The Freeway Stent Study: the 12 Months results highly favor the use of DEB in combination with stenting

J. Tacke, K.A. Hausegger, H. Schröder, J. Dambach, S. Stahnke,

S. Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg of Kiel University – Faculty of Medicine Ev.-Luth. Diakonissenanstalt zu Flensburg Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology
Disclosure

I have the following potential conflicts of interest to report:

- [x] Consulting: Terumo, BSCI, Eurocor
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Aim of the Study

- Evaluation of the inhibition of restenosis

**Post stent PTA with paclitaxel-eluting balloon**

*versus*

**Post stent PTA with standard balloon**

in stenotic or occluded femoropopliteal lesions.
FREEWAY™ DCB Coating

- Paclitaxel: 3 µg/mm²
- Coating is a 1:1 mixture of Paclitaxel and Shellac
- Shellac swells in blood and releases paclitaxel under pressure
- The coating is CE marked
- Balloon inflation 120 sec. at nominal pressure
Study Design & Methods

- Multicenter, prospective randomized study
- Patients with stenotic lesions or occlusions of the femoropopliteal artery
- 1:1 randomization
- 13 German & Austrian centers
- Independent, blinded corelab (Bad Krozingen)
Participating Centers
Freeway Stent Study

Germany: 10
Austria: 3
Endpoints

**Primary endpoint**
- Clinical driven TLR @ 6 months

**Secondary endpoints**
- Primary patency rate @ 6 and 12 months
- Clinical driven TLR @ 12 months
- Rutherford @ 6 and 12 months
- ABI @ 6 and 12 months
- MAE @ 6 and 12 months
Main Study Criteria

Inclusion criteria

- SFA and PI lesion or occlusion
- Rutherford 2 – 6
- Lesion length 4 to ≤ 15 cm, RVD 4 to 7 mm

Exclusion criteria

- Previous bypass or stenting of target vessel
- Significant inflow disease or inflow disease to target vessel treated in last 6 months
- No patent outflow vessel
Study Flow Chart

204 Patients

Randomisation 1:1

Nitinol stent + FREEWAY™ DEB Postdilatation (N = 105)

- 6 Months follow up N = 98
- 12 Months follow up N = 89

Nitinol stent + PTA Postdilatation (N = 99)

- 6 Months follow up N = 89
- 12 Months follow up N = 79

204 Patients
## Baseline Demographics

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 105</td>
<td>N = 99</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>78.1 %</td>
<td>76.8 %</td>
<td>ns</td>
</tr>
<tr>
<td>Age</td>
<td>64.7 ± 9.4 yrs</td>
<td>64.3 ± 9.8 yrs</td>
<td>ns</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>26.7 %</td>
<td>26.3 %</td>
<td>ns</td>
</tr>
<tr>
<td>History of PAD</td>
<td>37.1 %</td>
<td>44.4 %</td>
<td>ns</td>
</tr>
<tr>
<td>History of CAD</td>
<td>24.8 %</td>
<td>23.2 %</td>
<td>ns</td>
</tr>
<tr>
<td>Smoking</td>
<td>88.6 %</td>
<td>81.8 %</td>
<td>ns</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>60.0 %</td>
<td>57.6 %</td>
<td>ns</td>
</tr>
<tr>
<td>Hypertension</td>
<td>75.2 %</td>
<td>73.7 %</td>
<td>ns</td>
</tr>
</tbody>
</table>
## Baseline Clinical Status

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 101/105</td>
<td>N = 97/99</td>
<td>(ns &gt; 0.05)</td>
</tr>
<tr>
<td><strong>ABI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1.2</td>
<td>4.0 %</td>
<td>2.1 %</td>
<td>ns</td>
</tr>
<tr>
<td>1.0 – 1.2</td>
<td>1.0 %</td>
<td>2.1 %</td>
<td>ns</td>
</tr>
<tr>
<td>0.9 – 1.0</td>
<td>5.0 %</td>
<td>1.0 %</td>
<td>ns</td>
</tr>
<tr>
<td>0.8 – 0.9</td>
<td>9.9 %</td>
<td>5.2 %</td>
<td>ns</td>
</tr>
<tr>
<td>0.5 – 0.8</td>
<td>58.4 %</td>
<td>69.1 %</td>
<td>ns</td>
</tr>
<tr>
<td>&lt; 0.5</td>
<td>21.8 %</td>
<td>20.6 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Rutherford</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0.0 %</td>
<td>0.0 %</td>
<td>ns</td>
</tr>
<tr>
<td>1</td>
<td>0.0 %</td>
<td>0.0 %</td>
<td>ns</td>
</tr>
<tr>
<td>2</td>
<td>23.8 %</td>
<td>25.3 %</td>
<td>ns</td>
</tr>
<tr>
<td>3</td>
<td>69.5 %</td>
<td>68.7 %</td>
<td>ns</td>
</tr>
<tr>
<td>4</td>
<td>1.9 %</td>
<td>1.0 %</td>
<td>ns</td>
</tr>
<tr>
<td>5</td>
<td>4.8 %</td>
<td>2.0 %</td>
<td>ns</td>
</tr>
<tr>
<td>6</td>
<td>0.0 %</td>
<td>0.0 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td>2.88 ± 0.66</td>
<td>2.72 ± 0.65</td>
<td>ns</td>
</tr>
</tbody>
</table>

