Design principles of the BioMimics 3D stent and why it’s ideal for fempop intervention

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☒ 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
- Improve Haemodynamic Disturbance
- 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

Extension

90° Flexion

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.

% Axial Shortening*:

- BioMimics 3D: 4.4%
- Zilver: 3.2%
- Complete SE: 2.9%
- LifeStent: 2.5%

*Data on file at Veryan Medical
Biomechanical Compatibility
In older people, the SFA and popliteal arteries are less likely to shorten as leg bends.
Stent Placement - Managing Vessel Slack

Reported by:

Zocholl 1990

21 year old 78 year old

ARENA (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
Haemodynamic Disturbance & 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 Ghriallais, et al. JEVT, 2016,
3D helical technology proven in a pre-clinical model
30-day histology: 45% reduction in neointimal thickness (P < 0.001)\textsuperscript{1}

Swirling Flow

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

- No axial flow component
- Two direction axial flow (laminar swirling flow)

Swirling Flow

Low    High
**Swirling Flow**

**Mimics Clinical study**
Unique 3D Stent architecture generates swirling flow, raising wall shear to limit intimal hyperplasia \(^1\)
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
Using bi-planar X-ray imaging data from the MIMICS Study and CFD modeling to predict swirling flow vectors and map wall shear.
BioMimics 3D: Impact of Stent Design on Outcome

**Mimics study**

- 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

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