Can EVAS Fail: When and How

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Disclosure

Speaker name: Matt Thompson, MD

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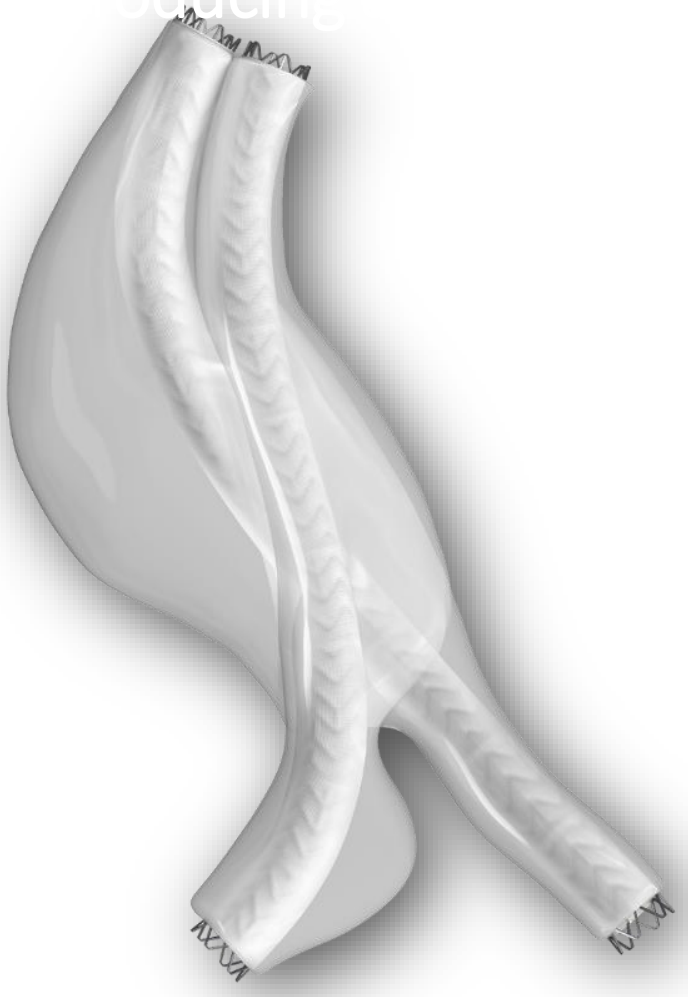
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☒ Employment in industry – Endologix, Inc., Chief Medical Officer
- ☒ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest



- Therapy NOT product
- Clinical conditions cannot be replicated in vitro
- Realized expectations of therapy
- Failure modes inevitable (20y vs 3y)
- Understand failure modes
- Define “sweet spot” of Nellix® – personalized medicine

Early vs Late

Patient Selection and Nellix

Commentary

JOURNAL OF ENDOVASCULAR THERAPY

Journal of Endovascular Therapy
1–2

DOI: 10.1177/1526602816664652
www.jevt.org
SAGE

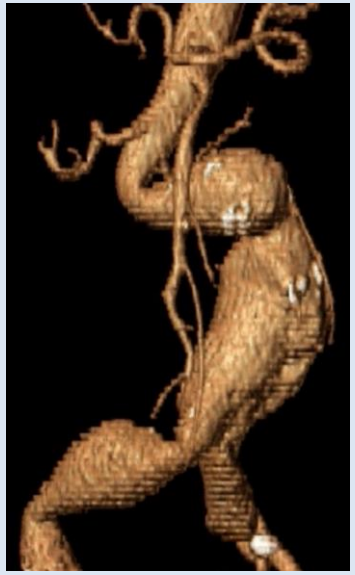
Seduction and Its Impact on Instructions for Use

Sebastian Zerwes, MD[1]

"The 'sealing the entire aneurysm' idea of the Nellix system quite simply represents a very seductive concept that seems to lure the vascular surgeon beyond the IFU."

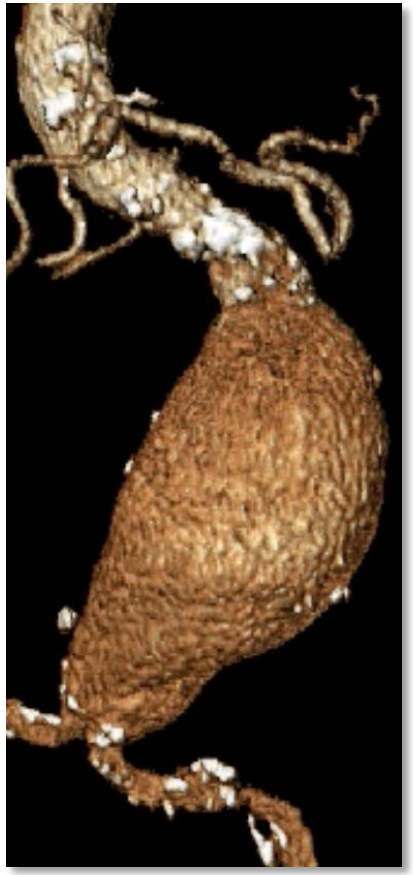
"Little to no neck?" Angulated necks? Large necks?....All not a problem, the endobags will take care of it....the sky seems the limit."

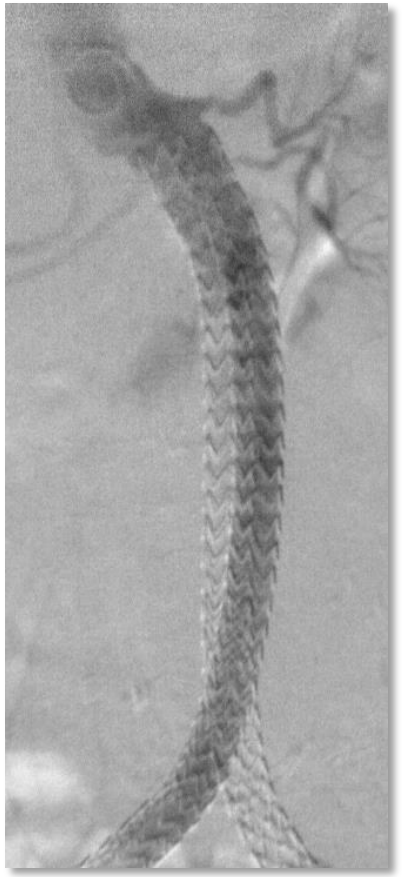
- Realistic patient selection
- Precise placement of stents
- Good endobag filling
- Adequate proximal and distal seal in parallel sided artery



