12-month outcomes in the EVOLUTION study
Investigating the iVolution stent in femoropopliteal lesions

Dr. Marc Bosiers

LINC 2018, Leipzig
Conflict of interest

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

![Graph showing primary patency at 12 months (PP @ 12 months)](image)

**Primary Patency at 12 months = +/- 78%**

- **FAST**
- **FACT**
- **RESILIENT**
- **DURABILITY**
- **ASTRON**
- **VIENNA**
- **4EVER**

<table>
<thead>
<tr>
<th>Lesion length (cm)</th>
<th>12-month Primary Patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>90</td>
</tr>
<tr>
<td>10</td>
<td>80</td>
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<tr>
<td>15</td>
<td>70</td>
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<tr>
<td>20</td>
<td>60</td>
</tr>
<tr>
<td>25</td>
<td>50</td>
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<tr>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>35</td>
<td>30</td>
</tr>
<tr>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>45</td>
<td>10</td>
</tr>
<tr>
<td>50</td>
<td>0</td>
</tr>
</tbody>
</table>

**FMRP - LINC 2018**
Too low...

Impossible to open the lesion

Residual stenosis

>50% residual stenosis
Stent Design Affects Chronic Outward Force

TOO HIGH...

Chronic stent-vessel irritation

Intimal Hyperplasia
Stent Design Affects Chronic Outward Force

Example: 8 mm stent

7.3 – 6.2 mm
6.2 – 5.0 mm
5.0 – 4.2 mm

HIGH OVERSIZING

Even when oversizing low rates of COF, due to the flat expansion curve
Stent Design Affects Chronic Outward Force

Bent Leg: vessel diameter range: 5.02 - 2.98 mm: 6mm stent implant

Expansion force increases with decreasing diameter.

Illustration is artist's rendition.
Expansion force increases with decreasing diameter.

Stent Design Affects Chronic Outward Force

Bent Leg: vessel diameter range: 5.02 - 2.98 mm: 6mm stent implant

Flat expansion force curves induce lower COF & offer less concern for precise vessel sizing.

Illustration is artist’s rendition.
iVolution Stent Design

Flexibility

Radial force

- Linkless continuous design
- Homogeneous radial force
- Lower tensions
- Recovery after impact
- Flexibility
- Total adaptability to vessel
- Open short-cell design
- No flaking
- Anti-kinking
- 4 RO markers in either end of the stent
- High visibility
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
Inclusion criteria

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>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Physical examination</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>
</tr>
<tr>
<td>ABI</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Core Lab Ultrasound</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Duplex Ultrasound</td>
<td></td>
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</tbody>
</table>

**Legend:**
- **Black**: Procedural
- **Discharge**: Discharge
- **Red/Pink**: Assessment
- **Grey**: Follow-up
# Patient Demographics

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

**Rutherford Classification**

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

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

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

N = 120
12-month Primary Patency

Primary Patency Rate - 120 pts - 12MFU

Number at risk

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

Cumulative Primary Patency Rate (%)

Time (days)

0 30 60 90 120 150 180 210 240 270 300 330 360 390

86.30%
12-month Freedom from TLR

Freedom from Target Lesion Revascularization - 120 pts - 12MFU

Cumulative Freedom from TLR Rate (%)

Time (days)

Number at risk

<table>
<thead>
<tr>
<th>Number at risk</th>
</tr>
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<tbody>
<tr>
<td>120</td>
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</tbody>
</table>

88.00%
12-month Rutherford evolution
Results with **stents** in the SFA – TASC A & B

Primary Patency @ **12 months**

- **Stent**
  1. FAST
  2. FACT
  3. RESILIENT
  4. DURABILITY
  5. ASTRON
  6. VIENNA
  7. 4EVER
  8. Evolution

**Graph:**
- **Y-axis:** 12-month Primary Patency (%)
- **X-axis:** Lesion length (cm)

- Points corresponding to stents:
  - FAST
  - FACT
  - RESILIENT
  - DURABILITY
  - ASTRON
  - VIENNA
  - 4EVER
  - Evolution

**Legend:**
- FAST
- FACT
- RESILIENT
- DURABILITY
- ASTRON
- VIENNA
- 4EVER
- Evolution
Conclusion

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