Mid-term results from ANCHOR:

How does this data influence the treatment algorithm for hostile EVAR anatomies

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Disclosures

Co-founder of Endovascular Diagnostics

**Consultant for Medtronic**, Bentley Innomed

**Advisory board member: Medtronic**

Research grants: Cardionovum, Stichting Lijf & Leven
AAA Therapy in 2018

• EVAR grafts offer different approaches to *longitudinal* graft fixation
• No grafts offer techniques for *radial* fixation
  • Yet AAA is a dilating disease

• Graft Deficiencies:
  • Often used outside IFU
  • Increases risk of migration, neck dilatation, & late Type Ia endoleaks
  • Adaptability to long-term disease process may improve outcomes

**Bottom Line:**
Long-term EVAR durability still a concern in AAA patients at high risk for late aortic events
Can we improve late outcomes by treating the hostile neck patient before EVAR failure?
Heli-FX EndoAnchor Implant System

Endovascular Interrupted Suture System – FDA approved 2011
Clinical History of EndoAnchor Implants

- **First Human Implant**: 2005 (Drs Deaton, Ohki, Condado)
- **2 US IDE Regulatory Trials**:
  - **STAPLE I**: safety & feasibility; 2006-2007; 21 pts across 5 US sites
    - 1yr data: no type Ia’s, 69% sac regression, no AAA ruptures
  - **STAPLE II**: safety & efficacy; 2007-2009; 155 patients across 33 US sites
    - 5yr data: no type Ia’s, 72% sac regression, no AAA ruptures
- **ANCHOR Global Registry**: >800 AAA pts to date; 5yr f/u planned
  - Multiple endografts, 3 cohorts of hostile necks patients

High quality evidence of ~1000 AAA patients across >100 sites globally
**ANCHOR Registry: Capturing Real-World Usage**

*Initiated in 2012*

<table>
<thead>
<tr>
<th>Registry Design</th>
<th>Prospective &amp; Observational, International &amp; Multi-Center, Dual-arm Registry with Core Lab Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry Principal Investigators</td>
<td></td>
</tr>
<tr>
<td>Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, University Medical Centre Groningen</td>
<td></td>
</tr>
<tr>
<td>US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine</td>
<td></td>
</tr>
<tr>
<td>Treatment Arms*</td>
<td>&quot;Primary&quot;</td>
</tr>
<tr>
<td></td>
<td>&quot;Revision&quot;</td>
</tr>
<tr>
<td>Enrollment &amp; Duration</td>
<td>Enrollment began 2012 and patients will be followed for 5 years</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Per Standard of Care at each center &amp; discretion of Investigator</td>
</tr>
</tbody>
</table>

*Expanded registry to include Thoracic and Advanced Disease arms.*

>800 Patients Enrolled
ANCHOR Registry
Primary Arm represents 72.5% of patients

806

ANCHOR REGISTRY

584
PRIMARY ARM

217
REVISION ARM

Prophylactic
456

Therapeutic
128

*Data cut June 13, 2018
ANCHOR Registry – Prophylactic Use (N=456)

Concern for Late Failure and/or Prevention of Neck Dilatation w/o Type la EL

Reason for EndoAnchoring

- 72.1% Concern for Late Failure
- 27.9% Prevention of Neck Dilatation
- 18.4% Urgent/Emergent Cases

Mean Age: 72.4 Years

Meanings:

- Hostile Necks: 85.8%
  Per the SVS definition

- Infrarenal Diameter: 25.5 mm
- Infrarenal Angulation: 24.9°
- Neck Length: 11.2 mm (median)
- Conical Neck (>10%/10mm): 43.9%

Male: 79% Female: 21%

Mean Core Lab measurements:

Infrarenal Diameter: 25.5 mm
Infrarenal Angulation: 24.9°
Aneurysm Diameter: 56.5 mm