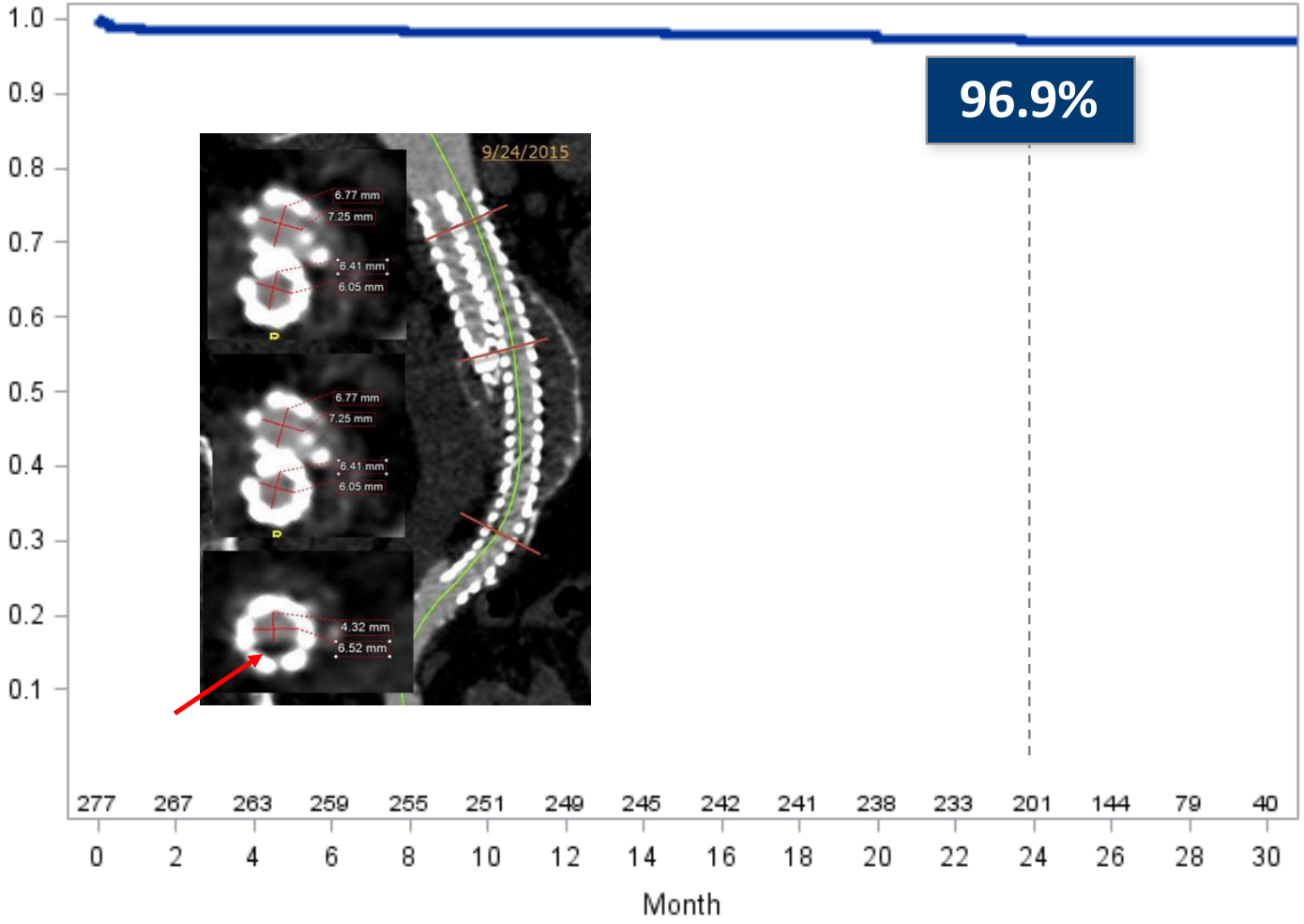
Evolution in Implant Procedure

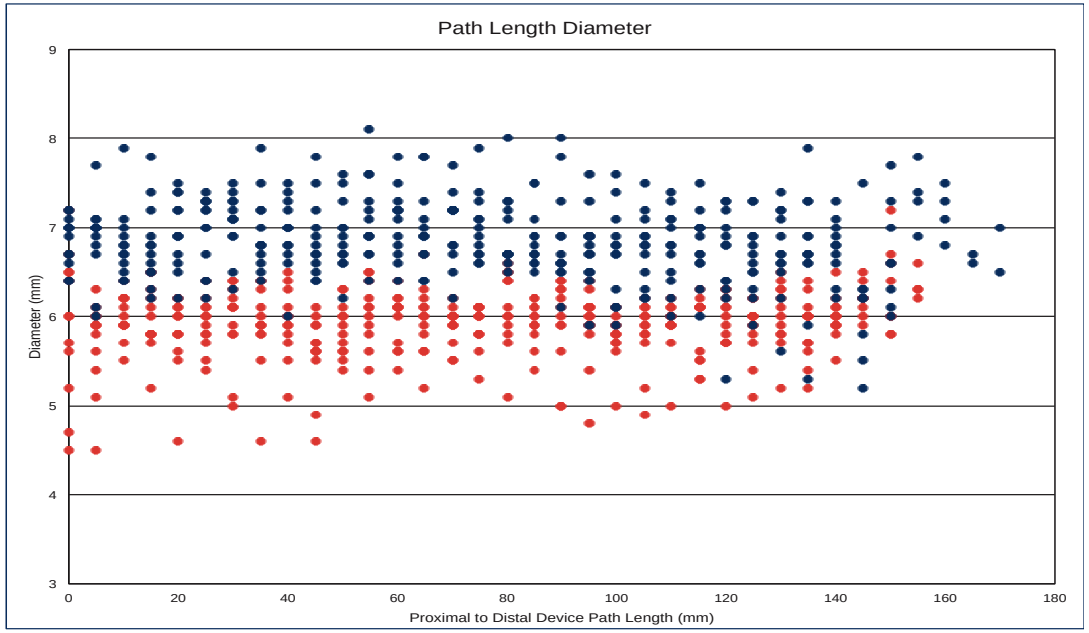
- EVAS conceptually different to EVAR
  - Procedure iterated over 3 years
    - Graft placement
    - Manufacture lumens
    - Create effective seal
- Troubleshooting specific anatomies





Evolution in Implant Procedure – Limb Thrombosis



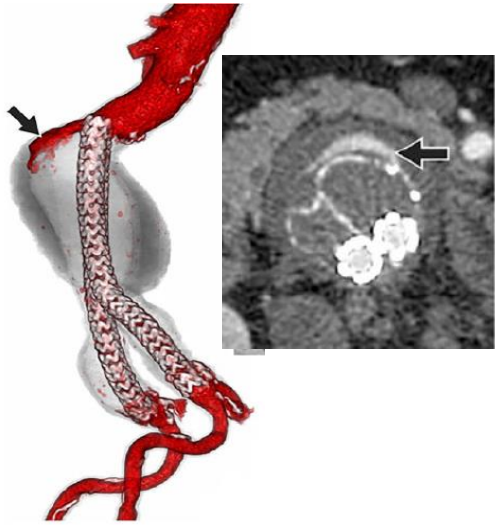


Thrombosis (red) / Patent (blue)

