

# Early Experience of EVAS With Nellix

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## Disclosure

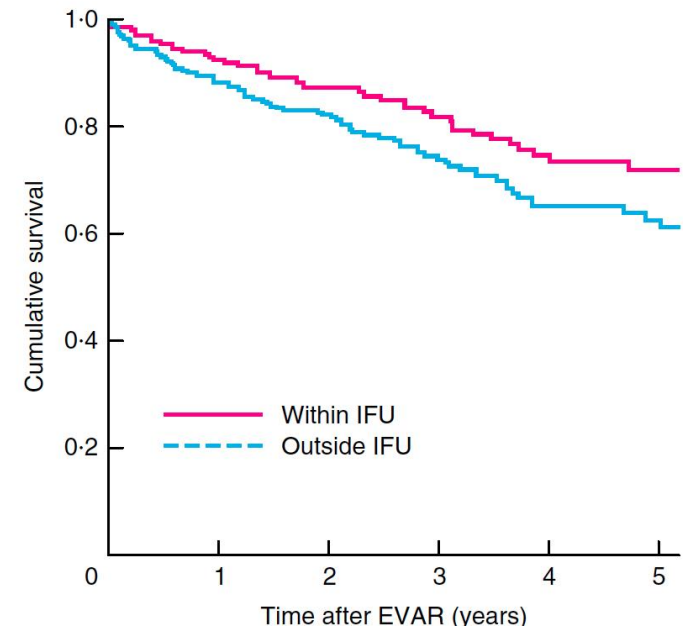
Speaker name: Ian Loftus

I have the following potential conflicts of interest to report:

- Consulting, Research Grants and Speaker:
- Endologix
- Abbott
- Cook
- Medtronic
- Covidien

# Long Term Outcomes Following EVAR

- Current endografts have significant rates of graft failure and endoleak
- Prevention of rupture depends on effective surveillance and re-intervention
- Lifelong surveillance requires considerable resource
- Patient never “cured”



*Holt et al BJS 2012*

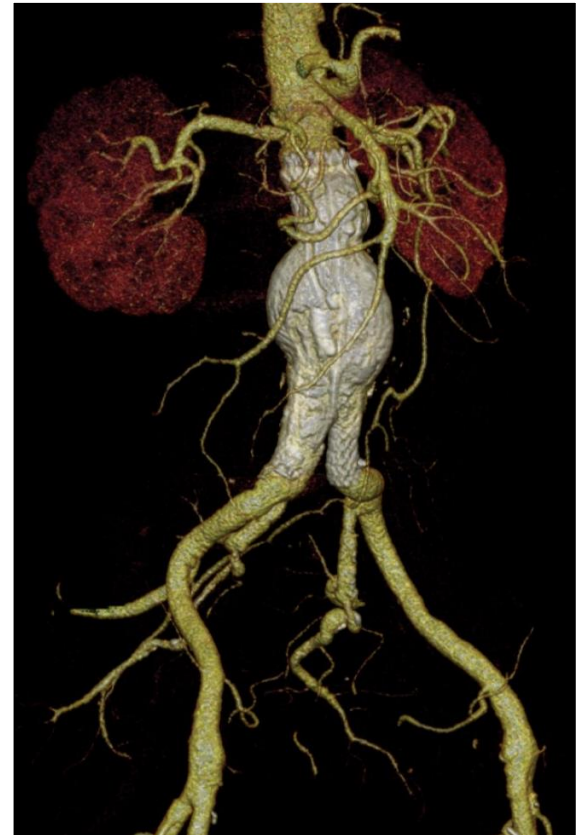
# Stent design: *Paradigm Shift*

- Generations of EVAR: subtle design change
- Technological innovation to produce endograft with:
  - Reduced incidence of graft failure and endoleak
  - Reduced need for surveillance
  - Abolish sac diameter change

