First generation stentgraft and typ I endoleak
How can endoanchors help?

PD Dr. med. Ph. Geisbüsch
Disclosure

- Honoraria Medtronic
- Honoraria Siemens Healthcare
- Research grant Siemens Healthcare
Incidence of Type I a Endoleak is low

3 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>
EVAR I Trial: Reintervention

Percentage Surviving without Reintervention

Endovascular repair, 72% (95% CI, 67–76)
Open repair, 90% (95% CI, 87–93)

No. at Risk
Endovascular repair 626 470 377 243 83
Open repair 626 503 428 271 97

Years since Randomization
### Causes for reintervention

**Long-term outcomes of secondary procedures after endovascular aneurysm repair**

Manish Mehta, MD, Yaron Sternbach, MD, John B. Taggert, MD, Paul B. Kreienberg, MD, Sean P. Roddy, MD, Philip S.K. Paty, MD, Kathleen J. Ozsvath, MD, and R. Clement Darling III, MD, Albany, NY

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>1,768</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Follow-up [SD]</td>
<td>34 Months [30]</td>
</tr>
<tr>
<td><strong>% with Secondary Intervention</strong></td>
<td><strong>19.2%</strong></td>
</tr>
<tr>
<td>Type II Endoleak</td>
<td>40.1%</td>
</tr>
<tr>
<td>Type I/III Endoleak</td>
<td>16.5%</td>
</tr>
<tr>
<td>Migration</td>
<td>13.6%</td>
</tr>
<tr>
<td>Limb Occlusion</td>
<td>7.4%</td>
</tr>
<tr>
<td>Rupture, Device Defect, etc.</td>
<td>8.6%</td>
</tr>
</tbody>
</table>
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 I EL

- Cuff extension
- Balloon expandable stents (e.g. Palmaz)
- Embolization (e.g. Onyx)
- Open Conversion
- Surveillance ?

* No comparative studies
* No randomized trials
Options for repair of type I EL

- Cuff extension
- Balloon expandable stents (e.g. Palmaz)
- EndoAnchor
- Embolization (e.g. Onyx)
- Open Conversion
- Surveillance ?
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
Concept behind EndoAnchors

- Intended to provide fixation & augment sealing of endovascular grafts to aortic wall

Cook Zenith®  Gore Excluder®  Medtronic AneuRx ®  Medtronic Endurant ®  Medtronic Talent ®
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
Tips for EndoAnchor implantation

- Minimum: 4 EndoAnchors
- Prox neck dia. > 29mm: >6 EndoAnchors
- Even circumferential spacing
- Aortic wall penetration

-CAVE: calcification/thrombus
C-Arm Positioning for 6 EndoAnchors

30° RAO  30° LAO

90°
Lateral

Note: C-arm positions above show just one possible combination
C-Arm Positioning for focal placement

Move C-Arm in 15-20 degree increments

- Identify leak channel and then create a “suture line” along wall.
Limitations of Endo Anchors

- severe neck calcification
- thrombusline > 2 mm and > 180° of circumference
- Distance between stentgraft and aortic wall > 2mm

**ANCHOR Registry**

<table>
<thead>
<tr>
<th>Registry Principal Investigators</th>
<th>Europe: Dr. Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US: Dr. William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Univ. of Alabama</td>
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</table>

<table>
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<tr>
<th>Registry Design</th>
<th>Prospective, observational, international, multi-center, dual-arm Registry</th>
</tr>
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<tbody>
<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>Duration</td>
<td>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 550 Patients enrolled as of April 2015
# ANCHOR Registry (n=319)

## Indications for treatment

<table>
<thead>
<tr>
<th>Primary Arm (n=242)</th>
<th>Treatment of Type 1a Endoleak</th>
<th>56 (24%)</th>
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<tr>
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<td>Concern for Late Failure</td>
<td>186 (76%)</td>
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<tr>
<td>Revision Arm (n=77)</td>
<td>Late type 1a Endoleak</td>
<td>45 (58%)</td>
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<td>Migration</td>
<td>11 (14%)</td>
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<td>Migration &amp; Endoleak</td>
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*Jordan W et al JVS 2014;60:885  
De Vries JP et al, JVS 2014;60:1460-7*
### “Hostile Neck” ANCHOR registry

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<th>Revision</th>
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<tr>
<td>Neck length ≤ 10mm</td>
<td>36 (47%)</td>
</tr>
<tr>
<td>Neck length ≤ 15mm</td>
<td>47 (61%)</td>
</tr>
<tr>
<td>Neck diameter(^1) (mm), mean (+ SD)</td>
<td>30 ± 7</td>
</tr>
<tr>
<td>Conical neck(^2)</td>
<td>36 (47%)</td>
</tr>
<tr>
<td>Thrombus ≥ 2mm</td>
<td>21%</td>
</tr>
<tr>
<td>Calcium ≥ 2mm</td>
<td>12%</td>
</tr>
</tbody>
</table>

*Note: Corelab sample sizes is different from total patients in ANCHOR. Corelab for all patients is still in-process. All above data is per Corelab except the ‘Hostile Neck’ line item which is investigator reported.

# ANCHOR Registry (n=319)

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# ANCHOR Registry

## Early results by Indication

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<th>Indication</th>
<th>Patients</th>
<th>Procedural success rate (%)</th>
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<tbody>
<tr>
<td>Late Type I EL</td>
<td>45</td>
<td>78%</td>
</tr>
<tr>
<td>Migration</td>
<td>11</td>
<td>73%</td>
</tr>
<tr>
<td>Migration &amp; EL</td>
<td>21</td>
<td>91%</td>
</tr>
<tr>
<td><strong>All</strong></td>
<td><strong>77</strong></td>
<td><strong>80.5%</strong></td>
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Jordan W et al, JVS 2014;60:885
De Vries JP et al, JVS 2014;60:1460-7
Freedom from type Ia EL at 1 year: 77%

Jordan W et al Vascular 2015 online first
Case: Migration and typ Ia EL
Case: Migration and typ Ia EL
Migration and typ Ia EL
Example EVAR & Endoanchors in conical neck with Type I EL
Primary Type Ia EL
Therapie: Aptus Endostapler
Postoperativer Befund
Follow-up
Treatment algorithm

Proximal Type I EL

Ballooning & persisting EL

sufficient remaining neck

Cuff extension

Embolisation

EndoAnchor

Palmaz Stent

insufficient remaining neck

- kinked neck
- non-calcified native aorta
- straight neck
- thrombus
- calcified neck
Summary

- Several options to treat type Ia endoleak
- Endoanchors can solve the problem in 80% cases
- Longterm data are missing and will be obtained
- Neck morphology based decision making
- Use cuffs (incl. FEVAR) if remaining infrarenal neck
- Consider primary FEVAR/Chimney for unfavorable neck morphology