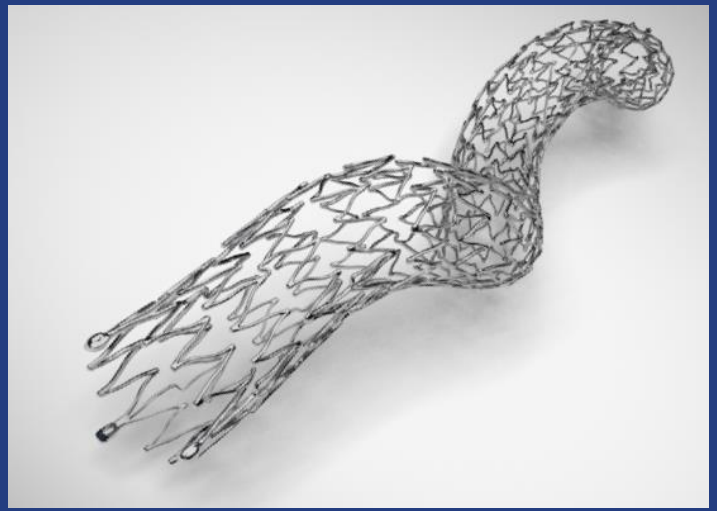
3-Year Results from the MIMICS-2 Study

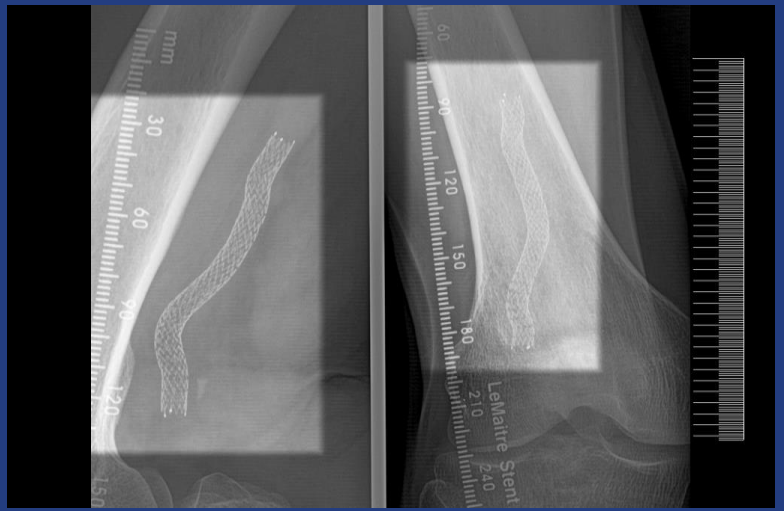
PAM 269 Version 1.0

DISCLOSURES

BioMimics 3D®: The Swirling Flow® Stent



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

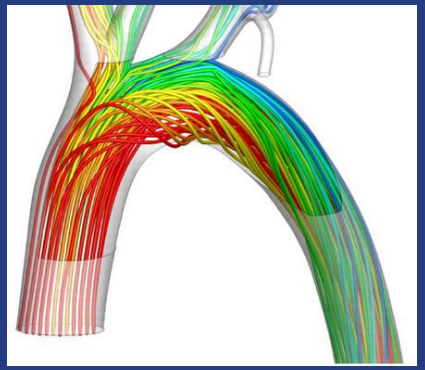


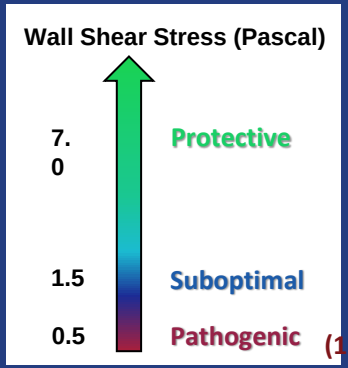
- Imparts non-planar curvature to stented femoropopliteal segment[1]
- Improved biomechanical performance compared to straight stents[1]
- 0% stent fracture MIMICS-2 IDE Study

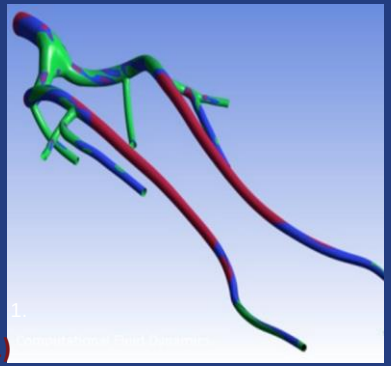
The BioMimics 3D Vascular Stent System has FDA, PMDA and CE Mark approval. Not available for sale in Japan
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1. Data on file at Veryan Medical

