MIMICS-3D: 2-year data from the BioMimics 3D Real-World Registry

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Disclosure

Speaker name:

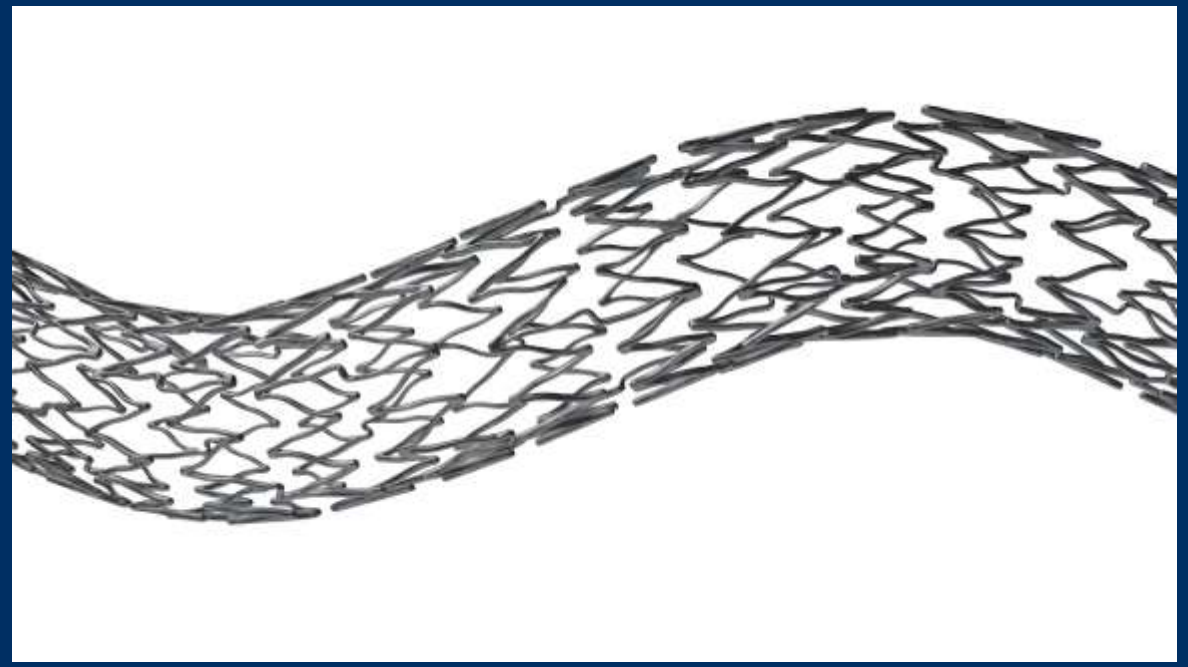
Dr. Michael Lichtenberg.....

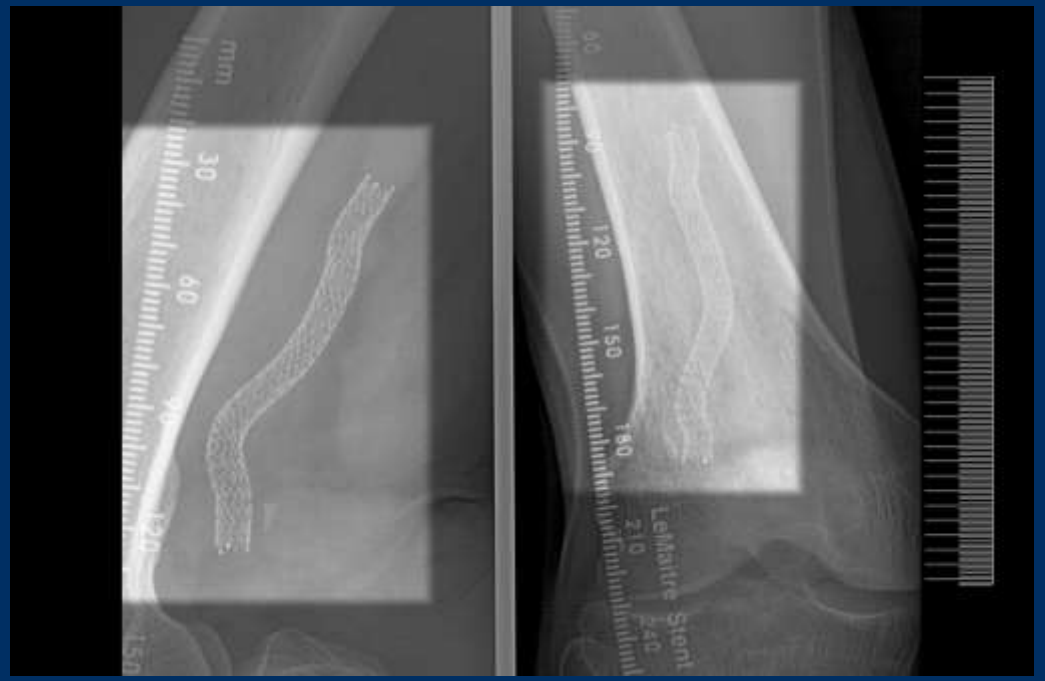
I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