* Mean Core Lab measurements
# ANCHOR Registry – Prophylactic Use

## Technical Success
Investigator defined successful deployment of EndoAnchor implants at their intended location

<table>
<thead>
<tr>
<th></th>
<th>1-Year</th>
<th>2-Year</th>
<th>3-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>0.6% (2/308)</td>
<td>1.1% (2/187)</td>
<td>1.7% (2/120)</td>
</tr>
<tr>
<td>Endograft Migration</td>
<td>0.0% (0/236)</td>
<td>0.0% (0/110)</td>
<td>0.0% (0/66)</td>
</tr>
</tbody>
</table>

## Aortic Penetration
EndoAnchor Implants adequately penetrated the aortic wall

<table>
<thead>
<tr>
<th></th>
<th>Avg. duration of Procedure (min)</th>
<th>Avg. time to EndoAnchor implants (min)</th>
<th>Avg. number of EndoAnchor implants</th>
</tr>
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<tbody>
<tr>
<td>Prophylactic</td>
<td>139</td>
<td>18.2</td>
<td>5.7</td>
</tr>
</tbody>
</table>
ANCHOR Registry – Prophylactic Use

1-Year $N=293$
- Decrease 37.2%
- Increase 4.1%
- Stable 58.7%

2-Year $N=175$
- Decrease 49.1%
- Increase 4.6%
- Stable 46.3%

3-Year $N=115$
- Decrease 50.4%
- Increase 3.5%
- Stable 46.1%

Freedom from Type Ia Endoleaks

3-Year FF Type Ia EL 95.4%
Propensity Matched Comparison With and Without EndoAnchors

More Competent Proximal Seal Enhances AAA Remodeling

In a propensity-matched study design, increased rate of AAA sac regression

Methodology

- Pre-EVAR CTs by core lab
- Neck lengths > 20 mm
- 2 cohorts:
  - 99 pts EVAR
  - 99 pts EVAR + EndoAnchor
- Propensity matching on 19 variables

Muhs, BE et al. JVS. 2018 June;67(6): 1699-1707
## ANCHOR Registry – Prophylactic Use

### Hostile Necks: 85.8%  
*Per the SVS definition*

<table>
<thead>
<tr>
<th>Kaplan-Meier Estimates</th>
<th>1 Year</th>
<th>2 Year</th>
<th>3 Year</th>
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<tr>
<td>Freedom from ACM</td>
<td>95.1%</td>
<td>89.0%</td>
<td>85.5%</td>
</tr>
<tr>
<td>Freedom from ARM</td>
<td>98.9%</td>
<td>98.9%</td>
<td>98.3%</td>
</tr>
<tr>
<td>FF 2\textsuperscript{nd} Endo Proc for Type Ia ELs</td>
<td>99.2%</td>
<td>99.2%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Freedom from Rupture</td>
<td>100%</td>
<td>100%</td>
<td>98.8%</td>
</tr>
<tr>
<td>Freedom from Conversion</td>
<td>99.8%</td>
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<td>98.1%</td>
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### SAEs through 3 Years

<table>
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<tr>
<th>EndoAnchor Device-Related SAE</th>
<th>1 patient within 3 years</th>
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<td>Vascular Procedure Complication</td>
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ANCHOR Registry

Revision Arm represents 27.5% of pts

806

ANCHOR REGISTRY

584 PRIMARY ARM

217 REVISION ARM

Prophylactic

456

Therapeutic

128

Stent Grafts - Revision Arm

*Data cut June 13, 2018
ANCHOR Registry – Therapeutic use in Revision Setting (N=217)

To treat complications (type 1a EL, migration, neck dilatation) post-EVAR

Reasons for EndoAnchoring
100% Failed EVARs
• Migration, Endoleak, Neck dilatation, or Combination
• 23.0% Urgent/Emergent Cases

