Aptus Heli-FX Overview

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Endograft migration
Stent no longer above renal artery
Do we really need any adjuncts to EVAR and TEVAR?
Rates of 2nd interventions in EVAR are high and not improving adequately
- Average re-intervention rate of 3.7%/yr from recent registry data. IDE trial data demonstrate average rate of 4.1%/yr.

Complicated anatomy results in more Type I endoleaks & higher re-intervention risk
- Short neck length (<15mm)
- Neck angulation (>40°)
- More complicated patients are being treated as EVAR devices improve

There is acceptance that current standard follow-up imaging...
+ Carries risk (radiation, contrast media)
+ Is expensive
+ Confers suboptimal benefit (<10% of re-interventions are triggered by routine follow-up imaging findings)

No other solutions exist for ‘radial fixation’ to break the cycle of this dilating disease

<table>
<thead>
<tr>
<th>Re-intervention-free survival¹</th>
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<tbody>
<tr>
<td>1 yr</td>
<td>89.9%</td>
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<tr>
<td>2 yr</td>
<td>86.9%</td>
</tr>
<tr>
<td>5 yr</td>
<td>81.5%</td>
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**Increased odds of type I endoleak and need for re-intervention**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>OR (95% CI)</th>
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<tbody>
<tr>
<td>Neck Length &lt; 15 mm</td>
<td>2.2 (1.4-3.5)³,†</td>
</tr>
<tr>
<td></td>
<td>6.2 (2.9-13)⁴,†</td>
</tr>
<tr>
<td></td>
<td>4.3 (2.1-8.7)⁴,‡</td>
</tr>
<tr>
<td>Neck angulation &gt; 40°</td>
<td>5.9 (1.3-27.6)⁵,*</td>
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Hostile Necks Continue to Challenge Durability

Meta-Analysis of 7 major studies in EVAR by Antoniou et al\(^1\) comparing outcomes in hostile vs. friendly neck anatomies

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Major Grafts</th>
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<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, Zenith, Talent</td>
</tr>
<tr>
<td>Hoshina et al, 2010</td>
<td>129</td>
<td>Excluder, Zenith</td>
</tr>
<tr>
<td>Abbruzzese et al, 2008</td>
<td>565</td>
<td>AneuRx, Excluder, Zenith</td>
</tr>
<tr>
<td>Choke et al, 2006</td>
<td>147</td>
<td>Talent, Zenith, Excluder, 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>

Total sample size: N=1559 patients

Hostile Necks Continue to Challenge Durability

Major findings:

» Adjunctive procedures more frequent in challenging proximal necks

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

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

### Neck Dilatation: A Cause for 2\textsuperscript{nd} Intervention

Multiple recent studies confirm neck dilatation in EVAR remains REAL

<table>
<thead>
<tr>
<th>Author</th>
<th>Follow-Up</th>
<th>Grafts studied</th>
<th>Proximal Neck Dilatation Rate</th>
<th>Outcomes in dilated necks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oberhuber et al.\textsuperscript{1}</td>
<td>39 mos average</td>
<td>Zenith (N=29), Talent (N=35), Excluder (N=39)</td>
<td>22% (defined as &gt;2mm diam increase)</td>
<td>31% re-interventions</td>
</tr>
<tr>
<td>Pintoux et al.\textsuperscript{2}</td>
<td>57 mos average</td>
<td>Talent (N=33), Aneurx (N=25)</td>
<td>24% (defined as &gt;3mm diam increase)</td>
<td>5% late type Ia endoleak 16% migration</td>
</tr>
<tr>
<td>Bastos Gonçalves et al.\textsuperscript{3}</td>
<td>5 yrs median</td>
<td>Excluder (N=144)</td>
<td>37% overall, 66% in pts &gt;7 yrs f/u (defined as &gt;2mm diam increase)</td>
<td>Increased odds of migration (≥5mm) 5.5x</td>
</tr>
</tbody>
</table>

\textsuperscript{1}Oberhuber A et al. J Vasc Surg 2012 April;55(4): 929-34
Strategies for Treating Type I Endoleaks

Current solutions do not offer consistent effectiveness

**Palmaz effectiveness is limited**
- Byrne et al reported:
  - *Persistent type Ia endoleak in 8.6% (14/162) pts* at the end of primary procedure\(^1\)
  - Can preclude future re-interventions, e.g. FEVAR, EndoAnchors

**Mixed results with Cuffs**
- Jim J et al. reported:
  - *12% (18/151) re-developed Type I/III Endoleaks* at 43 mos average f/u post Zenith Renu placement\(^2\)

**Limitations with Coils and Onyx**
- Require precise ID of leak paths: *non-target embolization risk*\(^3\)
- Time consuming\(^4\)
- Onyx could create CT artifacts precluding identification of endoleaks in F/U\(^4\)

- None of these resist further neck dilatation
- Frequently multiple devices needed, adding time & cost
- Palmaz, coils, Onyx not indicated for Tx of Type I Endoleak

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The Concept of EndoAnchors

BRINGING THE STABILITY OF SURGICAL ANASTOMOSIS TO EVAR

EndoAnchoring

Surgical Anastomosis

Case images courtesy of John Aruny MD, Bart Edward Muhs, MD, PhD and Burkhart Zipfel, MD.
Enhanced endograft fixation

