EVAR Revision Setting - How can Heli-FX EndoAnchors improve the outcomes?

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Disclosures

Speaker name:

Dittmar Böckler

I have the following potential conflicts of interest to report:

- [x] Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest
RCTs continue to highlight need for lifelong surveillance in EVAR

**DREAM**
De Bruin et al. NEJM 2010

**EVAR-1**
Greenhalgh et al. NEJM 2010

**ACE**
Becquemin et al. JVS 2011

Late ruptures in EVAR, none in open surgery

With EVAR, predictors for rupture (endoleaks and migration) increase with time

In ACE, 16% re-interventions in EVAR vs. 2.4% for open repair at 3yr median f/u
Neck Morphology is Crucial
Not All Necks Are The Same

- Straight
- Tapered
- Reversed Tapered
- Angulated*
- Bulge
- Short*

*Renal Arteries

Source: Droc et al (2012). InTech, DOI: 10.5772/48596
* Angulated less than 30 degrees (<30°)
* Modified from source, Additional anatomical criteria, not part of source
Hostile proximal neck predicts challenges

**Type I endoleaks** 4.5x more likely at 1-year after endograft implantation in hostile proximal aortic neck anatomy (P = .010)

Meta-Analysis of 7 major studies in EVAR by Antoniou et al\(^1\) compared outcomes in hostile vs. friendly neck anatomies (total patients \(N = 1559\))

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Endografts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torsello et al, 2011</td>
<td>177</td>
<td>Endurant™</td>
</tr>
<tr>
<td>AbuRahma et al, 2010</td>
<td>238</td>
<td>AneuRx™, Excluder™<em>, Zenith™</em>, Talent™</td>
</tr>
<tr>
<td>Hoshina et al, 2010</td>
<td>129</td>
<td>Excluder™<em>, Zenith™</em></td>
</tr>
<tr>
<td>Abbruzzese et al, 2008</td>
<td>565</td>
<td>AneuRx™, Excluder™<em>, Zenith™</em></td>
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<tr>
<td>Choke et al, 2006</td>
<td>147</td>
<td>Talent™, Zenith™<em>, Excluder™</em>, AneuRx™</td>
</tr>
<tr>
<td>Fulton et al, 2006</td>
<td>84</td>
<td>AneuRx™</td>
</tr>
<tr>
<td>Fairman et al, 2004</td>
<td>219</td>
<td>Talent™</td>
</tr>
</tbody>
</table>

**Aneurysm-related mortality** risk 9x greater in hostile neck anatomy at 1-year (P= .013)

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\(^1\) Antoniou GA et al. JVS. 2013;57(2):527-38.
ENGAGE
Incidence of Type I a Endoleak is low
5 year data from ENGAGE-Registry

<table>
<thead>
<tr>
<th></th>
<th>At 1 year n= 1079*</th>
<th>At 2 Year n= 900*</th>
<th>At 3 Year n= 333*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak (Total)</td>
<td>9.8% (106)</td>
<td>10% (90)</td>
<td>10.2% (34)</td>
</tr>
<tr>
<td>Type I</td>
<td>0.4% (4)</td>
<td>0.9% (8)</td>
<td>1.2% (4)</td>
</tr>
<tr>
<td>Type II</td>
<td>8.5% (92)</td>
<td>7.7% (69)</td>
<td>8.1% (27)</td>
</tr>
<tr>
<td>Type III</td>
<td>0.2% (2)</td>
<td>0.7% (6)</td>
<td>0.3% (1)</td>
</tr>
<tr>
<td>Type I and/or III</td>
<td>0.6% (6)</td>
<td>1.6% (14)</td>
<td>1.5% (5)</td>
</tr>
</tbody>
</table>

*n=evaluable diagnostic images
Potential Implications: Endoleaks and Migration
Predictors of Endograft Failure
> Migration and Endoleak Type 1a

- Angulated > 60° and short neck
- Large maximal AAA diameter
- Neck thrombus
- Complex iliac artery anatomy
- Stiffness of the stentgraft
- Postprocedural factors (e.g. neck dilatation)
Options for repair of type 1 EL

- Cuff extension
- FEVAR
- Chimney
- EVAS
- Balloon expandable stents (e.g., Palmaz)
- EndoAnchor
- Embolization (e.g., Onyx)
- Open Conversion
- Surveillance?