BioMimics 3D®: The Swirling Flow® Stent





- Helical centreline
- Simple, accurate placement using standard delivery system

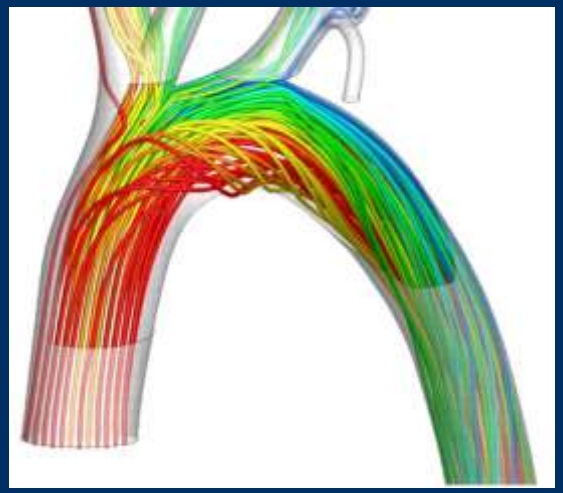
- Imparts non-planar curvature to stented femoropopliteal segment[1]
- Improved biomechanical performance compared to straight stents[1]

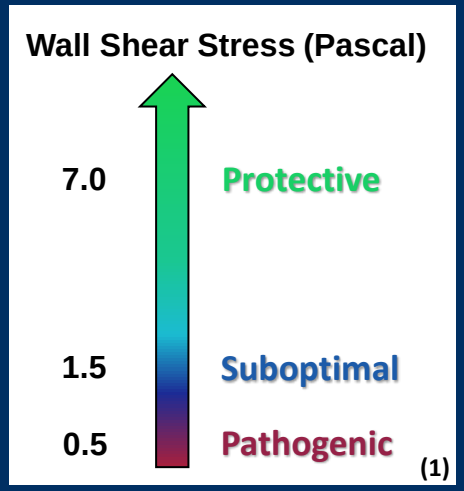
BioMimics 3D and Swirling Flow are Registered Trademarks of Veryan Medical Limited

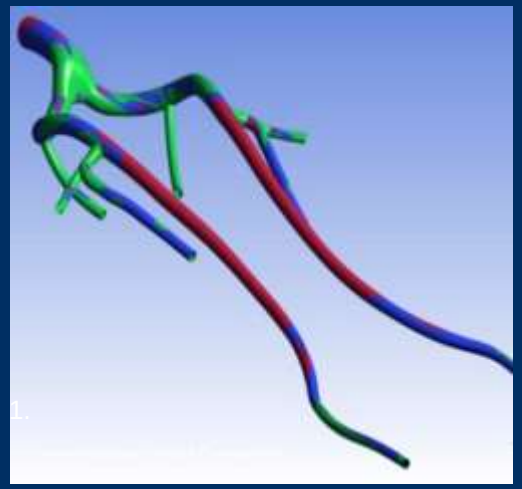
The BioMimics 3D Vascular Stent System has FDA, PMDA and CE Mark approval. Not available for sale in Japan
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1. Data on file at Veryan Medical

