

BioMimics 3D in my clinical practice

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Disclosure

Speaker name:

Michael Piorkowski

I have the following potential conflicts of interest to report:

- Consulting Veryan Medical, W.L.Gore
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

MIMICS Clinical Programme

The MIMICS Clinical Programme: An evolving database of the safety and effectiveness of the BioMimics 3D Swirling Flow® Stent

Gathering clinical evidence from a "real world" patient population from single de novo to complex, long and severely calcified lesions.



1250+
PATIENTS
AND
GROWING

N = 507
23 Sites
Pan-European

- Prospective Registry
- FU - 3 years
- 1 year complete

MIMICS-RCT

N = 50
8 sites - Germany

- Randomised controlled Trial
- FU - 2 years
- Completed

MIMICS-FH

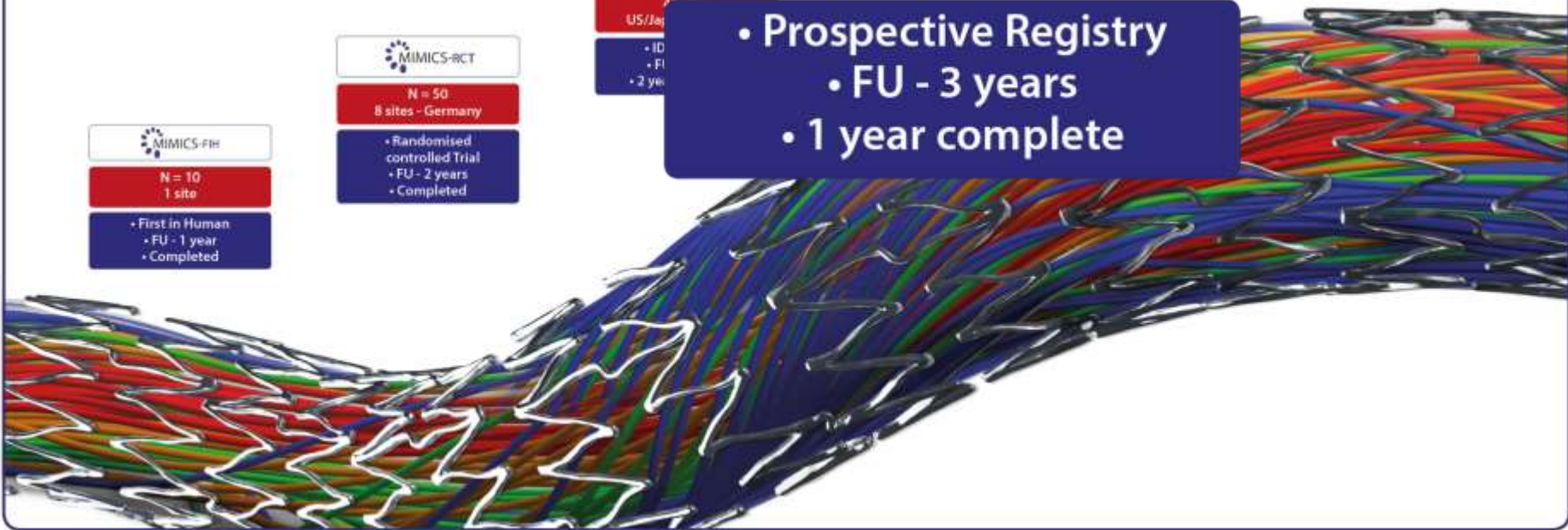
N = 10
1 site

- First In Human
- FU - 1 year
- Completed

N = 271

US/Jap

- ID
- FI
- 2 ye



MIMICS-3D Registry

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

- **PI: Michael Lichtenberg MD**
- **Primary Endpoints:**
 - **Safety:** composite of death, major amputation or CDTLR through 30 days
 - **Effectiveness:** freedom from CDTLR through 12-months
- **507** subjects enrolled at 23 European sites between 14-Sep-16 to 12-Jun-2018
- **Follow-up: 3 years**
- **Site 06:** CCB - Cardioangiologisches Centrum Bethanien, Frankfurt a.M. – PI: Michael Piorkowski

MIMICS-3D Registry: Site 06

Baseline Patient Demographics

		Enrolled Population N=75
Age	Mean years \pm SD (N)	69.97 \pm 9.2
Gender	% Male	74.67% (56/75)
Risk Factors	Diabetes Mellitus	38.67% (29/75)
	Smoker Current	40% (30/75)
Rutherford Category	0	0% (0/75)
	1	0% (0/75)
	2	4% (3/75)
	3	76% (57/75)
	4	6.67% (5/75)
	5	13.33% (10/75)
	6	0% (0/75)
Ankle Brachial Index	Mean \pm SD (N)	0.68 \pm 0.3

