Three-Year Data from the MIMICS-2 Study

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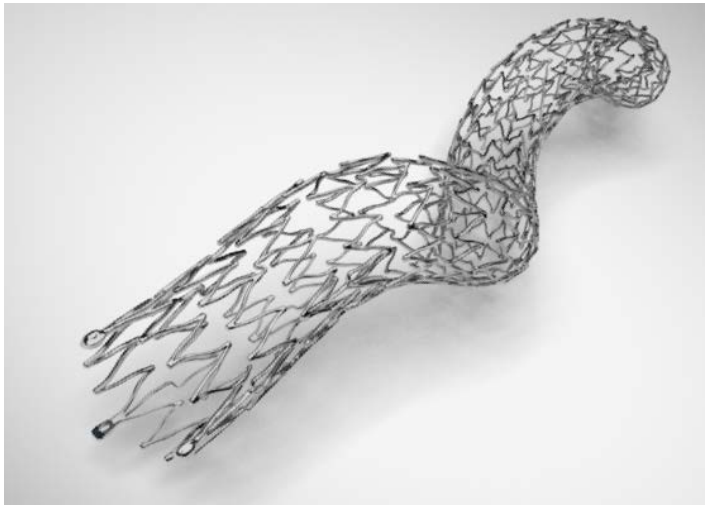
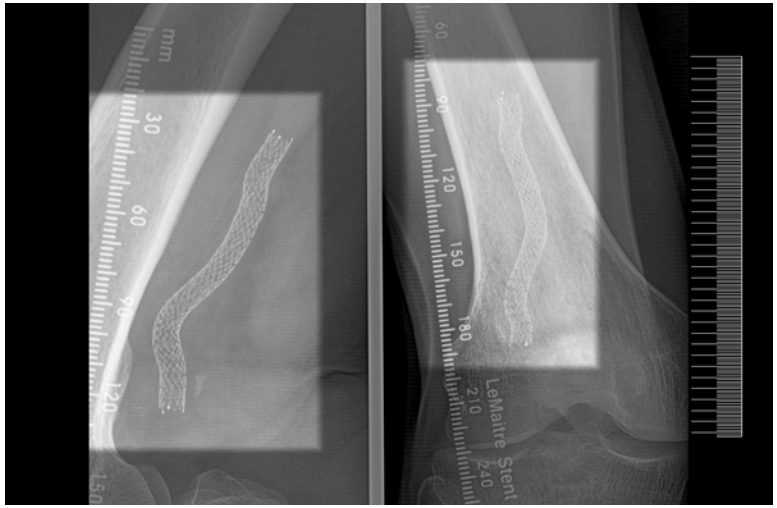
BioMimics 3D®: The Swirling Flow® Stent





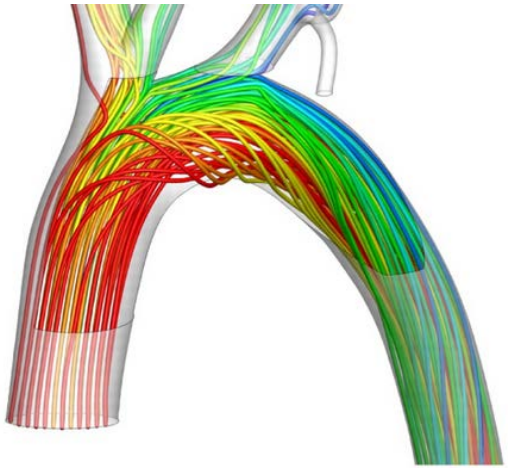
- Helical centerline
- Simple, accurate placement using standard delivery system

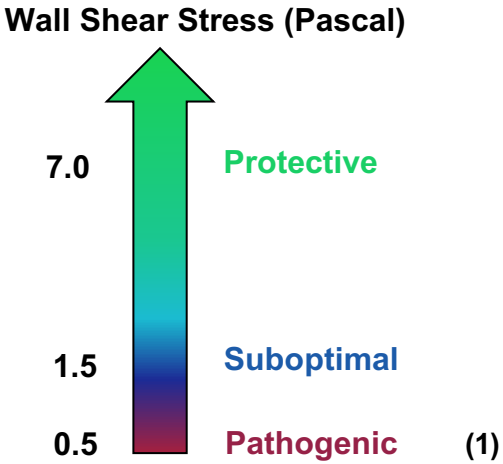
- Imparts non-planar curvature to stented femoropopliteal segment[1]
- Improved biomechanical performance compared to straight stents[1]
- 0% stent fracture Mimics 2 IDE

