Lessons Learned From The Nellix Experience: Why Sac Sealing Should Still Be Pursued For EVAR, But Not From The Nellix Platform: What Changes Would Make Sac Sealing Devices Work

Matt Thompson, MD., FRCS.
President and CEO Endologix LLC, Irvine, CA

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Disclosure

Matt Thompson:

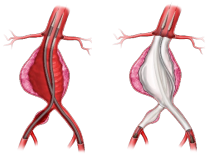
I have the following potential conflicts of interest to report:

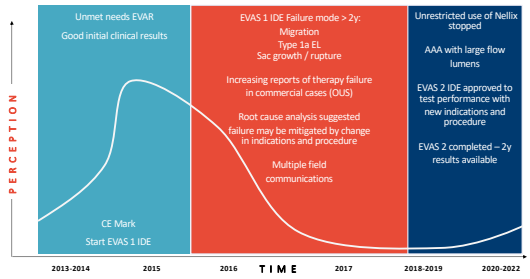
Employment and shareholder in Endologix LLC

Board Member: Vivos Therapeutics, Lifescal Vascular

Endovascular Aneurysm Sealing (EVAS) - Nellix

- EVAS pioneered active management of the aneurysm sac
- Design intent to reduce post-EVAR perfusion of the aneurysm sac and prevent sac growth
- Use of polymer filled endobags for proximal seal, distal seal, fixation and sac filling
- Mid-term failure mode with original indications, migration leading to Type 1a endoleak

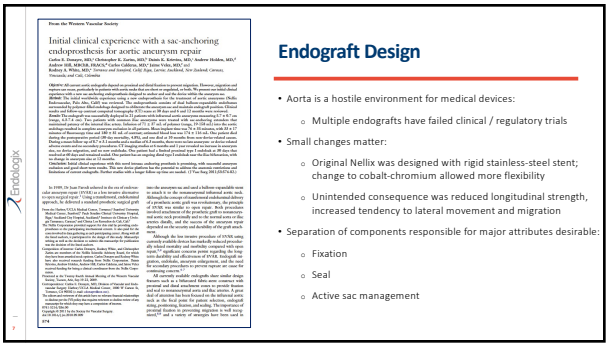




EVAS 2 IDE 2 Year Results

Outcome	60 months
Freedom from:	
Type IA endoleak	95.3%
Type II endoleak	95.3%
Type III endoleak	100%
Migration	97.3%
Graft occlusion	96.8%
Secondary interventions	84.2%
Aortic rupture	100%
Aortic related death	99%
All Cause mortality	82.4%

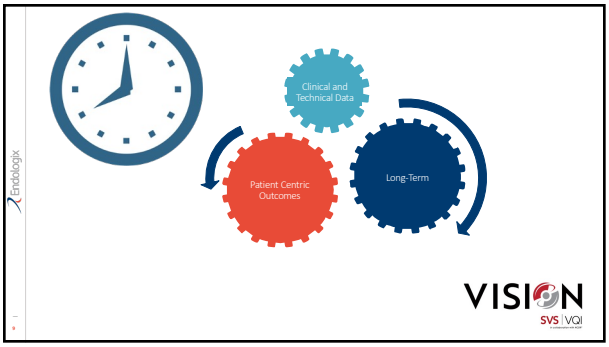
- Primary safety and efficacy end points met
- Applicability low due to constrained IFU (<20% all AAA)
- Outcomes off refined IFU poor



Endograft Design

- Aorta is a hostile environment for medical devices:
  - Multiple endografts have failed clinical / regulatory trials
- Small changes matter:
  - Original Nellix was designed with rigid stainless-steel stent; change to cobalt-chromium allowed more flexibility
  - Unintended consequence was reduced longitudinal strength, increased tendency to lateral movement and migration
- Separation of components responsible for major attributes desirable:
  - Fixation
  - Seal
  - Active sac management

Regulatory Environment



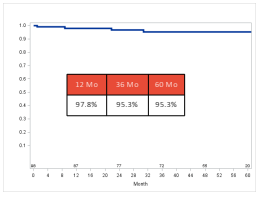
Understand Real World Device Performance (Off Label)

- Aortic endografts are routinely and repeatably used off label
- Majority of EVAR literature demonstrates a gradual deterioration of outcomes with the degree of off-label use
- Nellix achieves positive outcomes –only – when used within restrictive anatomic parameters

Benefits of Active Sac Management

- Design intent of active sac management (Type 2 EL) was realized
- Active sac management with the Nellix system was associated with:
  - Low rates of Type 2 endoleak through 5y
  - Reduced rate of Post Implantation Syndrome (PIS)
  - Reduced all cause mortality to 3y

Freedom from Type 2 EL
EVAS 2 IDE

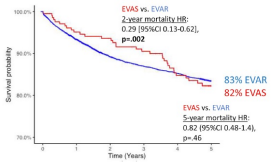


Benefits of Active Sac Management

	EVAS (n=58)	EVAR (n=111)
Incidence PIS	13.8%	38.7%

Multivariate analysis:
EVAS only independent predictor of lower PIS (OR 0.2 [0.08-0.5])

All Cause Mortality AAA > 5.5cm



Concluding Remarks

- EVAS / Nellix was a new therapy – not a new EVAR product:
  - Significant implications for launch metrics and outcome reporting
- Active management of aneurysm sac with Nellix demonstrated positive findings
- Active sac management should conform to principles that have been successful in EVAR – separation of function (fixation, seal, sac management)
  - Ability to replicate these with proposed adjunctive therapies to current endografts? - Lifeseal Vascular / Shape Memory