Value of the Supera Interwoven stent (Abbott) for common femoral artery (CFA) Lesions: 1 year results

Koen Deloose, MD
Head Vascular Surgery, AZ Sint Blasius, Dendermonde, Belgium

Among vascular surgeons, the common femoral artery remains one of the last areas of open reconstructive surgery

Location prone to crush
Bulky, eccentric, heavily calcified plaques

VMI-CFA trial
Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (RB 2-4) CFA disease treatment

VMI-CFA trial: Endpoints
• Primary endpoint
  Efficacy endpoint: Primary patency @12 months (DUS PSVR<2.5 - Core lab adjudicated*) in CFA with no reintervention
  Safety endpoint Periprocedural adverse events up to 30 days post procedure, as defined per ISO 14155:2011 (TLR, death, amputation)

*EuroImaging Srl, Rome, Italy

Disclosure slide
Speaker name: Koen Deloose, MD

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Biotronik, Abbott, Bard, Vascular, Bentley, Cook, GE, Healthcare, Terumo, Biotron Scientific, Contego Medical
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
**VMI-CFA trial: Inclusion criteria**

- RB 2-4 classification
- De novo/post POBA lesions
- Stenosis >50% occlusions

**Exclusion criteria**

- RB 5-6 classification
- In-stent lesions CFA
- Previous surgery CFA
- Non-treatable inflow lesion
- Thrombus, Debulking, DE technologies

**Inclusion**

- RB 2-4 classification
- De novo/post POBA lesions
- Stenosis >50%/occlusions

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**VMI-CFA trial: Timeline**

<table>
<thead>
<tr>
<th>1M</th>
<th>6M</th>
<th>12M</th>
<th>24M</th>
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<tr>
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<td>Regular Duplex Ultrasound</td>
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<tr>
<td>Core Lab Duplex Ultrasound</td>
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<tr>
<td>Adverse Events</td>
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</tbody>
</table>

**VMI-CFA trial: Demographics**

- Male (%): 81 (81%)
- Age (min-max ± SD): 72,72 (46,87-95,76 ± 8,59)
- Nicotine (%): 29 (29%)
- Hypertension (%): 78 (78%)
- Renal insufficiency (%): 14 (14%)
- Hypercholesterolemia (%): 62 (62%)
- Obesity (%): 25 (25%)
- Claudicant: 79 (79%)
- CLI patient: 21 (21%)

**VMI-CFA trial: Lesions**

- Lesion length (min-max ± SD): 44,17mm (15mm – 80mm ± 15,67)
- Ref vessel diameter (min-max ± SD): 7,29mm (5mm – 9mm ± 0,93mm)
- Degree of stenosis (min-max ± SD): 82,6% (60% - 100% ± 10,65%)
- Occlusion (%): 11 (11%)
- Calcified lesion (%): 82 (82%)
- Azéma classification B (%): 52%
- Azéma classification C (%): 47%

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**VMI-CFA trial: Procedure**

- Procedure time (min-max ± SD): 55,68min (15min – 150min ± 29,59min)
- Scopy time (min-max ± SD): 14,64min (4min – 55min ± 9,93min)
- Contrast (min-max ± SD): 82,54ml (10ml – 353ml ± 75,08ml)
- Femoral access (%): 92 (92%)
- Cross-over performed (%): 82 (89,13%)
- Inflow lesion (%): 23 (23%)
- Outflow lesion (%): 62 (62%)

**VMI-CFA trial: 1 year results**

- Freedom from > 50% restenosis as indicated by DUS PSV-ratio ≤ 2,5 in the target lesion – CORE-LAB VERIFIED

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**VMI-CFA trial: Technical Success**

- Technical success: 100%

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**VMI-CFA trial: 1 year results**

- Number at risk:
  - 12 months: 99
  - 9 months: 97
  - 6 months: 95
  - 3 months: 91
  - 1 month: 98

- Cumulative primary patency rate:
  - 1 year: 95.2%

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**VMI-CFA trial: 1 year results**