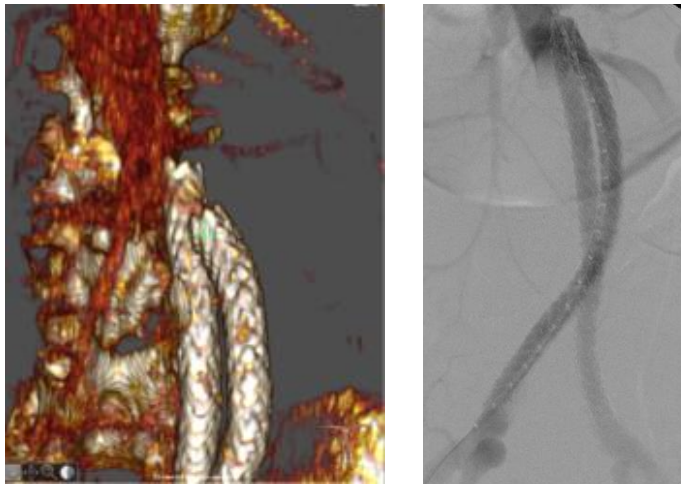
EVAS FORWARD GLOBAL REGISTRY

The Nellix® EndoVascular Aneurysm Sealing System is an investigational device in the United States, limited by federal (or United States) law to investigational use only. The Nellix® EndoVascular Aneurysm Sealing System approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.

