Experience with the GORE TIGRIS Vascular Stent in the femoropopliteal segment

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Disclosure

Speaker name: Martin Werner

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
Is there a relevance for scaffolding in the “leaving nothing behind” paradigm?

Drug Coated Balloons (DCBs) have widely changed the way of endovascular treatment of fem-pop lesions.
DCBs - Shortcomings:

No mechanical stabilization of the vessel wall

![Bar chart showing bail-out stent rates for different studies: ILLUMENATE EU-RCT (15%), IN.PACT SFA (7% to 15%), LEVANT 2 (3% to 7%).]
DCBs - Shortcomings:

No mechanical stabilization of the vessel wall

Stent rates from DEB Studies

- THUNDER [1]: 4.0% Stent, 7.5% CTO
- FEMPAC [2]: 9.0% Stent, 6.1% CTO
- IT Registry [3]: 12.3% Stent, 7.6% CTO
- Bad Krozingen [4]: 18.3% Stent
- Leipzig [5]: 23.3% Stent, 65.3% CTO

Lesion Length (cm)
Treatment algorithm for femoropoliteal lesions at Hanusch Hospital

Predilatation
1:1 ratio
At least 60 seconds

„PTA-responder“
Final Treatment with Drug Coated Balloon

"PTA non-responder"
Final Treatment with GORE TIGRIS Stent
„PTA responder“

90% stenosis right SFA

After predilatation (5/20mm)

Final result after DCB (6/40mm)
„PTA non-responder“

90% stenosis right SFA

After predilatation (6/20mm)

Final result after GORE TIGRIS 7/40
VIENNA TIGRIS REGISTRY

Single Center Prospective Registry

Enrollment: 100 Patients

Time: 2013 - 2017

Lesion length up to 100 mm

Treatment with a single TIGRIS Stent
GORE® TIGRIS Vascular Stent
Dual Component Stent Design

Clinically Proven Nitinol Stent Frame based on Viabahn

ePTFE Interconnecting Structure
CARMEDA Bioactive Surface
GORE® TIGRIS Vascular Stent
Dual Component Stent Design

- Maximizes flexibility while minimizing risk of stent fracture
- Allows axial compression while resisting stent elongation
- Naturally conforms and allows vessel movement
GORE® TIGRIS Vascular Stent
Device Configurations

- NiTi Stent based on fracture resistant Viabahn design
- ePTFE interconnecting structure with CARMEDA BioActive Heparin Surface
- Catheter
  - Single handed deployment
  - Compatible with 0.035” guidewire
  - 80 and 120 cm working length catheter

<table>
<thead>
<tr>
<th>Device Diameters</th>
<th>Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3cm</td>
</tr>
<tr>
<td>5 mm (6Fr)</td>
<td>X</td>
</tr>
<tr>
<td>6 mm (6Fr)</td>
<td>X</td>
</tr>
<tr>
<td>7 mm (6Fr)</td>
<td>X</td>
</tr>
<tr>
<td>8 mm (7Fr)</td>
<td>X</td>
</tr>
</tbody>
</table>
Fracture rates in the fem-pop segment

- 2005 - 2007
- 2009 - 2012
- 2014 - 2016

Stent fracture rate (%) vs. lesion length (cm)
VIENNA TIGRIS REGISTRY

Primary Efficacy Endpoint

→ Primary patency at 12 months post-procedure (defined as freedom from TLR and ultrasound or angiographic stenosis >50%)

Primary Safety Endpoint

→ Freedom from major target limb amputation or death at 30 days
Secondary Efficacy Endpoint

TLR rate at 1, 6, 12 and 24 months

Sustained clinical improvement (shift in the Rutherford classification at 1, 6, 12 and 24 months)

Binary restenosis at 1, 6, 12 and 24 months
Key Inclusion Criteria

- Rutherford Classification Category 1 - 5
- >70% stenosis or occlusion
- De-novo or restenotic lesion of the SFA or Pop
- Disease segment length ≤100mm
- Patent ipsilateral iliac artery
- Sufficient runoff to the ankle
- Target reference vessel diameter 4.0-7.5 mm
### Patient Demographics

<table>
<thead>
<tr>
<th>N= 100 patients</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>68.2 years (43 – 92)</td>
</tr>
<tr>
<td>Male sex</td>
<td>66 patients</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>27 (16-38)</td>
</tr>
<tr>
<td>Smoker</td>
<td>59 patients</td>
</tr>
<tr>
<td>Hypertension</td>
<td>78 patients</td>
</tr>
<tr>
<td>Coronary Artery Dis.</td>
<td>32 patients</td>
</tr>
<tr>
<td>Diabetes mellitus II</td>
<td>47 patients</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>85 patients</td>
</tr>
</tbody>
</table>
Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>5.6 cm</td>
<td>(2.0 cm – 10.0 cm)</td>
</tr>
<tr>
<td>Stented length</td>
<td>7.0 cm</td>
<td>(4.0 cm – 10.0 cm)</td>
</tr>
<tr>
<td>Mean stent diameter</td>
<td>5.9 mm</td>
<td>(5 mm – 8 mm)</td>
</tr>
<tr>
<td>Calcification (moderate to severe)</td>
<td>59 patients</td>
<td></td>
</tr>
<tr>
<td>Localisation</td>
<td>Prox. &amp; Mid SFA</td>
<td>41 stents</td>
</tr>
<tr>
<td></td>
<td>Dist. SFA &amp; Popliteal</td>
<td>59 stents</td>
</tr>
</tbody>
</table>
VIENNA TIGRIS REGISTRY