BioMimics 3D:Helical Centerline Promotes Swirling Flow







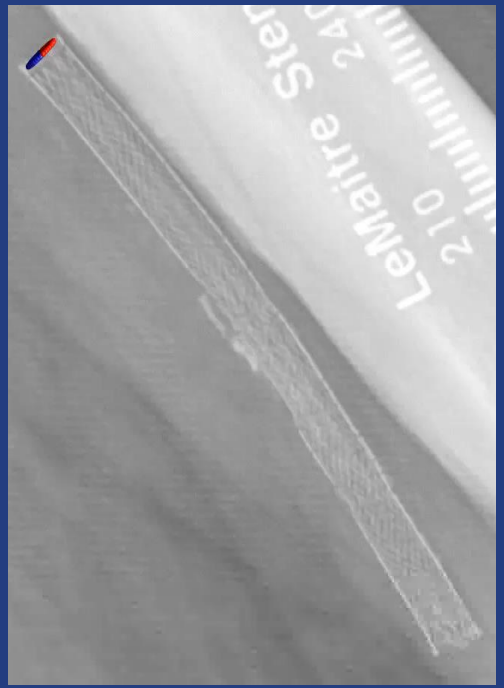
(1)

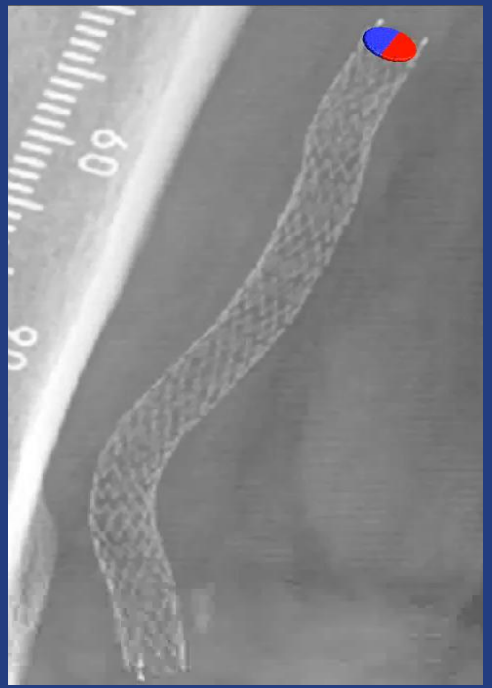
- Swirling flow increases wall shear stress (WSS) on endothelial cells
- WSS naturally protects against atherosclerosis and intimal thickening (2)
- Increased WSS has been shown (3) to provide an antiproliferative effect after stenting, without the need for a drug