BioMimics 3D: Helical Centreline Promotes Swirling Flow





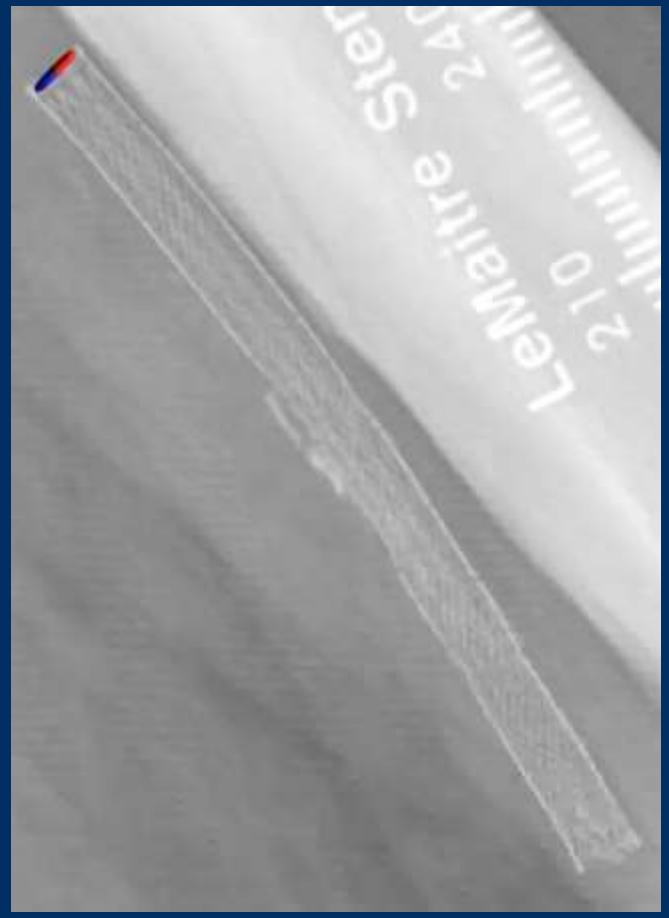


- Swirling flow increases wall shear stress (WSS) on endothelial cells
- WSS naturally protects against atherosclerosis and intimal thickening (2)
- Increased WSS has been shown (3) to provide an antiproliferative effect after stenting, without the need for a drug

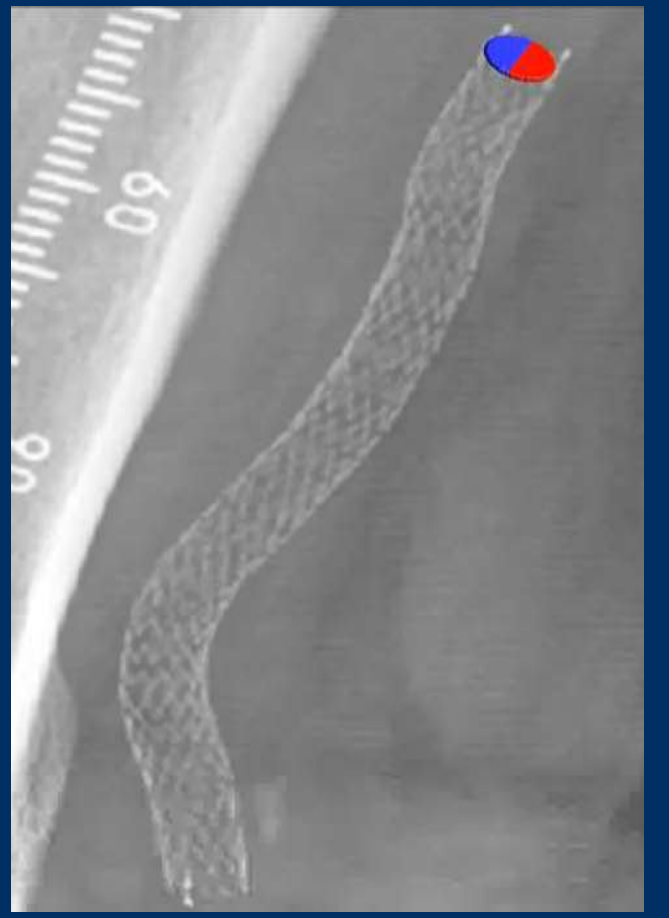
1. *Malek AM et al, JAMA 1999;252:2035–2042*
2. *Caro CG, Arterioscler Thromb Vasc Biol 2009, 29:158-161*
3. *Caro CG et al, J R Soc Interface 10: 20130578*

