

1-year results in unselected, real-world patients with the BioMimics 3D Swirling Flow stent in femoropopliteal lesions: The MIMICS-3D registry

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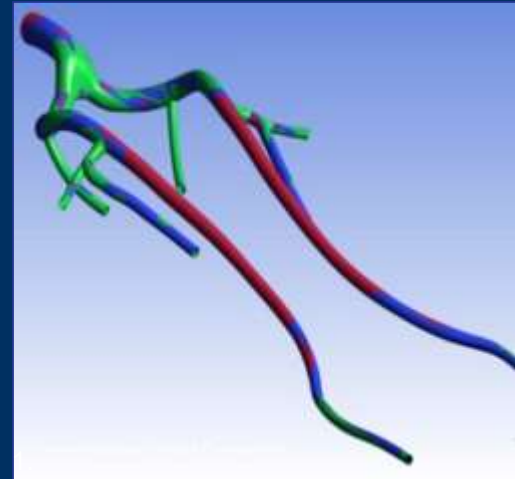
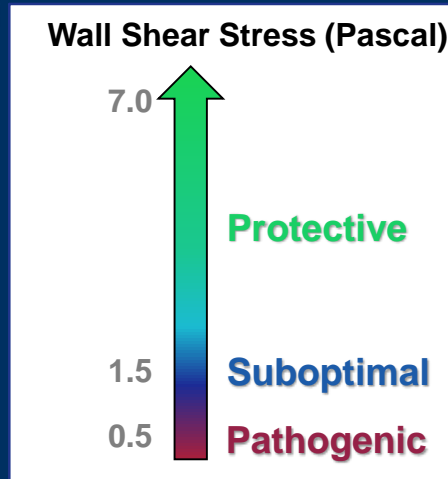
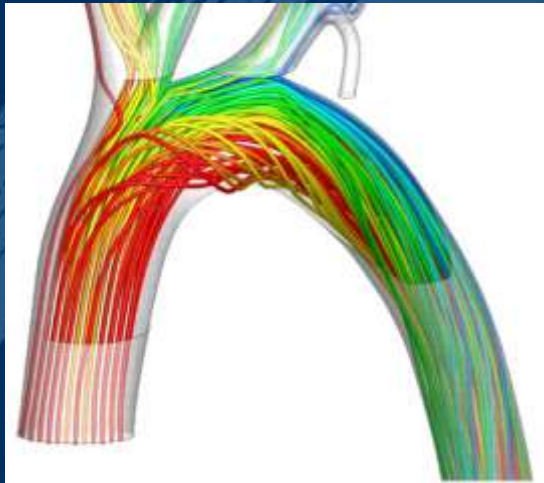
On behalf of the MIMICS-3D Investigators

Conflict of Interest Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

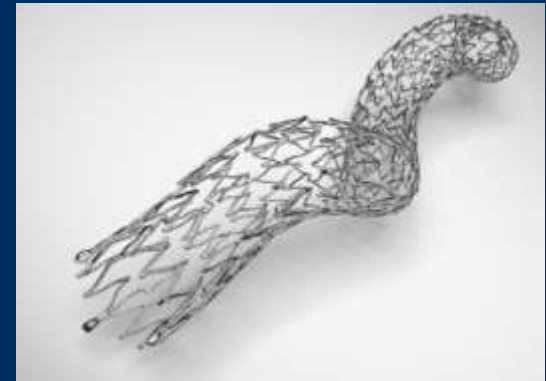
1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan
2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

Swirling Flow[®]: It's natural



- Non-planar vascular curvature promotes swirling blood flow
- Wall shear on endothelial cells naturally protects against atherosclerosis and restenosis
- Swirling flow provides an antiproliferative effect without the need for a drug