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

LifeStent (left) and **BioMimics 3D Stent (right)**



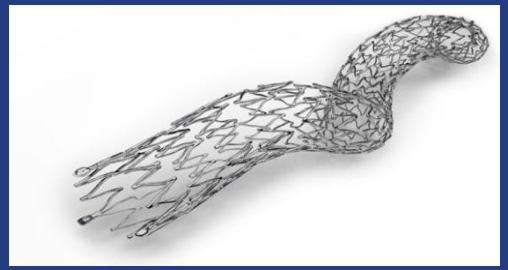


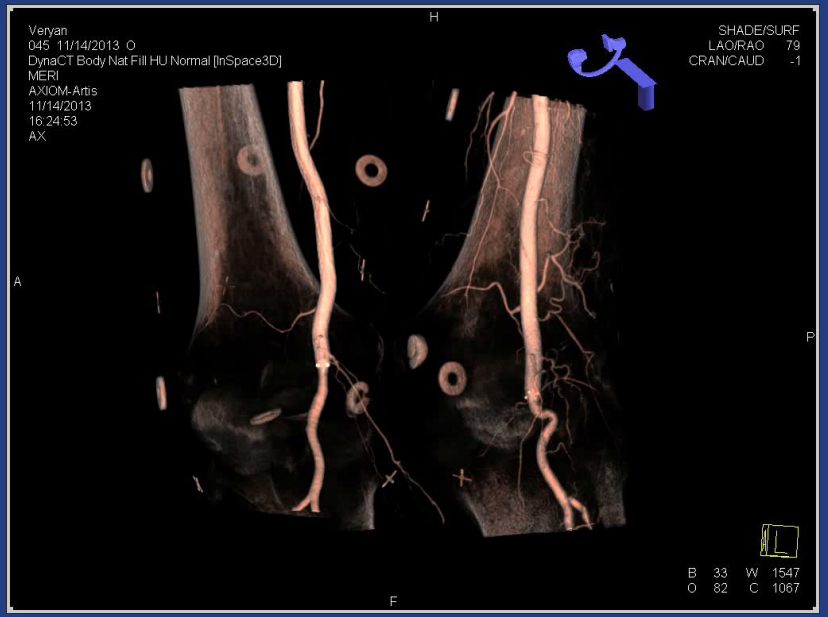
Data on file at Veryan Medical

Improving the Biomechanics

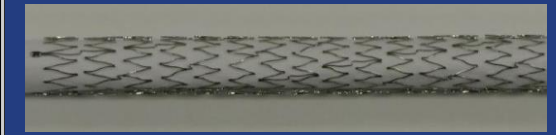
Bent knee cadaver study

BioMimics 3D



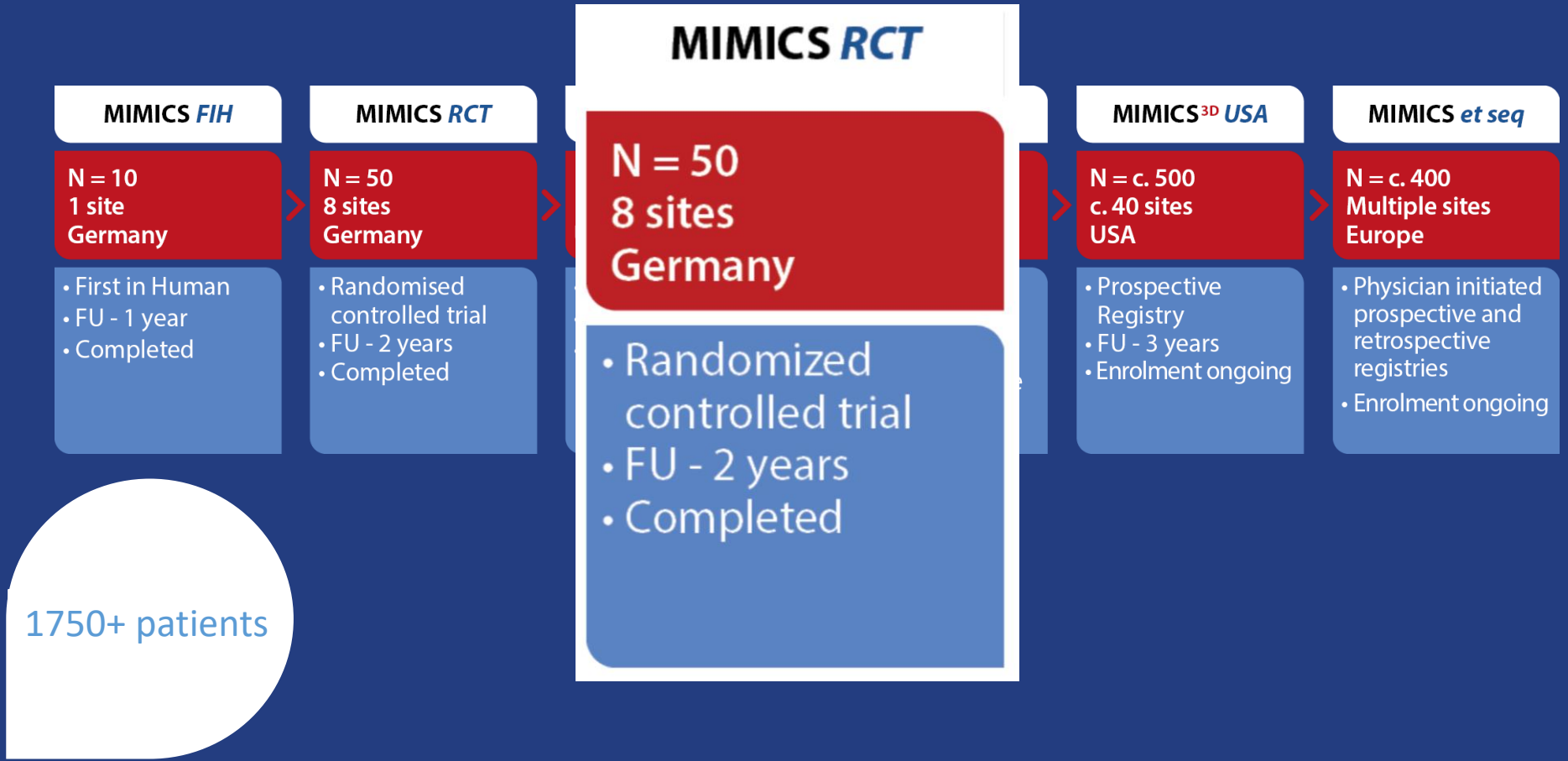