In Vivo CFD Modelling of Swirling Flow in the Stented Segment

Straight stent



BioMimics 3D Stent

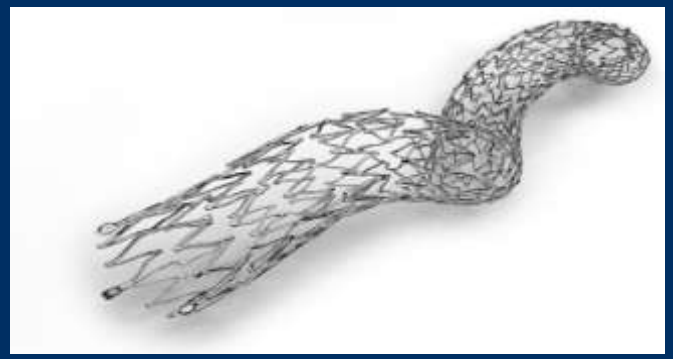


Data on file at Veryan Medical

Improving the Biomechanics

Bent knee cadaver study

BioMimics 3D Stent



Straight stent

Data on file at Veryan Medical

MIMICS Clinical Programme

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

1750+ patients

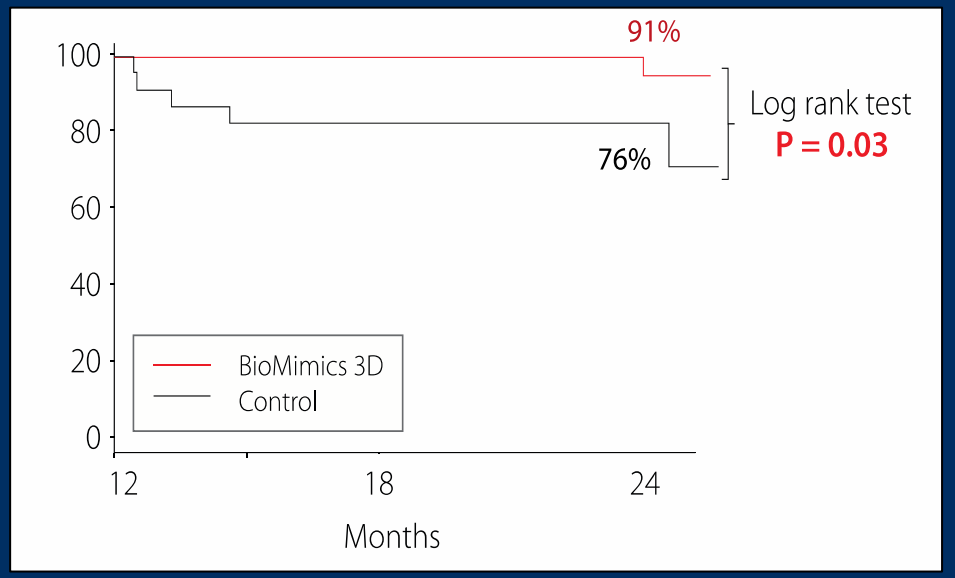
Data on file at Veryan Medical

MIMICS Randomised Controlled Trial

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

Freedom from CDTLR
Landmark Analysis[2]



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

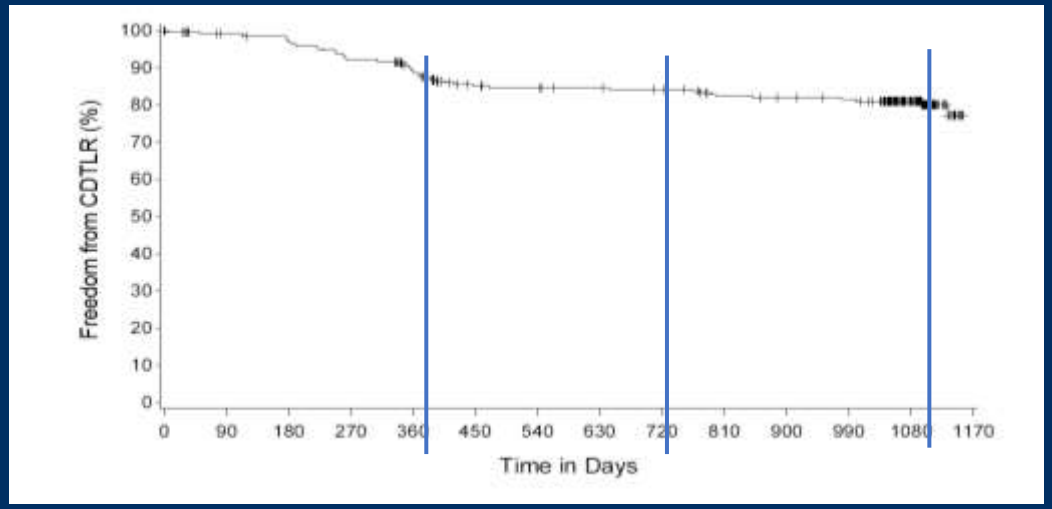
1. Zeller T et al; Circ Cardiovasc Interv. 2016
2. Sullivan TM et al; Int J Vasc Med. 2018

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 Primary Patency	**73.1%**
36-Month KM Freedom from CDTLR *	**81%**

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

1. Zeller T et al; Circ Cardiovasc Interv. 2016
2. Sullivan TM et al; Int J Vasc Med. 2018

MIMICS 3D

MIMICS-3D Registry

A Prospective, Multicentre Observational Study to Evaluate BioMimics 3D Stent in PAD in the Real World

- PIs: Michael Lichtenberg
- 43 Investigational sites
- 507 patients
- Independent Clinical Event Committee (adjudication)
- 3-year follow up (2-years COMPLETE)

Technical Success (procedure)	**99%**
Procedural Success	**98%**
Primary Endpoint – 30-Day Safety	**99%** (447/452) Freedom from MAE
Primary Endpoint - 12-month Effectiveness	**91%** (367/405) Freedom from CDTLR

