The AURORAA registry: 5 year results of the use of the Supera vascular mimetic implant in extensive femoropopliteal lesions

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Diclosure

Speaker’s name: Peter Goverde

I have the following potential conflicts of interest to report:

Consulting:

Abbott Vascular; Angioslide; Bard Peripheral Vascular; Bentley; Cardionovum; Cordis - Cardinal Health; IMDS; Ivascular; Maquet Getinge group Stille; Veyran; Ziehm Imaging
Real patients with real issues
Anatomical challenges of SFA and popliteal artery

Radial Compression
Axial Compression
Axial Extension
Torsion
Extension
Flexion
What with challenging lesions, like heavily calcified, in the femoropoliteal region?
Which stent to choose?
Which stent to choose?

- Avoiding:
  - problems
  - failure
  - rescue
    “the rescuers”
MIMETIC DESIGN ➔ radial strength with axial flexibility AND conformability.
Anatomical challenges of SFA & popliteal artery: how Supera deals with it.

- Axial Compression
- Radial Compression
- Axial Extension
Anatomical challenges of SFA & popliteal artery: how Supera deals with it.
AURORAA Registry

Antwerp SUPERa in Opliteal & Superficial Femoral Artery
Vascular Clinic ZNA
Supera follow-up: AURORAA

60 month data
• Physician initiated, single center, prospective

• Start June 2010 - July 2011 117 patients

• 88.89 % involving distal SFA + popliteal
• Highly diseased, heavily calcified lesions
  – TASC II C & D lesions
    • 58.12 % calcifications
    • 47.86 % stenotic disease
    • 52.12 % occlusive disease
Patient Characteristics:

- Diabetes (type 1 & 2): 53.84%
- Rutherford 2: 3 patients (2.56%)
- Rutherford 3-4: 82 patients (70.09%)
- Rutherford 5-6: 32 patients (27.35%)
• **Mean lesion length**: 143.43 +/- 35.6 mm (3 – 320 mm)
• **Mean Stent length**: 157.86 +/- 42.8 mm (6- 350 mm)
• **Mean number stents**: 1.62
• **Mean number outflow vessels**: 1.46

**Post procedure**:
- Flexion angio 90° & full flexion:
  - NO stent crush
  - NO flow compromising kinking
Vascular Clinic ZNA
Supera follow-up: AURORAA
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Supera follow-up: AURORAA

- Post procedure: aspirin + clopidogrel (3mo)
- Follow-up: 3, 6, 12, 18, 24, 36, 48, 60 months ultrasound
- Death: 11

- RX control @ 6 and/or 12 /24/36/60 mo
  - +/- 50 % of patients
  - At random
  - NO STENT FRACTURES
Case example 2010
Case example 2010
Case example 5 year later
Case example 5
year later

IT WORKS !!

2010  2015
Vascular Clinic ZNA
Supera follow-up: AURORAA

calcified n = 68

<table>
<thead>
<tr>
<th>Duration</th>
<th>Primary Patency 1</th>
<th>Primary Patency 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>91.9%</td>
<td>91.1%</td>
</tr>
<tr>
<td>12 months</td>
<td>80.8%</td>
<td>79.4%</td>
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<tr>
<td>18 months</td>
<td>76.07%</td>
<td>75%</td>
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<tr>
<td>24 months</td>
<td>73.5%</td>
<td>73.5%</td>
</tr>
<tr>
<td>30 months</td>
<td>71.8%</td>
<td>70.6%</td>
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<td>36 months</td>
<td>70.08%</td>
<td>69.1%</td>
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<tr>
<td>48 months</td>
<td>66.67%</td>
<td>64.7%</td>
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<tr>
<td>60 months</td>
<td>63.25%</td>
<td>58.82%</td>
</tr>
</tbody>
</table>
Conclusions

• Supera VMI mimics the natural anatomy, is dynamically conformable, adapts to its surroundings and adapts to the stresses placed on the stent

• The mechanical properties of the implant; its flexibility, its radial compression, kink and fracture resistance provides a structure which promotes maximum flow

• Once the VMI reaches its maximum diameter, it will no longer place an outward force (reduction of COF) on the artery wall minimizing the inflammatory response
Conclusions

THE SUPERA VMI can deal with challenging heavily calcified lesions

PROVEN LONG-TERM EFFICACY & DURABILITY
Thank you for your attention
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