The Nellix learning curve after 2000 patients treated

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Disclosures

- **Consultant**: Endologix Inc, Medtronic, Aptus Endosystems

- **Advisory Board**: Endologix Inc.

- **Research grant**: Cardionovum, Vascular Insights

- **Speaker fee**: BTG
Advantages of Nellix

<table>
<thead>
<tr>
<th>Weaknesses of Current Stent Graft Designs</th>
<th>NELLIX</th>
<th>Angio before/after polymer filling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomic fixation in limited landing zones</td>
<td>Complete anatomic apposition</td>
<td></td>
</tr>
<tr>
<td>Localized sealing</td>
<td>Complete anatomic seal</td>
<td></td>
</tr>
<tr>
<td>Lateral forces that displace the graft</td>
<td>Nowhere to move</td>
<td></td>
</tr>
<tr>
<td>Branch vessels perfusing the aneurysm</td>
<td>No Type II Endoleak</td>
<td></td>
</tr>
</tbody>
</table>
Lesson #1  Learning curve

Get familiar with the concept

Stay within IFU when starting

Get to know the Nellix-device
Lesson #2  Sizing/planning

Recent CT scan for accurate volume calculations

Use workstation for planning
Lesson #2  Sizing/planning

Recent CT scan for accurate volume calculations

Use workstation for planning

Endosize software

<table>
<thead>
<tr>
<th>Stent Reference</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>N10-120</td>
</tr>
<tr>
<td>Right</td>
<td>N10-130</td>
</tr>
<tr>
<td>Total Adjusted Volume</td>
<td>102 ml</td>
</tr>
<tr>
<td>Estimated Polymer Volume</td>
<td>84 ml</td>
</tr>
</tbody>
</table>
Lesson #2  Sizing/planning

- Estimated / actual endobag volume (n=40)

Boersen J et al; in press
Lesson #2  Sizing/planning

- Differences in pre- and post-EVAS aortic characteristics (n=40)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre</th>
<th>Post</th>
<th>Paired samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Range</td>
<td>Mean</td>
</tr>
<tr>
<td>Maximum AAA diameter</td>
<td>59.7</td>
<td>50-87</td>
<td>59.6</td>
</tr>
<tr>
<td>Volume (mL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow lumen</td>
<td>89.1</td>
<td>36.4-193.7</td>
<td>98.1</td>
</tr>
<tr>
<td>Thrombus</td>
<td>81.5</td>
<td>17.6-235.9</td>
<td>75.6</td>
</tr>
<tr>
<td>Total AAA</td>
<td>170.6</td>
<td>106-339.7</td>
<td>173.7</td>
</tr>
</tbody>
</table>

Boersen J et al; *in press*
Lesson #3 Procedure always use prefill

- Non-heparinized saline
- Predefined volume
- Pressure is key
  - 180 mmHg
  - DSA $\rightarrow$ type I endoleak $\rightarrow$ 200 mmHg $\rightarrow$ DSA

- In AAA with thrombus: thrombus might be compressed
- In doubt: contrast in saline.

- Watch the monitor and position of the stents
- Prefill allows repositioning of the Nellix device (!)
Lesson #4   Avoidance of aortic perforation

Concept volume vs pressure in the endobags

![Graph showing volume vs pressure relationship in endobags.](image)
Lesson #5  Use step by step implantation protocol

Optional re-measurement of device length

Angiography for positioning

Stent deployment with 7 atm.
Lesson #5   Use step by step implantation protocol

- DSA during saline prefill
- Pressure controlled polymer injection
- Inflation balloons during curing polymer
- Angiography after polymer curing
Lesson #6   Procedure avoid thrombotic issues

• Pre-EVAS sizing / planning
• Inflation Nellix balloons during cure of polymer
• Post-dilatation 10*4 mm balloons
Thrombus in EVAR is shear mediated

- Patient CT data
  - Lumen diameter and calculated shear rate measured for 3 thrombotic and 2 non-thrombotic patients
Lesson #6 Procedure avoid thrombotic issues

- Completion DSA without stiff guide wires.
- Rotational views distal landing zones
- Alignment bare / covered stents
Lesson #7   Procedure inflation Nellix balloons

• Might help to straighten the stents in challenging aortas.
  – Non-thrombosed, large diameter AAA
  – “Stomach shaped AAA”

Courtesy prof D. Bockler, Heidelberg
Lesson #7  Procedure inflation Nellix balloons

Endobags empty

Endobags filled
no inflation

Endobags filled
with inflation
Lesson #7  Procedure inflation Nellix balloons

• Be aware off:
  – Straightening stents due to balloons might change entire aortic anatomy
  – Pressure in endobags is false positive with balloons inflated
Lesson #8  Type IA endoleaks post-EVAS

- High flow Type IAs will not disappear spontaneously
- Type IA might increase due to clot reduction
- Embolization / glue
- Protect renal arteries during embolization
<table>
<thead>
<tr>
<th>St. Antonius experience (demographics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
</tr>
<tr>
<td>male, female</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>ASA 3 / 4</td>
</tr>
</tbody>
</table>
St. Antonius experience (aorta characteristics)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA (n)</td>
<td>61</td>
</tr>
<tr>
<td>Iliac aneurysm (n)</td>
<td>6</td>
</tr>
<tr>
<td>AAA- size (mm)</td>
<td>59 (42-81)</td>
</tr>
<tr>
<td>Neck diameter (mm)</td>
<td>28 (21-31)</td>
</tr>
<tr>
<td>Neck length (mm)</td>
<td>20 (8-51)</td>
</tr>
<tr>
<td>Non-IFU</td>
<td>27 %</td>
</tr>
</tbody>
</table>
St. Antonius experience (outcome, mean FU 11 ± 6 mths)

- Overall mortality: 0
- Aneuysm-associated mortality: 0
- Reintervention free survival: 93%
- Rupture / Conversion: 0 / 1
- Postop. renal failure / no dialysis: 0
St. Antonius experience (outcome, mean FU 11 ± 6 mths)

- Technical success 100 %
- Endoleak Type 2 0 %
- Type 1 (a and b) 0 %
- Device related reinterventions n=4
  - Thrombectomy for occlusion 3
  - All before introduction of ballooning stents
  - Explantation due to sec. infection 1
Conclusions

- EVAS technique different compared to modular devices
- Most growing pains have been overcome
- Following the step-by-step protocol (pre-, peri- and post-EVAS) minimizes complications
- Low incidence of type I / II endoleaks
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