1. Data on file at Veryan Medical

MIMICS 3D

Baseline Patient Demographics

		Enrolled Population N=507
Age	Mean years ± SD (N)	70.1 ± 10
Gender	% Male	65.5% (332/507)
Risk Factors	Diabetes Mellitus	36.9% (187/507)
	Smoker Current	37.7% (191/507)
Rutherford Category	0	0.4% (2/504)
	1	1.2% (6/504)
	2	17.1% (86/504)
	3	57.3% (289/504)
	4	7.5% (38/504)
	5	14.3% (72/504)
	6	2.2% (11/504)
Ankle Brachial Index	Mean ± SD (N)	0.6 ± 0.3 (417)

CLI present in 24% of enrolled subjects

Data on file at Veryan Medical

LINC

MIMICS 3D

Baseline Lesion Characteristics

		Enrolled Population N=507 subjects (518 lesions)
Reference Vessel Diameter (mm)	Mean ± SD	5.3 ± 0.6
Stent Location (%)	Mid to Distal SFA	85.9% (445/518)
	Prox. Pop	29% (150/518)
Diameter Stenosis (%)	Mean ± SD	94.6 ± 8 (518)
Occlusions	Total	56.8% (294/518)
Lesion Length (mm)	Mean ± SD	127 ± 92.4
Calcification (%)	Grade 0	17.6% (91/518)
	Grade 1	29.3% (152/518)
	Grade 2	24.1% (125/518)
	Grade 3	14.7% (76/518)
	Grade 4	13.9% (72/518)

38% of lesions had moderate to severe calcification

Data on file at Veryan Medical

MIMICS 3D

Baseline Procedural Data

		Enrolled Population N=507
BioMimics 3D Stents	# stents/lesions	674/518
	1 stent	76.4% (396/518)
	2 stents	18.3% (95/518)
	3 stents	3.9% (20/518)
	4 stents	1.4% (7/518)
Stented Segment Length	Mean ± SD (mm)	130.8 ± 79.2
Diameter Stenosis	Pre-stent % ± SD	94.6% ± 8
	Post-stent % ± SD	6.2 ± 8.8
Other Target Lesion Treatments	Drug coated balloon	50.0% (259/518)
	Atherectomy	7.5% (39/518)
Technical Success		99% (501/506)

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

Data on file at Veryan Medical

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MIMICS 3D

Longer, more complex lesions

Mean ± SD (mm)	MIMICS-RCT	MIMICS-2	MIMICS-3D
Lesion Length	66 ± 29	81 ± 38	**127 ± 92**
Stented Segment Length	**99** ± 30	**112** ± 36	**131 ± 79**

- Sicker patients, longer and more complex lesions
- BioMimics 3D stent use 50:50 primary or bail-out to DCB
- Highly relevant population for a contemporary registry

Data on file at Veryan Medical

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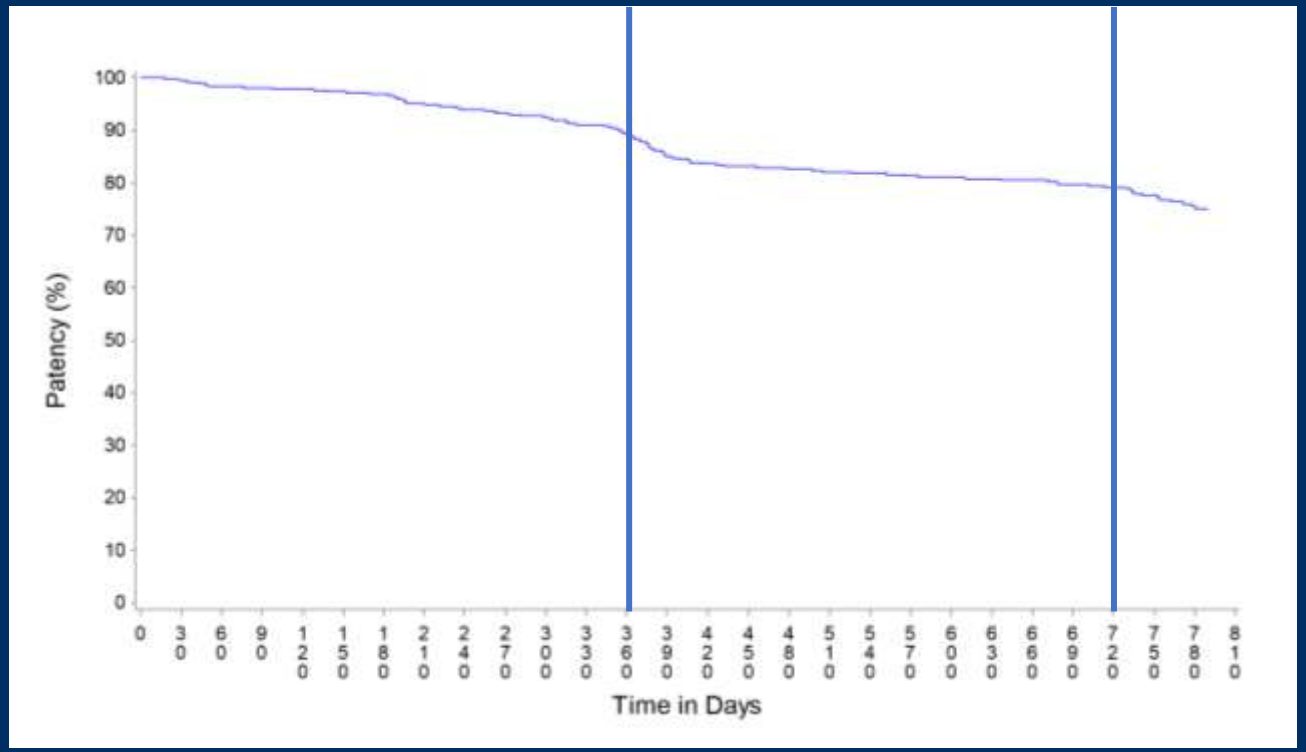
Freedom from Loss of Primary Stent Patency

