category	1 2 3 4	6% (3/50) 14% (7/50) 74% (37/50) 6% (3/50)	4% (1/26) 4% (1/26) 88% (23/26) 4% (1/26)	1.00 0.74 0.27 1.00
Ankle Brachial Index	Mean ± SD (N)	0.60 ± 0.23 (N=45)	0.59 ± 0.17	0.83

Lesion Characteristics		BioMimics 3D (N=50)	Control Stent (N=26)	P value
Lesion Location	SFA SFA/Popliteal Popliteal	92% 6% 2%	77% 12% 12%	0.08 0.41 0.11
TASC II	A B C	42% 56% 2%	42% 58% 0%	1.00 1.00 1.00
Lesion Length	mm	66 ± 29	63 ± 28	0.66
Stent Length	mm	99 ± 30	88 ± 22	0.08
Occlusion	Total	44%	46%	1.00
Calcification	Moderate to Severe	52%	58%	0.81

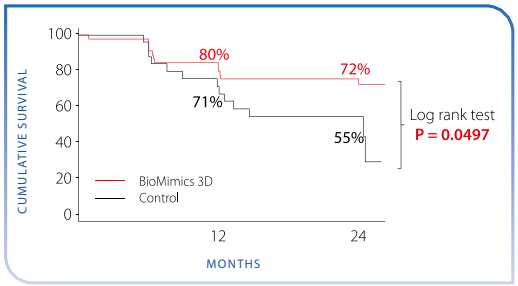
Study Principal Investigator:
Thomas Zeller, MD
Bad Krozingen, Germany
Enrolment: N=76
Clinical Sites: 8 Germany
Follow Up: 2 Years
Primary Endpoints:

Safety - Freedom from major adverse events (MAE) defined as death, amputation and target lesion revascularisation (TLR) at 30 Days.
Effectiveness - Freedom from clinically driven target lesion revascularisation (CDTLR) at 6 months.

2 Year Results

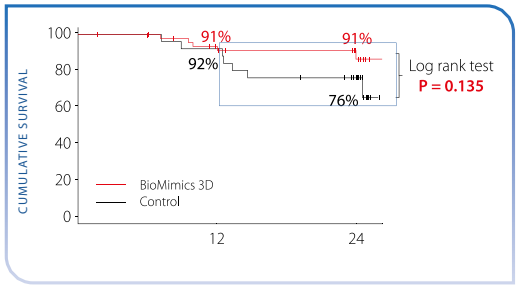
Patency

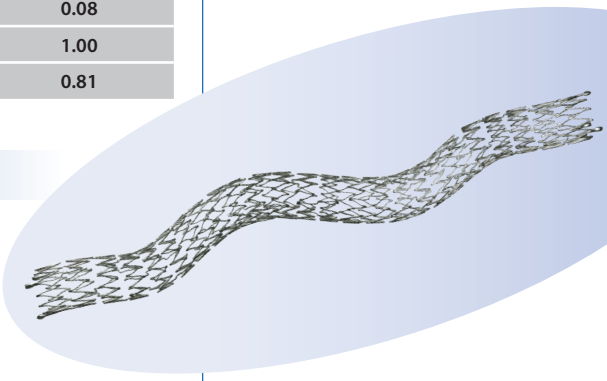
Significantly better primary patency (PSVR ≤2.0) through 2 years (P = 0.05)
- **72%** for BioMimics 3D at 2 years



CDTLR

Freedom from CDTLR *
- **91%** for BioMimics 3D maintained out to 2 years





*CDTLR determined through event adjudication

BioMimics 3D

The Swirling Flow® Stent

1750+

patients and growing

Conclusions[1]

- **Freedom from loss of Primary Patency at 2 years** - 72% for BioMimics 3D vs 55% for straight control stents (P=0.05). **
- **Freedom from CDTLR** - 91% for BioMimics 3D maintained out to 2 years.
- **Core lab X-ray imaging review confirmed 0% stent fractures at 2 years.**
- **Improvement in Rutherford Category** - 88% of patients treated with BioMimics 3D experienced an improvement of one or more Rutherford category at 2 years vs baseline.
- **Bi-planar X-ray imaging data indicated the ability of the femoropopliteal artery to adopt the three-dimensional curvature of the BioMimics 3D stent.**[1]
- **Computational fluid dynamic modelling (CFD) provided evidence of swirling flow within the stented segment and predicted zones of elevated wall shear.**[2]
  - Data indicate a correlation between primary patency and stent curvature.[3]
  - BioMimics 3D stented segments showed significantly greater curvature (P = 0.02) compared with the control.[4]
  - Elevated levels of swirling flow and wall shear were identified by CFD, which may explain the longer term patency protective effect seen with the BioMimics 3D. Vascular Stent System.[5]

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.

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 • 2 years complete	• Prospective Registry • FU - 3 years • Enrolment ongoing	• 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.[6]

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.[7,8]

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 a minimum of 500 patients in up to 40 sites across the United States.

** Straight control stents = 24/26 Bard LifeStent™; 1/26 Terumo Misago™; 1/26 Biotronik Pulsar

1,2,4,5 Data on file at Veryan Medical Zeller T et al; Circ Cardiovasc Interv. 2016;9

3 Zeller T. Oral Presentation VIVA 2014

6 Zeller T et al; Circ Cardiovasc Interv. 2016;9

7. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235

8. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

For additional information please contact your local representative.

PAM-251-version-2.0

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

Veryan

AN OTSUKA MEDICAL DEVICES COMPANY