24-month outcomes in the EVOLUTION study
Investigating the iVolution stent in fempop lesions

Dr. Marc Bosiers
LINC 2019 - Leipzig
My disclosures

☒ I do not have any potential conflicts of interest to report

☐ 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)
Results with stents in the SFA – TASC A&B

Primary Patency at 12 months = +/- 78%

Stent
1. FAST
2. FACT
3. RESILIENT
4. DURABILITY
5. ASTRON
6. VIENNA
7. 4EVER
iVolution Stent Design

Flexibility

Radial force

- Linkless continuous design
- Homogeneous radial force
- Lower tensions
- Recovery after impact
- Flexibility

- Open short-cell design
- No kinking
- Anti-kinking
- Total adaptability to vessel
- High visibility

- Fracture resistant
- Open short-cell design
- Homogeneous radial force
- Lower tensions
- Recovery after impact
- Flexibility
Evolution study

A Prospective, non-randomized, multi center study investigating the Efficacy of the Self-Expanding iVolution nitinol stent for treatment of femoropopliteal lesions
Study design

• **Study Objective:**
  To evaluate the short-term (up to 12 months) outcome of treatment by means of the self-expanding iVolution nitinol stent in symptomatic (RF 2-4) femoropopliteal stenotic or occlusive lesions

• **Primary Endpoint:**
  Primary Patency at 12Months, defined as freedom from >50% restenosis at 12months as indicated by an independently verified duplex ultrasound PSVR <2.5 in the target vessel with no reintervention.
Participating centers

• BELGIUM
  • M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  • P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  • L. Maene, R. Beelen - OLV, Aalst
  • K. Keirse - RZ Heilig Hart, Tienen
Main inclusion criteria

- Rutherford classification from 2 to 4
- De novo lesion in the femoropopliteal arteries, suitable for endovascular therapy
- Total target lesion length ≤ 150mm

EVOLUTION

120 out of 120 patients enrolled (100%)
### Study overview

<table>
<thead>
<tr>
<th>Timeline</th>
<th>proc</th>
<th>disch</th>
<th>1 M</th>
<th>6 M</th>
<th>12 M</th>
<th>24 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Physical examination</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Rutherford</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>ABI</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Core Lab Ultrasound</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Duplex Ultrasound</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
## Patient demographics

<table>
<thead>
<tr>
<th>Condition</th>
<th>N (%)</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td>71.67%</td>
<td>86/120</td>
</tr>
<tr>
<td><strong>Age (min – max; ±SD)</strong></td>
<td>71.07</td>
<td>42.74 – 94.88; ±10.68</td>
</tr>
<tr>
<td>Nicotine abuse</td>
<td>63.33%</td>
<td>76/120</td>
</tr>
<tr>
<td>Hypertension</td>
<td>72.50%</td>
<td>87/120</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td><strong>21.67%</strong></td>
<td><strong>26/120</strong></td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>15.83%</td>
<td>19/120</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>55.00%</td>
<td>66/120</td>
</tr>
<tr>
<td>Obesity</td>
<td>25.83%</td>
<td>31/120</td>
</tr>
</tbody>
</table>

