Advantages and Disadvantages of Nellix Endografts for EVAS Based on Experience in 5000 Cases

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Disclosures

- Consultant
  - Endologix, Gore, Medtronic
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- Advisory Board
  - Endologix, Gore, Medtronic, Siemens
- Major Stakeholder
  - None

2013 Nellix CE Marking
Feb 2013

2014 2015 2016 2017

“Early Learning Curve” Cases
171 consecutive patients treated at 7 centers between Oct 2012 – March 2014

Results (5 mo follow-up)
- 8% endoleak
- 5% limb occlusion
- 9% reintervention
- No rupture
- No conversions

Early Techniques and Learning Curve

- Attempted Complex AAA
- Procedure Was Early in Its Maturity
- Juxtarenal AAA, Hostile Necks
- Nellix Stent Misalignment
- Low Stent Placement

Early Techniques and Learning Curve

- Insufficient correction for parallax
- Didn’t use contrast in prefill
- Didn’t leave balloons up or maintain nominal inflation pressure during polymer fill and curing
Limb Thrombosis Occurs in Under-dilated Nellix Stents

Increasing Clinical Evidence

IFU Compliance Matters

"The 'sealing the entire aneurysm' idea...quite simply represents a very seductive concept that seems to lure the vascular surgeon beyond the IFU."

"Little to no neck? Angulated necks? Large necks?...All not a problem, the endobags will take care of it...the sky seems the limit."
Select Anatomies Well Suited for Nellix

- Concomitant Iliac Aneurysm
- Short Common Iliacs
- Patent IMA/Lumbars
- Distal Endobag Attachment for Precise Placement

Proximal Neck Utilization Reduces Reintervention Risk

<table>
<thead>
<tr>
<th>Condition</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Endoleak</td>
<td>0.946</td>
<td>0.884, 1.013</td>
<td>0.1121</td>
</tr>
<tr>
<td>Proximal Reintervention</td>
<td>0.939</td>
<td>0.891, 0.990</td>
<td>0.0195</td>
</tr>
</tbody>
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Increasing Neck Utilization Reduces Migration Risk

- Early Technique: Less neck utilization in Global Registry
- Key Learning: Greater neck utilization in IDE

Establishing Seal during EVAS Procedure

- Optimal seal requires precise management of Pressure AND Volume
- Inflate Nellix balloons to nominal pressure (7 Atm) for 30 seconds
- Leave balloons up during polymer fill

Successful Repair of Type 1a Endoleak after EVAS

- Transcatheter Embolization
- 99.6% Freedom from Persistent Type 1A Endoleaks, demonstrated by successful secondary repair

Conclusions

- EVAS procedure has matured within since its commercial introduction only 3 years ago
- Excellent outcomes when IFU Compliant
  - Avoid short neck, hostile neck; consider f-EVAR or chimneys
- Excellent outcomes when adopting procedural best practices
  - Proximal neck utilization, Nellix stent management, and polymer fill strategies mandatory to achieve adequate fill
  - Distal landing zone required in iliac arteries
- EVAS maintains an important role for endovascular AAA therapy