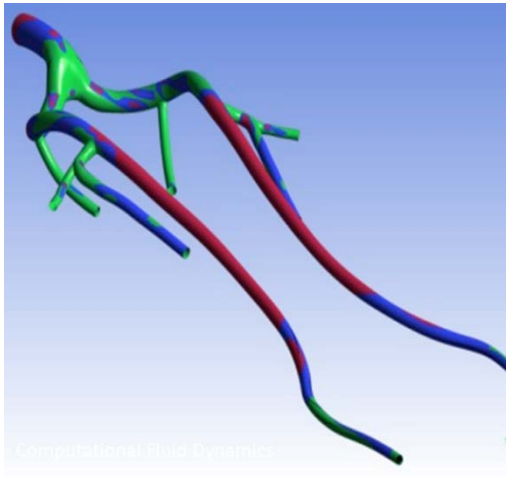
The BioMimics 3D Vascular Stent System has FDA, PMDA and CE Mark approval. Not available for sale in Japan
CAUTION: Federal law restricts this device to sale by or on the order of a physician..

1. Data on file at Veryan Medical

BioMimics 3D:Helical Centerline Promotes Swirling Flow





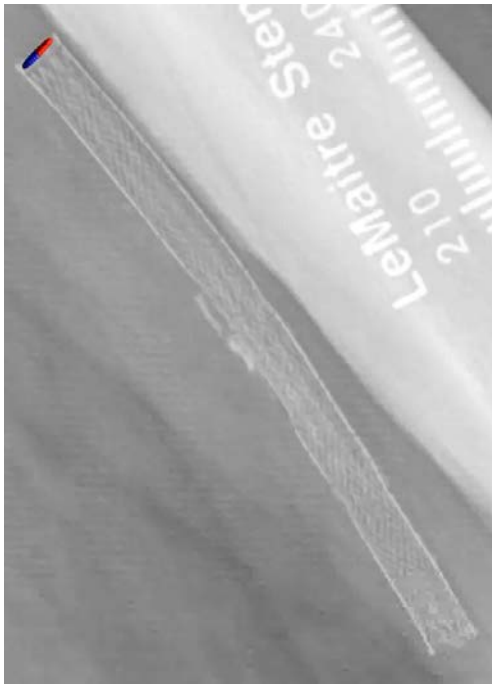


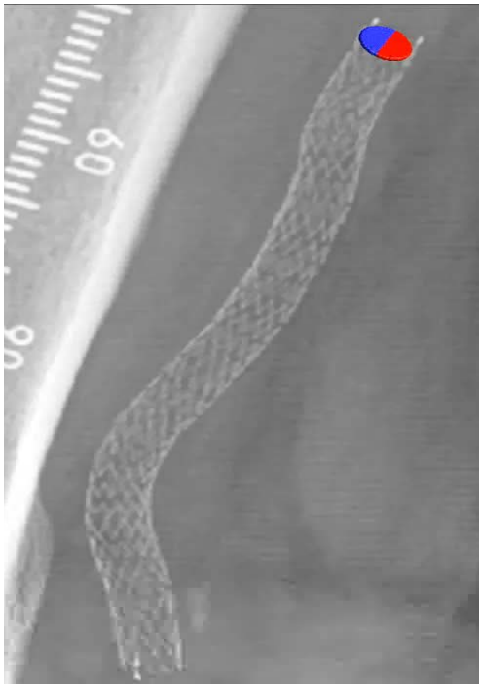
- Swirling flow increases wall shear stress (WSS) on endothelial cells
- WSS naturally protects against atherosclerosis and intimal thickening (2)
- Increased WSS has been shown (3) to provide an antiproliferative effect after stenting, without the need for a drug

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)**





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MIMICS 2

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

- **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: NCT02400905

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)