No comparative studies
No randomized trials
Concept behind EndoAnchors to fix Type 1a Endoleaks

Aptus Heli-FX EndoAnchor:

- Guide
- Applier
- Cassette with EndoAnchors

EndoAnchor Dimensions:

4.5mm length
3.0mm diameter

*Based on ANCHOR Registry, STAPLE-1 & STAPLE-2 US IDE Studies & Heli-FX commercial experience*
Indications for Use:

- Intended to provide fixation and sealing between endovascular aortic grafts and the native artery

- Indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications

- In whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion

- At the time of the initial endograft placement, or during a secondary (i.e. repair) procedure
EVAR in conical neck with Type I EL
CONTRAINDICATIONS

Treatment with the Aptus™ Heli-FX™ EndoAnchor™ system is contraindicated for use in the following circumstances:

- In patients with known allergies to the EndoAnchor™ implant material (MP35N-LT) (US & OUS IFU)
- In conjunction with the Endologix Powerlink™ endograft (US & OUS IFU)
- In patients with a condition that threatens to infect the endograft (OUS IFU)
- In patients with a bleeding diathesis (OUS IFU)

Polymer-based technologies are also not indicated for EndoAnchor™ implants.
Limitations of Endo Anchors

- severe neck calcification
- thrombus line > 2 mm and > 180° of circumference
- Distance between stentgraft and aortic wall > 2mm
- Attaching multiple stentgraft components

Endostapler repair of Type III Endoleak
Techniques to use for type I EL

- Circumferential
- Focal (EVAR)
- Focal (TEVAR)

Image courtesy of Drs. Muhs & Aruny, Yale New Haven Hospital
Image courtesy of Dr. Zhou, Stanford University
Image courtesy of Dr. Wheatley, Temple University

Approved for Type I EL = within IFU
Does it improve outcomes?

Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

William D. Jordan Jr, MD,1 Manish Mehta, MD, MPH,1 David Varnagy, MD, William M. Moore Jr, MD,1 Frank R. Arko, MD,1 Tomas Jofré, MD,1 Kenneth Ouriel, MD,2 and Juan Paul V. Vides, MD1

1Borrowing, Ala, Atlanta and New York, NY; Orlando, Fla; Lexington, SC; Charlotte, NC; Mountain View, Calif; and Nieuwerkerk, The Netherlands.

Objective: Prevalence attachment site complications continue to occur after endovascular repair of abdominal aortic aneurysm (EVAR), specifically type Ia endoleaks and endograft migration. EndoAnchors (Atrium Biosciences, Sunnyvale, Calif) were designed to enhance endograft proximal fixation and sealing, and the current study was undertaken to evaluate the potential benefit of this treatment.

Methods: During the 23-month period ending in December 2013, 159 subjects were enrolled at 45 sites in the United States. Device placement was attempted in 342 patients (77.9%) at the time of an intended EVAR procedure (primary arm) and in 77 patients with an existing endograft and proximal aortic neck complications (revision arm). Technical success was defined as deployment of the desired number of EndoAnchors, adequate coverage of the proximal neck wall, and absence of EndoAnchors fractures. Procedural success was defined as technical success without a type Ia endoleak and completion angiography. Values are expressed as mean ± standard deviation or standard error of the mean.

Results: The 239 male patients (76.8%) and 120 females (23.2%) had an average age of 74.3 ± 8.8 years. Anatomic criteria were as follows: 125 (36.4%) were <15 cm in diameter at the site of EndoAnchors implantation (core laboratory measurement). The proximal aortic neck was assessed with ascending and descending aorta evaluation in 309 patients (89.5%) and procedural access in 39 patients (11.5%). The mean number of EndoAnchors deployed was 2.8 ± 2.0. The mean aortic diameter was 132 ± 34.6 degrees. The number of EndoAnchors deployed was 2.8 ± 2.0 (1-6). Technical success was documented in 318 patients (92.2%) and procedural success in 37 patients (11.5%). The three patients (9.5%) who required re-intervention (2 secondary procedures) were free from secondary procedures. Among the 18 secondary procedures, eight were performed for residual type Ia endoleaks, and the other were EndoAnchors. There were no open surgical conversions, there were no aneurysm-related deaths, and no aneurysm rupture during follow-up.

