Consequences of SFA stenting and how to overcome them

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Disclosure

Speaker’s name: Peter Goverde

- I have the following potential conflicts of interest to report:

  - Consulting:
    Abbott Vascular, Angioslide, Bard Peripheral, Cardionovum, Cordis J&J, IMDS, Maquet Getinge group, Stille SA, Ziehm Imaging
Which factors can determine the boundaries of current femoropopliteal treatment?

- Complexity of the lesion
- Anatomy & characteristics of the vessel
- Access to the lesion
- Used material
- Effects of the intervention to the treated vessel
- etc
Forces acting in the SFA

SFA Challenges

- Shortening
- Increased Curvature
- Twist
- Flexion

Forces acting in the SFA & popliteal artery

EXTENSION
RADIAL COMPRESSION
AXIAL EXTENSION
AXIAL COMPRESSION
FLEXION / KINKING
TORSION
SFA boundaries and therapeutical consequences

- SFA poses unique anatomic challenges
- Femoral atherosclerosis is histologically unique forming long, eccentric lesions
- Arterial motion is dynamic and varies with age/disease/lesion and personal habit
- Arterial motion causes local biomechanical forces
- These biomechanical forces pose a significant challenge

Hypothesis:
- Technique matters
- Ideal mechanical implant would mimic rather than resist the vessel
Stent design should respond to natural anatomic forces

- **Goal**: Allow arteries to maintain as much natural behavior and function as possible while addressing atherosclerotic issues
- **Dynamic forces** of the SFA require a **compliant stent** to minimize chronic vessel injury and stresses on stent that can lead to fracture
  - Mismatch can lead to stresses and fracture on stent or injury to the vessel
  - Energy should transfer to either stent or vessel
  - Stent should mimic rather than resist the vessel

The oversizing Self-Expanding Stents leads to Chronic Outward Force : COF

- Self-expanding stents are oversized to the vessel to assure wall apposition
- Oversizing causes the stent to exert COF on the vessel
- Not all SES have the same COF
- Too much COF may lead to chronic stent-vessel irritation

Late Stent Expansion and Neointimal Proliferation of Oversized Nitinol Stents in Peripheral Arteries

Chronic Outward Force

Outward force exerted on vessel by self expanding stents to achieve preset diameter

Preclinical animal model.
Oversizing can lead to Chronic Stent-Vessel Irritation

<table>
<thead>
<tr>
<th>Optimal Oversizing</th>
<th>Medium Oversizing</th>
<th>High Oversizing</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3 – 6.2 mm</td>
<td>6.2 – 5.0 mm</td>
<td>5.0 – 4.2 mm</td>
</tr>
<tr>
<td>(1.1-1.3)</td>
<td>(1.3-1.6)</td>
<td>(1.6-1.9)</td>
</tr>
</tbody>
</table>

Example: 8 mm stent

Oversizing can lead to Chronic Stent-Vessel Irritation: in vivo examples
Chronic Stent-Vessel Irritation: in vivo examples
Chronic Stent-Vessel Irritation: in vivo examples
SFA: Essential objectives for a Self-Expanding Stent

- Minimize re-stenosis risk with reduced chronic outward force
- Maximize usage range for each size
  - “Easy to Choose”
  - “Easy to Use”
- Provide optimum scaffolding to promote healing and maintain patency without fracturing
How to avoid stent kinking?

SFA loading creates risk of kinking and vessel injury

3D stent geometry accommodates loading in SFA and mimics its movements
Case example
Case example

90° flexion

Full flexion
How to avoid this?
S.M.A.R.T.® Flex Stent Design

The fully connected design of S.M.A.R.T.® Flex Stent is different and unique from other stents on the market today...

- **S.M.A.R.T.® Flex Stent** is a fully connected, yet highly flexible, laser cut Nitinol self-expanding stent.
- **Helical Strut Bands** are interconnected by **Flex Bridges**.
- Diameter specific design to maximize performance.
- 4 Radiopaque markers distally, 5 Radiopaque markers proximally.
S.M.A.R.T.® Flex Stent
Diameter Specific Design

- **Diameter specific design** to maximize performance
  - 5 & 6 mm ø S.M.A.R.T.® Flex Stent:
    - 13 bridges
    - 26 struts (32 struts on end rings)
  - 7 & 8 mm ø S.M.A.R.T.® Flex Stent:
    - 16 bridges
    - 32 struts (34 struts on end rings)

- **High radial strength for all diameter sizes.**
- **Good metal / tissue ratio** for all ø sizes.
- **Optimal scaffolding** in various types of anatomy.
# S.M.A.R.T.® Flex Stent

## Stent Features and Benefits

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
</table>
| • Helical Strut Bands and diameter specific design | • S.M.A.R.T.® Stent like radial force*  
• Excellent fracture resistance* |
| • Fully connected design          | • For optimal scaffolding and greater longitudinal stability* |
| • Flex Bridges                    | • Stent Flexibility                                           |
| • Portfolio of sizes              | • More solutions to treat longer and smaller diameter disease in SFA and Proximal Popliteal |
  • 30-200mm lengths
  • 5-8 mm diameters
Feeling is Believing

- Superior Fracture resistance
- High Radial Force
- Greater Longitudinal Stability
- Deployment Confidence
- Noticeably Flexible
- Complete Portfolio of Sizes
Vascular Clinic ZNA S.M.A.R.T.® Flex Stent follow-up registry

- Single centre, physician initiated follow-up registry
- Started end 2013
- now **43** patients,
  - **31** TASC II C&D lesions
  - Moderate to heavy calcifications: **65 %**
- Stenosis Severity: **87.9%**
- Lesion Length: **149.6 mm (4–375 mm)**
- Mean stent length: **171.2 mm (6–390 mm)**
- Regions:
  - Proximal SFA: **3**
  - Mid SFA: **18**
  - Distal SFA + popl: **22**

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Vascular Clinic ZNA S.M.A.R.T.® Flex Stent
follow-up registry

30-Days results

• Freedom from MAE 100 %
• Primary Patency 100 %
• Freedom from TLR 100 %
• Fracture Rate : 0%
• Kinking/ bending
  Distal SFA + poplitea flexion angiogram
  – 90° flexion 0%
  – Full flexion 0%

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Case example
Case example

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Case example
Conclusions

• COF induces stress on vessel wall
• Minimize impact of COF by requiring proper stent sizing and vessel prep
• The right stent and technique are crucial for optimal outcomes
• Not all SES are the same – choose one that is more compliant to the SFA:
  - S.M.A.R.T.® Flex Stent
    – Low chronic outward force
    – Conformable
    – Fatigue resistant
Consequences of SFA stenting and how to overcome them

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