Straight Stent



Data on file at Veryan Medical

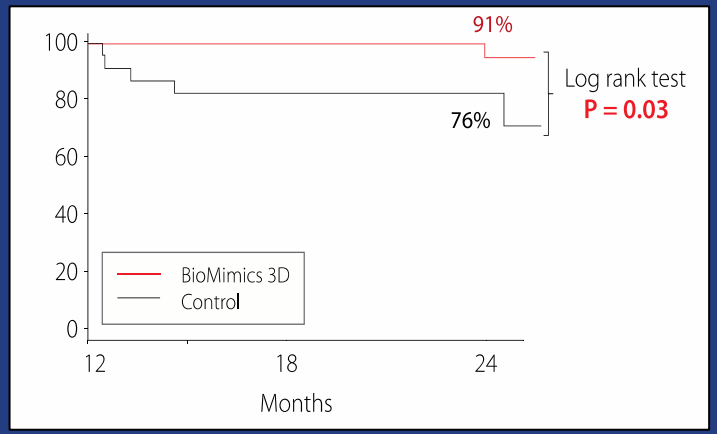
MIMICS Clinical Programme



MIMICS Randomized Controlled Trial

8 Investigational Sites *Corelab (DUS; angiography; Xray)*		
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%**

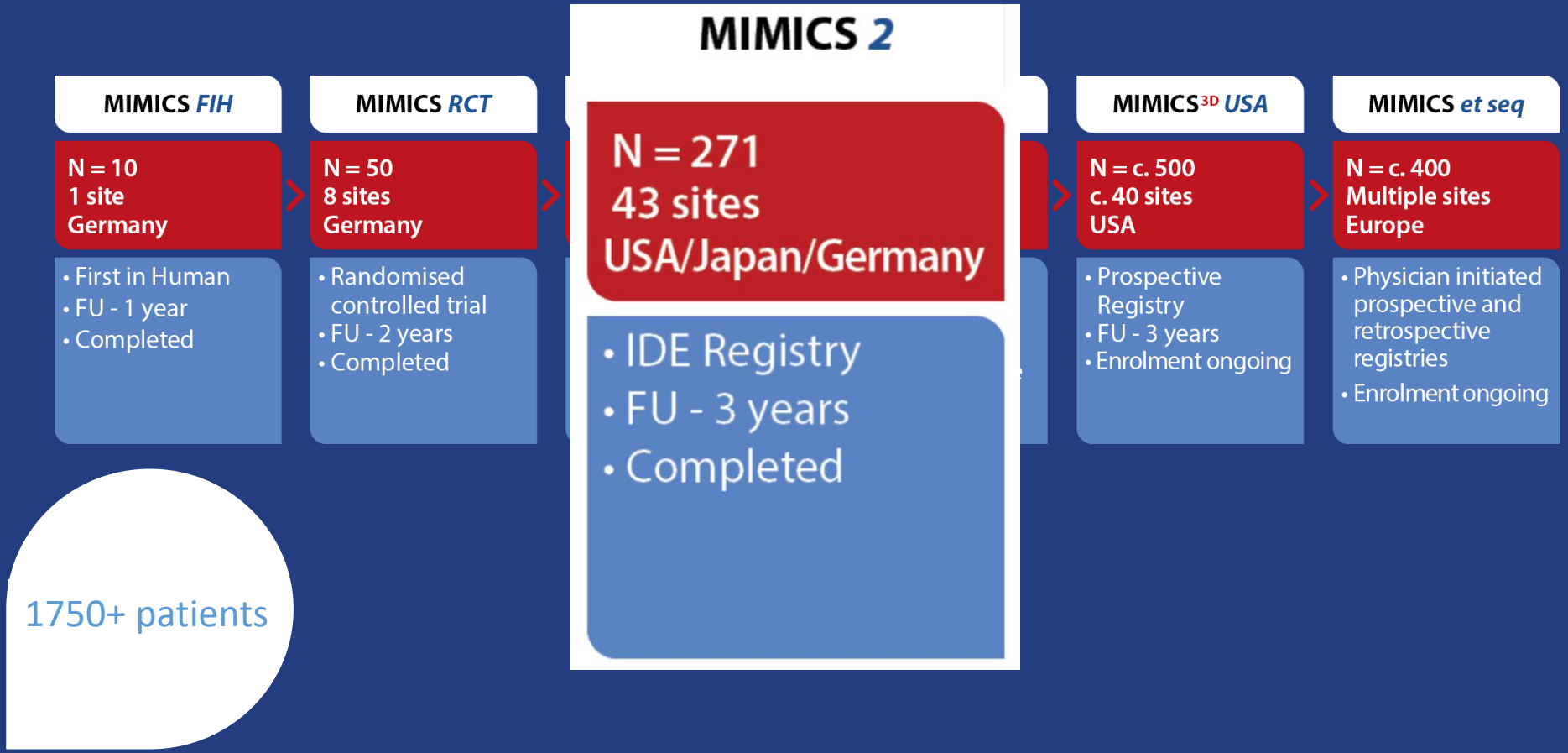
Freedom from CDTLR
Landmark Analysis[2]



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 Clinical Programme



Evaluation of Safety and Effectiveness of the BioMimics 3D Stent System in the Femoropopliteal Arteries of Patients with Symptomatic Peripheral Arterial Disease

MIMICS *2*

- **Primary Endpoints**
  - Safety: composite of death, major amputation or CDTLR through 30 days
  - Effectiveness: primary patency at 12-months
- **Follow-up**: 3 years
- 43 investigational sites enrolled 271 subjects
  - US: 31 sites N = 162
  - Germany: 6 sites N = 78
  - Japan: 6 sites N = 31
- **Study Principal Investigators**
  - Timothy M. Sullivan, MD Minneapolis, MN, USA
  - Thomas Zeller, MD Bad Krozingen, Germany
  - Masato Nakamura, MD Tokyo, Japan

Independent Core labs:

- **ultrasound; angiography; X-ray**

Independent Clinical Event Committee

- **adjudication**

Data on file at Veryan Medical

ClinicalTrials.gov Identifier: NCT0240090

MIMICS 2

Baseline Patient Demographics

		N= 271 Subjects
Age	Mean years ± SD (N)	68.4 ± 9.5 (271/271)
Gender	Male / Female	180 (66.4%) / 91 (33.6%)
Risk Factors	Diabetes Mellitus	45.4% (123/271)
	Hypertension	90.0% (244/271)
	Hypercholesterolemia	81.9% (222/271)
	Smoker Current / Former	80.8% (219/271)
Coronary Revascularization	Previous Percutaneous or Surgical	43.2% (117/271)
Previous Peripheral Intervention	None in target vessel	98.2% (266/271)
Rutherford Category	1	0% (0/271)
	2	26.9% (73/271)
	3	67.5% (183/271)
	4	5.2% (14/271)
	5	0.4% (1/271)
Ankle Brachial Index	Mean ± SD (N)	0.70 ± 0.20 (257/271)

Data on file at Veryan Medical

MIMICS 2

Baseline Angiography and QVA

Core Laboratory Data		N= 271 Subjects
Reference Vessel Diameter (mm)	Mean ± SD	5.2 ± 0.9 (269/271)
Lesion Type[1]	De novo	100% (271/271)
Lesion Location in Femoropopliteal Artery	Prox	11.5% (31/270)
	Mid	48.1% (130/270)
	Distal	40.4% (109/270)
Diameter Stenosis (%)	Mean ± SD	77.8 ± 18.3 (269/271)
Lesion Length (mm)	Mean ± SD	81.2 ± 38.4 (269/271)
Total Occlusion (%)		30.0 (81/270)
Calcification (%)	None - Mild	54.1 (146/270)
	Moderate - Severe	45.9 (124/270)
Run-off (%) - 1 or more patent tibial artery (<50% stenosis)		98.8 (237/240)

[1] *Investigator-reported*

Data on file at Veryan Medical

MIMICS 2

Index Procedure Data

		N= 271 Subjects
BioMimics 3D stents placed[1]	# Stents / N	305 / 271
	# Subjects with 1 stent	87.5% (237/271)
	# Subjects with 2 stents	12.5% (34/271)
Stented Segment Length[2]	Mean ± SD (mm)	112.3 ± 36.3 (269/271)
Diameter Stenosis[2]	Pre-stent % ± SD	77.8 ± 18.3 (269/271)
	Post-stent % ± SD	12.6 ± 7.5 (269/271)
Dissections[2]	No Dissection	97.8% (263/269)
	Type A-C	2.2% (6/269)
	Type D-F	0% (0/269)
Device Success		100% (271/271)
Technical Success		100% (269/269)

Technical Success: Core Lab determined ≤50% residual diameter stenosis (in-stent) at end of index procedure

Device Success: Successful delivery of System; placement of stent and retrieval of System

1 Investigator-reported

2 CoreLab-reported

Data on file at Veryan Medical

MIMICS 2

Primary Endpoint: Safety

Composite of CEC-adjudicated Major Adverse Events through 30 days, including death, any major amputation performed on the target limb, or Clinically-Driven Target Lesion Revascularisation

	Performance Goal	Rate (n/N) [95% CI]
Freedom from MAE through 30 days	>88%	**99.6%** (268/269) [97.7%, 100%]
Primary safety endpoint		**Achieved**

Data on file at Veryan Medical

MIMICS 2

Primary Endpoint: Effectiveness

Primary stent patency rate at 12 months.

