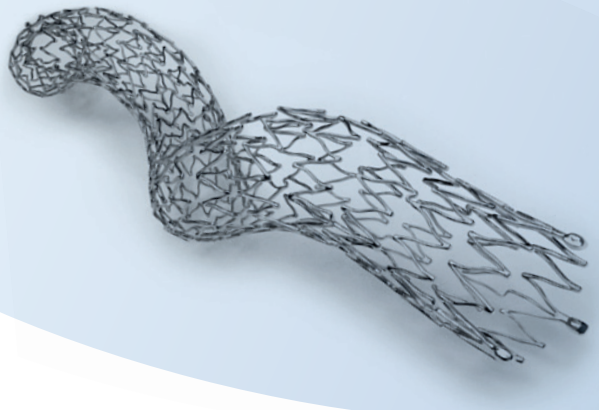
BioMimics 3D

The Swirling Flow® Stent

MIMICS 3D

Three-Year Results



Veryan

AN OTSUKA MEDICAL DEVICES COMPANY

BioMimics 3D
The Swirling Flow® Stent

Veryan

MIMICS 3D Three-Year Results

Summary

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.

24% of subjects enrolled in MIMICS-3D had Critical Limb Threatening Ischemia (CLTI)

Baseline Patient Demographics		N=507 Subjects
Age	Mean years ± SD (N)	70 ± 10 (507)
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)

38% of lesions had moderate to severe calcification

Baseline Lesion Characteristics		N=507 Subjects (518 lesions)
Reference Vessel Diameter	Mean ± SD (N)	5.5mm ± 0.7
Lesion Location	Mid to Distal SFA	86% (445/518)
	Prox. Pop	29% (150/518)
Diameter Stenosis	Mean ± SD	95% ± 8 (518)
Occlusions	Total	57% (294/518)
Lesion Length	Mean ± SD	126mm ± 91
Calcification	Grade 0	18% (91/516)
	Grade 1	30% (152/516)
	Grade 2	24% (126/516)
	Grade 3	15% (76/516)
	Grade 4	14% (71/516)

Study Principal Investigator:
Michael Lichtenberg MD, Arnsberg, Germany

Enrolment complete:
N=507

Clinical Sites: 23 Pan European

Follow Up: 3 Years

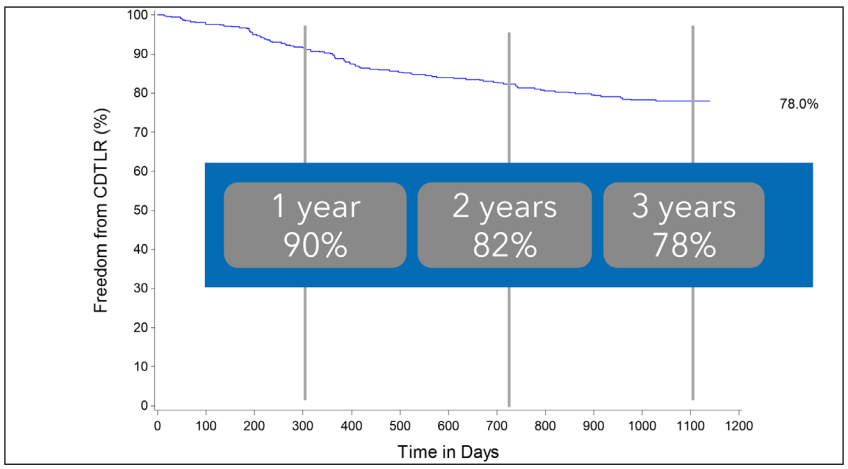
Primary Endpoints:

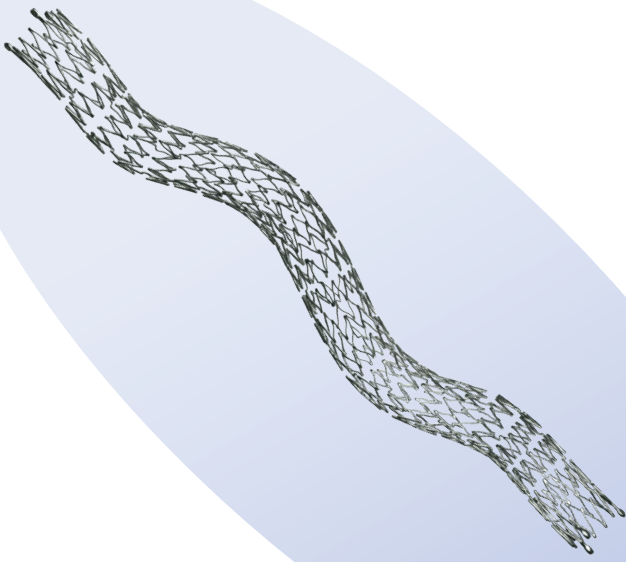
Safety – Composite of major adverse events (MAE), death, major amputation performed or clinically-driven target lesion revascularization (CDTLR) through 30 days.

Effectiveness – Freedom from CDTLR through 12 months.

KM Freedom from CDTLR at 3 years

Data from a challenging real-world population continue to demonstrate the therapeutic value of swirling flow in the BioMimics 3D stent.





Conclusions

MIMICS-3D data contribute real-world experience to the evolving database supporting the therapeutic value of swirling flow in the BioMimics 3D stent.

More challenging population than typically enrolled in registry studies:

- 24% CLTI; longer, more complex lesions; 50% with DCB.
- 78% Freedom from CDTLR at 3 Years.
- Rate of CDTLR was independent of concomitant DCB use, lesion calcification and stent length.

MIMICS Clinical Programme 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-eluting devices. [1]

The MIMICS Clinical Programme: 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.

1750+ patients and growing

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

MIMICS *RCT*

A randomised 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 stent.[2]

MIMICS *2*

A multicentre, 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.[3,4]

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, multicentre 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.

1. Data on file at Veryan Medical
2. Zeller T et al; Circ Cardiovasc Interv. 2016;9
3. Kenneth Rosenfield et al :N Engl J Med 2015;373:145-53. DOI: 10.1056/NEJMoa1406235
4. Michael D. Dake et al : Circ Cardiovasc Interv. 2011;4:495-504

The BioMimics 3D Vascular Stent System has CE Mark approval.

AN OTSUKA MEDICAL DEVICES COMPANY

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.

The BioMimics 3D Vascular Stent System is FDA approved.
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

For additional information please contact your local representative.

FOR SALES
T (844) 864 2001
E ussales@veryanmed.com

FOR ORDERS & CUSTOMER SERVICE
T (844) 864 2001
E us-customerservice@veryanmed.com
W veryanmed.com

PAM-256-version-3.0