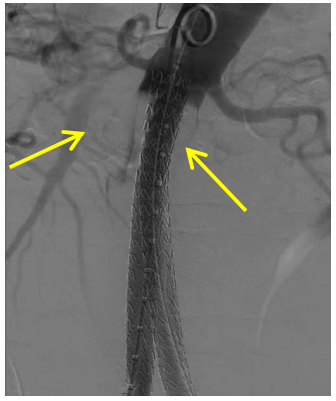
Low stent deployment

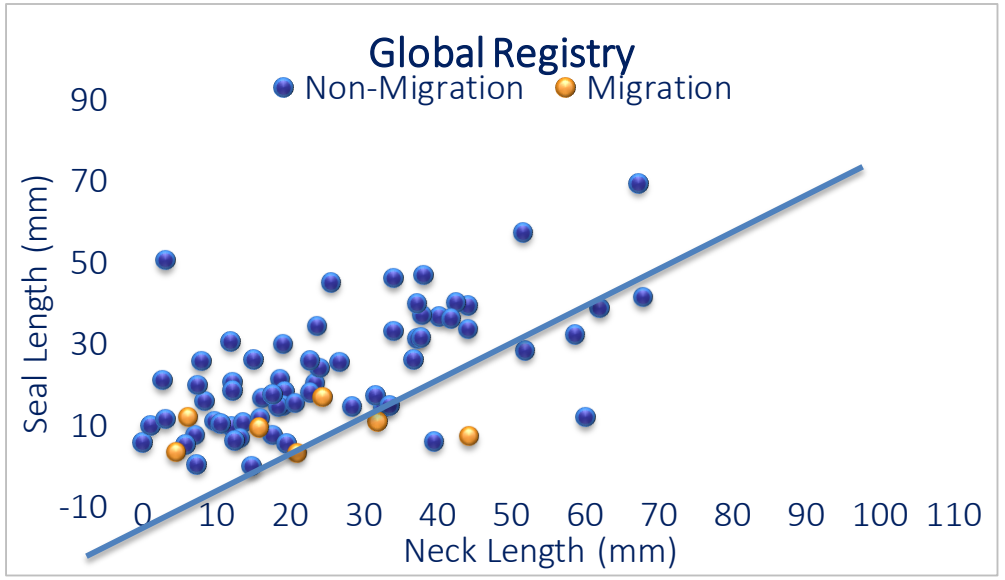


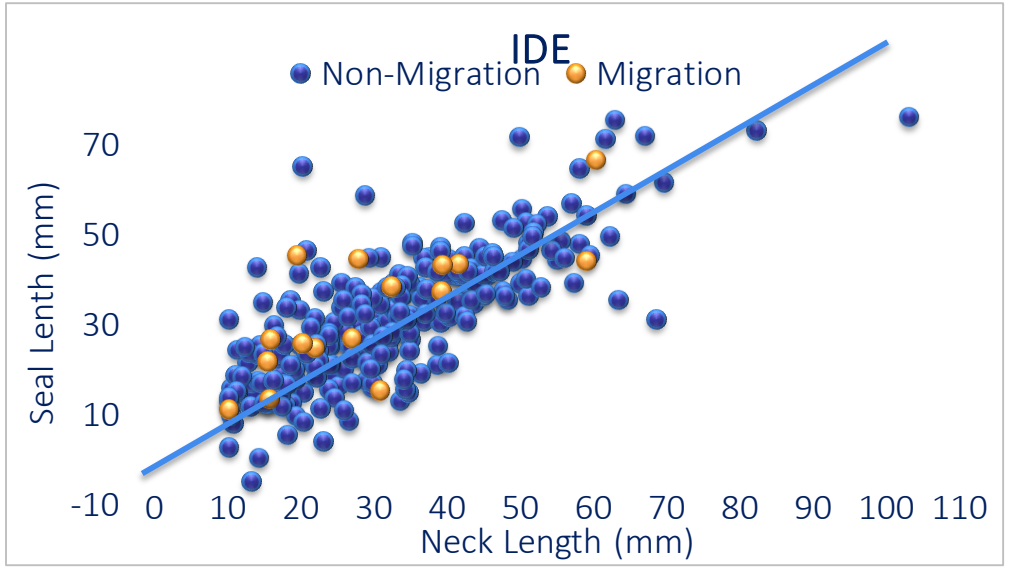
Stent malalignment



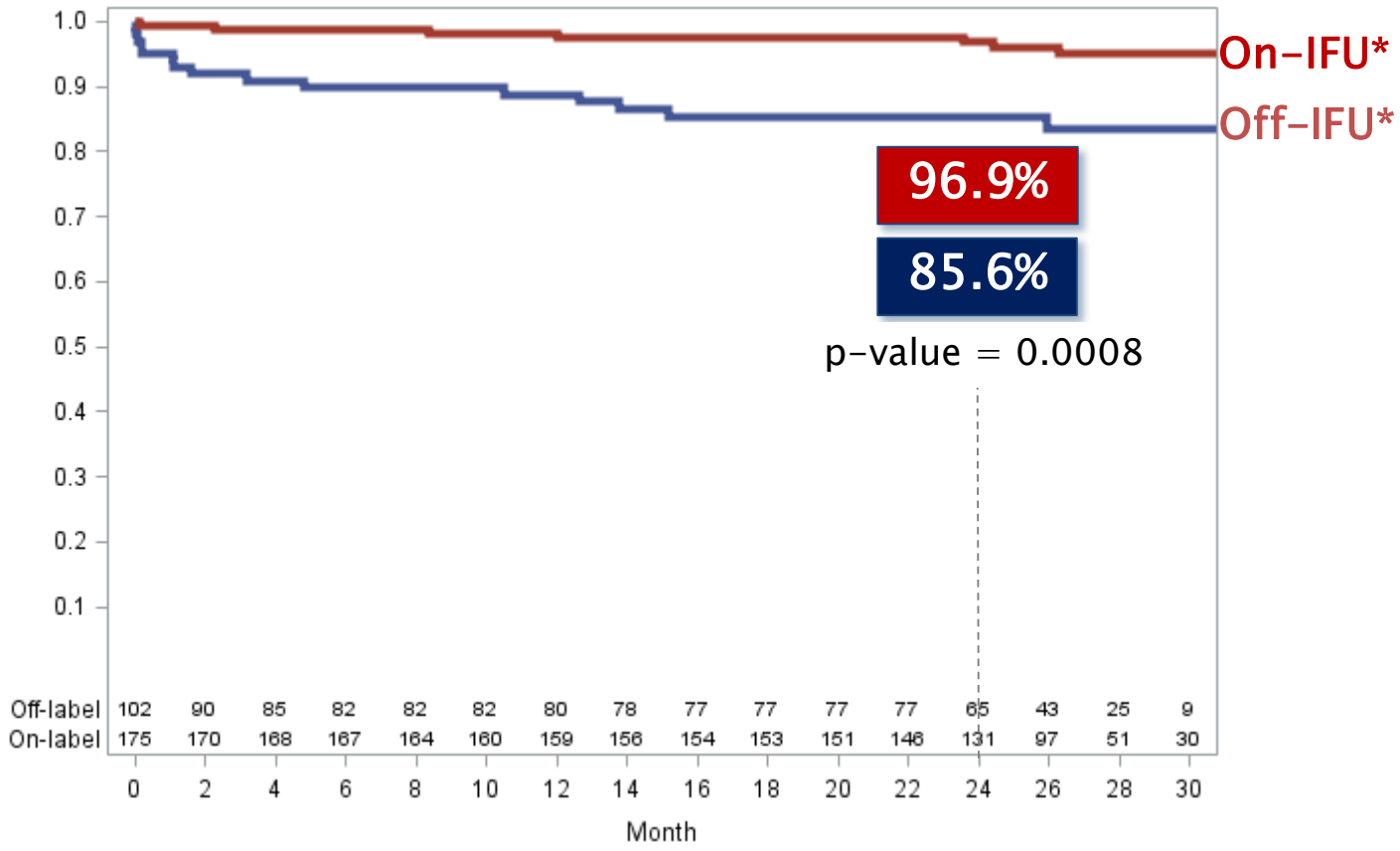
Underfilling of the endobags







Freedom from Type 1a Endoleak



*Based on previous Nellix IFU

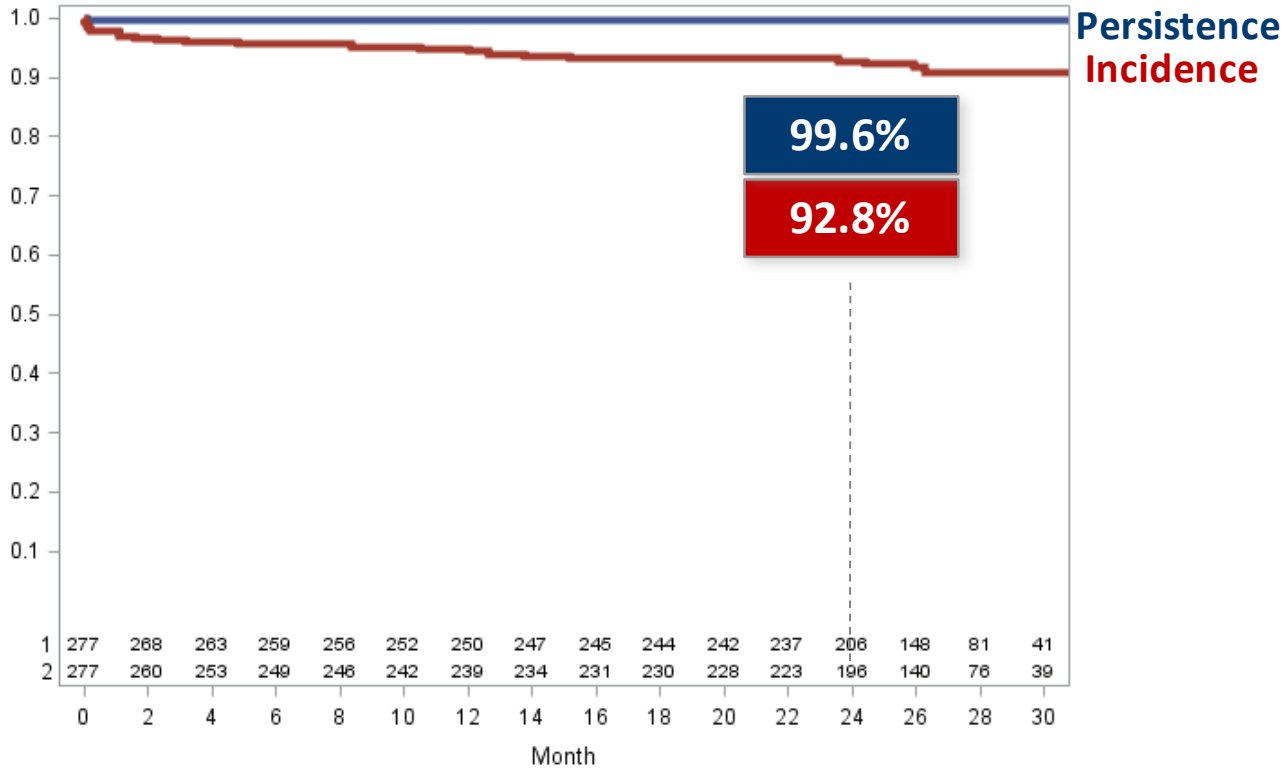
Complex Proximal Neck Anatomy

Large proximal necks >28mm
Thrombus-laden necks

EVAS FORWARD GLOBAL REGISTRY

Treatment of Type 1a Endoleak – Transcatheter Embolisation

99.6% Freedom from Persistent Type 1A Endoleaks, demonstrated by successful secondary repair



Transcatheter Embolization

Brownrigg et al. et al. *Eur J Vasc Endovasc Surg* 2015: 50, 157-64.