**Rutherford Classification**

- RF 2: 22
- RF 3: 76
- RF 4: 22
**Procedural characteristics**

<table>
<thead>
<tr>
<th></th>
<th>N = 120</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure time</strong> (min-max; ±SD)</td>
<td><strong>41.93 min (13.0 – 109.0; ±15.74)</strong></td>
</tr>
<tr>
<td><strong>Scopy time</strong> (min – max; ±SD)</td>
<td><strong>10.39 min (3.40 – 70.00; ±8.11)</strong></td>
</tr>
<tr>
<td><strong>Contrast</strong> (min – max; ±SD)</td>
<td><strong>76.88 mL (15.00 – 200.00; ±34.08)</strong></td>
</tr>
<tr>
<td>Cross-over performed</td>
<td><strong>87.50% (105/120)</strong></td>
</tr>
<tr>
<td>Inflow Lesion</td>
<td><strong>15 (18/120)</strong></td>
</tr>
<tr>
<td>Outflow lesion</td>
<td><strong>18.33% (22/120)</strong></td>
</tr>
</tbody>
</table>
## Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion length</strong> &lt;br&gt; (min – max; ±SD)</td>
<td>89.63 mm (9.0 – 150.0; ±44.68)</td>
</tr>
<tr>
<td><strong>Ref Vessel Diameter</strong> &lt;br&gt; (min – max; ±SD)</td>
<td>5.63 mm (4.00 – 7.00; ±0.58)</td>
</tr>
<tr>
<td>1 study stent implanted</td>
<td>93.33% (112/120)</td>
</tr>
<tr>
<td>2 study stents implanted</td>
<td>6.67% (8/120)</td>
</tr>
<tr>
<td><strong>Occlusion</strong></td>
<td>40.00% (48/120)</td>
</tr>
<tr>
<td><strong>Calcified lesion</strong></td>
<td>71.67% (86/120)</td>
</tr>
</tbody>
</table>
12-month Primary Patency

Primary Patency Rate - 120 pts - 12MFU

Cumulative Primary Patency Rate (%)

Time (days)

Number at risk

120 118 114 113 111 110 108 104 100 96 94 92 90 89

86.30%
12-month Freedom from TLR

Freedom from Target Lesion Revascularization - 120 pts - 12MFU

88.00%
12-month evolution in Rutherford Classification

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL</td>
<td>96</td>
<td>84</td>
<td>75</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1M</td>
<td>22</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>8</td>
<td>96</td>
</tr>
<tr>
<td>6M</td>
<td>76</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>8</td>
<td>96</td>
</tr>
<tr>
<td>12M</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

---

**Legend:**
- **RF5**: Yellow
- **RF4**: Orange
- **RF3**: Green
- **RF2**: Yellow
- **RF1**: Light Green
- **RF0**: Dark Green
24-month Primary Patency

Primary Patency - 24MFU - 120 pts

Cumulative Primary Patency Rate (%) vs Time (days)

Number at risk:
120 118 115 114 112 111 108 104 100 96 94 92 90 89 80 77 76 75 72 69 66 65 64 64 63 19

76.70%
24-month Freedom from TLR

Cumulative Freedom from TLR Rate (%)

Time (days)

Number at risk

120 117 116 114 111 110 109 107 103 99 96 94 93 90 80 77 76 75 72 69 66 66 64 64 64 20

77.20%
Results with stents in the SFA – TASC A&B

Primary Patency @ **12 months**

- **1. FAST**
- **2. FACT**
- **3. RESILIENT**
- **4. DURABILITY**
- **5. ASTRON**
- **6. VIENNA**
- **7. 4EVER**
- **8. Evolution**
## Results in perspective...

<table>
<thead>
<tr>
<th></th>
<th>ALL (mm)</th>
<th>Occlusions (%)</th>
<th>2-Year PP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVOLUTION</td>
<td>89.63</td>
<td>40.00</td>
<td>76.70</td>
</tr>
<tr>
<td>DURABILITY II</td>
<td>89</td>
<td>48.00</td>
<td>66.00</td>
</tr>
<tr>
<td>SUPERA</td>
<td>90</td>
<td>31.00</td>
<td>76.10</td>
</tr>
<tr>
<td>STROLL</td>
<td>77</td>
<td>23.60</td>
<td>74.90</td>
</tr>
<tr>
<td>ZILVER PTX</td>
<td>66</td>
<td>30.00</td>
<td>74.80</td>
</tr>
<tr>
<td>4EVER</td>
<td>71</td>
<td>20.80</td>
<td>72.30</td>
</tr>
</tbody>
</table>
Conclusion

• Final results show that the iVolution stent is a very effective treatment for femoropopliteal TASC A&B lesions

• Even on the longer term...