	Performance Goal	Rate (n/N) [95% CI]
Primary stent patency	>66%	**73.1%** (182/249) [67.3%, 78.2%]
Primary effectiveness endpoint		**Achieved**

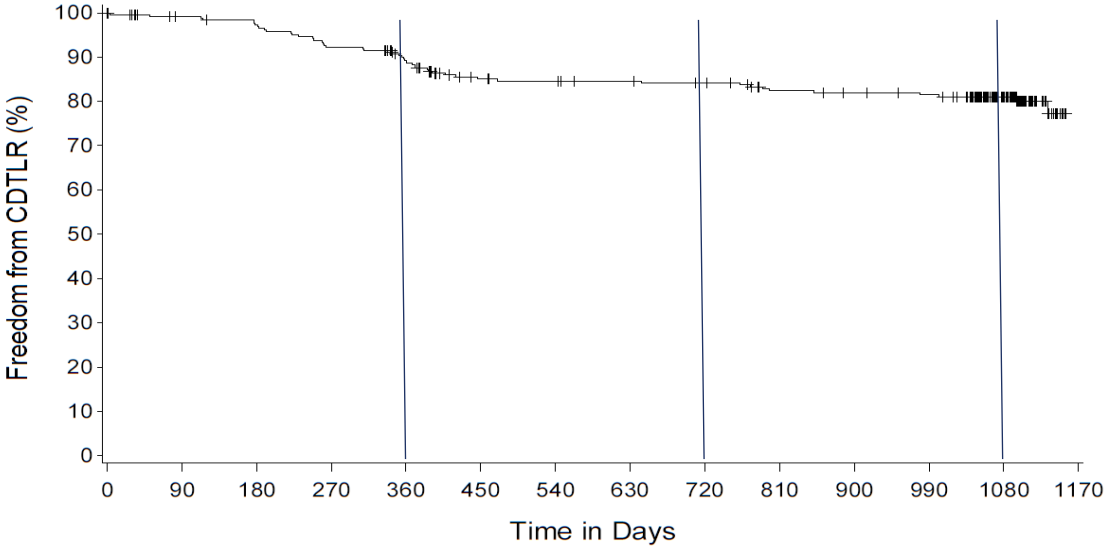
Patency was defined as no significant reduction in luminal diameter (< 50% diameter stenosis) since the index procedure.

Loss of patency was determined by an independent core laboratory when the peak systolic velocity ratio (PSVR) exceeds 2.0, or where angiography revealed > 50% diameter stenosis, or where the subject had a CDTLR.

Data on file at Veryan Medical

MIMICS *2*

Freedom from Clinically-Driven TLR at 3 Years = 81%



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

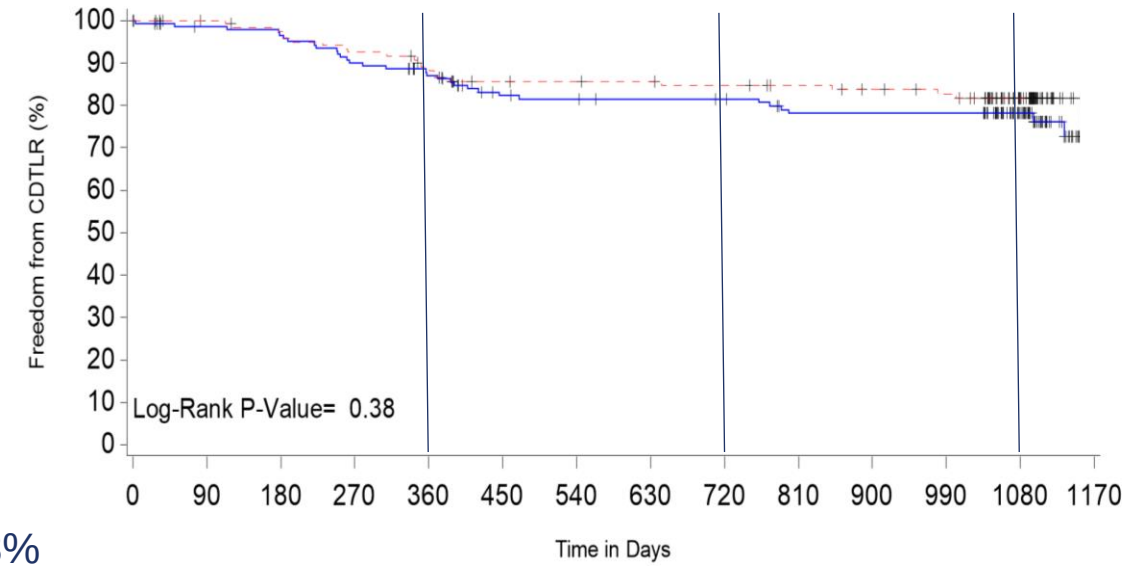
**Core Lab adjudicated, clinically-driven TLR with objective evidence*
Subjects are censored at their last known follow-up, or at time of study exit (withdrawal or lost to follow-up) or death