1-year = 88% 2-year = 76%



Per protocol analysis

Subjects are considered patent only up to the first indication of loss of patency. Subjects are censored at their last known follow-up (regardless of patency assessment).'

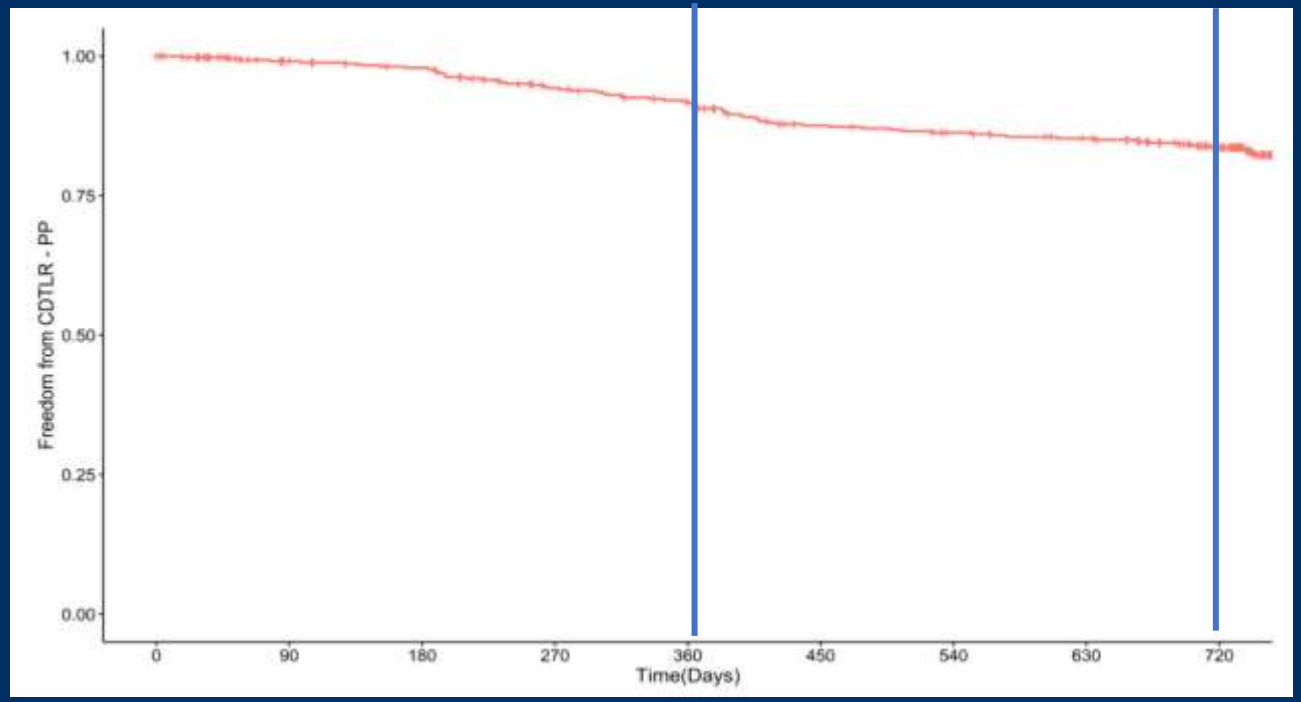
'Patency is defined as the composite of (1) fre edom from more than 50% restenosis within t he stented segment as observed by DUS or An giography and
(2) freedom from clinically-
driven target lesion revascularisation (TLR)'