Clinical Characteristics

- Rutherford 2: 9%
- Rutherford 3: 73%
- Rutherford 4: 13%
- Rutherford 5: 5%

Mean ABI before Intervention: 0.69
VIENNA TIGRIS REGISTRY

Primary Safety Endpoint
100% Freedom from major target limb amputation or death at 30 days

Device Related Adverse Events
100% Freedom from device related adverse events at 30 days

Procedure Related Adverse Events
93% Freedom from procedure related adverse events at 30 days

→ 3 Pseudoaneurysms at puncture site
   (2 treated conservatively, 1 treated with Thrombin injection)
→ 3 Hematoma at puncture site
   (2 treated conservatively, 1 treated with surgery)
→ 1 Plaque embolization during predilatation
   (treated with aspiration)
# VIENNA TIGRIS REGISTRY

## Follow Up Status (22.01.2018)

<table>
<thead>
<tr>
<th>Time Point</th>
<th>n</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Discharge</td>
<td>100/100</td>
<td></td>
</tr>
<tr>
<td>1 Months Follow-Up</td>
<td>100/100</td>
<td></td>
</tr>
<tr>
<td>6 Months Follow-Up</td>
<td>95/100</td>
<td>1 cardiac death 2 months, 1 patient lost to FU, 3 patients FU in Feb/Mar 18</td>
</tr>
<tr>
<td>12 Months Follow-Up</td>
<td>79/100</td>
<td>1 cardiac death 2 months, 1 patient lost to FU, 17 patients FU in 2018</td>
</tr>
<tr>
<td>24 Months Follow-Up</td>
<td>19/100</td>
<td>1 cardiac death 2 months, 1 patient lost to FU, 79 patients FU in 2018/19</td>
</tr>
</tbody>
</table>
VIENNA TIGRIS REGISTRY
preliminary results

Clinical Improvement

Baseline
- Rutherford 2: 13%
- Rutherford 3: 9%
- Rutherford 4: 5%
- Rutherford 5: 1%
- Rutherford 0 and 1 and 2 and 3 and 4 and 5
- Baseline: 94%

1 MFU
- Rutherford 2: 3%
- Rutherford 3: 3%
- Rutherford 4: 3%
- Rutherford 5: 1%
- Rutherford 0 and 1 and 2 and 3 and 4 and 5
- 1 MFU: 94%

6 MFU
- Rutherford 2: 4%
- Rutherford 3: 4%
- Rutherford 4: 1%
- Rutherford 5: 1%
- Rutherford 0 and 1 and 2 and 3 and 4 and 5
- 6 MFU: 89%

12 MFU
- Rutherford 2: 4%
- Rutherford 3: 1%
- Rutherford 4: 1%
- Rutherford 5: 1%
- Rutherford 0 and 1 and 2 and 3 and 4 and 5
- 12 MFU: 93%
VIENNA TIGRIS REGISTRY
preliminary results

Hemodynamic Improvement

<table>
<thead>
<tr>
<th>Time</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>baseline</td>
<td>0.6905</td>
</tr>
<tr>
<td>discharge</td>
<td>0.95</td>
</tr>
<tr>
<td>1MFU</td>
<td>0.98</td>
</tr>
<tr>
<td>6MFU</td>
<td>0.91</td>
</tr>
<tr>
<td>12MFU</td>
<td>0.91</td>
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VIENNA TIGRIS REGISTRY
preliminary results

### Stent Patency

freedom from ultrasound detected stenosis > 50% (PSVR 2.5)

<table>
<thead>
<tr>
<th></th>
<th>Stent Patency (N)</th>
<th>Stent Patency (%)</th>
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<tbody>
<tr>
<td>Discharge</td>
<td>100/100</td>
<td>100%</td>
</tr>
<tr>
<td>1MFU</td>
<td>100/100</td>
<td>100%</td>
</tr>
<tr>
<td>6MFU</td>
<td>92/95</td>
<td>96.8%</td>
</tr>
<tr>
<td>12 MFU</td>
<td>74/79</td>
<td>93.7%</td>
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## VIENNA TIGRIS REGISTRY
preliminary results

### Freedom from TLR

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Typical study case

- Male patient
- Age 69
- Smoker
- PMH: MI, coronary stenting
- Claudication left calf walking distance < 200m
Implanted stent:

Gore Tigris 7/100 mm
Result in the distal SFA

Knee bent 90°
Functional angiography
VIENNA Experience with the GORE TIGRIS Vascular Stent in the femoropopliteal segment

CONCLUSIONS

Even in the „leave nothing behind“ endovascular paradigm, stents are necessary in > 10% of cases, also in focal lesions
VIENNA Experience with the GORE TIGRIS Vascular Stent in the femoropopliteal segment

CONCLUSIONS

Excellent Efficacy in focal lesions

→ With a > 93% Freedom from TLR

→ And persistent Clinical Improvement >93%

After 12 months
VIENNA Experience with the GORE TIGRIS Vascular Stent in the femoropopliteal segment

CONCLUSIONS

Data Collection will be continued until 2019, in order to assess the mid-term efficacy of the Tigris Stent in Focal Fem-Pop Lesions
The GORE TIGRIS Stent is a safe, easy to use and efficient modern generation stent system for the treatment of fempop lesions.
Experience with the GORE TIGRIS Vascular Stent in the femoropopliteal segment

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