[1] Investigator-reported

[2] CoreLab-reported

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

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

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Primary Endpoints

MIMICS 2

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**

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**

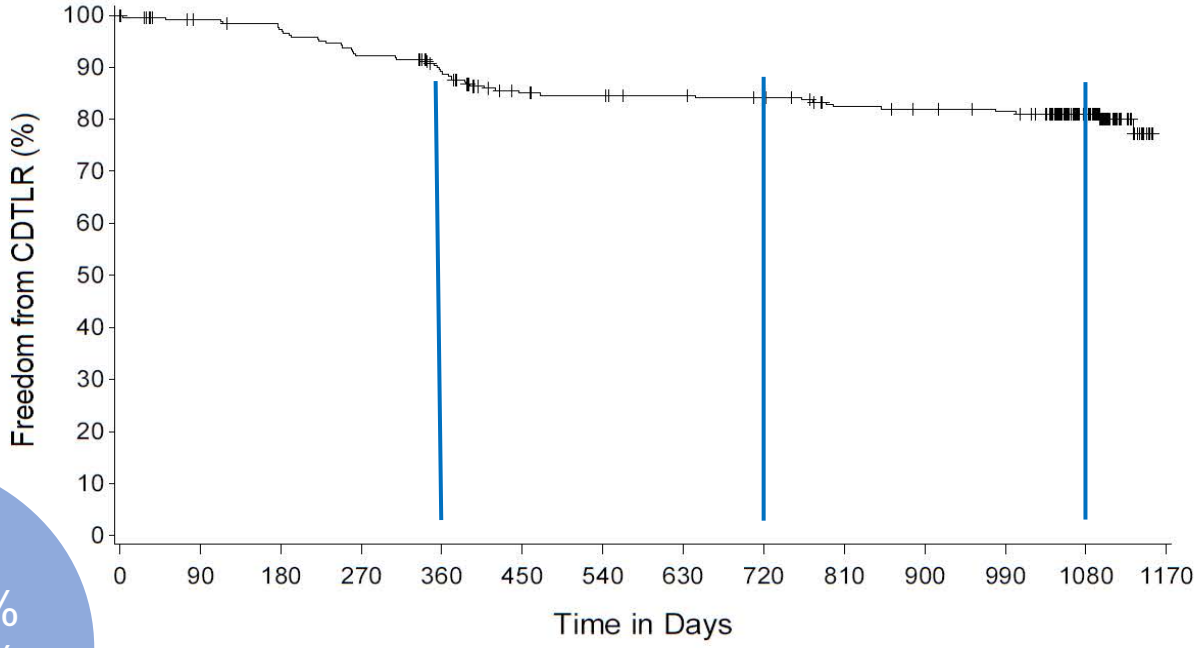
Patency was defined as no significant reduction in luminal diameter (< 50% diameter stenosis) since the index procedure.

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%



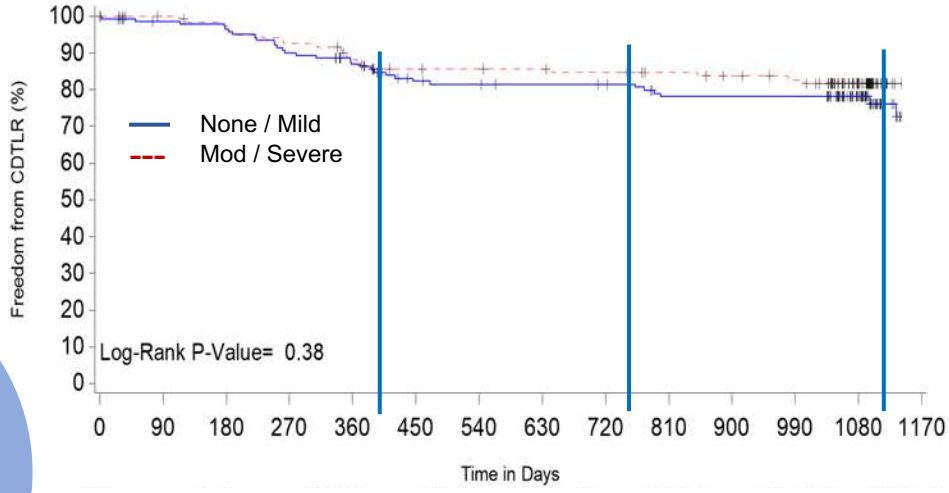
1-year = 89%
2-year = 84%
3-year = 81%

*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

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%

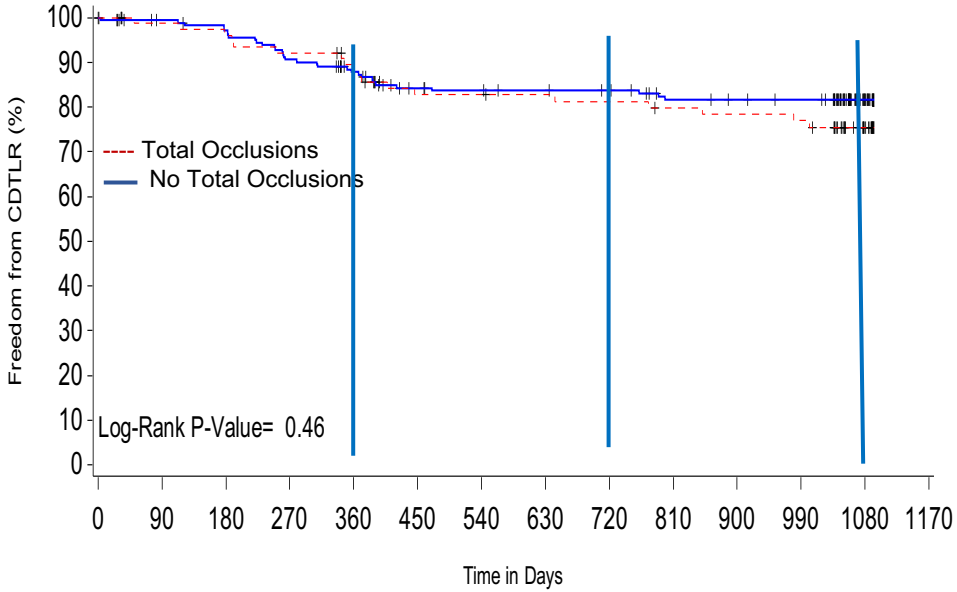
Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
Subjects who are PATENT at DUS follow-up are censored at the end of follow-up window

No statistically significant difference between both groups

Data on file at Veryan Medical

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

Total Occlusion % at baseline	30.0 (81/270)



CTO = 76%
Stenosis = 82%

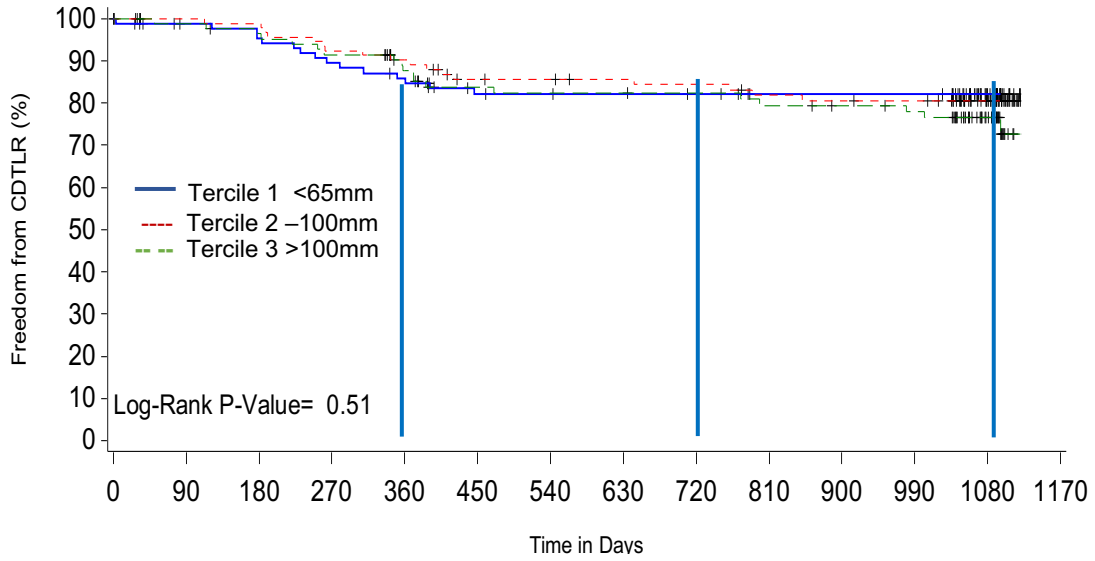
Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
Subjects who are PATENT at DUS follow-up are censored at the end of follow-up window

