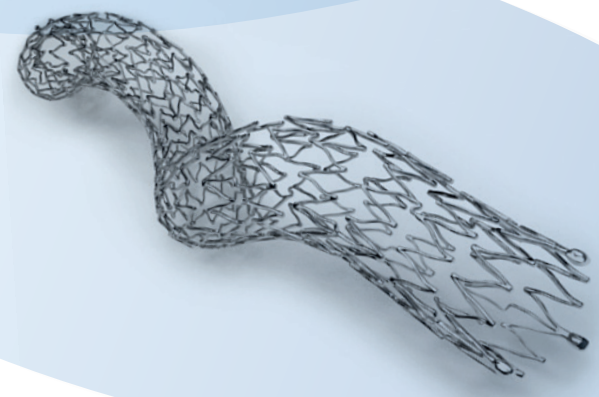
BioMimics 3D

The Swirling Flow® Stent

MIMICS *RCT*

Two-Year Results



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The Swirling Flow® Stent

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MIMICS *RCT* Two-Year Results

Summary

A randomized study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control. The study evaluated the performance of the BioMimics 3D Vascular Stent System in the treatment of diseased SFA/proximal popliteal arteries.

Baseline Patient Demographics		BioMimics 3D (N=50)	Control Stent (N=26)	P value
Age	Mean ± SD (N)	68 ± 10.4	67 ± 8.9	0.66
Gender	Male	66%	65%	1.0
Risk Factors	Diabetes Type 2 Insulin-dependent Hypertension Smoking current	26% 14% 88% 42%	42% 19% 85% 50%	0.16 1.00 0.73 0.63
Medical History	Carotid artery disease Iliac disease	10% 18%	8% 15%	1.00 1.00
Previous Interventions	Previous PTA Previous Stent	16% 2%	12% 8%	0.74 0.27
Rutherford category	1 2 3 4	6% (3/50) 14% (7/50) 74% (37/50) 6% (3/50)	4% (1/26) 4% (1/26) 88% (23/26) 4% (1/26)	1.00 0.74 0.27 1.00
Ankle Brachial Index	Mean ± SD (N)	0.60 ± 0.23 (N=45)	0.59 ± 0.17	0.83

Lesion Characteristics		BioMimics 3D (N=50)	Control Stent (N=26)	P value
Lesion Location	SFA SFA/Popliteal Popliteal	92% 6% 2%	77% 12% 12%	0.08 0.41 0.11
TASC II	A B C	42% 56% 2%	42% 58% 0%	1.00 1.00 1.00
Lesion Length	mm	66 ± 29	63 ± 28	0.66
Stent Length	mm	99 ± 30	88 ± 22	0.08
Occlusion	Total	44%	46%	1.00
Calcification	Moderate to Severe	52%	58%	0.81

Study Principal Investigator:
Thomas Zeller, MD
Bad Krozingen, Germany

Enrolment: N=76

Clinical Sites: 8 Germany

Follow Up: 2 Years

Primary Endpoints:

Safety - Freedom from major adverse events (MAE) defined as death, amputation and target lesion revascularization (TLR) at 30 Days.

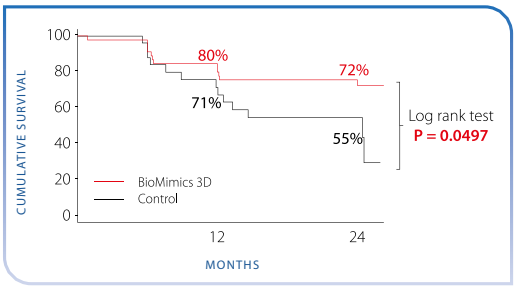
Effectiveness - Freedom from clinically driven target lesion revascularization (CDTLR) at 6 months.

2 Year Results

Patency

Significantly better primary patency (PSVR ≤2.0) through 2 years (P = 0.05)

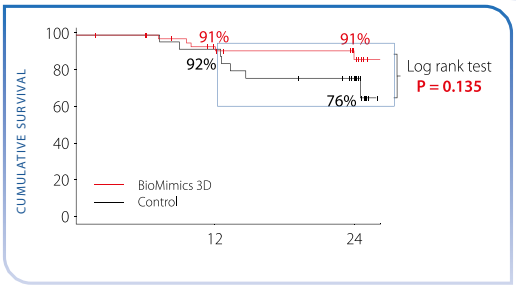
- **72%** for BioMimics 3D at 2 years

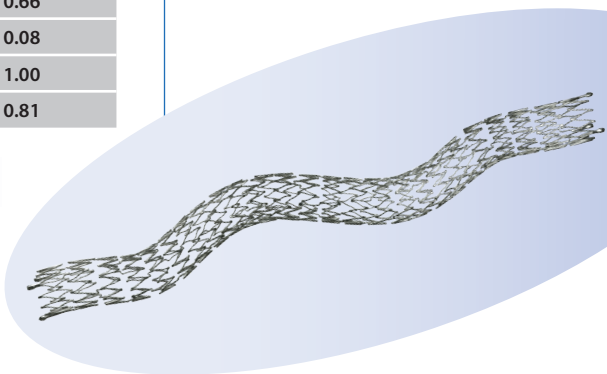


CDTLR

Freedom from CDTLR *

- **91%** for BioMimics 3D maintained out to 2 years





*CDTLR determined through event adjudication

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Conclusions[1]