Days Since Index Procedure	0	30	365	395	730	790
KM Estimate (95% CI) PSVR>2.0	100.0% (100.0%,100.0%)	99.8% (99.3%,100.0%)	87.7% (84.5%,90.9%)	83.1% (79.4%,86.8%)	76.2% (72.0%,80.4%)	71.2% (66.5%,75.9%)
Number Failed	0	1	50	68	94	108
Number Remaining at Risk	463	438	349	324	249	163

Data on file at Veryan Medical

Freedom from clinically-driven target lesion revascularisation (CDTLR)

1-year = 92% 2-years = 84%

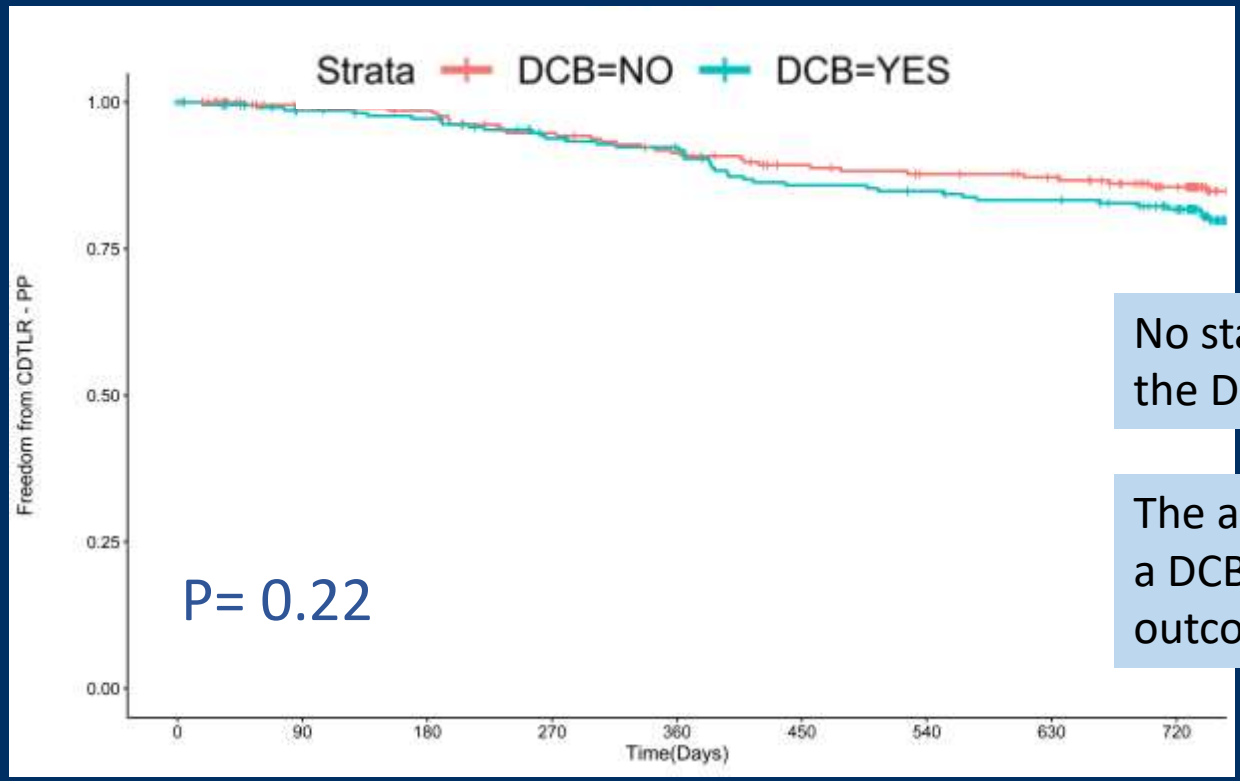


Subjects are censored at their last known follow-up or death

Day	0	90	180	270	360	450	540	630	720
Number at risk	463	421	411	386	371	344	335	326	290
Survival probability	100%	99.1%	97.9%	94.3%	91.8%	87.6%	86.3%	85.3%	83.6%

Data on file at Veryan Medical

Freedom from CDTLR at 2 years: DCB vs no-DCB



No statistical difference between the DCB and no-DCB cohorts

The addition of paclitaxel by use of a DCB adds no benefit to clinical outcome in this study.

