### Clinical Trials for SFA Stenting

**LifeStent Vascular**
- **Vienna [Austria]**
- **Bard Peripheral Stent**
- **Self-expanding**
- **Complete SE**
  - **Prof. Thomas University of Vienna**
- **Innova Self-Expanding**
- **RESILIENT**
  - **SF A Study**
  - **Biotronik**
- **Absolute Resilience**
  - **Medical University of Vienna (Austria)**
  - **Peripheral General Hospital (Austria)**
  - **Complete RES**
    - **Study**
    - **SFA**
- **DURABILITY**
  - **Endovascular Peripheral Stent Systems**

<table>
<thead>
<tr>
<th>Study Document(s)</th>
<th>Sample Size</th>
<th>Design</th>
<th>Study Details</th>
<th>Inclusion Criteria</th>
<th>Baseline Patient Demographics</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>LifeStent Vascular</td>
<td>246 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was follow-up of 8% of patients, with minimal in-stent restenosis.</td>
<td>120 patients, Multicenter, prospective, randomized</td>
<td>12 months, 1% stent fractures</td>
</tr>
<tr>
<td>Vienna [Austria]</td>
<td>246 patients</td>
<td>Randomized trial</td>
<td>Self-expanding</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
<tr>
<td>Biotronik</td>
<td>120 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
<tr>
<td>Medical University of Vienna (Austria)</td>
<td>246 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
<tr>
<td>Complete RES</td>
<td>246 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
<tr>
<td>RESILIENT</td>
<td>120 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
<tr>
<td>Absolute Resilience</td>
<td>246 patients</td>
<td>Randomized, prospective, multicenter</td>
<td>According to EVS2006</td>
<td>Clinical success was defined by angiographic and clinical success.</td>
<td>12 months, 1% stent fractures</td>
<td></td>
</tr>
</tbody>
</table>

**General Information**

**Sample Size**
- 120 patients
- 246 patients
- 120 patients
- 246 patients
- 246 patients
- 246 patients
- 246 patients
- 246 patients

**Study Design**
- Randomized, prospective, multicenter
- Randomized trial
- Self-expanding
- Randomized, prospective, multicenter
- Randomized, prospective, multicenter
- Randomized, prospective, multicenter
- Randomized, prospective, multicenter
- Randomized, prospective, multicenter

**Inclusion Criteria**
- Length of the target lesion ≤ 20 cm
- Symptomatic patients with peripheral limb
- Length of the target lesion ≤ 20 cm
- Symptomatic patients with peripheral limb
- Length of the target lesion ≤ 20 cm
- Symptomatic patients with peripheral limb
- Length of the target lesion ≤ 20 cm
- Symptomatic patients with peripheral limb

**Baseline Patient Demographics**

**Results**
- Clinical success was follow-up of 8% of patients, with minimal in-stent restenosis.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
- Clinical success was defined by angiographic and clinical success.
### General Information

#### Baseline Patient Demographics

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient</th>
<th>Study Design</th>
<th>Randomization</th>
<th>Power Calculation</th>
<th>Follow-up</th>
<th>Study Start</th>
<th>Authors</th>
<th>Journal</th>
<th>Year</th>
</tr>
</thead>
</table>

#### Results

<table>
<thead>
<tr>
<th>Study</th>
<th>TLR Stent Fracture Rate</th>
<th>Mean No. of Stents Implanted</th>
<th>Mean Length of Lesion Implanted</th>
<th>Mean Range of Lesion Implanted</th>
<th>Mean Length of Lesion Shunted</th>
<th>Mean Range of Lesion Shunted</th>
<th>Core Lab &amp; Follow-up</th>
<th>Published</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUPERB</td>
<td>0.7%</td>
<td>63</td>
<td>24.7</td>
<td>6.4–140</td>
<td>9.5</td>
<td>2.1</td>
<td>Yes; core lab for endpoints</td>
<td>2013</td>
<td>For details see Clinical Trials Notes for SFA Stenting (Vol 2, 2013)</td>
</tr>
</tbody>
</table>

#### Clinical Trial Notes for SFA Stenting

**Vol 2, 2013**

**Study Design:** Single-arm, single-centre trial of 119 limbs 11 centers, 63 in BNS device arm, 56 in Viaspan device arm; per protocol: 129 in Viaspan arm; per protocol: 72 in Gore endoprosthesis, 47 in Zilver endoprosthesis. Protocol defined by 2 classes or to Rutherford class II, 5 or 6.

**Protocol:** 6 months to 2 years, 36 months to 12 years, 6 months to 5 years, 2 years to 10 years, 1 year to 7 years, 6 months to 1 year, 3 months to 2 years, 1 year to 3 years, 6 months to 1 year, 1 year to 2 years, 6 months to 1 year.

**Follow-up:** 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years, 6 months to 2 years.

**Core Lab & Follow-up:** Yes; core lab for endpoints.

**Publication Notes:** For details see Clinical Trials Notes for SFA Stenting (Vol 2, 2013).