Data on file at Veryan Medical

MIMICS 2

Freedom from Clinically-Driven TLR at 3 Years
Lesion Calcification

Calcification % at baseline	None - Mild	54.1 (146/270)
	Moderate - Severe	45.9 (124/270)



None/Mild = 78%
Mod/Severe = 82%

No statistically significant difference between the groups

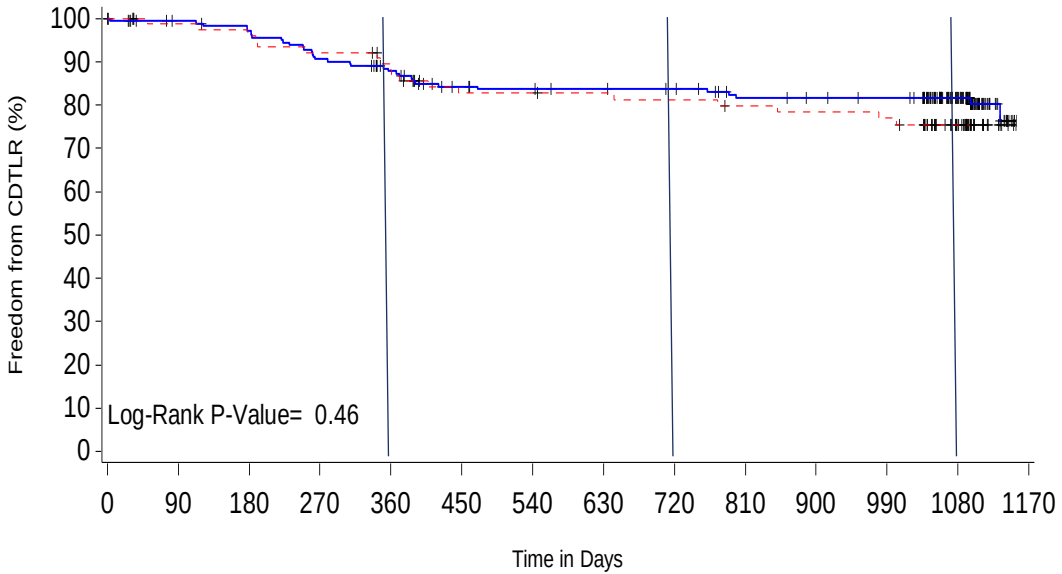
Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
Subjects who are PATENT at DUS follow-up are censored at the end of follow-up window

Data on file at Veryan Medical

MIMICS *2*

Freedom from Clinically-Driven TLR at 3 Years
CTO vs. Stenosis

Total Occlusion % at baseline	30.0 (81/270)



CTO = 76%
Stenosis = 82%

No statistically significant difference between the groups

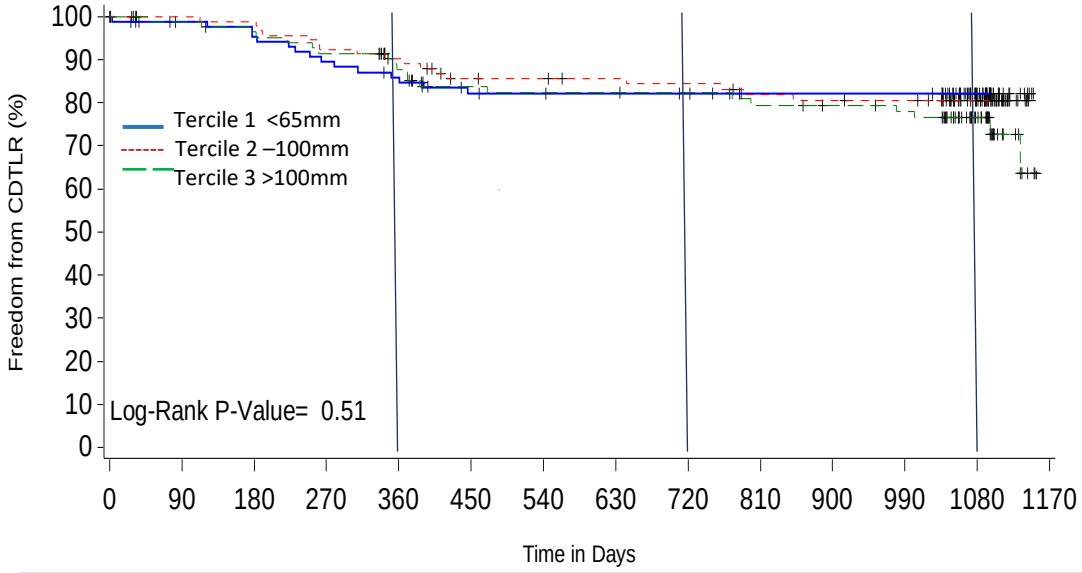
Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
Subjects who are PATENT at DUS follow-up are censored at the end of follow-up window