[deviation in N due to non measurability of ABI for few patients]
## Baseline Lesion Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent N = 105</th>
<th>PTA + Stent N = 99</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SFA prox</td>
<td>6.7 %</td>
<td>7.1 %</td>
<td>ns</td>
</tr>
<tr>
<td>SFA mid</td>
<td>48.6 %</td>
<td>43.4 %</td>
<td>ns</td>
</tr>
<tr>
<td>SFA distal</td>
<td>43.8 %</td>
<td>50.5 %</td>
<td>ns</td>
</tr>
<tr>
<td>PI</td>
<td>1.9 %</td>
<td>0.0 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Lesion length</strong></td>
<td>7.7 ± 4.2 cm</td>
<td>8.3 ± 4.1 cm</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Diameter stenosis</strong></td>
<td>91.7 %</td>
<td>90.9 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Total occlusion</strong></td>
<td>63.8 %</td>
<td>63.6 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Ref. vessel diameter</strong></td>
<td>4.7 ± 0.8 mm</td>
<td>4.6 ± 0.9 mm</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Infrapopliteal run-off vessels</strong></td>
<td>2.26 ± 0.85</td>
<td>2.06 ± 0.85</td>
<td>ns</td>
</tr>
</tbody>
</table>

* Determined by an independent, blinded corelab (Bad Krozingen)
## Baseline Procedural Data

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent N = 105</th>
<th>PTA + Stent N = 99</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predilatation</strong></td>
<td>73.3 %</td>
<td>69.7 %</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Stent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>97.9 ± 37.1 mm</td>
<td>98.9 ± 36.0 mm</td>
<td>ns</td>
</tr>
<tr>
<td>Diameter</td>
<td>6.2 ± 0.7 mm</td>
<td>6.3 ± 0.6 mm</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Postdilatation study balloon</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>86.9 ± 26.7 mm</td>
<td>80.3 ± 26.9 mm</td>
<td>ns</td>
</tr>
<tr>
<td>Diameter</td>
<td>5.4 ± 0.6 mm</td>
<td>5.4 ± 0.6 mm</td>
<td>ns</td>
</tr>
<tr>
<td>Inflation pressure study device</td>
<td>9.1 ± 2.0 atm</td>
<td>8.9 ± 1.5 atm</td>
<td>ns</td>
</tr>
<tr>
<td>2nd study balloon used</td>
<td>54.3 %</td>
<td>58.6 %</td>
<td>ns</td>
</tr>
</tbody>
</table>
## Results at 6 and 12 Months FU

<table>
<thead>
<tr>
<th>Primary Patency Rate*</th>
<th>FREEWAY DCB + Stent % (n)**</th>
<th>PTA + Stent % (n)**</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Months</td>
<td>90.3 (93)</td>
<td>69.8 (86)</td>
<td>0.001</td>
</tr>
<tr>
<td>12 Months</td>
<td>77.4 (84)</td>
<td>61.0 (77)</td>
<td>0.027</td>
</tr>
</tbody>
</table>

* Determined by an independent, blinded corelab (Bad Krozingen)

<table>
<thead>
<tr>
<th>Clinical driven target lesion revascularization (TLR)</th>
<th>FREEWAY DCB + Stent % (n)**</th>
<th>PTA + Stent % (n)**</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Months</td>
<td>4.1 (98)</td>
<td>9.0 (89)</td>
<td>0.234</td>
</tr>
<tr>
<td>12 Months</td>
<td>7.9 (89)</td>
<td>17.7 (79)</td>
<td>0.064</td>
</tr>
</tbody>
</table>