Data on file at Veryan Medical

No statistically significant difference between both groups

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%

Subjects are censored at their last DUS follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
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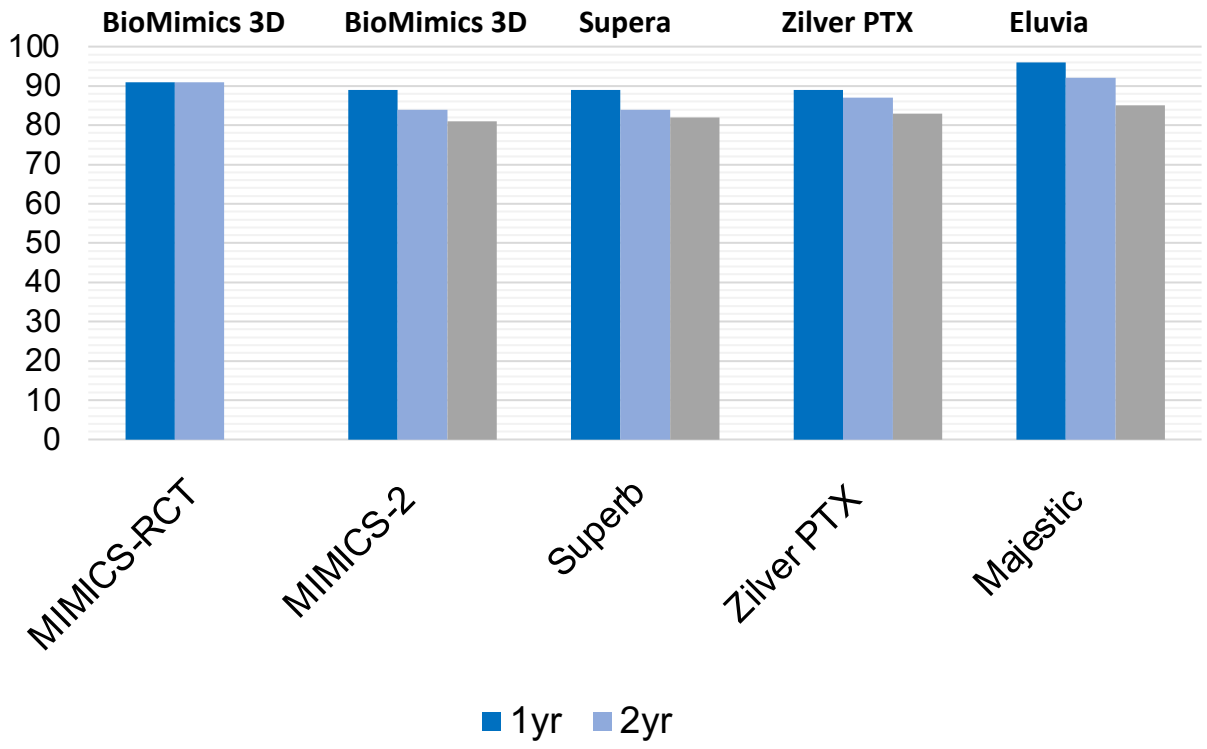
No statistically significant difference between groups

Data on file at Veryan Medical

Mimetic/DES Study Comparisons-Freedom from CDTLR



Comparable outcomes to DES and Supera in challenging lesions without the need for lesion preparation (Not head to head)

MIMICS-2 Results

BioMimics 3D

- 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 challenging lesions without the need for lesion preparation – providing ease-of-use simplici and long-term benefits (NOT HEAD TO HEAD)
- 0% stent fracture

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

Data on file at Veryan Medical