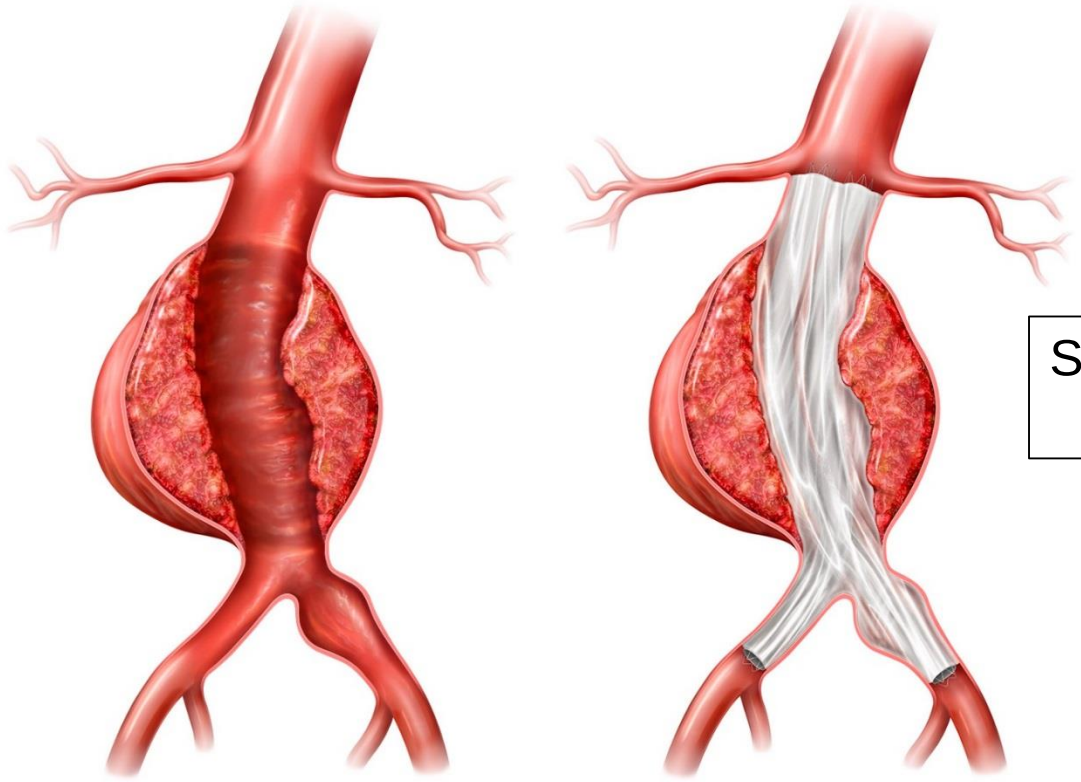
EVAS FORWARD GLOBAL REGISTRY

Mid to Late Failure Modes of EVAS

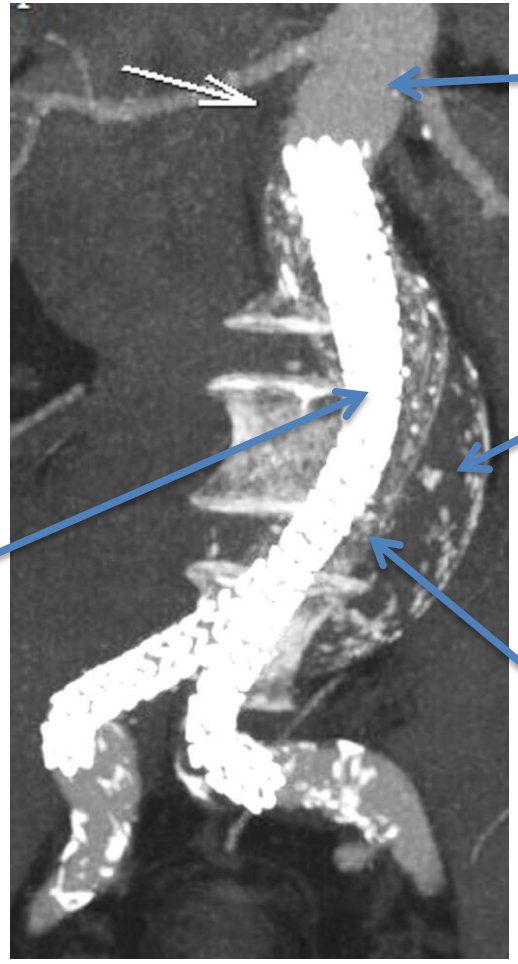
- Physiological stresses on endografts
- Mid to late failure modes of medical devices inevitable
- Took 20y+ to define mechanisms for EVAR failure
- Mid to late failures EVAS (migration / sac growth)
- Challenge is to understand late failure modes of EVAS at 2-3y by leveraging clinical data allied to high resolution imaging

Nellix Stent Migration (Polymer and Thrombus)

Polymer and Thrombus



Stiffness of stent graft



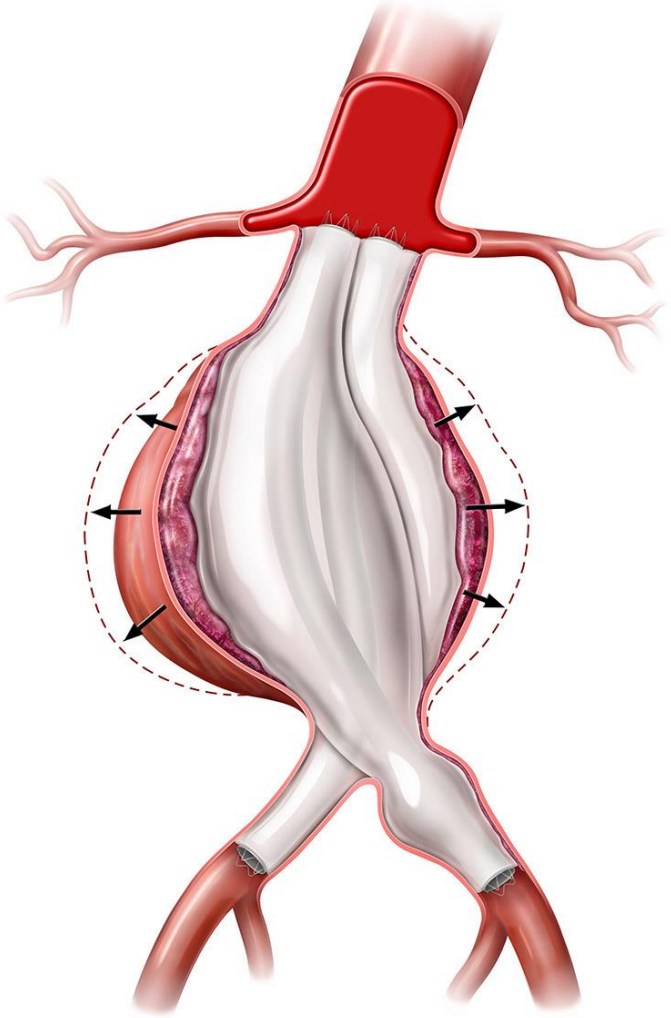
Seal zone engagement

Thrombus volume and stability

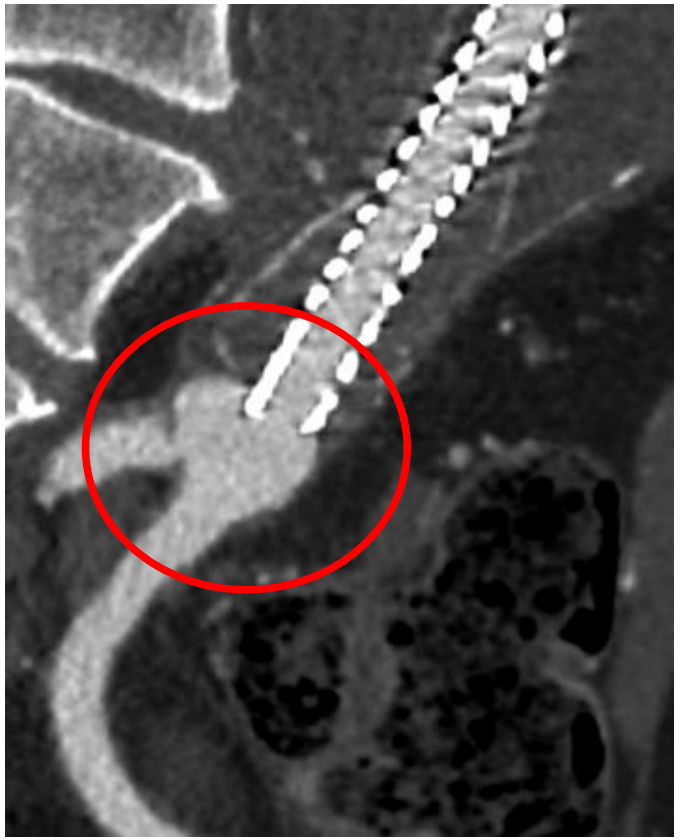
Polymer thickness and distribution

Resistance to Migration

Aneurysm Sac Enlargement in Partially Sealed Iliac Artery



Partial Seal

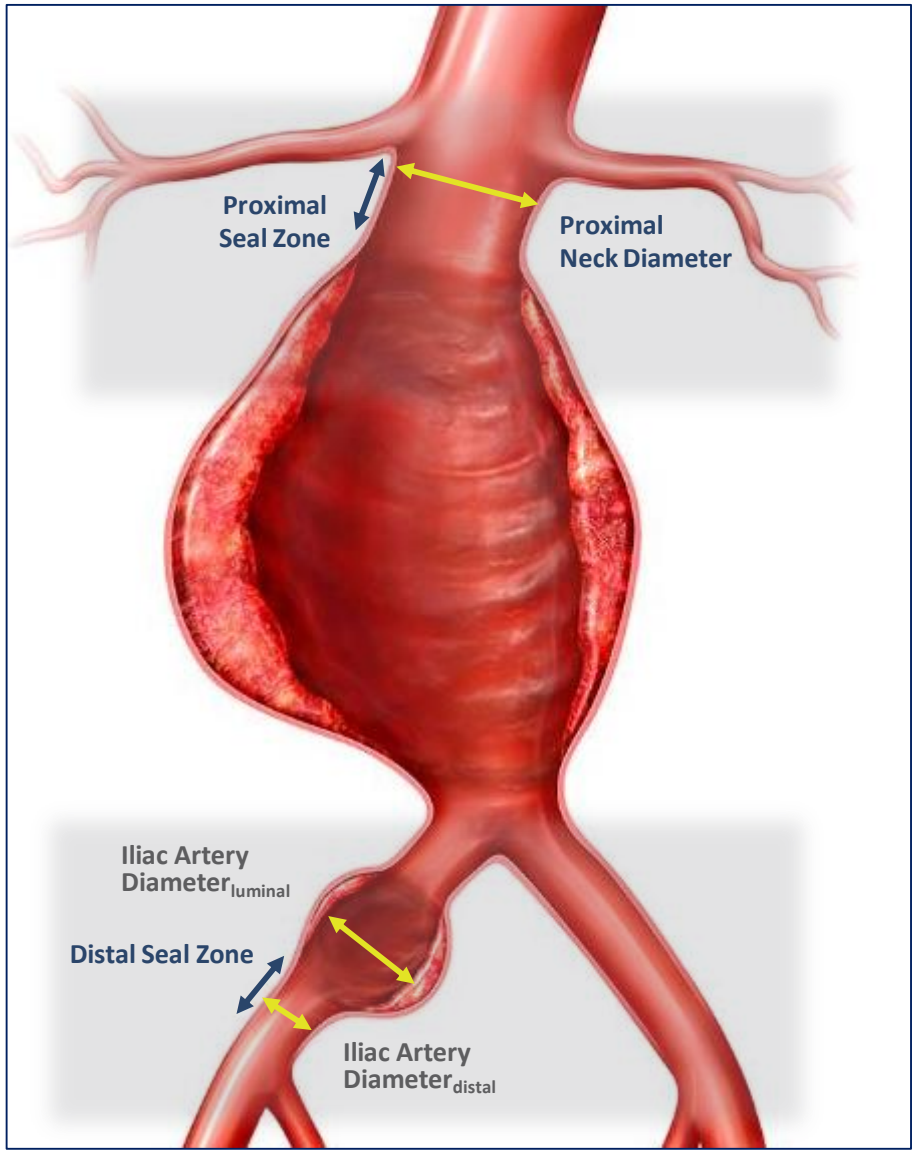


Krievins et al, *J Vasc Surg* 2016

- Permits mural thrombus pressure transmission (endotension) to AAA Sac
- Addressed by current generation Nellix (3.5)
- Can be treated with distal extensions / covered stents

Refinement of the IFU – “Traditional Factors”

1. **Proximal Neck Diameter**
   - From: 18-32mm
   - To: 18-28mm
2. **Neck Diameter Change**
   - From: ≤20%
   - To: ≤10%
3. **Iliac Artery Luminal Diameter - *Unchanged***
   - 9-35mm
   - **Distal Seal Zone**
     - **Iliac Artery Inner Wall Diameter**
     - **Distal Iliac Artery Seal Zone**
     - ≥10mm length
     - 9-25mm



Refinement of the IFU – “Aneurysm Sac”