BioMimics 3D: The Swirling Flow Stent

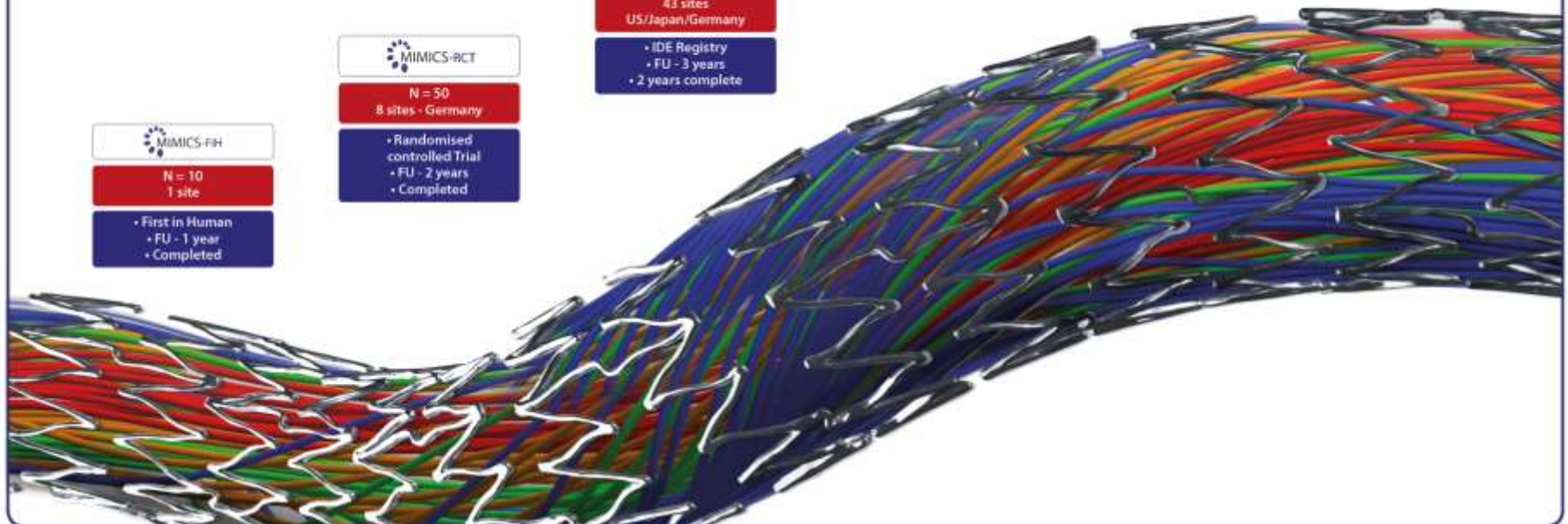


- Helical centerline
- Simple, accurate placement using standard delivery system
- Imparts non-planar curvature to stented femoropopliteal segment
- Improved biomechanical performance compared to straight stents

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.



Mimics RCT and MIMICS-2

What have we learned so far about the Swirling Flow stent?

- Randomized data from Mimics RCT showed patency superiority for BioMimics 3D over a straight nitinol stent and no CD-TLR between 12 and 24 months
- MIMICS-2 is an IDE study of 271 subjects with more complex lesions
 - CD-TLR outcomes comparable with drug eluting devices
 - Outcomes not affected by calcification, lesion length or number of stents

The Swirling Flow[®] Stent: delivering continuing benefit at **2 Years**, even in challenging cases

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MIMICS et seq

N = c. 400
multiple sites

- Physician initiated prospective and retrospective registries
- Enrolment ongoing

1250+
PATIENTS
AND
GROWING

MIMICS^{3D}

N = 507
23 Sites
Pan-European

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

MIMICS^{3D}

N = 507
23 Sites
Pan-European

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

MIMICS-2

N = 271
43 sites
US/Japan/Germany

- IDE Registry
- FU - 3 years
- 2 years 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

MIMICS-3D Registry

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

Principal Investigator: Michael Lichtenberg MD, Arnsberg, Germany

- 23 European investigators enrolled 507 subjects
 - 24% critical limb ischemia (RCC 4-6)
 - 38% moderate to severe calcification (PACSS 2 or 4)
 - 50% of lesions concomitantly treated with DCB
- Primary Endpoints:
 - 30-day CEC-adjudicated Safety: death, major amputation or CDTLR
 - 12-month Effectiveness: freedom from CDTLR

Longer, more complex lesions

Mean \pm SD (mm)	MIMICS-RCT	MIMICS-2	MIMICS-3D
Lesion Length	66 \pm 29	81 \pm 38	127 \pm 92
Stented Segment Length	99 \pm 30	112 \pm 36	131 \pm 79



- Sicker patients, longer and more complex lesions
- BioMimics 3D stent use 50:50 primary or bail-out to DCB
- Highly relevant population for a contemporary registry

MIMICS-3D Study Results

Primary Endpoints

- **30-day Safety:**
 - **99%** (486/492) Freedom from MAE
 - 2 TLR (Day 13, 18); 2 Amputations (Day 3, 8); 2 Deaths (closure system failure & leukemia)
- **12-month Effectiveness:**
 - **89%** (380/427) Freedom from CDTLR