** n= number of evaluated patients
Results Rutherford at 6 and 12 Months FU

<table>
<thead>
<tr>
<th>Shift in Rutherford from baseline ≥ 1</th>
<th>FREEWAY DCB + Stent % (n)**</th>
<th>PTA + Stent % (n)**</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Months</td>
<td>94.9 (98)</td>
<td>84.3 (89)</td>
<td>0.027</td>
</tr>
<tr>
<td>12 Months</td>
<td>95.5 (84)</td>
<td>79.9 (79)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

** n= number of evaluated patients
## Results ABI 6 and 12 Months FU

<table>
<thead>
<tr>
<th>ABI Index</th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline N = 101</td>
<td>Baseline N = 97</td>
</tr>
<tr>
<td>&gt; 1.2</td>
<td>4.0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>1.0 – 1.2</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
<tr>
<td>0.9 – 1.0</td>
<td>5.0%</td>
<td>48.2%</td>
</tr>
<tr>
<td>0.8 – 0.9</td>
<td>9.9%</td>
<td>16.5%</td>
</tr>
<tr>
<td>0.5 – 0.8</td>
<td>58.4%</td>
<td>9.4%</td>
</tr>
<tr>
<td>&lt; 0.5</td>
<td>21.8%</td>
<td>69.1%</td>
</tr>
</tbody>
</table>
# MAE at 6 and 12 Months

<table>
<thead>
<tr>
<th>MAE</th>
<th>FREEWAY DCB + Stent</th>
<th>PTA+ Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 Months N = 98</td>
<td>12 Months N = 90</td>
</tr>
<tr>
<td>MAE</td>
<td>1.0 %</td>
<td>2.2 %</td>
</tr>
<tr>
<td>Death</td>
<td>0.0 %</td>
<td>1.1 %*</td>
</tr>
<tr>
<td>Study related amputation</td>
<td>0.0 %</td>
<td>0.0 %</td>
</tr>
<tr>
<td>Thrombosis of target lesion</td>
<td>1.0 %</td>
<td>1.0 %</td>
</tr>
</tbody>
</table>

[no significant differences between both arms]

*death not related to study
Conclusions

- **Majority** of patients presented at baseline with **total occluded** lesion

- **Significant** higher **patency rate** at 6 and 12 months for stent + FREEWAY™ DCB arm (90.3 % and 77.4 % vs. 69.8 % and 61.0 %)

- **Highly favoured TLR rate** at 12 months for the stent + FREEWAY™ arm (Stent + FREEWAY™ DCB 7.9 % vs. Stent + PTA 17.7 %)

- **Significant better improvement** of ≥1 of **Rutherford** clinical category in the stent + FREEWAY™ DCB arm at 6 and 12 months (94.9 % and 95.5 % vs. 84.3 % and 79.9 %)
Thanks to all participating centers

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jüdisches Krankenhaus, Berlin, D</td>
<td>Dr. Schröder</td>
</tr>
<tr>
<td>Gemeinschaftskrankenhaus, Bonn, D</td>
<td>Dr. Textor</td>
</tr>
<tr>
<td>St. Johannes Hospital, Dortmund, D</td>
<td>Prof. Schürmann</td>
</tr>
<tr>
<td>Diakonissenkrankenhaus, Flensburg, D</td>
<td>Prof. Müller-Hülsbeck</td>
</tr>
<tr>
<td>Asklepiosklinik Hamburg-Altona, Hamburg, D</td>
<td>Prof. Fischbach</td>
</tr>
<tr>
<td>Asklepiosklinik Hamburg-Harburg, Hamburg, D</td>
<td>Prof. Gross-Fengels</td>
</tr>
<tr>
<td>Klinikum Idar-Oberstein, Idar-Oberstein, D</td>
<td>Dr. Boguth</td>
</tr>
<tr>
<td>Klinikum Klagenfurt, Klagenfurt, A</td>
<td>Prof. Hausegger</td>
</tr>
<tr>
<td>Elisabethinen Krankenhaus, Linz, A</td>
<td>Dr. Gschwendtner</td>
</tr>
<tr>
<td>Klinikum Passau, Passau, D</td>
<td>Prof. Tacke (PI)</td>
</tr>
<tr>
<td>Klinikum Rosenheim, Rosenheim, D</td>
<td>Prof. Tepe</td>
</tr>
<tr>
<td>Klinikum Straubing, Straubing, D</td>
<td>Dr. Häuser</td>
</tr>
<tr>
<td>Allgemeines Krankenhaus Wien, Vienna, A</td>
<td>Prof. Lammer/Prof. Loewe</td>
</tr>
</tbody>
</table>
The Freeway Stent Study: the 12 Months results highly favor the use of DEB in combination with stenting

J. Tacke, K.A. Hausegger, H. Schröder, J. Dambach, S. Stahnke,

S.Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology