Long-term results of endoanchors in minimizing EVAR failures in hostile necks: Update from the ANCHOR registry

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On behalf of the ANCHOR trial collaborators
Disclosures:

Consultant for **Medtronic**, Endologix Inc

**Co-PI of the ANCHOR registry**

Research grants: Cardionovum, Angiocare, Endologix, BTG, St. Antonius Fund
Tailored seal and fixation with EndoAnchors

Surgical Anastomosis

EndoAnchoring

Displacement force in Newtons

Melas et al. JVS 2012;55(6):1726-33
ANCHOR Registry: *Real-World Use/ Outcomes of the Heli-FX EndoAnchor System – 2012- current*

| US Principal Investigator | William Jordan, MD  
Emory University, Atlanta, GA, USA |
|----------------------------|--------------------------------------------------|
| EU Principal Investigator | Jean Paul de Vries, MD, PhD  
St. Antonius Hospital, The Netherlands |
| Registry Design            | Prospective, observational, international, multi-center, dual-arm |
| Treatment Arms             | “Primary” – Up to 1000 pts  
“Revision” – Up to 1000 pts |
| Duration                   | 5 Years |
| Follow-up                  | Per Standard of Care at each center & discretion of Investigator |
| Current Enrollment         | 604 patients as of 15 June 2016,  
40 US Sites, 17 European Sites |
Prophylactic Use: Application of EndoAnchor™ implants without evidence of type 1a endoleak, but concern for late failure and/or prevention of neck dilatation.
Primary arm, prophylactic use (n = 314)

Baseline characteristics & aneurysm measurements*

Infrarenal Diameter: **25.6 mm**
Infrarenal Angulation: **24.6°**
Avg Neck Calcium Thickness: **1.2 mm**
Neck Length (median): **11.5 mm**
Conical Neck (>10%/10mm): **41.4%**
Max Aneurysm Diameter: **55.7 mm**

* Mean Core Lab measurements based on ≥51 patients with baseline CTs

HOSTILE NECKS: **91.2%** (229/251)
- Diameter at renals >28mm
- Proximal Neck Length <15mm
- Neck Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium >2mm OR
- Thrombus/Calcium >1mm / 180°

Male: 78%
Female: 22%
Mean Age: 72.4 Years
Prophylactic use, initial outcomes

**TECHNICAL SUCCESS***
Successful deployment of EndoAnchor™ implants with adequate penetration into aortic wall

**PROCEDURAL SUCCESS***
Technical success without type la endoleak at completion arteriography

* Site-reported data

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. duration of Procedure</td>
<td>141.1</td>
</tr>
<tr>
<td>Avg. time to EndoAnchor™ implants</td>
<td>15.8</td>
</tr>
<tr>
<td>Avg. Number of EndoAnchor™ implants</td>
<td>5.5</td>
</tr>
</tbody>
</table>
Prophylactic use, 2 years follow-up

Proximal Endoleaks and Migration | Core Lab

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>0.6% (1/181)</td>
<td>0.0% (0/86)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.0% (0/129)</td>
<td>0.0% (0/43)</td>
</tr>
</tbody>
</table>

Migration was assessed in comparison to the 1-month CT scan
Prophylactic use

AAA Sac Diameter Changes* | Core Lab

At 12 months
N=182
- Decrease 45.6%
- Increase 1.6%
- Stable 52.7%

At 24 months
N=85
- Decrease 61.2%
- Increase 1.2%
- Stable 37.6%

* >5mm change as compared to 30-day post-procedure imaging
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Example of prophylactic use
Therapeutic Use cohort consists of patients receiving EndoAnchor™ implants to treat complications (type 1a EL, migration, neck dilatation) in the Primary and Revision Arms.
Baseline characteristics & aneurysm measurements*

- Infrarenal Diameter: 29.3 mm
- Infrarenal Angulation: 21.3°
- Neck Length (median): 10.2 mm
- Aneurysm Diameter: 69.6 mm
- Conical Neck (>10%/10mm): 50.7%
- Avg Neck Calcium Thickness: 0.27 mm

* Mean Core Lab measurements based on 146 patients with baseline CTs

HOSTILE NECKS: 88.4%
(129/146)
- Diameter at renals >28mm
- Proximal Neck Length <15mm
- Neck Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium >2mm OR
- Thrombus/Calcium >1mm / 180°

Male: 81%
Female: 19%
Mean Age: 77.6 Years
**Therapeutic use, initial outcomes**

**TECHNICAL SUCCESS**
Successful deployment of EndoAnchor™ implants with adequate penetration into aortic wall

- **94.3% Intra-op T1 EL**
- **90.2% Revision**

**PROCEDURAL SUCCESS**
Technical success without type Ia endoleak at completion arteriography

- **87.0% Intra-op T1 EL**
- **89.0% Revision**

<table>
<thead>
<tr>
<th>Avg. duration of Procedure (min)</th>
<th>Avg. time to EndoAnchor™ implants (min)</th>
<th>Avg. number of EndoAnchor™ implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>163 Intra-op T1 EL</td>
<td>23.7 Intra-op T1 EL</td>
<td>6.2 Intra-op T1 EL</td>
</tr>
<tr>
<td>152 Revision</td>
<td>24.2 Revision</td>
<td>7.5 Revision</td>
</tr>
</tbody>
</table>

* Site-reported data
Proximal Endoleaks and Migration | Core Lab

### Intra-Op Type 1 EL

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>1.4% (1/70)</td>
<td>2.9% (1/35)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.0% (0/44)</td>
<td>0.0% (0/17)</td>
</tr>
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### Revision Setting

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>24 months</th>
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<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>19.2% (15/78)</td>
<td>11.1% (3/27)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.0% (0/55)</td>
<td>0.0% (0/16)</td>
</tr>
</tbody>
</table>

Migration was assessed in comparison to the 1-month CT scan.
AAA Sac Diameter Changes* | Core Lab

* >5mm change as compared to 30-day post-procedure imaging
Example of treatment acute type IA endoleak
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Example of treatment acute type IA endoleak
Lack of EndoAnchor penetration in aortic tissue may increase risk of developing/re-developing type I endoleaks

- Porcelain aortic neck
- Diffuse thrombus burden >2 mm
- Undersized endograft

Misdeployment
- Below aortic neck
- Above fabric
Successful deployment of 4 EndoAnchors (prophylactic)

Endograft: Gore Excluder
Misdeployment of EndoAnchors (>2 mm gap)

Endograft: Cook Zenith
Misdeployment of EndoAnchors (undersized endograft)

- Undersized endograft
  - Gore Excluder 28.5mm
  - Aortic diameter 32 mm
Conclusions

Excellent results for patients at risk for late failure
- 99% free from late T1 EL
- 99% smaller or stable AAA

Excellent results for primary endoleak treatment
- 97% free from late T1 EL
- 97% smaller or stable AAA

Therapeutic benefit in treating late endoleaks
- 89% free from continued EL
- 90% smaller or stable AAA
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