Conclusion: Use of EndoAnchors to treat existing and acute type Ia endoleaks and endograft migration was successful in most cases. Preemptive use of EndoAnchors in patients with hostile aortic neck anatomy appears promising, but future evaluations must await longer-term follow-up data. (J Vasc Surg 2014;60[2]:462–9.)

The use of EndoAnchors to rescue complicated TEVAR procedures

Sarah B. Onstad1, Daniel F. Miller1, and Jean M. Panneton1,2

1Virginia Vascular Surgery, Eastern Virginia Medical School, Norfolk, VA, USA; 2Veterans Affairs Healthcare System, Norfolk, VA, USA

Objective: To describe outcomes of the use of EndoAnchors to rescue complicated thoracic endovascular aortic repair (TEVAR) procedures.

Methods: A retrospective review of all thoracic endovascular aortic repair (TEVAR) procedures performed at a single institution were reviewed. EndoAnchors were utilized in 12 patients (12 of 379 TEVAR procedures) for failed deployment or endoleak following endograft placement. The number of EndoAnchors was 3.2 ± 2.6 (range, 1-7); technical success was achieved in 9 patients (90.9%) and failed in 2 patients (19.1%). Procedural success was achieved in 11 (91.7%) of patients with the procedural failure occurring in 88.9%.

Results: The overall mean interval from the initial procedure to EndoAnchors deployment was 3.5 months. Mean initial symptoms of the patients were 58.1%. These were not improved by drug management. The overall mortality rate was 20%. One patient with aortic rupture died. EndoAnchors could not be deployed because of severe aortic calcification in 3 patients. One patient was not improved by initial management. Three patients were successfully deployed with EndoAnchors and were not improved by EndoAnchors deployment. Only one reintervention was associated with EndoAnchors placement. A meta-analysis of the 20 patients who elected EndoAnchors placement revealed a 25.5% success rate.

Conclusion: EndoAnchors were successfully deployed in 9 of 12 patients (75%), and in 8 of 11 patients (72.7%) who required rescue procedures. These results demonstrate the potential to enhance thoracic endograft efficacy and durability with the use of EndoAnchors and propylene EndoAnchors. Long-term data is needed to further define the role of this technology in the thoracic aorta.

One-year results of the ANCHOR trial of EndoAnchors for the prevention and treatment of aortic neck complications after endovascular aneurysm repair

William D. Jordan Jr1, Manish Mehta2, Kenneth Ouriel2, Frank R. Arko3, David Varnagy3, James Joyce4, and William M. Moore Jr1 and Jean-Paul V. Vides5

1Borrowing, Ala, Atlanta and New York, NY; Orlando, Fla; Lexington, SC; Charlotte, NC; Mountain View, Calif; and Nieuwerkerk, The Netherlands.

Original Article

Does it improve outcomes?

Results of the ANCHOR prospective, multicenter registry of EndoAnchors...
ANCHOR registry capturing real-world usage

<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>Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital</td>
</tr>
<tr>
<td></td>
<td>US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine</td>
</tr>
<tr>
<td>Treatment Arms</td>
<td>“Primary” – Up to 1000 pts, Prophylactic</td>
</tr>
<tr>
<td></td>
<td>“Revision” – Up to 1000 pts, Therapeutic</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>

Over 660 Patients Enrolled as of August 2016
ANCHOR Registry – Revision Arm represents 26% of pts.

593 Subjects (74.9% US/25.1% OUS)

439 PRIMARY ARM

154 REVISION ARM

*Data cut Aug 10, 2015
1 Despite Endurant being 1 in 2 grafts in the primary arm, it is only a subset of what's being presented with complications in the revision arm
2 No longer commercially available in the US
Therapeutic Use cohort (N=263) consists of patients receiving EndoAnchor™ implants to treat Type 1a Endoleaks in the Primary and Revision Arms.
Indications for EndoAnchor™ Implants

Intra-Op T1 EL Pts- within index procedure
N=141
- 9.2% (13/141) Urgent Cases
- 100% Type 1a Endoleak