20% of subjects enrolled in MIMICS-3D by site 06 have Critical Limb Ischemia

MIMICS-3D Registry: Site 06

Baseline Lesion Characteristics

		Enrolled Population N=75 subjects (77 lesions)
Reference Vessel Diameter (mm)	Mean ± SD	5.25 ± 0.43
Lesion Location (%)	SFA, ostial	7.79% (6/77)
	SFA, proximal third	11.69% (9/77)
	SFA, middle third	36.36% (28/77)
	SFA, distal third	35.06% (27/77)
	Popliteal, proximal	9.09% (7/77)
Diameter Stenosis (%)	Mean ± SD	94.19 ± 7.96
Occlusions	Total	48.05% (37/77)
Lesion Length (mm)	Mean ± SD	81.82 ± 49.02
Calcification (%)	Grade 0	31.17% (24/77)
	Grade 1	35.06% (27/77)
	Grade 2	25.97% (20/77)
	Grade 3	7.79% (6/77)
	Grade 4	0% (0/77)

34% of Site 06 lesions had moderate to severe calcification

MIMICS-3D Registry: Site 06

Baseline Procedural Data

		Enrolled Population N=75
BioMimics 3D Stents	# stents/lesions	90/77
	1 stent	84.42% (65/77)
	2 stents	14.29% (11/77)
	3 stents	1.3% (1/77)
	4 stents	0% (0/77)
Stented Segment Length	Mean \pm SD (mm)	104.74 \pm 45.08
Diameter Stenosis	Post-stent % \pm SD	3.67 \pm 8.54
Other Target Lesion Treatments	Drug coated balloon	93.5% (72/77)
	Atherectomy	0% (0/77)

MIMICS-3D Registry: Site 06

Results

Technical Success	98.67% (74/75)
Procedural Success	98.67% (74/75)

Stent Fracture: 0%

MIMICS-3D Registry: Site 06

Results

Primary Safety Endpoint: 30 Days

Composite of major adverse events (MAE) comprising death, any major amputation performed on the index limb or clinically-driven target lesion revascularization through 30 days

TLR	0% (0/75))
Major amputation target limb	0% (0/75))
Death	0% (0/75)
Any MAE	0% (0/75))

MIMICS-3D Registry: Site 06 Results

**Primary Effectiveness Endpoint: 1 -Year
Freedom from clinically-driven target lesion
revascularization through 12 months**

Freedom from CDTLR 94.4% (67/71)

MIMICS-3D Registry: Site 06

1-Year Clinical Outcomes

Rutherford Clinical Category

Mean \pm SD	Baseline	30 days	12 months
RCC	3.29 \pm 0.75	1.36 \pm 1.22	1 \pm 1.13
Change from baseline RCC (matched pairs)	N/A	-1.93 \pm 1.03	-2.3 \pm 1.3
% subjects with improvement of >1 category compared to baseline	N/A	65.34%	75.72%
% subjects with improvement of >2 categories compared to baseline	N/A	34.67%	51.43%

MIMICS-3D Registry: Site 06

1-Year Clinical Outcomes

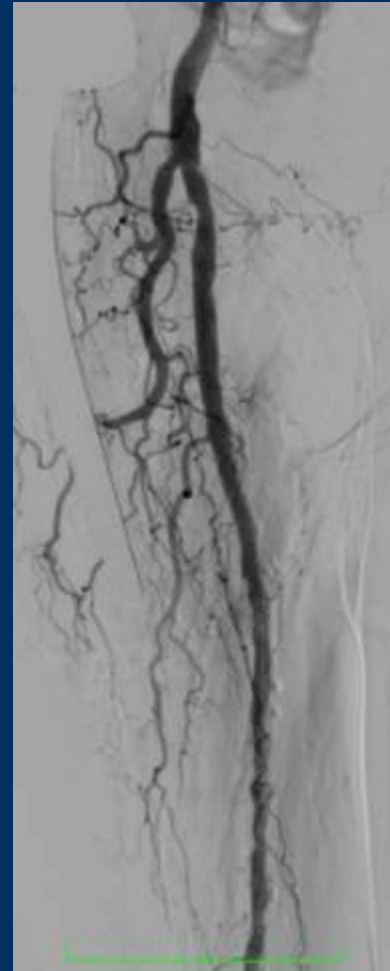
Target leg ABI

Mean \pm SD	Baseline	30 Days	12 Months
Target Leg ABI	0.68 \pm 0.3	1.09 \pm 0.24	1 \pm 0.23
Change from baseline ABI (matched pairs)	N/A	0.39 \pm 0.32	0.31 \pm 0.36

BioMimics 3D Case Study 1

- 88 year old female
- CLI gangrene D1 and heel right foot
- Atrial fibrillation
- Arterial Hypertension

