The Auckland Experience with the Nellix EVAS System

Andrew Holden, MBChB, FRANZCR
Disclosure

Speaker name:
Associate Professor Andrew Holden

I have the following potential conflicts of interest to report:

☒ Consulting – Clinical Investigator for Endologix
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Nellix EndoVascular Aneurysm Sealing System (EVAS)

*New generation endovascular AAA therapy*
*Designed to seal the entire aneurysm and overcome limitations with conventional endografts*
Nellix Evolution: Toward a Commercial Product

<table>
<thead>
<tr>
<th>Year</th>
<th>Gen 1</th>
<th>Gen 2</th>
<th>Gen 3</th>
</tr>
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<tbody>
<tr>
<td>2008</td>
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<tr>
<td>2009</td>
<td>Gen 1</td>
<td></td>
<td></td>
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<tr>
<td>2010</td>
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<td>Gen 2</td>
<td>Gen 3</td>
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<td>2011</td>
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<td>2012</td>
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<td>2013</td>
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Nellix Pilot Study: Early Outcomes

- **N = 35 patients**
  - Dec 2010 and Dec 2012
  - NZ and Latvia
  - Core Lab observations

- No deaths or surgical conversions
- No stent fracture, endobag fatigue, or device migration
- No type I, III, or IV endoleak
- Two small, clinically insignificant Type II EL (<1mL volume)
  - No changes in aneurysm sac diameters to current follow-up

- **Sac diameters remain stable in all patients to current follow-up**

Nellix Pilot Study: Early Outcomes

Eur J Vasc Endovasc Surg 2011;42:38-46
Nellix Early Commercial Experience: Developing the EVAS Procedure

- Report of first commercial patients treated with Nellix
- Purpose: To document early initial commercial outcomes and key learnings
- 171 patients, 7 centers, over a 17 month period
- Mean follow-up 5 months (range 0-14)
- Centers:
  - Auckland City Hospital (NZL)
  - University of Heidelberg (DE)
  - St. George’s Hospital London (UK)
  - Addenbrooke’s Hospital Cambridge Univ. (UK)
  - Arnhem Hospital (NL)
  - St. Antonius Hospital (NL)
  - University Hospital Riga (LAT)
Nellix Early Commercial Experience: Results

- 99% technical success
- Type Ia EL = 5
- Type Ib EL = 4
- Type II EL = 4
- Limb occlusion = 4
- 95% freedom from aneurysm-related intervention
- *No aneurysm rupture*
- *No conversions*

**Key Learnings**
- ✓ Ensure proper device positioning
- ✓ Ensure adequate filling
- ✓ Optimize flow lumen
- ✓ “Blow Back” completion angiogram to confirm adequate deployment
Advantages of Nellix EVAS or Standard EVAR

- **Procedural Simplicity**
  - Essentially “kissing stent” procedure
  - Predictable procedure time
- Extended Applications for the Proximal Neck
- Extended Applications for the Iliac Arteries
- Advanced Applications
Durability

1 month

3 years

5 years
Advantages of Nellix EVAS or Standard EVAR

• Procedural Simplicity
  – Essentially “kissing stent” procedure
  – Predictable procedure time

• Extended Applications for the Proximal Neck

• Extended Applications for the Iliac Arteries

• Advanced Applications
EVAS for Conical Neck Anatomy
EVAS for Short Neck Anatomy

LAO 15°, Cran 15°

LAO 15°, Cran 15°
Advantages of Nellix EVAS or Standard EVAR

- Procedural Simplicity
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- Extended Applications for the Proximal Neck

- Extended Applications for the Iliac Arteries

- Advanced Applications
EVAS for Concomitant CIAAs
EVAS for Short CIAs
Advantages of Nellix EVAS or Standard EVAR

• Procedural Simplicity
  – Essentially “kissing stent” procedure
  – Predictable procedure time

• Extended Applications for the Proximal Neck

• Extended Applications for the Iliac Arteries

• **Advanced Applications**
Advanced Applications for Nellix EVAS

- Chimney EVAS
- Ruptured AAA repair
- Isolated iliac aneurysm repair
- Repair of supra-anastomotic AAAs
- Repair of failed EVAR devices (eg type 1A, type 3 endoleaks)
Chimney EVAS (Ch-EVAS)
Nellix EVAS in Failed Surgical AAA Repair
EVAS FORWARD Global Registry

