Should all stents promote swirling flow?

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Disclosure

Speaker name: Thomas Zeller

I have the following potential conflicts of interest to report:

- [x] Consulting to Veryan
- [ ] 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 Study - Randomized Control Trial

Lead-in Phase I
N=10

BioMimics 3D
N=50
- Death (1); withdrawn consent (3); lost to follow-up (2)
- Withdrawn consent (1); no re-consent to 24 month protocol (2)
- 12-Month assessments
  N=44/44
- 24-Month assessments
  N=41/41

Randomised Phase II
N=76

Control stent
N=26
- Lost to follow-up (1); missed 12-m visit (1)
- 12-Month assessments
  N=24/25
- 24-Month assessments
  N=22/22

*N=24/26 LifeStent (CR Bard)
Mimics Study: Target Lesion Primary Patency

Kaplan Meier Estimate of Survival from Loss of Patency
(defined as PSVR >2.0, or where angiography reveals >50% diameter stenosis; or adjudicated clinically driven TLR)

Log rank test
$P = 0.0497$
Mimics Study: TLR

Kaplan Meier Estimate of Survival from CDTLR
(Clinically-driven TLR determined through Event Adjudication)

What is the value of the longer term benefit?

- Improved patency improves clinical outcomes in claudicants.
- Incremental health economic benefits.

Log rank test
P = 0.135
Mimics Study: Longer Term TLR Benefit

12-Month Landmark Analysis (i.e. all subjects in study at Landmark)

Kaplan Meier Estimate of Survival from CDTLR
(Clinically-driven TLR determined through Event Adjudication)

Log rank test
P = 0.0263
What’s unique about the BioMimics 3D stent?

Complete SE
SHORT co-linear connectors

Zilver PTX
LONG co-linear connectors

LifeStent
SPIRAL connectors

Unique BioMimics 3D design:
SHORT + LONG connectors SPIRAL configuration
… and 3D helical centreline in Nitinol shape memory.

Promotes swirling flow to increase wall shear stress.

Improves biomechanical performance.
Biomimicry: Platform for Stent Design Innovation

Vascular system uses **helical curvature** to promote swirling blood flow that (1) protects vessels by increasing wall shear on endothelial cells and (2) promotes diffusion of Oxygen to the arterial wall.

Confidential
Pre-clinical evidence of swirling flow
Pre-clinical – Histology porcine model

Control

3D Helical
Pre-clinical - Importance of stent curvature

- 3D centreline curvature calculated for each stent
- Stents with greater curvature associated with reduced % stenosis

![Graph showing correlation between mean stent 3D curvature and average stenosis percentage. The R² value is 0.6817.](image)
Mimics Study: Stented Segment Curvature

- BioMimics 3D Stents show greater curvature in leg extension \((P = .019)\) and flexion \((P = .018)\).
  - **Hemodynamic benefit**
  - ...and increased curvature when leg flexed \((P < .001)\).
  - **Biomechanical benefit**
Mimics Study: Stent Curvature & Patency

- Calculated mean stent curvature in BioMimics 3D subjects via bi-planar X-rays
- Plotted maximum observed PSVR for each evaluable subject free from CDTLR at 24-months’ assessment visit (N=36/41).
- All stents with mean curvature >0.02 mm\(^{-1}\) remained patent (PSVR ≤ 2.0).
Mimics Study: Swirling Flow

Mimics X ray and ultrasound data: computational fluid dynamics

BioMimics 3D

Control
In the Mimics randomized clinical trial, compared to Control stents, **BioMimics 3D** stents generated:

- 55% more swirling flow** (P= 0.017)
- 18% more wall shear stress (P= 0.054)

** Student t-test

** Swirling flow = Steady state adaptation of helical flow defined by Gallo J. Biomech. 45, (2012), 2398-2404
In subjects treated with BioMimics 3D stents:

- Stent curvature was independent of the level of vascular calcium present.

Mimics Study: Calcium & Stent Curvature

\[ P = 0.15 \]
Mimics Study: Calcium & Primary Patency

In subjects treated with BioMimics 3D stents:

- Moderate/severe calcium present at baseline in 52% of BioMimics 3D subjects.
- Primary patency is independent of baseline calcium through 24 months.

Log rank test
P = 0.73
Mimics Study: Conclusions

- Freedom from loss of primary patency at 24 months for BioMimics 3D stents was superior to straight control stents.

- In patients treated with BioMimics 3D Stent System:
  - No change in KM rate of CDTLR from 12 to 24 months.
  - No stent fractures.

Mimics Randomized Controlled Study provides confirmation of patency-protection using a unique biomimetic stent design:
  - Curvature imposed by the helical centerline of the BioMimics 3D stent is independent of vascular calcium at baseline.
  - Primary patency is independent of baseline calcium through 24 months.
  - All BioMimics 3D stents with mean curvature >0.02 mm\(^{-1}\) remained patent, and free from CDTLR, through 24 months.

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  - Mimics study data indicate instent swirling flow could be beneficial to maintain longer term patency
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