How new stent design can improve outcome: the BioMimics story

H. Robert Smouse M.D.
Disclosure

Speaker name:

**H. Robert Smouse M.D.**

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Stent Design Objective

Provide radial support to the vessel to optimize patency

- Minimise Stent Fracture
- Reduce In-Stent Restenosis
- Optimise Biomechanical Compatibility
Stent Fracture
Stent Fracture

Scheinert (2005)¹
• Established a link between stent fracture and patency

STELLA study (2012)².
• Mean lesion length 220 ± 160 mm
• 16 fractures in 42 limbs (38%) or 90 stents (17.7%)

Vibrant study (2009)³.
• Fracture rate in BMS 32% @12 mths

Stent Fracture Risk factors
• Stent flexibility and length
• Elongation or overlapping
• Anatomical location

3. VIBRANT Study; 12-month data presentation; G Ansel VIVA 2009
Loading Environment

Dominant loads in SFA/Pop
- Axial compression
- Bending
- Torsion
Variations in Stent Design

Laser cut Nitinol stents have different configurations of ring and connecting struts

**Connectors:**
- Short co-linear
- Longer co-linear
- Spiral

**Optimised configuration:**
SHORT + LONG connectors in SPIRAL configuration

**BioMimics 3D Stent Pattern**

... with 3D helical centerline
Importance of Good Stent Design

More flexible stent designs are more able to move with the native vessel.

**Nitinol Stents Evaluated**

- Veryan BioMimics 3D
- Medtronic Complete SE
- Cook Zilver
- Bard LifeStent

**Straight Stent**

**BioMimics 3D Stent**

Early stent designs fractured because they were not designed for the specific loading environment of the SFA/Pop.

Clinical studies utilising stents designed for use in the SFA/pop (e.g. BioMimics 3D: Mimics Study)\(^1\) have reported 0% fracture rates.

*Data on file at Veryan Medical
\(^1\) Zeller et al Circulation 2016
Biomechanical Compatibility
In older people, the SFA and popliteal arteries are less likely to shorten as leg bends.

Cheng et al. JVIR 2010
Biomechanical Compatibility

Prior to Treatment

Post Treatment – Straight Stent

Tamashiro et al, 2015
Stent Placement - Managing Vessel Slack

Reported by:

Zocholl 1990

21 year old

78 year old

ARENAs (2005)

Wensing et al. (1995)

Smouse (2005)
A stent that can shorten naturally, accommodating the deformations of the SFA/Pop, may provide the most favourable solution.
Stent Placement - Managing Vessel Slack

Veryan BioMimics 3D

Straight Stent
In-Stent Restenosis
In-Stent Restenosis

Multiple injury sources stimulate intimal hyperplasia
- Predilatation and lesion preparation
- Biomechanical incompatibility
- Stent fracture
- Haemodynamic disturbance

Haemodynamic risk factor for restenosis
- Iliac arteries naturally generate athero-protective swirling flow
- Straight stents can straighten the SFA which can exacerbate the loss of protective swirling flow in diseased SFA, risking:
  - Pathogenic wall shear stress
  - Diffuse restenosis patterns

2. Ni Ghrialailais, et al. JEVIS, 2016,
Swirling Flow

3D helical technology proven in a pre-clinical model
30-day histology: 45% reduction in neointimal thickness (P < 0.001)\(^1\)

Swirling Flow

Transverse ultrasound: probe orthogonal to vessel measures Doppler shift of axial flow

- Straight Stent: No axial flow component
- 3D Helical Stent: Two direction axial flow (laminar swirling flow)
Mimics Clinical study
Unique 3D Stent architecture generates swirling flow, raising wall shear to limit intimal hyperplasia

1. Zeller T Oral Presentation VIVA 2014
MIMICS Study: BioMimics 3D Stent Geometry

AP & Lateral X-ray Images Combined to Yield 3D Curvature CAD Model

Curvature evident on 2 view X-rays (AP & lateral) combined to reveal the actual geometry of the BioMimics 3D stented segment.
MIMICS Study: BioMimics 3D Stent Geometry

The 3D geometry model and Computational Fluid Dynamics (CFD) combined to map swirling flow and wall shear
MIMICS: Mapping Wall Shear to Swirling Flow

Using bi-planar X-ray imaging data from the MIMICS Study and CFD modeling to predict swirling flow vectors and map wall shear.

Curvature Promotes Swirling Flow

Swirling Flow Increases Wall Shear
BioMimics 3D: Impact of Stent Design on Outcome

- Freedom from loss of primary patency at 24 months (72%) significantly better than the straight control stent (55%)

- In patients treated with BioMimics 3D:
  - CDTLR rate unchanged from 12 to 24 months
  - No stent fractures

Mimics study¹

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