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

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Disclosure

Speaker name:

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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)

🚫 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

**12-month Primary Patency (%)** vs. **Lesion length (cm)**
Stenting in 2018

- Primary stenting vs bail-out stenting
- Adjunctive therapies
- Calcified lesions
- Elastic recoil
- Dialysis Access
iVolution stent design

ANTIKINKING

TOTAL ADAPTABILITY TO THE VESSEL
High flexibility and radial force

HIGH VISIBILITY
Stent: 4 radiopaque markers
Delivery system: 3 radiopaque markers

OPTIMISED MATERIAL
Biocompatibility and fracture resistant

MAX INCLUSION AREA FRACTION (µ2)

- Complete ES (M)
- Smart Flex (C)
- EPIC (BS)
- Lifestent (B)
- Absolute Pro (A)
- iVolution (IV)

Flexibility
Radial force

Graph showing comparison of flexibility and radial force among different stent models.
Stent Design

Flexibility

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

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

Timeline

Medication
Physical examination
Rutherford
ABI
Core Lab Ultrasound
Duplex Ultrasound
# 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>Diabetes mellitus (%)</td>
<td>26</td>
<td>21.67%</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>
## 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>Scopy time ((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>105 ((87.50%))</strong></td>
</tr>
<tr>
<td>Inflow Lesion (%)</td>
<td><strong>18 ((15.00%))</strong></td>
</tr>
<tr>
<td>Outflow lesion (%)</td>
<td><strong>22 ((18.33%))</strong></td>
</tr>
</tbody>
</table>
## Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion length ((\text{min – max; } \pm \text{SD}))</th>
<th>89.63 mm ((9.0 – 150.0; \pm 44.68))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref Vessel Diameter ((\text{min – max; } \pm \text{SD}))</td>
<td>5.63 mm ((4.00 – 7.00; \pm 0.58))</td>
</tr>
<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>
12-Month Primary Patency

Primary Patency Rate - 120 pts - 12MFU

Cumulative Primary Patency Rate (%)

- 96.5% at 180 days
- 86.3% at 360 days

Number at risk:
120 118 114 113 111 110 108 104 100 96 94 92 90 89
12-month Freedom from TLR

Freedom from Target Lesion Revascularization - 120 pts - 12MFU

Cumulative Freedom from TLR Rate (%)

Time (days)

Number at risk

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

98.2% 88.0%
12-month Rutherford evolution

<table>
<thead>
<tr>
<th></th>
<th>BL</th>
<th>1M</th>
<th>6M</th>
<th>12M</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF5</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>RF4</td>
<td>22</td>
<td>0</td>
<td>0</td>
<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>
</tr>
<tr>
<td>RF1</td>
<td>0</td>
<td>8</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>RF0</td>
<td>0</td>
<td>96</td>
<td>84</td>
<td>75</td>
</tr>
</tbody>
</table>
Results with stents in the SFA – TASC A & B

Primary Patency @ **6 months**

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

### Graph Details

- **Y-axis:** 6-month Primary Patency (%)
- **X-axis:** Lesion length (cm)
- **Stents:**
  - FAST
  - FACT
  - RESILIENT
  - DURABILITY
  - ASTRON
  - VIENNA
  - 4EVER
  - Evolution

### Legend

- **Points:** Represent patency rates for different lesion lengths.
Results with stents in the SFA – TASC A & B

Primary Patency @ 12 months

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

Stent
1. FAST – N.A.
2. FACT – N.A.
3. RESILIENT
4. DURABILITY
5. ASTRON
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Conclusion

Final results show that the iVolution stent is a valid and effective alternative to treat femoropopliteal TASC A&B lesions.
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