Or is the iVolution stent a better alternative?

EVOLUTION 12-month data

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

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**

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

![Graph showing normalized radial force during stent expansion for different stent designs.](image)
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.
Stent Design Affects Chronic Outward Force

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**

- Tenino Wakro
- Abbott Zeniual Pro LR
- Boston Scientific Complete SE
- Boston Valve
- Medtronic Complete SE
- iVolution

**Radial force**

- Tenino Wakro
- Abbott Zeniual Pro LR
- Boston Scientific Complete SE
- Boston Valve
- Medtronic Complete SE
- iVolution

- iVolution

**Key Features**

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

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

Timeline

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

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

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

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

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

Pre-op
12-month Primary Patency

Primary Patency Rate - 120 pts - 12MFU

Cumulative Primary Patency Rate (%)

Time (days)

Number at risk

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
120 118 115 113 111 110 107 103 99 96 94 93 90

88.00%
12-month Rutherford evolution

<table>
<thead>
<tr>
<th></th>
<th>BL</th>
<th>1M</th>
<th>6M</th>
<th>12M</th>
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<tr>
<td>RF5</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>4</td>
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<tr>
<td>RF4</td>
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<td>0</td>
</tr>
<tr>
<td>RF3</td>
<td>76</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>RF2</td>
<td>22</td>
<td>1</td>
<td>4</td>
<td>2</td>
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<tr>
<td>RF1</td>
<td>0</td>
<td>8</td>
<td>7</td>
<td>6</td>
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<tr>
<td>RFO</td>
<td>0</td>
<td>96</td>
<td>84</td>
<td>75</td>
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</table>
Results with stents in the SFA – TASC A & B

Primary Patency @ 12 months

- **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
Or is the iVolution stent a better alternative?

EVOLUTION 12-month data

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