MIMICS-3D:

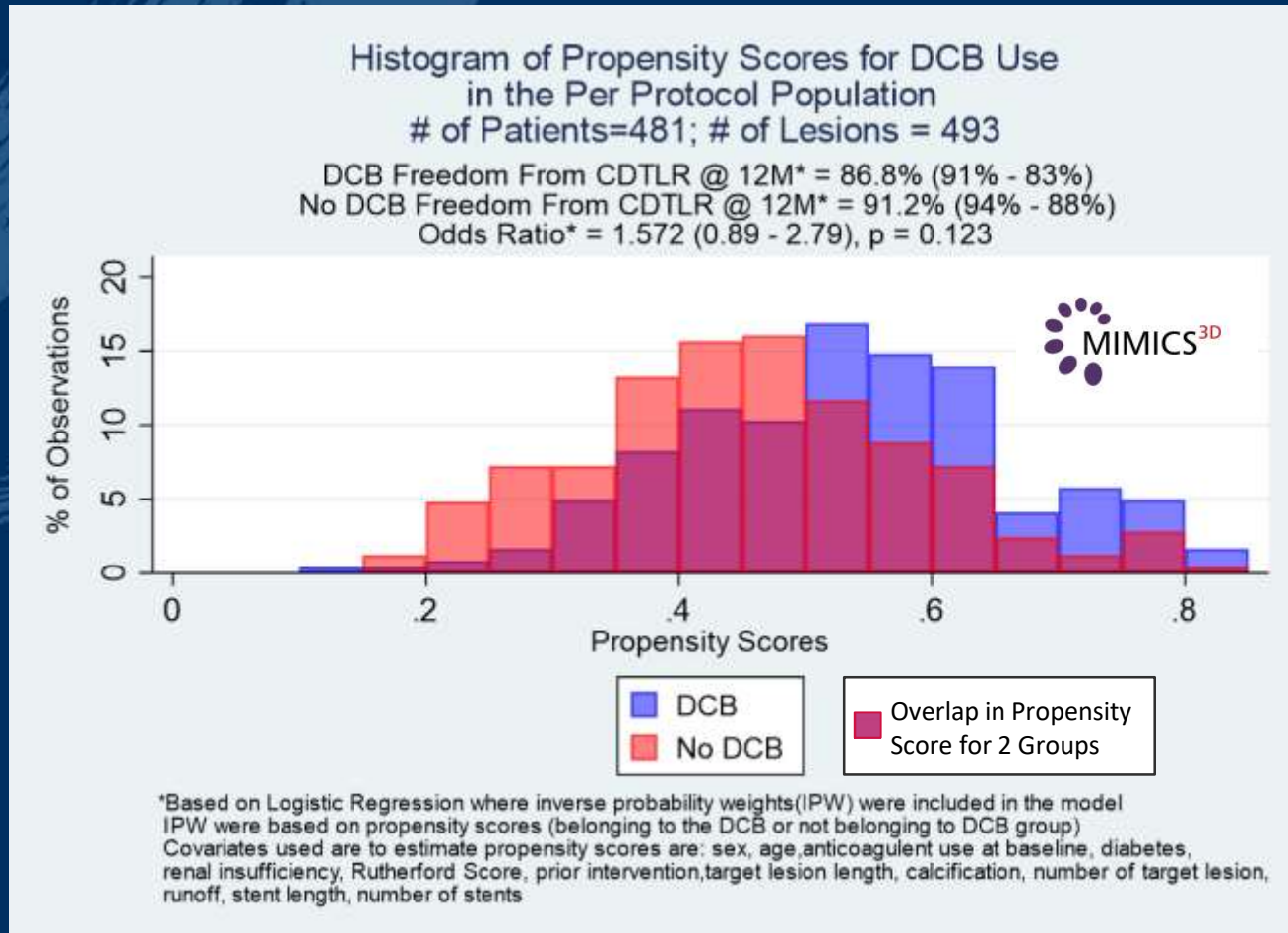


± Drug-Coated Balloon

	BioMimics 3D <i>with</i> DCB	BioMimics 3D <i>without</i> DCB	Overall result
Freedom from CDTLR at 12 months <i>(ITT population)</i>	89.5%	88.5%	89.0% [p > .88]