Aneurysm Ratio

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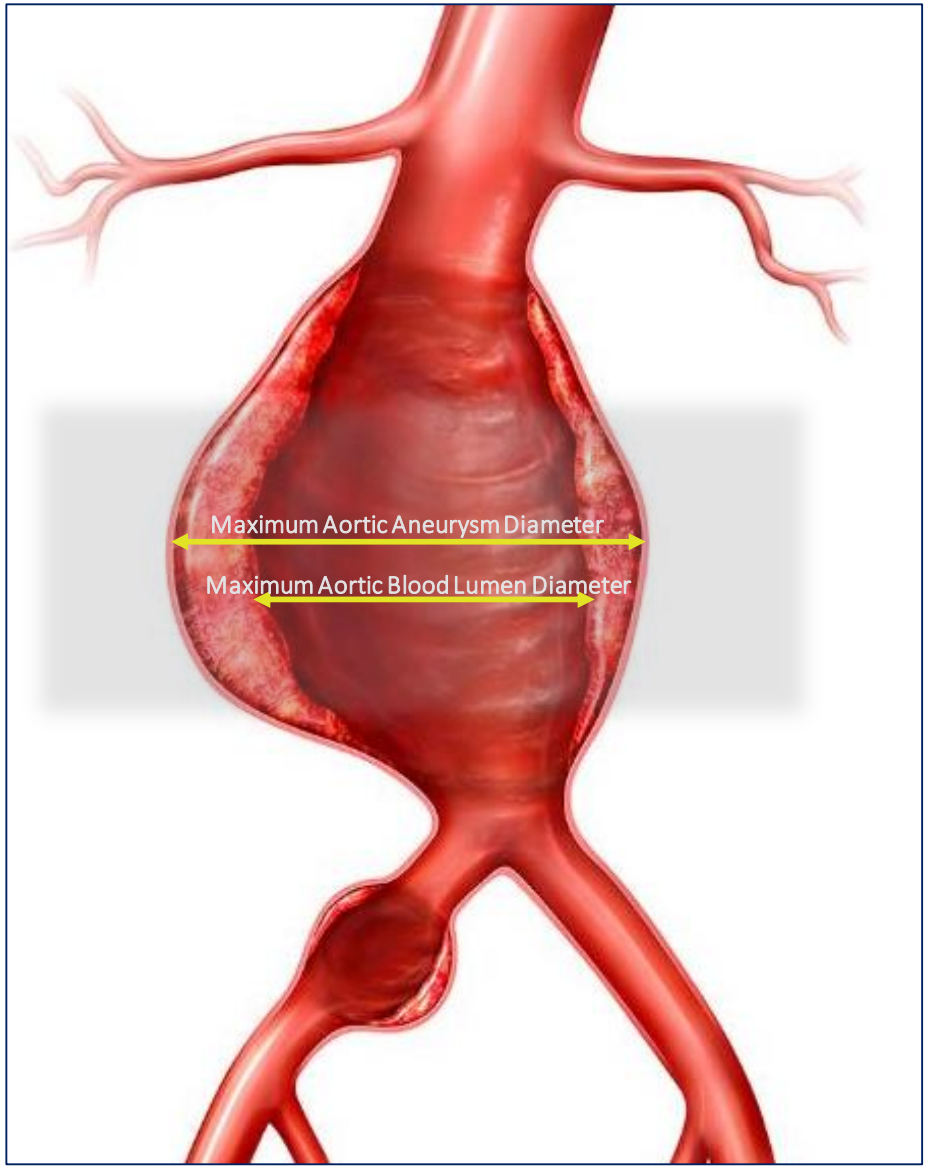
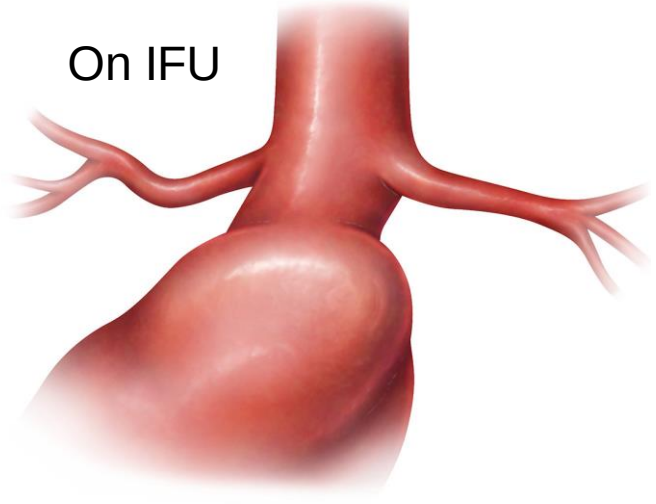
$$\frac{\text{Max aortic aneurysm dia}}{\text{Max aortic blood lumen dia}} < 1.4$$

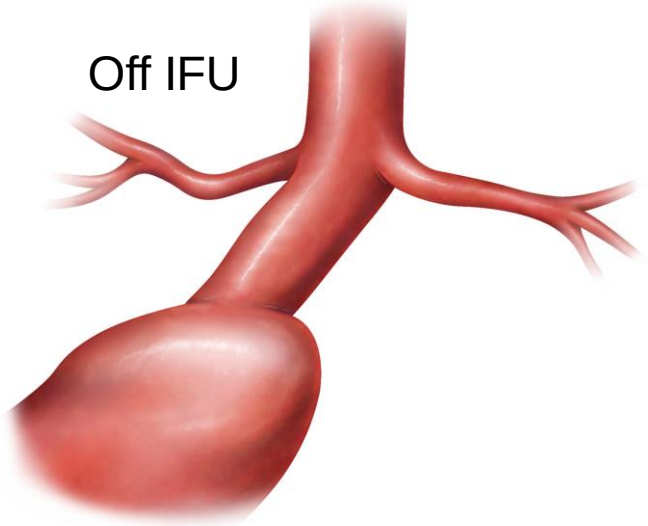
Aneurysm ratio varies according to proximal seal