- Freedom from > 50% restenosis as indicated by DUS PSV-ratio ≤ 2,5 in the target lesion – CORE-LAB VERIFIED

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**VMI-CFA trial: In- / exclusion criteria check**

- Patient informed consent
- Medical / clinical history
- Physical examination
- Rutherford
- ABI
- Regular Angiography
- Regular Duplex Ultrasound
- Core Lab Duplex Ultrasound
- Adverse Events

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**VMI-CFA trial: Assay**

- In- / exclusion criteria check
- Medical / clinical history
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- Regular Angiography
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- Core Lab Duplex Ultrasound
- Adverse Events

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**VMI-CFA trial: In- / exclusion criteria**

- RB 2-4 classification
- De novo/post POBA lesions
- Stenosis >50% occlusions

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**VMI-CFA trial: Exclusion criteria**

- RB 5-6 classification
- In-stent lesions CFA
- Previous surgery CFA
- Non-treatable inflow lesion
- Thrombus, Debulking, DE technologies
VMI-CFA trial: 1 year results

Freedom from TLR - 100 patients - 12MFU

Cumulative freedom from TLR rate (%)

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>0</th>
<th>60</th>
<th>120</th>
<th>180</th>
<th>240</th>
<th>300</th>
<th>360</th>
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<tr>
<td>%</td>
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<td>92.6</td>
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97.8%

VMI-CFA trial: 1 year results

Survival - 100 patients - 12MFU

Cumulative survival rate (%)

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<tr>
<th>Time (days)</th>
<th>0</th>
<th>60</th>
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91.8%

VMI-CFA trial: 1 year results

At risk

<table>
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<td>91.5</td>
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100% 99% 95% 92% 88% 88%

VMI-CFA trial: 1 year results

At risk

Azema B

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<tr>
<th>Time (days)</th>
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<th>180</th>
<th>240</th>
<th>300</th>
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</thead>
<tbody>
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<td>%</td>
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<td>89</td>
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100% 100% 100% 97.7% 95.1% 95.1%

Azema C

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<tr>
<th>Time (days)</th>
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<th>240</th>
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<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>97.7%</td>
<td>95.1%</td>
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100% 100% 100% 97.7% 95.1% 95.1%

p=0.94

VMI-CFA trial: Clinical outcome

Primary safety endpoint

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>30 days</th>
<th>6 months</th>
<th>12 months</th>
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<tbody>
<tr>
<td>Device or procedure related death (N)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>CD-TLR (N)</td>
<td>0</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Target limb major amputation (N)</td>
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VMI-CFA trial: Safety Profile

Freedom from > 50% restenosis as indicated by DUS PSV-ratio <2.5 in the target lesion - CORE-LAB VERIFIED

p<0.05

Screening

<table>
<thead>
<tr>
<th>Group</th>
<th>RF 0</th>
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<th>RF 2</th>
<th>RF 3</th>
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<tr>
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<td>7</td>
<td>10</td>
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p=0.48

VMI-CFA trial: 1 year results

Freedom from TVR - 100 patients - 12MFU

Cumulative freedom from TVR rate (%)

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92.6%

VMI-CFA trial: 1 year results

Freedom from TVR - 100 patients - 12MFU

Cumulative freedom from TVR rate (%)

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p=0.04

VMI-CFA trial: 1 year results

Freedom from TVR - 100 patients - 12MFU

Cumulative freedom from TVR rate (%)

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95.3%

VMI-CFA trial: 1 year results

Freedom from TVR - 100 patients - 12MFU

Cumulative freedom from TVR rate (%)

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95.1%
Conclusion

• In 2018, although CFE still remains the golden standard, the historical “no endovascular for this baby” statement is wrong.

• Newer generation of devices, like the high crush resistant, repuncturable interwoven Supera stent, are facilitating this endo-approach

• With this particular device, the VMI-CFA trial shows excellent 1 year results: Primary Patency of 95.2%, freedom TLR of 97.8%, clear clinical benefit & a 100% safety profile

• A head to head RCT Supera versus endarterectomy seems to be a logical sequence to clarify definitively the CFA-treatment discussion