Hostile Necks: 90.6%
Per the SVS definition

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
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<tbody>
<tr>
<td>Infrarenal Diameter</td>
<td>29.4 mm</td>
</tr>
<tr>
<td>Infrarenal Angulation</td>
<td>21.0°</td>
</tr>
<tr>
<td>Neck Length (median)</td>
<td>10.2 mm</td>
</tr>
<tr>
<td>Conical Neck (&gt;10%/10mm)</td>
<td>49.4%</td>
</tr>
<tr>
<td>Aneurysm Diameter</td>
<td>68.6 mm</td>
</tr>
</tbody>
</table>

* Mean Core Lab measurements

Male: 85% Female: 15%

Mean Age: 77.9 Years
ANCHOR Registry – Therapeutic use in Revision Setting

Mean time from initial EVAR implant to EndoAnchor implant: 1750 days (~5yrs)

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<td>94.9% Revision</td>
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<tr>
<th>Avg. duration of Procedure (min)</th>
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<tr>
<td>146</td>
<td>26.1</td>
<td>7.2</td>
</tr>
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<tr>
<th>1-Year</th>
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<tr>
<td>Type 1a Endoleak</td>
<td>7.9% (11/140)</td>
<td>5.9% (4/68)</td>
</tr>
<tr>
<td>Endograft Migration</td>
<td>0.0% (0/118)</td>
<td>0.0% (0/45)</td>
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</table>
ANCHOR Registry – Therapeutic use in Revision Setting

1-Year: N=132
- Increase 9.1%
- Decrease 15.9%
- Stable 75.0%

2-Year: N=68
- Increase 20.6%
- Decrease 30.9%
- Stable 48.5%

3-Year: N=40
- Increase 20.0%
- Decrease 32.5%
- Stable 47.5%

3-Year FF Type Ia EL 83.3%
# ANCHOR Registry – Therapeutic use in Revision Setting

## Hostile Necks: 90.6%
Per the SVS definition

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</thead>
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<tr>
<td>Freedom from ACM</td>
<td>88.0% (205)</td>
<td>75.8% (144)</td>
<td>60.9% (94)</td>
</tr>
<tr>
<td>Freedom from ARM</td>
<td><strong>96.8% (205)</strong></td>
<td><strong>93.7% (144)</strong></td>
<td><strong>91.1% (94)</strong></td>
</tr>
<tr>
<td>FF 2nd Endo Proc for Type Ia ELs</td>
<td>92.9% (200)</td>
<td>89.3% (133)</td>
<td>86.3% (82)</td>
</tr>
<tr>
<td>Freedom from Rupture</td>
<td>99.3% (204)</td>
<td>97.6% (143)</td>
<td>94.6% (93)</td>
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<td>Freedom from Conversion</td>
<td>97.8% (205)</td>
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## SAEs through 3 Years

<table>
<thead>
<tr>
<th>EndoAnchor Device-Related SAE</th>
<th>3 patients within 3 years</th>
</tr>
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<tr>
<td></td>
<td>2 Endoleaks; 1 Infection</td>
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</table>
3 year FU shows improvement in long term outcomes

Protective Against Neck Dilatation

1. Prophylactic anchors can improve results against 3 year failure of EVAR in hostile aortic neck anatomy

2. Therapeutic anchors can avoid conversions and further revisions in 80+% of failed endografts

Tassiopoulos, AK et al. JVS. 2017 July;66(1): 45-52
Conclusions

1. In challenging aortic neck anatomy with indication for standard EVAR EndoAnchors will increase durable outcome and sac regression.
2. In revision surgery after failed EVAR EndoAnchors can treat the problem in a substantial part of the patients
3. Other options are preferred in aortic necks with
   1. Circumferential thrombus, calcium
   2. Length <10 mm in combination with severe angulation
   3. Diameter >30 mm
   4. Apposition loss of endografts due to neck dilatation
Mid-term results from ANCHOR:

How does this data influence the treatment algorithm for hostile EVAR anatomies

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