- **Principal Investigators**
  - Andrew Holden, MBChB, Auckland, NZ
  - Matt Thompson, MD, London, UK

- 300 patients, 30 centers with five year follow-up
- Real-world experience; no prospective screening of patients
- CT scan core lab analysis (Cleveland Clinic Core Lab)
- Independent adverse events adjudication
- Primary outcomes typical of therapy

- Enrollment completed September, 2014 (enrollment period 10 months)
- Mean follow-up 165 days; range 0 to 1 year

Total Patients (n=300)

- **Cohort 1** (n=190)
- **Cohort 2** (n=41)
- **Cohort 3** (n=31)
- **Cohort 4** (n=12)

26 (9%) CTs to be classified by core lab
Real World Observations

Cohort 1
69%
N=190
Neck Length ≥ 10mm
Infrarenal Angle ≤ 60°

Cohort 2
15%
N=41
Neck Length 5 -10mm
Infrarenal Angle 61 - 90°

Cohort 3
11%
N=31
Neck Length < 5mm
Infrarenal Angle > 90°
Juxtarenal / Pararenal

Cohort 4
5%
N=12
Ruptured AAA EVAR revisions

16 Chimney Procedures

26 (9%) CTs still in review
Real World Registry Anatomical Classifications

- Neck Length <10mm: 17.0%
- Neck Angle >60°: 9.0%
- Chimney Procedure: 5.7%
- Rupture or EVAR Repair: 3.5%

EVAS Global Registry
ENGAGE Registry
GREAT Registry
### Study Comparison: Endoleak / Limb Occlusion

<table>
<thead>
<tr>
<th></th>
<th>≤30d</th>
<th>&gt;30d</th>
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<tbody>
<tr>
<td></td>
<td>REVIEW (n=130)</td>
<td>GLOBAL (n=288)</td>
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<tr>
<td>Type IA</td>
<td>3 (2%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Type IB</td>
<td>3 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Type II</td>
<td>3 (2%)</td>
<td>1 (0.3%)</td>
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<tr>
<td>Type III</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Type IV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Occlusion</td>
<td>3 (2%)</td>
<td>3 (1%)</td>
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<tr>
<td>Stenosis</td>
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Longer Term Follow Up:
Single Centre Experience at Auckland Hospital

- Experience from December 2008 to November 2014
- Mean follow up 46 months
- Median follow up 14 months
- 120 cases:
  - 104 elective AAA repair
  - 4 symptomatic, non-ruptured aneurysms
  - 2 RAAAs
  - 5 Ch-EVAS
  - 2 AUI EVAS
  - 3 isolated CIAAS
Longer Term Follow Up: Single Centre Experience at Auckland Hospital

- Technical success in 119 patients (99.2%)
- 4 cases with early device prototype without ePTFE covering on the stent required covered stent re-lining of the stent lumens
- 2 type 1A endoleaks – successfully treated with catheter directed embolization
- 1 surgical repair of a CFA occlusion due to a vascular closure device complication
- 1 type 2 endoleak (0.8%)
- Overall re-intervention rate 6.7% but only 4% in the last 100 cases with the commercial device
Nellix Evolution: Toward Evidence-Based Results

2013
- Nellix Pilot Study: Gen 2,3 N=35
- CE Mark Jan 2013

2014
- Retro Review: Early Commercial Experience
  - 7 Ctrs n=171

2015
- Initiate Global Registry N=300
- Enrollment Completion
- 1 YR FU N=300
- 2 YR FU N=300
- 3 YR FU N=300

2016
- Initiate IDE N=180
- Enrollment Completion

2017
- PMA Submission
- US Commercial Launch
Conclusions

- Experience with Nellix EVAS at Auckland Hospital extends from early first in man, through the post-approval registries to new product developments.
- Without doubt, the most innovative and potentially disruptive new device platform I have been involved in.
- Long awaited clinical data is becoming available.
- Future looks exciting.
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