Klinikum Hochsauerland
Karolinen-Hospital Hüsten
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster

iSET International Symposium on Endovascular Therapy

3-Year Results From The MIMICS-3D EU Study

Clinical Outcomes for the BioMimics 3D Stent in a Real-World Population

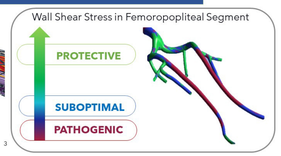
Michael Lichtenberg MD on behalf of the MIMICS-3D investigators.

BioMimics 3D®: The Swirling Flow® Stent

- Helical centerline
- Simple, accurate placement using standard delivery system
- Imparts non-planar curvature to stented femoropopliteal segment which generates swirling flow providing an antiproliferative effect without the need for a drug[1,2]
- Improved biomechanical performance compared to straight stents[1]

Atheroprotective & anti-restenotic effects of elevated wall shear stress

- Non-planar vascular curvature promotes swirling blood flow[3]
- Swirling flow increases wall shear stress on endothelial cells[4]
- Elevated wall shear stress has been shown to reduce intimal hyperplasia[3]



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MIMICS Clinical Program

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

1750+ patients

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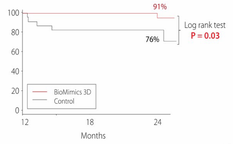
MIMICS Randomised Controlled Trial

- PI: Thomas Zeller
- 86 patients
- 8 Investigational sites
- Independent corelab (DUS; angiography; Xray)
- 2-year follow up: STUDY COMPLETE

FIM Lead-in	N=10 BioMimics 3D	
Prospective Randomization	BioMimics 3D N=50	Straight nitinol stent N=26
24-Month Primary Patency (p=0.05)	**72%**	**55%**
Freedom from CDTLR 12-24 months (p=0.03)	**91%**	**76%**
Stent fracture	**0%**	**0%**

Freedom from CDTLR
Landmark Analysis[2]



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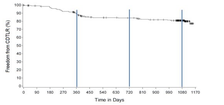
Provided the first clinical proof supporting the durable outcome benefit arising from the BioMimics 3D stent compared to a straight nitinol stent[1,2]

MIMICS-2 IDE Study

- PIs: Timothy Sullivan (US), Thomas Zeller (Europe), Masato Nakamura (Japan)
- 43 Investigational sites
- 271 patients
- Independent core lab (DUS; angiography; Xray)
- Independent Clinical Event Committee (adjudication)
- 3-year follow up COMPLETE

12-Month KM Freedom from loss of Primary Patency	**83%**
36-Month KM Freedom from CDTLR *	**81%**
Stent fracture	**0%**

Kaplan Meier survival estimates of Freedom from Clinically-Driven TLR at 3 Years



1-year = 89%
2-year = 84%
3-year = **81%**

*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

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The MIMICS-2 study validated the outcomes of the randomised study by providing clinical proof in a larger, more challenging cohort[1]

MIMICS[3D] Baseline Patient Demographics

		Enrolled Population N=507
Age	Mean years ± SD (N)	70.1 ± 10
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)

CLTI present in 24% of enrolled subjects

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MIMICS[3D] Baseline Lesion Characteristics

		Enrolled Population N=507 subjects (518 lesions)
Reference Vessel Diameter (mm)	Mean ± SD	5.5 ± 0.7
Diameter Stenosis (%)	Mean ± SD	95 ± 8 (518)
Occlusions	Total	57% (294/518)
Lesion Length (mm)	Mean ± SD	126 ± 91
Calcification (%)	Grade 0	18% (91/516)
	Grade 1	30% (152/516)
	Grade 2	24% (125/516)
	Grade 3	15% (76/516)
	Grade 4	14% (72/516)

Longer, more complex lesions than previously studied

38% of lesions had moderate to severe calcification

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MIMICS[3D] Baseline Procedural Data

