2-year results of a novel Bi-Directional SFA stent design: A comparative study of safety and efficacy

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on behalf of the Q3-Investigators

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Bi-directional, self-expanding stent for SFA lesions - 2-year interim-results from the Q3 registry

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Disclosure

Speaker name: Hans Krankenberg

I have the following potential conflicts of interest to report.

- **Speakers fee**: QualiMed Medizinprodukte, Wedel, Germany
Hans Krankenberg, Hamburg
Jarwed Arjumand, Christian Jacke, Gabriela Marin, Wuppertal
Gunnar Tepe, Rosenheim
Erwin Blessing, Karlsbad
Markus Spanagel, Achmet Mechmet, Eric Ipcsics, Walddbröl
Viktor Reichert, Sindelfingen
Stefan Betge, Bad Bevensen
Ralph Wickenhöfer, Thorsten Kanis, Dernbach
Jörg Teßarek, Lingen

ClinicalTrials.gov NCT02307292
Bi-directional SFA stent*

- Self-expanding Nitinol stent, laser-cut
- Wave-like segments with flexible connectors
- 8 Tantalum markers
- Delivery catheter is operable by one hand
- 5-zone flexibility delivery catheter

Designed to resist „bi-directional torsion“.

* QualiMed Medizinprodukte, Wedel, Hamburg; Germany
Bi-directional SFA stent

Resistance to bending and torsion

360° turn to the left

360° turn to the right

Bi-directional SFA Stent

Competitors
### Q3 Registry

#### Patient Characteristics

N = 193 (Dec 2014 – Nov 2017)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>69.7 ± 10.9</td>
</tr>
<tr>
<td>Male</td>
<td>69.9%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>37.8%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>82.9%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>70.9%</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>11.9%</td>
</tr>
<tr>
<td>Smoker (current and former)</td>
<td>56.5%</td>
</tr>
<tr>
<td>Adipositas</td>
<td>23.3%</td>
</tr>
<tr>
<td>Critical ischemia</td>
<td>11.4%</td>
</tr>
<tr>
<td>ABI</td>
<td>0.60 ± 0.25</td>
</tr>
</tbody>
</table>
### Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>98.0 ± 83.9 mm</td>
</tr>
<tr>
<td>Lesions ≥ 150 mm</td>
<td>23.3%</td>
</tr>
<tr>
<td>Stents/lesion</td>
<td>1.4 ± 0.7</td>
</tr>
<tr>
<td>Stented length</td>
<td>115.3 ± 83.0 mm</td>
</tr>
<tr>
<td>% Diameter stenosis</td>
<td>91.2 ± 13.2%</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>47.7%</td>
</tr>
<tr>
<td>PTA Restenosis</td>
<td>3.1%</td>
</tr>
<tr>
<td>Multifocal or diffuse pattern</td>
<td>46.1%</td>
</tr>
<tr>
<td>Heavy calcification</td>
<td>37.3%</td>
</tr>
</tbody>
</table>
# Immediate Procedural Results

<table>
<thead>
<tr>
<th>Technical success</th>
<th>Successful access and completion of the procedure and ≤30% residual stenosis.</th>
<th>99.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute procedural success</td>
<td>Technical success without flow-limiting dissection or MAE within 72h of the index procedure.</td>
<td>96.4%</td>
</tr>
</tbody>
</table>
| **Periprocedural complications** | • Dissection  
  Flow-limiting dissection  
  • False aneurysm  
  • Distal embolization | 6.7%  
2.6%  
0.5%  
0.5% |
Interim Analysis

6-month FU completed: 64.8%

12-month FU completed: 40.4%

24-month FU completed: 26.4%
Clinical Improvement

Clinical improvement by ≥ 1 Rutherford category

<table>
<thead>
<tr>
<th>Rutherford Category</th>
<th>Baseline</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>3</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>4</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Clinical improvement by ≥ 1 Rutherford category:
- Baseline: 91.7% (n=121)
- 6 months: 90.4% (n=73)
- 1 year: 89.8% (n=49)

p < 0.0001 for each FU vs. Baseline
Hemodynamic Improvement

Hemodynamic improvement by ≥ 0.15 or to ≥ 0.9

84.9% 77.3% 75.0% 80.4%

n=146 n=110 n=68 n=46

p < 0.0001 for each FU vs. Baseline
Freedom from TLR

Patients at risk 193 125 76 41

6 months 99.2% (SE 0.8%)
12 months 97.9% (SE 1.5%)
24 months 83.9% (SE 5.1%)
Freedom from TLR

- Lesions < 150 mm Ø 57 mm
- Lesions ≥ 150 mm Ø 229 mm

Mean survival time: 20.7 months (21.1 to 21.2)
Mean survival time: 16.6 months (15.3 to 17.8)

Log-rank p = 0.006

Patients at risk
- 145
- 88
- 53
- 30

- 45
- 34
- 21
- 10
Freedom from TLR

- Bi-directional SFA stent (98 mm)
- BioMimics3D (66 mm)
- Protege (89 mm)
- Everflex (61 mm)
- Complete SE stent
- LifeStent (<150 mm)
- Supera (126 mm)
- ZilverPTX RCT (65 mm)
- ZilverPTX single arm (100 mm)

- 12 months
- 24 months

Freedom from MAVE

Patients at risk

- 6 months: 96.8% (SE 1.6%)
- 12 months: 94.2% (SE 2.4%)
- 24 months: 77.5% (SE 5.7%)

Events:
- 0 Death
- 0 Major amputation
- 9 TLR
- 3 Myocardial infarctions
- 1 TIA
- 1 Bypass surgery

Graph showing the percentage of patients free from MAVE over time.
Conclusion

Interim analysis suggests a comparatively high effectiveness of the bi-directional SFA stent.

It did not raise any safety concerns.
Bi-directional, self-expanding stent for SFA lesions - 2-year interim-results from the Q3 registry

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