Nellix Endograft System from Endologix for EVAS
Clinical Experience To Date
Type Ia Endoleaks Can Occur and Cause Rupture But They Can Be Detected And Fixed: How To Do So?

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• Advisory Board
  – Endologix, Gore, Medtronic, Siemens
• Major stokeholder
  – none

Concept of EVAS is established
(Endovascular Aneurysm Sealing)

Clinical Experience and Evidence is Increasing
25 Peer-Reviewed Publications to Date

Objectives – Type Ia Endoleak after EVAS

• What is the incidence?
• How to prevent?
• Can we predict and select patients at risk?
• How to detect?
• If Type Ia EL occurs, what to do?
Incidence of Type I a Endoleak
(Single & Multicenter Center Experience)


Incidence of Type I a Endoleak
(US IDE Trial)

30-Day Core Lab Observations

• Endoleaks
  • Type 1A: 1 (0.7%)
  • Type 1B: None
  • Type 2: 8 (5.4%)
  • Type 3: None
  • Type 4: None
  • No Stent Fracture
  • No Lumen Thrombosis or Occlusion

Ref: Carpenter J et al, JVS 2015, October 16, online

EVAS Forward Registry Data will be presented by
Andrew Holden, Auckland, NZ

How to prevent Type Ia Endoleak?

- Remove parallax using sheath marker bands
- Always perform pre-fill procedure
- Keep Nellix balloons up during pre-fill and polymer fill to maintain stent position
- Reposition stents before polymer fill to correct stent position
- Angiography in multiple views – lateral view
- Angiography through pig-tail catheter after one Nellix device removed
- Utilize secondary fill
- Do NOT remove both Nellix devices until full seal confirmed

Remove Parallax Using Sheath Marker Bands

Insufficient correction for parallax
Distal deployment of the Nellix stents
Always Perform Pre-Fill Procedure

1. Provides **accurate estimation** of polymer volume and fill pressure

2. **Simulates** polymer filling of endobags, **visualizes position** of endobag edges and **interaction** between endobags

3. **Visualizes** endobag apposition to anatomy and potential **movement** for **optional repositioning**

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Prefill Procedure

- Stents deployed
- Stent moves during pre-fill
- Stents repositioned
- Polymer fill with stent balloons up

Endobags empty
Endobags filled with saline
Saline aspirated from endobags
Endobags filled with polymer

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Know the Correlation of Volume & Pressure

- **Correlation of Volume & Pressure**

![Volume vs. Pressure Chart]

- Volume (ml of blood lumen volume)
- Pressure (kPa)

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Keeping Balloons Up To Maintain Stent Position

- **Keeping Balloons Up To Maintain Stent Position**

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Potential Causes for Type Ia EL

- **Procedural Factors**
  - Pre-fill step skipped
  - Uneven stent alignment at proximal shelf
  - Stent bowing on outer curve of aneurysm
  - Low device placement (c-arm movement, parallax not removed, or poor procedure technique)

- **Anatomic Factors**
  - Hostile or Off-IFU Aortic proximal necks – severe calcification, significant thrombus, angulation >60°
  - Stomach shaped or asymmetric aneurysms

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Patients at Risk for type Ia EL

- **Stomach shaped morphology**

- Stent bowing and loss of proximal alignment
Non IFU Use – Risk factor for Type Ia Endoleak
Heidelberg Experience
with n=55 pat. with completed 1 year follow-up

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Non IFU cases are at higher risk for endoleaks (p<0.01)
Ref: unpublished data

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How to detect Type Ia Endoleak?

Normal appearance on CT scan
Curvilinear area of flow between endobag and aortic wall on Duplex ultrasound

Ref: Holden A et al. JEVT 2015 Nov, online

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Examples of Type Ia Endoleak

Ref: Holden A et al. JEVT 2015 Nov, online

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Is Type Ia EL associated with rupture risk?

Ref: unpublished data

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Endoleak Type Ia – What to do?

Key Learnings:

- Type 1 endoleaks with Nellix do not resolve spontaneously!
- Diagnose and treat early!
Endoleak Type Ia – What to do?

- **Intraoperative primary Type Ia EL**
  - secondary fill with contrast
  - staged repair if persisting

- **Secondary Type Ia EL**
  - Liquid embolization with scaffolding
  - Proximal Extension with Chimneys
  - Conversion

Use of Nellix for Post-EVAR Type Ia EL

Summary

Endoleak Type Ia using Nellix

- can occur but is rare (1-3%)
- can be prevented
  - by anatomical risk identification (non-IFU, neck anatomy, stomach shaped AAA)
  - by procedural best practice (parallax, pre-fill, balloons up)
- can be detected on ce- CT scan adn Duplex
- is associated with rupture risk
- needs to be treated
  - with embolisation or proximal extension

Conclusions

- Be careful with case selection & optimize procedure
- Need to identify predictors for Type Ia in larger series
- Experience, evidence and ongoing technological improvement will help to reduce Type Ia endoleaks