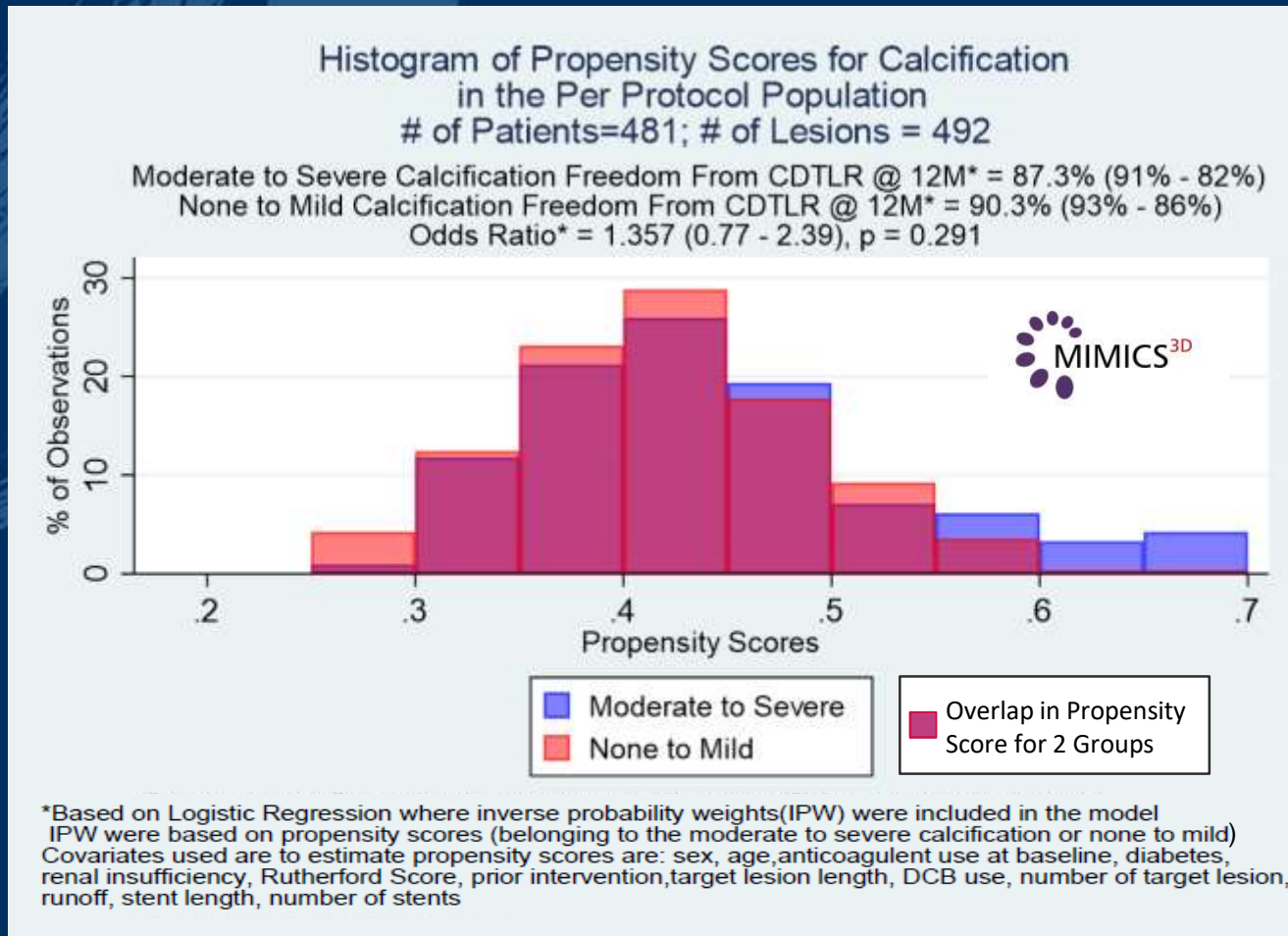
- Could imbalance in distribution of lesion characteristics or patient demographics be confounding?
- Propensity score analysis of per-protocol population adjusts for the difference between patient-level characteristics within selected subgroups

