3-Year Results from the ANCHOR Registry: How EndoAnchors can Improve EVAR Results and Salvage (some) Failed EVARs

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DISCLOSURES
• CME Standards → NONE
• Clinical Investigator – paid to Emory
  → Gore, Medtronic, Case, Endologix, Trivascular, Bolton
• Consultant – paid to Emory
  → Gore, Medtronic, Cardinal Health
• Equity Shareholder
  → None

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
  • Adaptable to long-term disease process may improve outcomes
  • Don’t fight the disease but learn to live with the pathologic environment
  
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: safety & feasibility; 2006-2007; 21 pts across 5 US sites
  • 1y data: no type Ia’s, 49% sac regression, no AAA ruptures
  → STAPLE II: safety & efficacy; 2007-2009; 155 patients across 33 US sites
  • 5y data: no type Ia’s, 72% sac regression, no AAA ruptures
• ANCHOR Global Registry: >800 AAA pts to date; 5y 1V 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

Registry Design
Prospective & Observational International & Multi-Center, Dual-arm Registry with Core Lab Analysis

Registry Principal Investigators
Europe: Dr. Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital
US: Dr. William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine

Treatment Arms*
“Primary”
“Revision”

Enrollment & Duration
Enrollment began 2012 and patients will be followed for 5 years

Follow-up
Per Standard of Care at each center & discretion of Investigator

*Expanded registry to include Thoracic and Advanced Disease arms.

ANCHOR Registry – Prophylactic Use
Concern for Late Failure and/or Prevention of Neck Dilatation w/o Type Ia EL

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

Mean Age: 72.4 Years
Male: 79%
Female: 21%

Mean Core Lab measurements
Hostile Necks: 85.8%
Per the SVS definition
Concern for Late Failure and/or Prevention of Neck Dilatation w/o Type Ia EL

1-Year 2-Year 3-Year
Type 1a Endoleak 0.6% (2/308) 1.1% (2/187) 1.7% (2/120)
Endograft Migration 0.0% (0/236) 0.0% (0/110) 0.0% (0/66)

Freedom from Type Ia Endoleaks
Years
1-Year 258 3-Year
3-Year FF Type Ia EL 95.4%

Freedom from ACM
1-Year 2-Year 3-Year
Freedom from ACM 95.1% (424) 89.0% (326) 85.5% (229)

Freedom from ARM
1-Year 2-Year 3-Year
Freedom from ARM 98.9% (424) 98.9% (326) 98.3% (229)

FF 2nd Endo Proc for Type Ia ELs 99.2% (423) 99.2% (323) 98.7% (226)

Freedom from Rupture
1-Year 2-Year 3-Year
Freedom from Rupture 100% (424) 100% (326) 98.8% (229)

Freedom from Conversion
1-Year 2-Year 3-Year
Freedom from Conversion 99.8% (423) 99.8% (326) 98.1% (229)

SAEs through 3 Years
EndoAnchor Device-Related SAE 1 patient within 3 years
Vascular Procedure Complication

ANCHOR Registry – Prophylactic Use
Stent Grafts – Primary Arm
Medtronic Endurant
Gore Excluder
Cook Zenith
Jotec
Other

Stent Grafts – Revision Arm
Medtronic Endurant
Medtronic Talent
Medtronic AneuRx
Gore Excluder
Cook Zenith
Jotec
Other/Unknown

Prophylactic Therapeutic

456
128

456
128

3-Year FF Type Ia EL 15.4%
Propensity Matched Comparison

With and Without EndoAnchors

More Competent Proximal Seal
Enhances AAA Remodeling

Methodology
- 1% Patients Bled
- 1% No EVA
- 1% No EndoAnchor
- 1% EndoAnchor

ANCHO Registry

Revision Arm represents 27.5% of pts

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

Muhs, BE et al. JVS. 2018 June;67(6): 1699-1707

ANCHOR Registry

PRIMARY ARM

584

Stent Grafts - Primary Arm

Medtronic Endurant
Gore Excluder
Cook Zenith
Jotec
Other

ANCHOR REGISTRY

REVISION ARM

217

Stent Grafts - Revision Arm

Medtronic Endurant
Medtronic Talent
Medtronic AneuRx
Gore Excluder
Cook Zenith
Jotec
Other/Unknown

Prophylactic Therapeutic

456

HOSTILE NECKS: 90.6%

Per the SVS definition

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

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

1-Year 2-Year 3-Year

Type 1a Endoleak 7.9% (11/140) 5.9% (4/68) 2.4% (1/41)

Endograft Migration 0.0% (0/118) 0.0% (0/45) 0.0% (0/33)

Aortic Penetration

EndoAnchor Implants adequately penetrated the aortic wall

Freedom from Type Ia Endoleaks

Years

3-Year FF Type Ia EL

83.3%

Kaplan-Meier Estimates

1 Year 2 Year 3 Year

Freedom from ACM 88.0% (205) 75.8% (144) 60.9% (94)

Freedom from ARM 96.8% (205) 93.7% (144) 91.1% (94)

FF 2nd Endo Proc for Type Ia ELs 92.9% (200) 89.3% (133) 86.3% (82)

Freedom from Rupture 99.3% (204) 97.6% (143) 94.6% (93)

Freedom from Conversion 97.8% (205) 95.5% (144) 91.4% (93)

SAEs through 3 Years

EndoAnchor Device-Related SAE

3 patients within 3 years
- 2 Endoleaks; 1 Infection

Mean Age: 77.9 Years

Male: 85%
Female: 15%

Mean core lab measurements

Infrarenal Diameter:
29.4 mm

Infrarenal Angulation:
21.0°

Neck Length:
10.2 mm (median)

Aneurysm Diameter:
68.6 mm

Conical Neck (>10%/10mm):
49.4%

* Data cut June 13, 2018

1-Year 2-Year 3-Year
3 year FU shows improvement in long term outcomes

1. Prophylactic anchors can improve results against late failure of EVAR in hostile aortic neck anatomy
2. Therapeutic anchors can avoid conversions and further revisions in 80+% of failed endografts