Revision Pts. – post-EVAR follow-up
N=122
- 14.8% (18/122) Urgent Cases
- 67.2% (82/122) Late Type 1a Endoleak
- 32.8% (40/122) Migration & Type 1a Endoleak

Mean Age: 76.3 Years
Male: 77%  Female: 23%
Mean Age: 80.1 Years
Male: 80%  Female: 20%
Baseline characteristics & aneurysm measurements*

- Infrarenal Diameter: 26.1 mm
- Angulation: 37.8°
- Neck Length: 16.8 mm
- Aneurysm Diameter: 56.6 mm
- Conical Neck (>10%/10mm): 38.7%
- Avg Neck Calcium Thickness: 1.3 mm

HOSTILE NECKS: 73.6%
- Diameter >28mm
- Length <10mm
- Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium burden >2mm

<table>
<thead>
<tr>
<th>Anatomic Index</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Neck Length (mm)</td>
<td>16.2</td>
</tr>
<tr>
<td>Infrarenal Diameter (mm)</td>
<td>27.2</td>
</tr>
<tr>
<td>Conical Neck (&gt;10%/10mm)</td>
<td>42.2</td>
</tr>
<tr>
<td>Hostile Necks</td>
<td>74.5</td>
</tr>
</tbody>
</table>

* Mean Core Lab measurements based on 205 pts with baseline CTs
Baseline characteristics & aneurysm measurements*

**Infrarenal Diameter:** 29.2 mm

**Infrarenal Angulation:** 34°

**Neck Length:** 14.8 mm

**Aneurysm Diameter:** 65.9 mm

**Conical Neck (>10%/10mm):** 49.1%

**Avg Neck Calcium Thickness:** .4 mm

**HOSTILE NECKS:** 76.4%

- Diameter >28mm
- Length <10mm
- Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium burden >2mm

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<td>Hostile Necks</td>
<td>74.5</td>
</tr>
</tbody>
</table>

* Mean Core Lab measurements based on 205 pts with baseline CTs
# ANCHOR REGISTRY – THERAPEUTIC USE FOR PROXIMAL ELs

## TECHNICAL SUCCESS
Deployment of desired number of EndoAnchor™ implants without fracture or loss of integrity

<table>
<thead>
<tr>
<th></th>
<th>Intra-op T1 EL</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>95.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>93.4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Intra-op T1 EL</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>85.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>82.8%</td>
<td></td>
<td></td>
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</tbody>
</table>

### Avg. duration of Procedure (min)

<table>
<thead>
<tr>
<th>Intra-op T1 EL</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>159</td>
<td></td>
</tr>
<tr>
<td>158</td>
<td></td>
</tr>
</tbody>
</table>

### Avg. time to EndoAnchor™ implants (min)

<table>
<thead>
<tr>
<th>Intra-op T1 EL</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

### Avg. number of EndoAnchor™ implants

<table>
<thead>
<tr>
<th>Intra-op T1 EL</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>7.7</td>
<td></td>
</tr>
</tbody>
</table>

* Site-reported data
# ANCHOR REGISTRY – THERAPEUTIC USE FOR PROXIMAL ELs

## Adjunctive Devices

<table>
<thead>
<tr>
<th>Adjunctive Devices</th>
<th>Intra-op T1 EL (N=141)</th>
<th>Revision (N=122)</th>
<th>All (N=263)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Extender Cuff</td>
<td>25 (17.7%)</td>
<td>62 (50.8%)</td>
<td>87 (33.1%)</td>
</tr>
<tr>
<td>Giant Bare Stent (e.g. Palmaz)</td>
<td>2 (1.4%)</td>
<td>4 (3.3%)</td>
<td>6 (2.3%)</td>
</tr>
<tr>
<td>Cuff + Palmaz</td>
<td>0 (0%)</td>
<td>2 (0.8%)</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>Chimney</td>
<td>0 (0%)</td>
<td>2 (0.8%)</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>Fenestrated</td>
<td>0 (0%)</td>
<td>1 (0.4%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Debranching</td>
<td>0 (0%)</td>
<td>1 (0.4%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td><strong>EndoAnchor™ implants Alone</strong></td>
<td><strong>114 (80.9%)</strong></td>
<td><strong>50 (41.0%)</strong></td>
<td><strong>164 (62.4%)</strong></td>
</tr>
</tbody>
</table>
Mean follow-up 18.9 months