Antegrade Recanalisation of PA
BioMimics 3D for PA AND distal SFA



BioMimics 3D Case Study 1

Th:

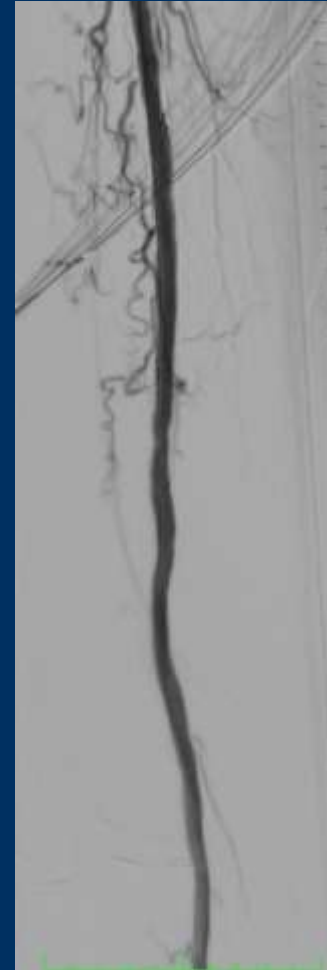
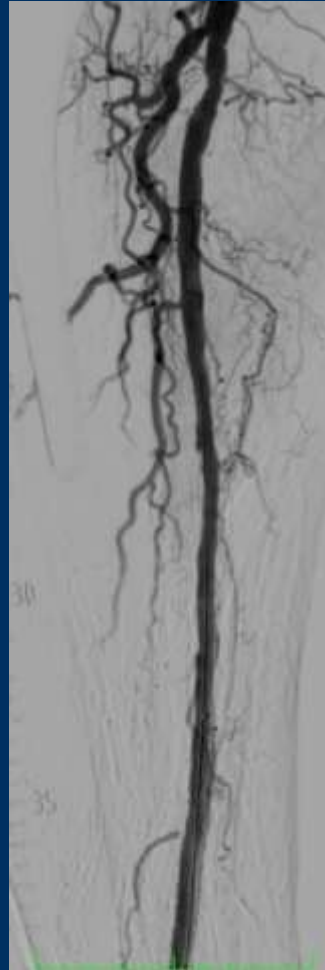
Antegrade Recanalisation of PA
BioMimics 3D for PA
AND medial/distal SFA

FU:

Wound healed after few weeks

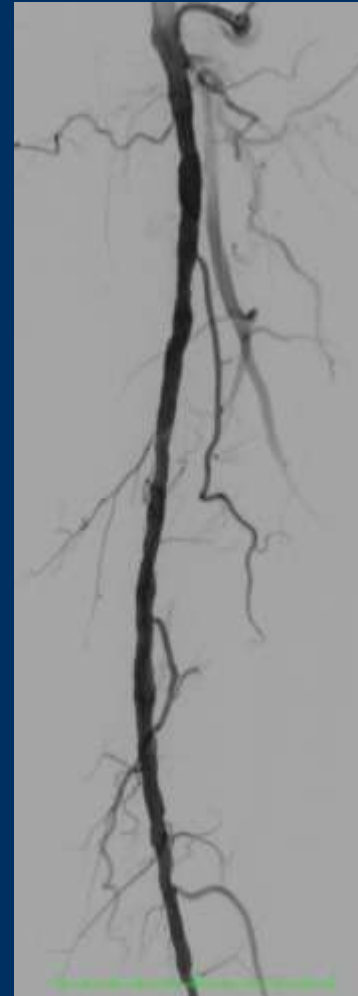
4y later:

Patient still free of symptoms



BioMimics 3D Case Study 2

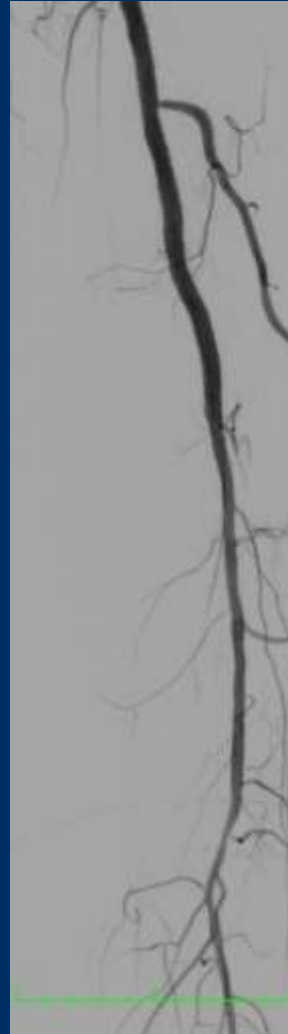
- 75 year old female
- ischemic rest pain
- Diabetes, art hypertension
- Hypercholesterolemia