Data on file at Veryan Medical

MIMICS *2*

Freedom from Clinically-Driven TLR at 3 Years
Tercile of Lesion Length

Lesion Length (mm)	Mean ± SD	81.2 ± 38.4 (269/271)



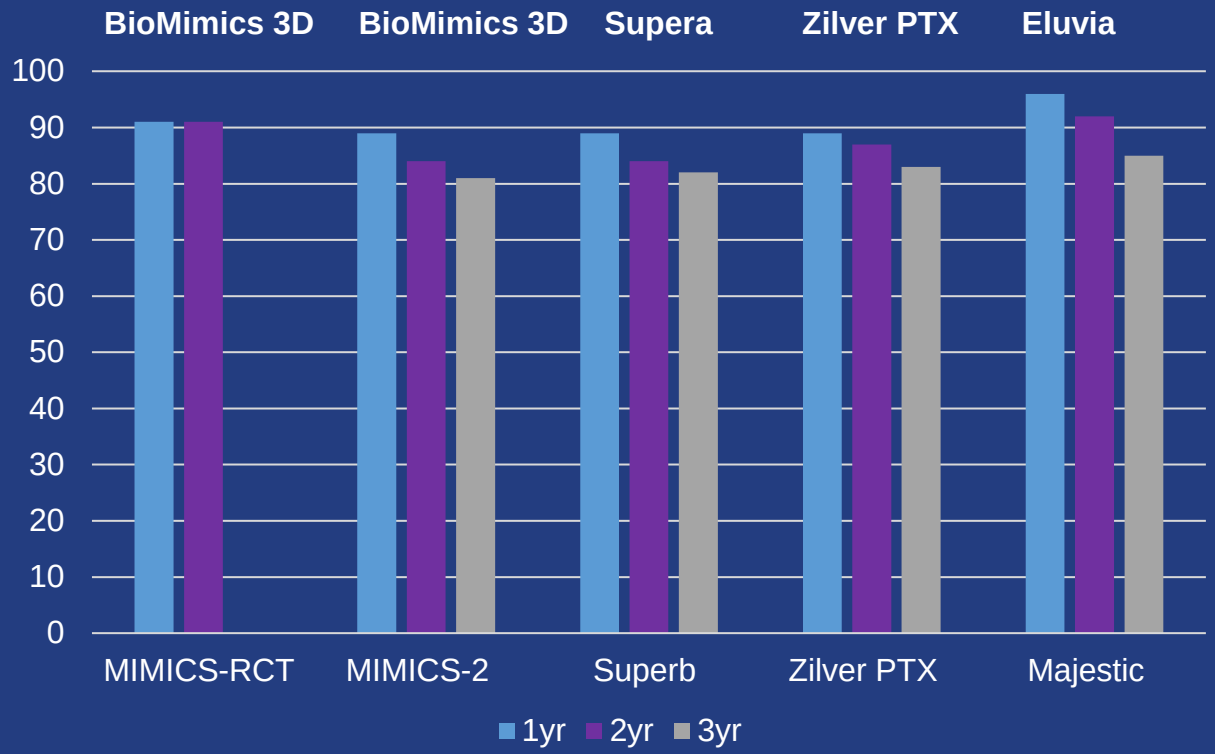
Tercile 1 = 82%
Tercile 2 = 81%
Tercile 3 = 77%

No statistically significant difference between the groups

Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
Subjects who are PATENT at DUS follow-up are censored at the end of follow-up window

Data on file at Veryan Medical

Mimetic/DES Study Comparisons-Freedom from CDTLR



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

MIMICS-2 Results

- **Reproducible, rigorous, high quality data from US, Japan and Europe**
- **81% freedom from CDTLR at 3 years**
- **Comparable outcomes to DCB, DES and Supera despite more challenging lesions and without the need for lesion preparation – providing ease-of-use simplicity and long-term benefits**
- **0% stent fracture**

BioMimics 3D

MIMICS-2 study shows continuing benefit of BioMimics 3D at ***3 Years***, even in challenging cases

Data on file at Veryan Medical

Conclusion

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

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

MIMICS3D *USA*

Post Approval Study

A prospective, multicenter 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.

- 40 sites across US
- 500 total patients
- CEC and Independent Core Lab
- First enrollments targeted for Q4 2020
- Coordinating Investigators:
  - Dr. Sahil Parikh
  - Dr. Miguel Montero Baker
  - Dr. Bob Beasley