		Enrolled Population N=507
BioMimics 3D Stents	# stents/lesions	676/518
	1 stent	76% (395/518)
	2 stents	19% (96/518)
	3 stents	4% (19/518)
	4 stents	2% (8/518)
Stented Segment Length	Mean ± SD (mm)	131 ± 80.1
Diameter Stenosis	Pre-stent % ± SD	95% ± 8.0
	Post-stent % ± SD	6% ± 8.7
Other Target Lesion Treatments	Drug coated balloon	50.0% (259/518)
	Atherectomy	8% (39/518)

50% of the lesions were treated with BioMimics 3D and Drug Coated Balloon

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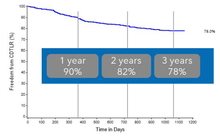
MIMICS[3D] European Registry: 3-year Results

Kaplan Meier survival estimates of Freedom from Clinically-Driven TLR at 3 Years



*1 patient did not have a final diameter stenosis recorded
**ITT population. PSVR>2.4

Technical Success (procedure)	99% (501/506)*
Procedural Success	97%
Primary Endpoint: 30-day safety	98.6% (486/493) Freedom from MAE
Primary Endpoint: 12-month effectiveness	89.1% (399/448) Freedom from CDTLR
36-Month KM Freedom from loss of Primary Patency**	71%
36-Month KM Freedom from CDTLR	78%
Stent fracture (site reported)	0.6% (4/676)
Stent fracture (confirmed by investigation)	0.4% (3/676)

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MIMICS[3D] European Registry: Comparison of CDTLR results with and without DCB

		BioMimics 3D *with* DCB	BioMimics 3D *without* DCB	Log rank P- value
KM Freedom from CDTLR	1 Year	91.4%	88.7%	
	2 Year	81.5%	83.1%	
	3 Year	76.4%	79.6%	0.4789

- No statistical difference in CDTLR between DCB and no-DCB cohorts
- The addition of paclitaxel added no benefit to clinical outcome in this study

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Data on file at Veryan Medical

MIMICS Clinical Program

Enrolling progressively longer and more complex lesions

	MIMICS-RCT	MIMICS-2	MIMICS-3D
Lesion Length Mean ± SD (mm)	66 ± 29	81 ± 38	126 ± 91
Stented Segment Length Mean ± SD (mm)	99 ± 30	112 ± 36	131 ± 80
CTO	44%	30%	57%
Mod/Severe Ca++	52%	46%	38%
CLI	6%	6%	24%

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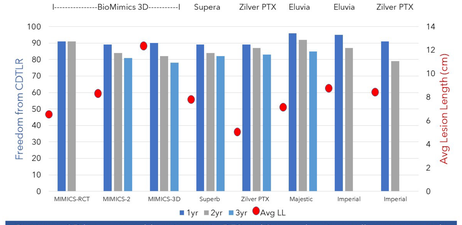
Indicative Study Comparisons-Freedom from CDTLR



BioMimics 3D has comparable outcomes to DES and Supera despite enrolling progressively longer lesions in the MIMICS Clinical program

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MIMICS[3D] Conclusions

- More challenging population than typically enrolled in registry studies:
  - 24% CLTI
  - longer, more complex lesions
- KM freedom from loss of primary stent patency at 3 years = **71%**
- KM freedom from CDTLR at 3 years = **78%**
- No statistical difference in CDTLR between DCB and no-DCB cohorts
  - The addition of paclitaxel added no benefit to clinical outcome in this study
- Comparable outcomes to DES and Supera despite more challenging lesions and without the need for extensive lesion preparation

MIMICS Clinical Program 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-coated and drug-eluting devices

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References
1. Data on file at Veryan Medical
2. Caro CG et al. J R Soc Interface 10:20130578, 2013
3. Malek AM et al. JAMA 1999;252:2035–2042
4. Caro CG. Arterioscler Thromb Vasc Biol 2009; 29:158-161
5. Data on file at Veryan Medical
6. Zeller T et al. Circ Cardiovasc Interv. 2016
7. Sullivan TM et al. Int J Vasc Med. 2018
8. Data on file at Veryan Medical
9. Data on file at Veryan Medical
10. Data on file at Veryan Medical

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The BioMimics 3D Vascular Stent System has FDA, PMDA and CE Mark approval.

PAM 302 Version 1.0