First 6-month results in 75 patients in the EVOLUTION study

Investigating the iVolution stent in femoropopliteal lesions

Dr. Marc Bosiers

LINC 2017, Leipzig
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

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

Stent
1. FAST
2. FACT
3. RESILIENT
4. DURABILITY
5. ASTRON
6. VIENNA
7. 4EVER
Stent design Affects *Chronic Outward Force*

**TOO LOW...**

- Impossible to open the lesion
- Residual stenosis

>50% residual stenosis
Stent Design Affects **Chronic Outward Force**

![Diagram showing the effect of stent design on chronic vessel irritation and intimal hyperplasia](image)

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

Stent Design Affects Chronic Outward Force

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.

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

Illustration is artist's rendition.

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

Flexibility

Radial force

- Linkless continuous design
- Homogeneous radial force
- Lower tensions
- Recovery after impact
- Flexibility
- Total adaptability to vessel
- 4 RO markers in either end of the stent
- Open short-cell design
- No flaking
- Anti-kinking
- 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 12 Months, defined as freedom from >50% restenosis at 12 months 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

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

Timeline

- Medication
- Physical examination
- Rutherford
- ABI
- Core Lab Ultrasound
- Duplex Ultrasound

Timeline:
- proc
- disch
- 1 M
- 6 M
- 12 M

Rutherford ABI Core Lab Ultrasound Duplex Ultrasound
## Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>N = 75 out of 120</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male (%)</strong></td>
<td>55 (73.33%)</td>
</tr>
<tr>
<td><strong>Age (min - max; ±SD)</strong></td>
<td>71.22 (50.23 – 89.91; ±9.67)</td>
</tr>
<tr>
<td><strong>Nicotine abuse (%)</strong></td>
<td>50 (66.67%)</td>
</tr>
<tr>
<td><strong>Hypertension (%)</strong></td>
<td>45 (64.29%)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus (%)</strong></td>
<td>15 (21.43%)</td>
</tr>
<tr>
<td><strong>Renal insufficiency (%)</strong></td>
<td>9 (12.00%)</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia (%)</strong></td>
<td>37 (49.33%)</td>
</tr>
<tr>
<td><strong>Obesity (%)</strong></td>
<td>17 (22.67%)</td>
</tr>
</tbody>
</table>

### Rutherford Classification

- RF 2: 18
- RF 3: 47
- RF 4: 10
### Procedural characteristics

<table>
<thead>
<tr>
<th></th>
<th>N = 75 out of 120</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure time</strong></td>
<td>41.49 min (16.0 – 109.0; ±41.49)</td>
</tr>
<tr>
<td>(min-max ; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Scopy time</strong></td>
<td>10.02 min (3.40 – 70.00 ; ±8.47)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Contrast</strong></td>
<td>78.67 mL (15.00 – 200.00 ; ±35.81)</td>
</tr>
<tr>
<td>(min – max; ±SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Cross-over performed</strong></td>
<td>67 (89.33%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Inflow Lesion</strong></td>
<td>14 (18.67%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Outflow lesion</strong></td>
<td>7 (9.33%)</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
</tr>
</tbody>
</table>
# Lesion Characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 75 out of 120</td>
<td></td>
</tr>
<tr>
<td><strong>Lesion length</strong> <em>(min – max; ±SD)</em></td>
<td>*<em>86.64 mm (9.0 – 150.0; ±45.24)</em></td>
</tr>
<tr>
<td><strong>Ref Vessel Diameter</strong> <em>(min – max; ±SD)</em></td>
<td>*<em>5.57 mm (4.00 – 7.00 ; ±0.591)</em></td>
</tr>
<tr>
<td>1 stent received (%)</td>
<td><strong>67 (89.33%)</strong></td>
</tr>
<tr>
<td>2 stents received (%)</td>
<td><strong>8 (10.67%)</strong></td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td><strong>31 (41.33%)</strong></td>
</tr>
<tr>
<td>Calcified lesion (%)</td>
<td><strong>48 (64.00%)</strong></td>
</tr>
</tbody>
</table>

**Pre-op**
6-month Primary Patency

Primary Patency at 6 months - 75pts

Cumulative Primary Patency Rate (%)

Time (days)

Number at risk

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Number at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-30</td>
<td>75</td>
</tr>
<tr>
<td>31-60</td>
<td>73</td>
</tr>
<tr>
<td>61-90</td>
<td>69</td>
</tr>
<tr>
<td>91-120</td>
<td>67</td>
</tr>
<tr>
<td>121-150</td>
<td>67</td>
</tr>
<tr>
<td>151-180</td>
<td>66</td>
</tr>
<tr>
<td>181-210</td>
<td>64</td>
</tr>
<tr>
<td>211-240</td>
<td>26</td>
</tr>
</tbody>
</table>

- 95.6%
- 94.1%
## 6-month Rutherford evolution

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Discharge</th>
<th>1MFU</th>
<th>6MFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF5</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>RF4</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>RF3</td>
<td>47</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>RF2</td>
<td>18</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>RF1</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>RF0</td>
<td>0</td>
<td>68</td>
<td>55</td>
<td>50</td>
</tr>
</tbody>
</table>
Results with stents in the SFA – TASC A & B

Primary Patency @ 6 months

- Stent 1: FAST – N.A.
- Stent 2: FACT – N.A.
- Stent 3: RESILIENT
- Stent 4: DURABILITY
- Stent 5: ASTRON
- Stent 6: VIENNA
- Stent 7: 4EVER
- Evolution

Graph showing the relationship between lesion length (cm) and 6-month primary patency (%).
Results with stents in the SFA – TASC A & B

Primary Patency @ 12 months

12-month Primary Patency (%) vs. Lesion length (cm)

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

• Preliminary results suggest that the iVolution stent is a valid and effective alternative to treat femoropopliteal TASC A&B lesions

• Awaiting for the final 12-month results
First 6-month results in 75 patients in the EVOLUTION study

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