BioMimics 3D With / Without DCB



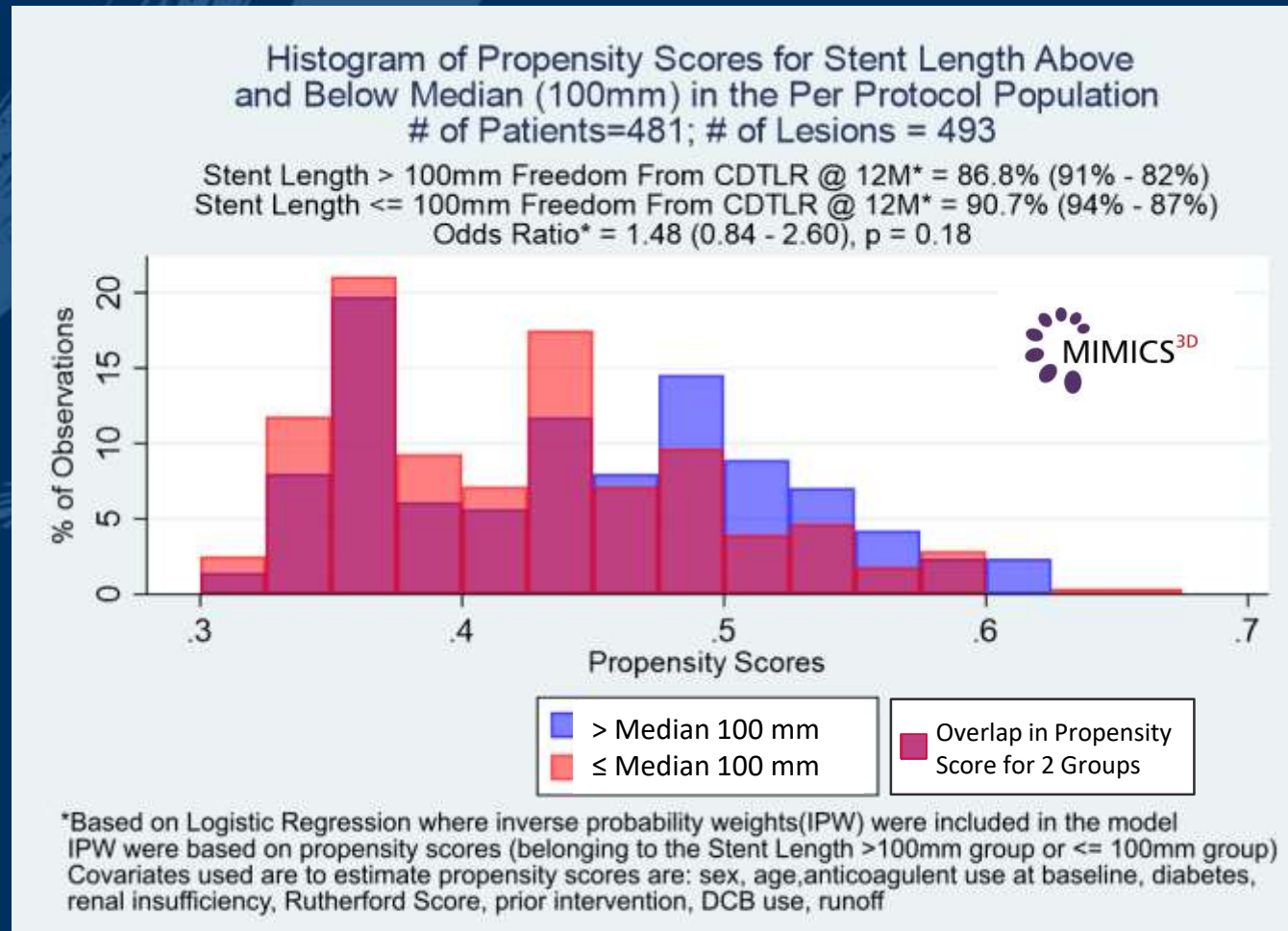
Propensity matched analysis reveals the rate of CDTLR in MIMICS-3D was independent of DCB use

Effect of Lesion Calcification



Propensity matched analysis reveals the rate of CDTLR in MIMICS-3D was independent of lesion calcification

Effect of Stent Length



Propensity matched analysis reveals the rate of CDTLR in MIMICS-3D was independent of stent length

MIMICS-3D Registry

- 12-month freedom from CD-TLR was 89% in a challenging real-world population
- Rate of CD-TLR was independent of concomitant DCB use, lesion calcification and stent length
- MIMICS-3D data contribute real-world experience to the evolving database supporting the therapeutic value of swirling flow in the BioMimics 3D stent
- 3-year follow-up continues



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