BioMimics 3D
The Swirling Flow® Stent

Veryan

MIMICS 3D Three-Year Results

Summary

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.

24% of subjects enrolled in MIMICS-3D had Critical Limb Threatening Ischemia (CLTI)

Baseline Patient Demographics		N=507 Subjects
Age	Mean years ± SD (N)	70 ± 10 (507)
Gender	% Male	66% (332/507)
Risk Factors	Diabetes Mellitus	37% (187/507)
	Smoker Current	38% (191/507)
Rutherford category	0	0.4% (2/504)
	1	1% (6/504)
	2	17% (86/504)
	3	57% (289/504)
	4	8% (38/504)
	5	14% (72/504)
	6	2% (11/504)
Ankle Brachial Index	Mean ± SD (N)	0.6 ± 0.3 (417)

38% of lesions had moderate to severe calcification

Baseline Lesion Characteristics		N=507 Subjects (518 lesions)
Reference Vessel Diameter	Mean ± SD (N)	5.5mm ± 0.7
Lesion Location	Mid +/- Distal Third	86% (445/518)
	Prox. Pop	29% (150/518)
Diameter Stenosis	Mean ± SD	95% ± 8 (518)
Occlusions	Total	57% (294/518)
Lesion Length	Mean ± SD	126mm ± 91
Calcification	Grade 0	18% (91/516)
	Grade 1	30% (152/516)
	Grade 2	24% (126/516)
	Grade 3	15% (76/516)
	Grade 4	14% (71/516)

Study Principal Investigator:
Michael Lichtenberg MD, Arnsberg, Germany

Enrolment complete:
N=507

Clinical Sites: 23 Pan European

Follow Up: 3 Years

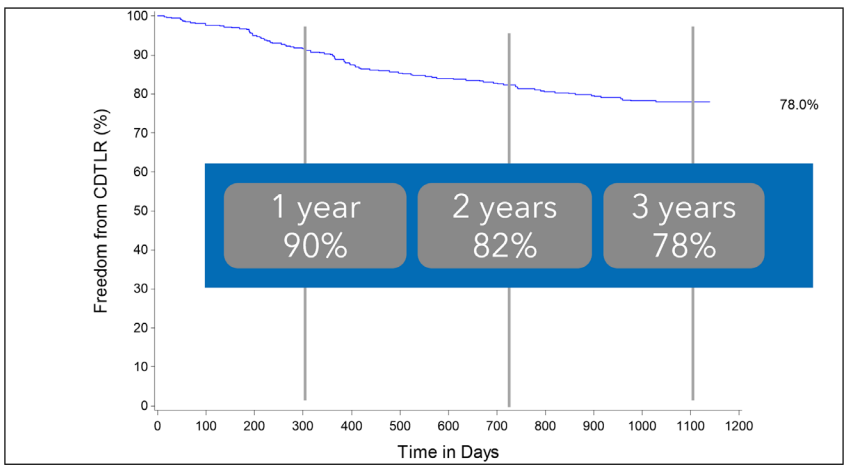
Primary Endpoints:

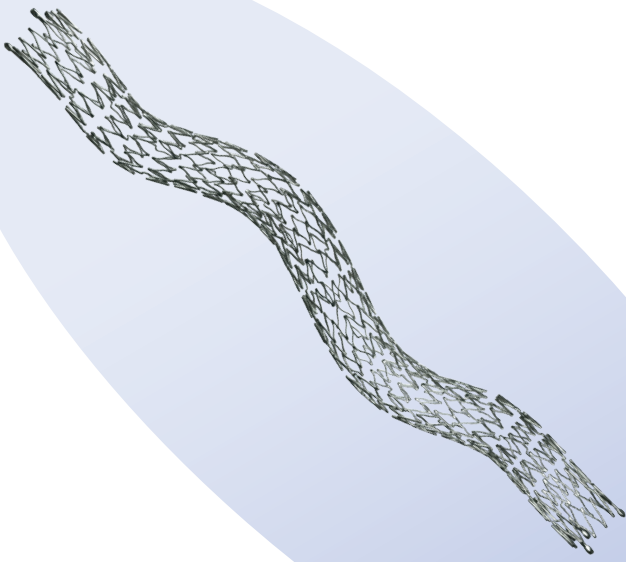
Safety – Composite of major adverse events (MAE), death, major amputation performed or clinically-driven target lesion revascularisation (CDTLR) through 30 days.

Effectiveness – Freedom from CDTLR through 12 months.

KM Freedom from CDTLR at 3 years

Data from a challenging real-world population continue to demonstrate the therapeutic value of swirling flow in the BioMimics 3D stent.





Conclusions

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MIMICS-3D data contribute real-world experience to the evolving database supporting the therapeutic value of swirling flow in the BioMimics 3D stent.

More challenging population than typically enrolled in registry studies:

- 24% CLTI; longer, more complex lesions; 50% with DCB.
- 78% Freedom from CDTLR at 3 Years.
- Rate of CDTLR was independent of concomitant DCB use, lesion calcification and stent length.

MIMICS Clinical Programme investigations into the performance of the BioMimics 3D Vascular Stent system support the hypothesis that imparting non-planar curvature to the femoropopliteal artery to promote swirling blood flow and increase wall shear stress, results in clinical outcomes that are comparable to those of drug-eluting devices. [1]

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 • Completed	• 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 stent.[2]

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.[3,4]

MIMICS 3D

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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.

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

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

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