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Intra-op T1 EL (N=141) Subjects with Events</th>
<th>Revisions (N=122) Subjects with Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Adverse Events</td>
<td>44</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>31.4%</td>
<td>44.3%</td>
</tr>
<tr>
<td>Procedure-Related SAE</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>6.4%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Endograft-Related SAE</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>0.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td><strong>EndoAnchor™ implants-Related SAE</strong></td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>0.0%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Aneurysm-Related SAE</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>2.1%</td>
<td>7.4%</td>
</tr>
<tr>
<td><strong>Rupture of AAA</strong></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>0.0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>All-Cause Mortality</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>4.3%</td>
<td>4.9%</td>
</tr>
</tbody>
</table>
**Successful is defined by no type Ia endoleak on imaging studies after the reintervention.**

18/24 had no subsequent interventions to repair the persistent/recurrent type 1a endoleaks

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Successful**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open surgical conversion</td>
<td>2/2</td>
</tr>
<tr>
<td>Fenestrated graft</td>
<td>0/2</td>
</tr>
<tr>
<td>Additional EndoAnchor™ implants</td>
<td>0/1</td>
</tr>
<tr>
<td>Aortic extension cuff</td>
<td>No Imaging</td>
</tr>
</tbody>
</table>

**Successful is defined by no type Ia endoleak on imaging studies after the reintervention.**

ANCHOR REGISTRY – THERAPEUTIC USE FOR PROXIMAL ELs

Reinterventions on 24 pts with persistent/recurrent type 1a ELs
**Persistent/Recurrent Type Ia Endoleaks**
Mean follow-up 10.4 months

<table>
<thead>
<tr>
<th></th>
<th>Type 1a ELs</th>
<th>CTs</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-op T1 EL</td>
<td>3</td>
<td>76</td>
<td>3.9%</td>
</tr>
<tr>
<td>Revision</td>
<td>21</td>
<td>66</td>
<td>31.8%</td>
</tr>
<tr>
<td>All</td>
<td>24</td>
<td>142</td>
<td>16.9%</td>
</tr>
</tbody>
</table>

Majority of corelab identified type I endoleaks did not warrant re-intervention. 2.3% (6/263) necessitated re-intervention for recurrent Type 1a endoleak.
SAC Diameter Changes*

At 1-Year follow-up

**Intra-op Type 1 EL Pts**
- Increase 4.8%
- Decrease 25.0%
- Stable 70.2%

N=84

**Revision Pts**
- Increase 12.5%
- Decrease 12.5%
- Stable 75.0%

N=48

*Core Lab Analysis
Diameter change between 1-month and 1-year CTs
Therapeutic Use Summary

- **EndoAnchor™ implants to treat index procedure Type Ia endoleaks associated with excellent results through 1-Year follow-up**

- **EndoAnchor™ implants for Type Ia endoleak revision post-index successful in majority of cases**

- **95.2%** 95.2% of patients treated for Intra-op T1 EL had decreasing or stable AAA sacs at 1-year

- **87.5%** 87.5% of patients treated in the Revision Arm had decreasing or stable AAA sacs at 1-year

- **2.3%** 2.3% reintervention rate after therapeutic use of EndoAnchor™ implants
Heidelberg Algorythm for Type 1a EL

Proximal Type I EL

PTA & persisting EL

sufficient remaining neck
- Cuff / fenestrated SG- extension

Embolisation or Conservative

insufficient remaining neck
- Embolisation or Conservative
- EndoAnchor
- Palmaz Stent
- kinked neck
- non-calcified native aorta
- straigt neck
- thrombus
Consider primary CHEVAR or FEVAR in short necks < 10 mm!

But also limitations: waiting time gutters, max. 1-2 chimneys
Summary

• Type 1 a EL are rare but need Tx to prevent secondary rupture
• Several options to treat Type 1 a Endoleak
• Endoanchors are approved for revisions and Type I EL
• Endoanchors are easy to use and improve outcome
• Anchor registry shows excellent results
• No comparative studies for different modalities
• Do not stress neck morphology and short necks < 10 mm
EVAR Revision Setting - How can Heli-FX EndoAnchors improve the outcomes?

D. Böckler
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