TIGRIS Vascular Stent
Case Discussion: Fracture Resistance

PD Dr. Martin Werner
Department of Internal Medicine/Angiology
Hanusch Hospital Vienna
Disclosure

Speaker name:
PD Dr. 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
Stent fractures – Clinical implications

Restenosis

Courtesy Prof. Scheinert
Stent fractures – Clinical implications

Pseudoaneurysm formation

Courtesy Prof. Zeller
Stent fracture and In-Stent Restenosis of a Nitinol Stent
Background: SFA anatomy and dynamics

Longest, most stressed of body’s vessels

Cyclic forces and vessel deformations

- Torsion
- Flexion
- Compression
- Bending
- Shortening

TIGRIS Vascular Stent: ZERO fracture rate after 12 and 24 months

TIGRIS IDE Trial

<table>
<thead>
<tr>
<th>STENT FRACTURES OBSERVED AT 12-MONTH FOLLOW UP</th>
<th>GORE® TIGRIS® VASCULAR STENT*</th>
<th>BARD® LIFESTENT® VASCULAR STENT*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1: single strut fracture</td>
<td>0 (0.0%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Grade 2: multiple strut fractures</td>
<td>0 (0.0%)</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Grade 3: stent fracture retaining alignment</td>
<td>0 (0.0%)</td>
<td>7 (10.0%)</td>
</tr>
<tr>
<td>Grade 4: misaligned stent fractures</td>
<td>0 (0.0%)</td>
<td>5 (7.1%)</td>
</tr>
<tr>
<td>Grade 5: transaxial-spiral fracture</td>
<td>0 (0.0%)</td>
<td>5 (7.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STENT FRACTURES OBSERVED AT 24-MONTH FOLLOW UP</th>
<th>GORE® TIGRIS® VASCULAR STENT*</th>
<th>BARD® LIFESTENT® VASCULAR STENT*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1: single strut fracture</td>
<td>0 (0.0%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Grade 2: multiple strut fractures</td>
<td>0 (0.0%)</td>
<td>3 (17.6%)</td>
</tr>
<tr>
<td>Grade 3: stent fracture retaining alignment</td>
<td>0 (0.0%)</td>
<td>3 (17.6%)</td>
</tr>
<tr>
<td>Grade 4: misaligned stent fractures</td>
<td>0 (0.0%)</td>
<td>5 (29.4%)</td>
</tr>
<tr>
<td>Grade 5: transaxial-spiral fracture</td>
<td>0 (0.0%)</td>
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</tr>
</tbody>
</table>
1-year stent fracture rates in fempop trials
TIGRIS Stent: Dual Component Design

- Clinically Established Stent Frame Nitinol Wire
- Fluoropolymer Interconnecting Structure

ALL SURFACES INCORPORATE CBAS HEPARIN SURFACE

TIGRIS Stent: Flexible Design

Designed to:

• Maximize flexibility while **minimizing risk of stent fracture**
• Allow axial compression while resisting stent elongation
• Naturally conform and allow vessel movement
Case 1 – Occlusion of the popliteal artery

- 64-year-old male with left calf claudication

- Relevant History:
  - Walking capacity 90 meters, symptoms for years, slowly progressing
  - Smoking history
  - Coronary artery disease (stent 2011)
  - Ankle Brachial Index (ABI) left 0.6
  - Duplexsonography: 7cm occlusion in the P1-segment of the popliteal artery. No popliteal aneurysm.
Case 1 – Occlusion of the popliteal artery

Treatment:

• Left antegrade placement of a 6F 45cm sheath

• Recanalisation of the occlusion with an 0.035” standard hydrophilic wire
Case 1 – Occlusion of the popliteal artery

- Predilatation with 5/60mm Bare Balloon
- Implantation of a 5/80mm TIGRIS Vascular Stent
Case 1 – Occlusion of the popliteal artery

- Functional „bent-knee“ angiogram
Case 1 – Occlusion of the popliteal artery

- Functional „bent-knee“ angiogram
Conclusions

Amongst other factors (safety, patency, flexibility, accuracy, ease–of–use, cost effectiveness) – fracture resistance is an important property in modern generation stents.

The TIGRIS Vascular Stent has proven a ZERO Fracture rate after one and two years compared to a 27% Fracture rate of the Lifestent in the TIGRIS IDE trial.
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