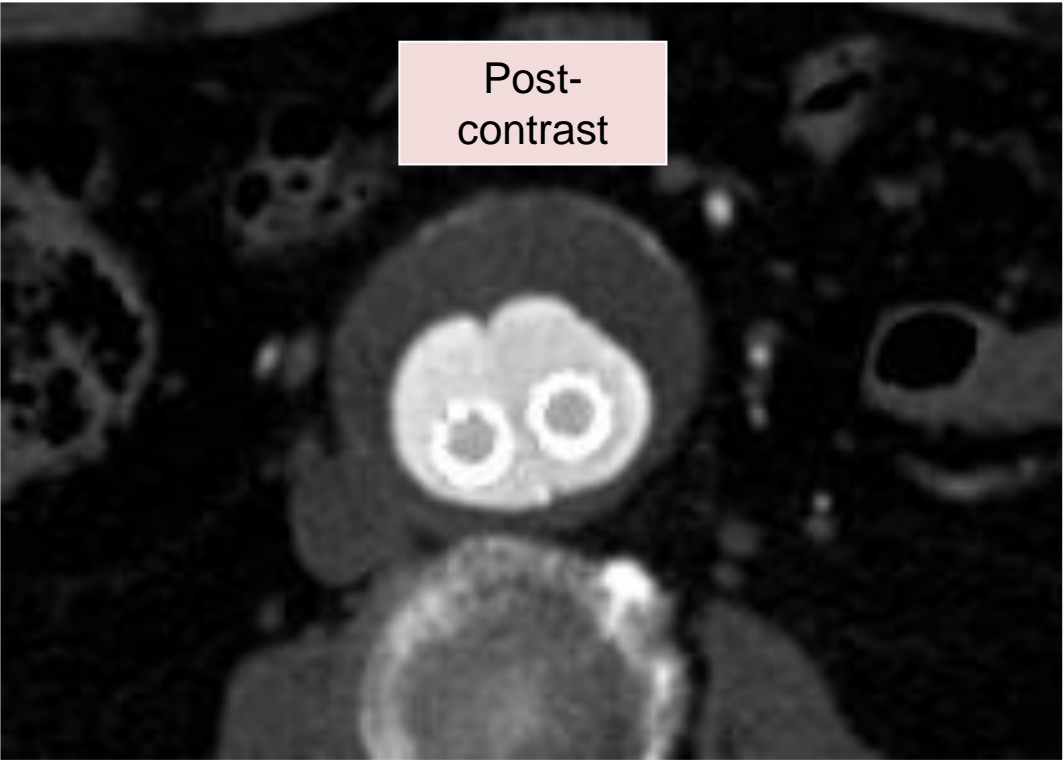
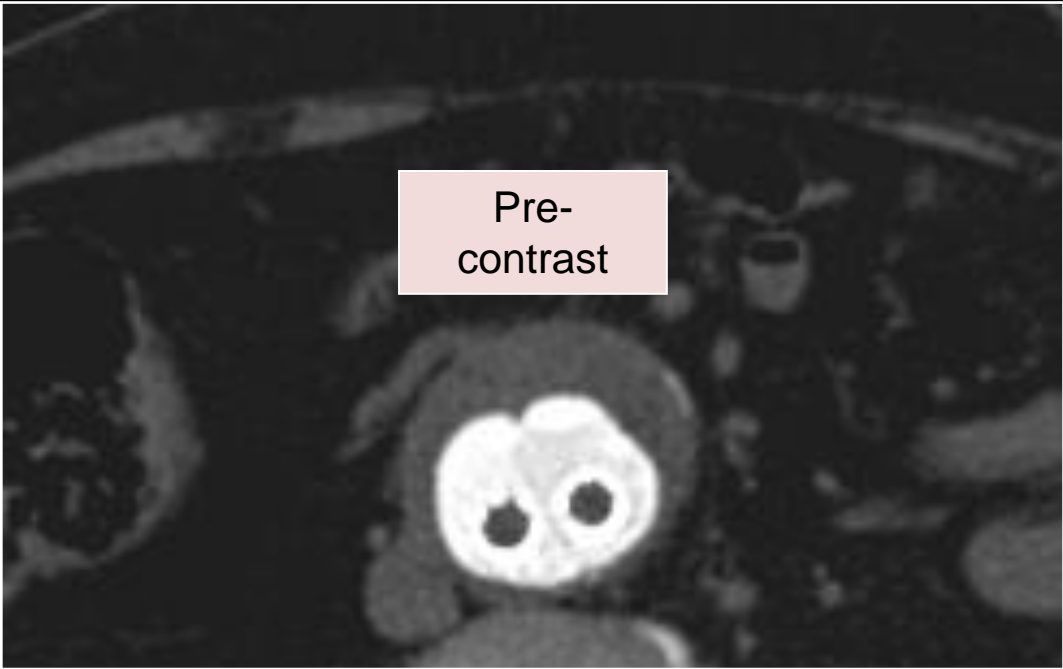