BioMimics 3D Case Study 2

Th:
Antegrade Recanalisation of PA
BioMimics 3D for PA

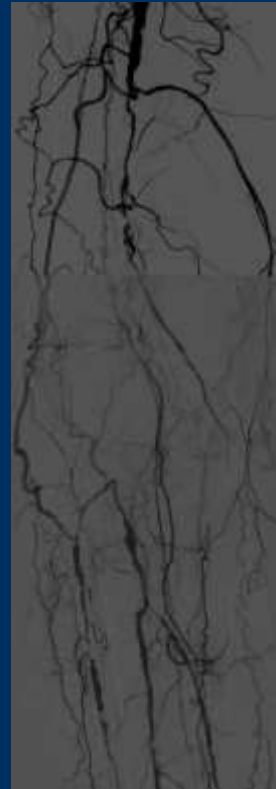
FU:
3 years later free of symptoms



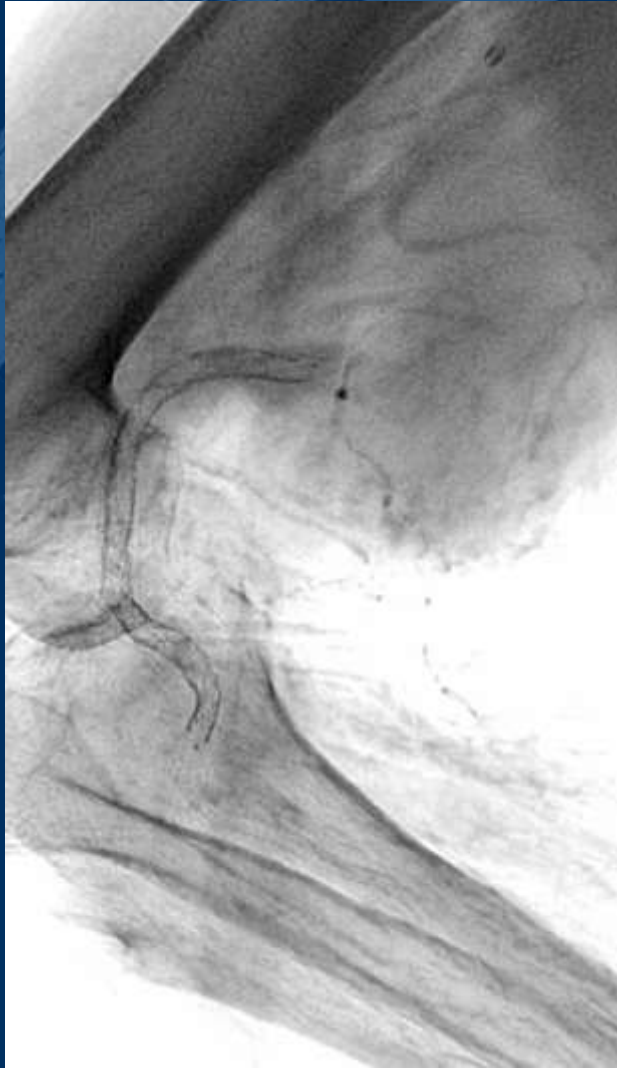
BioMimics 3D Case Study 3

- 87 year old male
- CLI gangrene D1 right
- Diabetes, renal failure,
- CAD w CABG

Antegrade and retrograde
Recanalisation of PA and TPT
BioMimics 3D for PA, DES for TPT



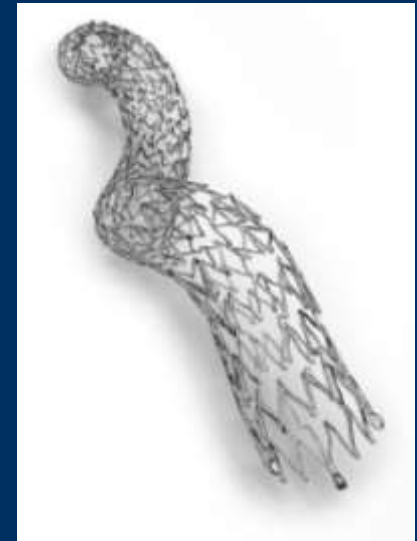
BioMimics 3D Case Study 3



MIMICS-3D Registry: Site 06

1-Year Conclusions

- More challenging population than typically enrolled in registration studies
 - 20% CLI; longer, more complex lesions
- 12-month freedom from CDTLR 94.4%
- Confirms that imparting a helical shape onto the vessel with BioMimics 3D and imparting swirling flow improves outcomes





Vielen Dank für Ihre Aufmerksamkeit!

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