- **Freedom from loss of Primary Patency at 2 years** - 72% for BioMimics 3D vs 55% for straight control stents (P=0.05). **
- **Freedom from CDTLR** - 91% for BioMimics 3D maintained out to 2 years.
- **Core lab X-ray imaging review confirmed 0% stent fractures at 2 years.**
- **Improvement in Rutherford Category** - 88% of patients treated with BioMimics 3D experienced an improvement of one or more Rutherford category at 2 years vs baseline.
- **Bi-planar X-ray imaging data indicated the ability of the femoropopliteal artery to adopt the three-dimensional curvature of the BioMimics 3D stent.**[1]
- **Computational fluid dynamic modelling (CFD) provided evidence of swirling flow within the stented segment and predicted zones of elevated wall shear.**[2]
  - Data indicate a correlation between primary patency and stent curvature.[3]
  - BioMimics 3D stented segments showed significantly greater curvature (P = 0.02) compared with the control.[4]
  - Elevated levels of swirling flow and wall shear were identified by CFD, which may explain the longer term patency protective effect seen with the BioMimics 3D Vascular Stent System.[5]

1750+

patients and growing

The MIMICS Clinical Program: 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.

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	• Randomized 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

MIMICS *RCT*

A randomized 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 Vascular Stent System.[6]

MIMICS *2*

A multicenter, 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.[7,8].

MIMICS 3D

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.

MIMICS 3D *USA*

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. MIMICS-3D USA will enrol a minimum of 500 patients in up to 40 sites across the United States.

** Straight control stents = 24/26 Bard LifeStent™; 1/26 Terumo Misago™; 1/26 Biotronik Pulsar

1,2,4,5 Data on file at Veryan Medical Zeller T et al; Circ Cardiovasc Interv. 2016;9

3 Zeller T. Oral Presentation VIVA 2014

6 Zeller T et al; Circ Cardiovasc Interv. 2016;9

7. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235

8. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

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Contraindications, warnings and precautions

CONTRAINDICATIONS

All customary contraindications for angioplasty must be considered when using the BioMimics 3D Vascular Stent System.
There are additional contraindications:

- Patients whose lesions cannot be crossed with a wire and/or balloon catheter and cannot be dilated sufficiently to allow passage of the delivery system.
- Patients with known intolerance to antiplatelet and/or anticoagulation therapies.
- Patients who are judged to have a lesion that prevents proper placement or deployment of the stent.
- A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion.
- Patients with a known hypersensitivity to nickel, titanium or tantalum.

WARNINGS

General Warnings

- DO NOT use after the "use by" date specified on the label.
- DO NOT use if the sterile package is opened or damaged or any information provided is obscured.
- DO NOT use if the device is damaged or if the stent is partially deployed.
- DO NOT reuse the BioMimics 3D Stent Delivery System (SDS) – this may lead to infection, contamination and non-performance.
- DO NOT re-sterilize the BioMimics 3D Vascular Stent System.

Deployment Warnings

- DO NOT force passage if resistance is encountered at any time during delivery of the SDS. This may cause damage to the stent, the SDS, or vessel or may lead to partial deployment. If the stent cannot be deployed, remove the entire delivery system (a partially deployed stent may require surgical removal).
- DO NOT push or advance the SDS forward (distally) once stent deployment has commenced.
- DO NOT attempt to recapture a partially deployed stent using the stent delivery system.
- DO NOT force removal of the delivery system if resistance is encountered at any time during withdrawal (post stent deployment); instead hold the bifurcated Luer stationary and retract the inner shaft until the SDS tip contacts the outer sheath marker and withdraw the system as one unit. Applying excessive force could result in loss of delivery system components or damage to the stent, delivery system, or vessel.

PRECAUTIONS

- The SDS is not designed for use with power injection systems.
- Always use an introducer or guide sheath for the implant procedure, to protect the access site.
- Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.
- The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label.
- Prior to deployment, ensure adequate distance between the proximal end of stent and the introducer/guide sheath to prevent deployment within introducer/guide sheath.
- This device has not been tested in patients who are pregnant or patients who may be pregnant.
- Take caution when considering whether to use this device in a vessel in which there may be a residual stenosis of 50% diameter or larger in the target vessel after the planned intervention.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.
- The stent is intended for use by physicians who have received appropriate training in endovascular intervention and placement of vascular stents.
- Failure to hold the Luer hub in a fixed position during stent deployment may result in partial or inaccurate deployment, incorrect deployed stent length or increased deployment forces.
- The reference vessel diameter should be measured accurately to reduce the possibility of stent migration or vessel damage due to incorrect sizing.
- The SDS is not intended for repositioning or recapturing a partially or completely deployed stent.
- If a second BioMimics 3D stent is required, deliver the most distal stent first to minimize the risk of stent dislodgement/damage or unsuccessful delivery of the second stent.
- If a second BioMimics 3D stent is placed in sequence and overlapped, the overlap should be less than 10mm. Overlapping more than two stents has not been evaluated.
- If the procedure requires additional non-BioMimics 3D stent placement, a nitinol stent should be selected. The risk of corrosion increases if stents of differing metals contact one another.
- Caution should be used when crossing the deployed stent with any ancillary devices.
- The BioMimics 3D SDS is not designed for guidewire exchanges. If a guidewire exchange is needed or desired, remove the delivery system first.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.
- The BioMimics 3D SDS is provided sterile for single use only and should be used by the end of the month of the "Use By" date printed on the package.
- After use the BioMimics 3D SDS is a potential biohazard. Handling and disposal should be in accordance with medical practice and local regulations.

For additional information please contact your local representative.

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