EndoAnchoring

Displacement force in Newtons

Talent | Endurant | Excluder | Zenith | Mean | Hand Sewn

- No EndoAnchors
- With EndoAnchors
Replicate surgical anastomosis, arrest neck dilatation

Prevent late term seal complications in primary setting

Treat seal complications & prevent recurrence in revision setting

Mitigate reinterventions, expand candidates for EVAR

Reduce follow-up by preventing type I leaks and sac growth
Published Initial Experiences with EndoAnchors

Feasibility in replicating surgical anastomosis and arresting neck dilatation

Experience in Primary EVAR

Experience in EVAR Revision

TEVAR experience
The Heli-FX EndoAnchor System is intended to provide fixation and augment sealing between endovascular aortic grafts and the aorta.

The Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications.

The Aptus EndoAnchor and Heli-FX have been evaluated and determined to be compatible with the following endografts:

- Medtronic Endurant®
- Gore Excluder®
- Cook Zenith®
Heli-FX™ for Managing Late Seal Complications

✓ No late Type 1 endoleak in 4-5 year f/u
  > STAPLE-1 & 2 IDE study

✓ High success in treating late Type I Endoleaks
  > >90% success in revision cases per ANCHOR registry

✓ Demonstrated safety in >2,000 pts treated
  > In >10,000 implanted EndoAnchors to-date, no reported late Anchor Dislocations, Fractures, Graft Damage or Fistula
  > 400MM cycles fatigue testing

Images courtesy of Aptus Endosystems, Inc.

1Based on article: ANCHOR registry demonstrates safety and technical success of utilizing endoanchors in primary and revision EVAR Vascular News 11 Oct 2013
2Based on commercial and study data on file at Aptus
**ANCHOR Registry capturing *real-world* usage**

<table>
<thead>
<tr>
<th>Registry Design</th>
<th>Prospective, observational, international, multi-center, dual-arm Registry</th>
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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>
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</tbody>
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**Over 350 Patients enrolled as of Feb 2014**
Current Use of EndoAnchors

Treatment of Acute or Remote Type I endoleaks

Prophylactic (Application of EndoAnchors without evidence of endoleak)

- PROPHYLACTIC USE (61.3%)
- INTRA-OP TYPE IA ENDOLEAKS (38.7%)

ANCHOR REGISTRY

PRIMARY ARM

REVISION ARM
Heli-FX System: Applier + Guide + 10 EndoAnchors

Images courtesy of Aptus Endosystems, Inc.
Aptus Heli-FX Product Offerings

Aptus™ Heli-FX™ Thoracic EndoAnchor™ System
- 16Fr OD, 62cm working length

Aptus™ Heli-FX™ EndoAnchor™ System
- 18Fr OD, 90cm working length

Images courtesy of National Institute of Health and Aptus Endosystems, Inc.
<table>
<thead>
<tr>
<th>PROPHYLAXIS</th>
<th>HOSTILE ANATOMY</th>
<th>NORMAL ANATOMY</th>
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<tbody>
<tr>
<td>Overcoming concerns for implant stability</td>
<td>Challenging neck anatomies (e.g. wide, short, conical, angulated)</td>
<td>Severe comorbidities that preclude safe re-intervention</td>
</tr>
<tr>
<td>Difficult landing (e.g. birdbeaking, close to branched vessels)</td>
<td>Patients potentially lost during F/U</td>
<td>Long remaining life expectancy (young pts)</td>
</tr>
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<thead>
<tr>
<th>TREATMENT</th>
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<tr>
<td>Resolve proximal seal failures</td>
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<tr>
<td>Acute type I endoleaks during primary procedure</td>
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<tr>
<td>Late-term type I endoleaks</td>
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<tr>
<td>Augmenting stability in migrated grafts</td>
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</table>
Case Example – EndoAnchors in Primary EVAR

- Short, reverse taper proximal neck
- Intraoperative Type I post-implantation of Cook Zenith
- 6 EndoAnchors implanted - Type I endoleak resolved

Images from article: Gandi RT and Katzen BT, Treating a Type Ia Endoleak Using EndoAnchors, Endovascular Today, March 2012
Case Example – EndoAnchors in EVAR Revision

- 3 year F/U showed migrated Talent with type Ia endoleak
- Endurant cuff and EndoAnchors implanted - endoleak resolved

Type I Leak
Chimney + Aptus
Chimney + Aptus
Angulated Neck
Type I Leak
Type I Leak - Endostaples
Improved fixation of abdominal and thoracic endografts with use of EndoAnchors to overcome sealing issues
Conclusions

» Major EVAR studies highlight late durability limitations
  > e.g. ‘EVAR 1,’ ‘ACE,’ ‘DREAM’
  > Proximal seal stability remains key

» EndoAnchors designed to bring long-term stability of surgical anastomosis to EVAR

» High safety and efficacy
  > Demonstrated safety profile
  > High success in type I endoleak Tx per ANCHOR registry
  > More definitive data for prevention in-process