zone, neck engagement and iliac diameter

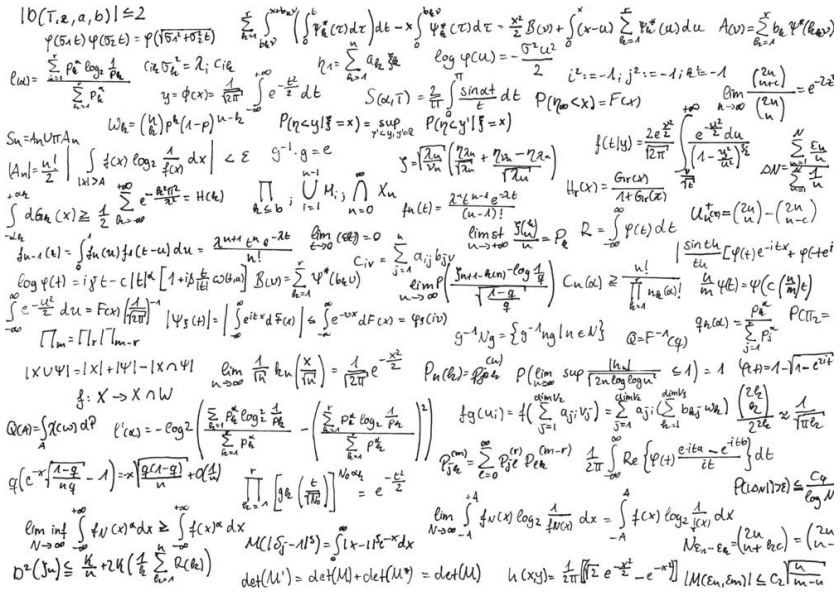


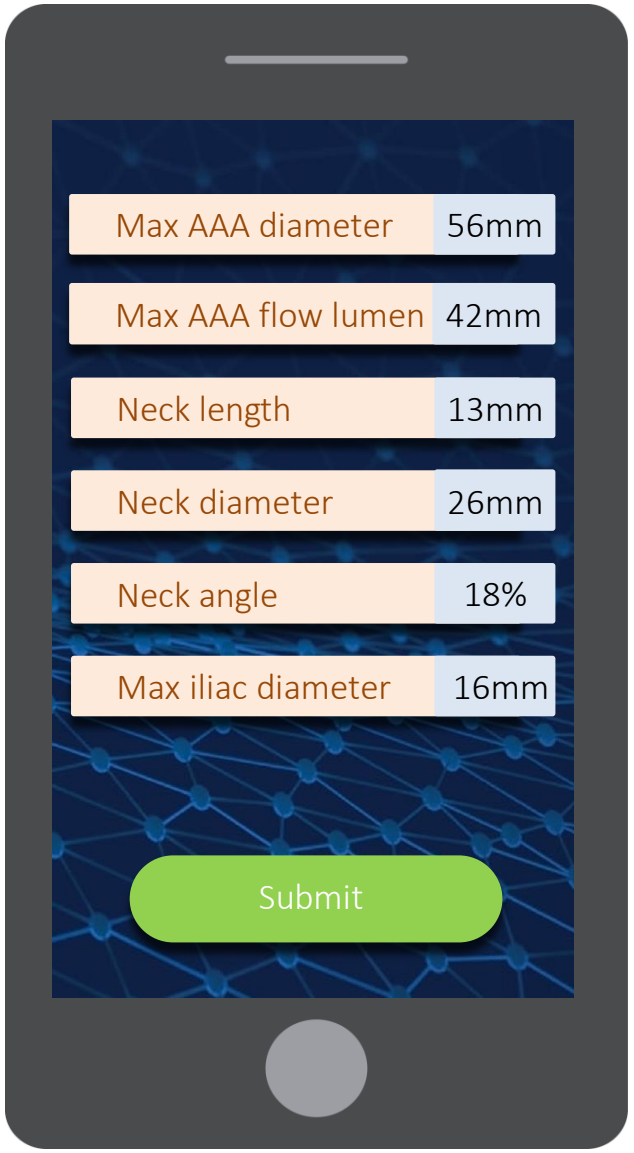
Introducing a Complex Algorithm to IFU – IFU Not Binary





- Format of IFU unchanged for 20y+
- Factors in IFU not regarded as binary
- Clinicians integrate separate factors to estimate outcome
- Complex algorithm more attuned to modern practice
- Computed algorithms used commonly in clinical practice
- Opportunity to set new standard of care

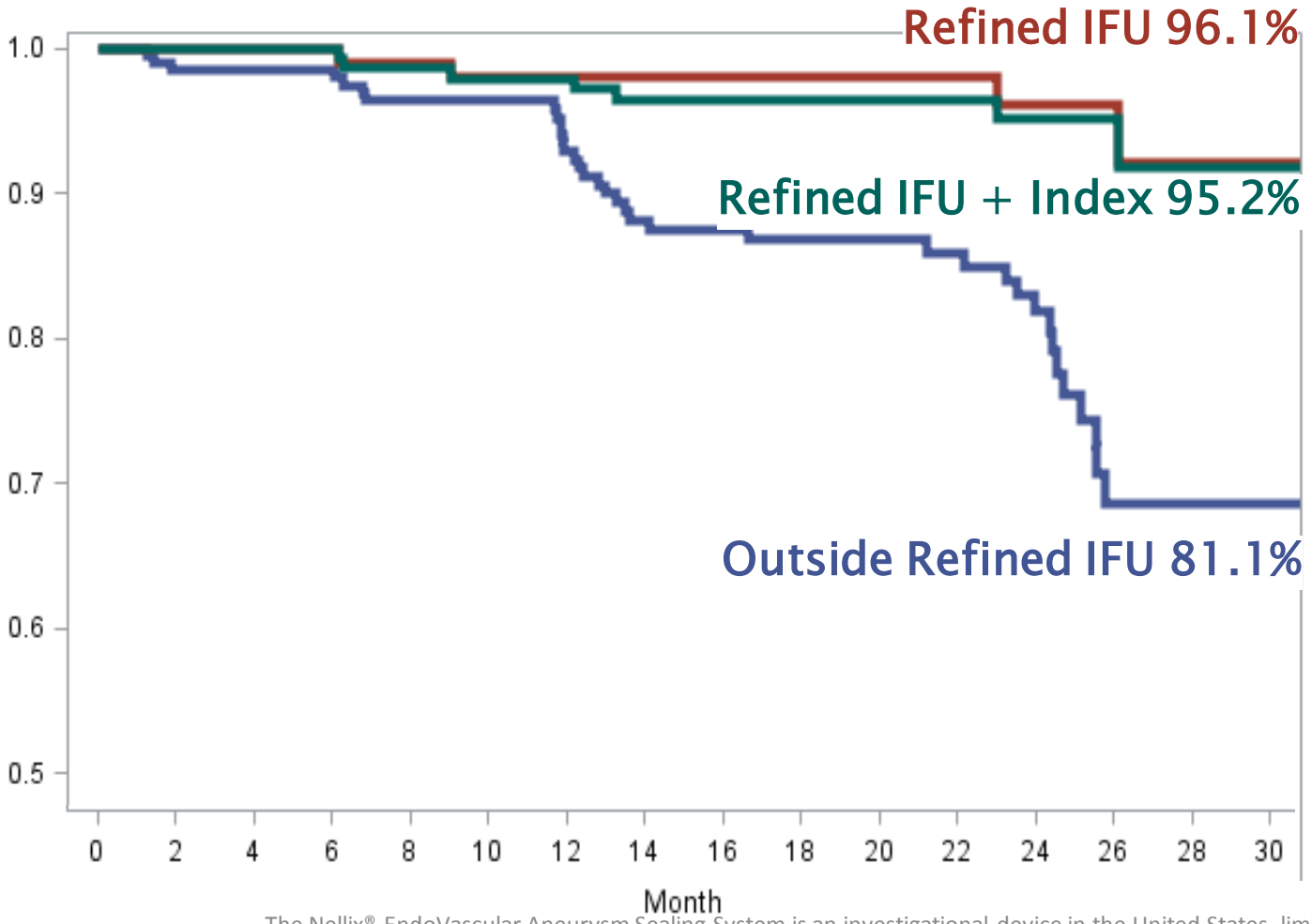




- Personalize treatment
- Select graft that provides exceptional outcomes
- Applicable across portfolio
- Timescale

Freedom from Aortic Events - 2 Year Data

2-Year Freedom from Core Lab Reported Migration >5mm OR Type 1A Endoleaks OR Sac Enlargement >5mm



Estimated Comparison EVAR

Sac expansion 7.2%

Type 1 endoleak 2%

Migration 2%

Schanzer et al Circulation 2011; 123

Summary and Conclusions

- Evolution of endovascular surgery for AAA include active management of aneurysm sac
- Low Type 2 rate, modify biologic response to aneurysm repair, neck dilatation
- Understand mechanisms of early and late failure modes
- Aim for personalized aneurysm repair by selecting patients appropriate for the device