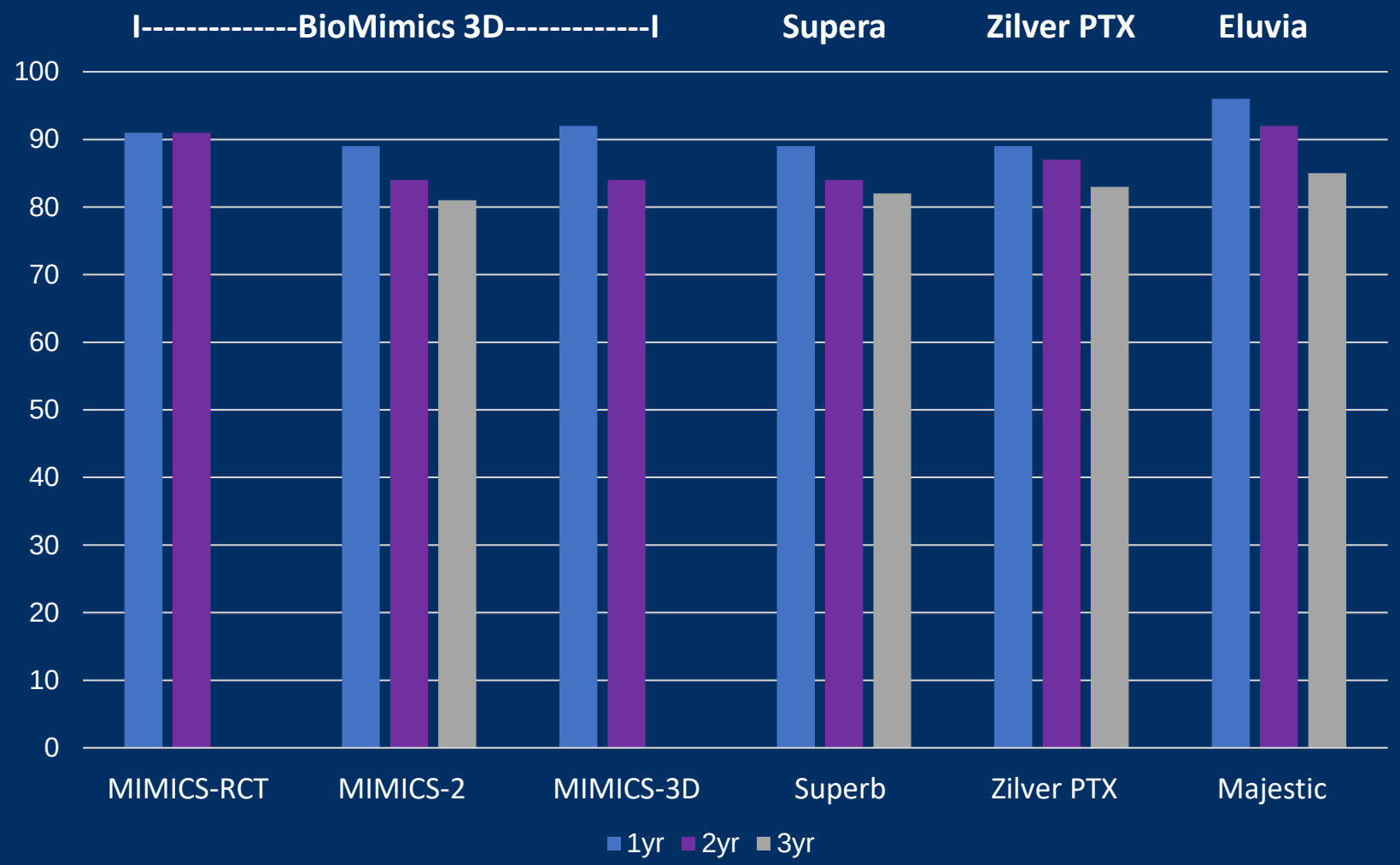
	0	90	180	270	360	450	540	630	720
Survival probability – DCB = NO	100%	99.5%	98.6%	94.7%	91.3%	89.3%	87.7%	87.2%	85.5%
Survival probability – DCB + YES	100%	98.6%	97.2%	93.8%	92.3%	85.8%	84.8%	83.3%	81.7%

Number at risk

DCB = NO	238	211	206	195	185	173	167	162	141
DCB = YES	225	210	205	191	186	171	168	164	149
TIME (DAYS)	0	90	180	270	360	450	540	630	720

Data on file at Veryan Medical

Industry Study Comparisons-Freedom from CDTLR



Comparable outcomes to DES and Supera despite more challenging lesions and without the need for lesion preparation

Data on file at Veryan Medical

Conclusions

- More challenging population than typically enrolled in registry studies:
  - 24% CLI
  - longer, more complex lesions
  - 50% with DCB
- KM freedom from loss of primary stent patency at 2 years = 76%*
- KM freedom from CDTLR at 2 years = 84%
- No statistical difference in CDTLR between DCB and no-DCB cohorts. The addition of paclitaxel adds no benefit to clinical outcome
- Comparable outcomes to DES and Supera despite more challenging lesions and without the need for lesion preparation
- Data support the therapeutic value of swirling flow
- 3-year follow-up continues

** PSVR >2.0*

1. Data on file at Veryan Medical
2. Kearns BMJ 2016

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