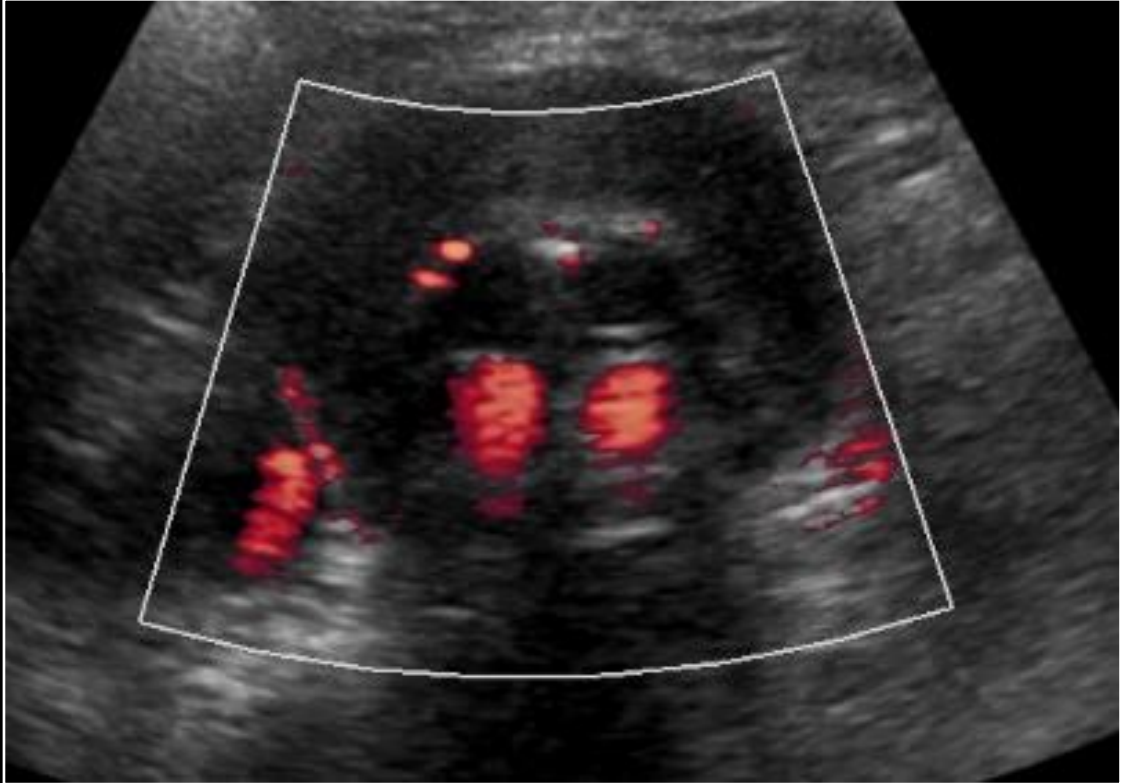
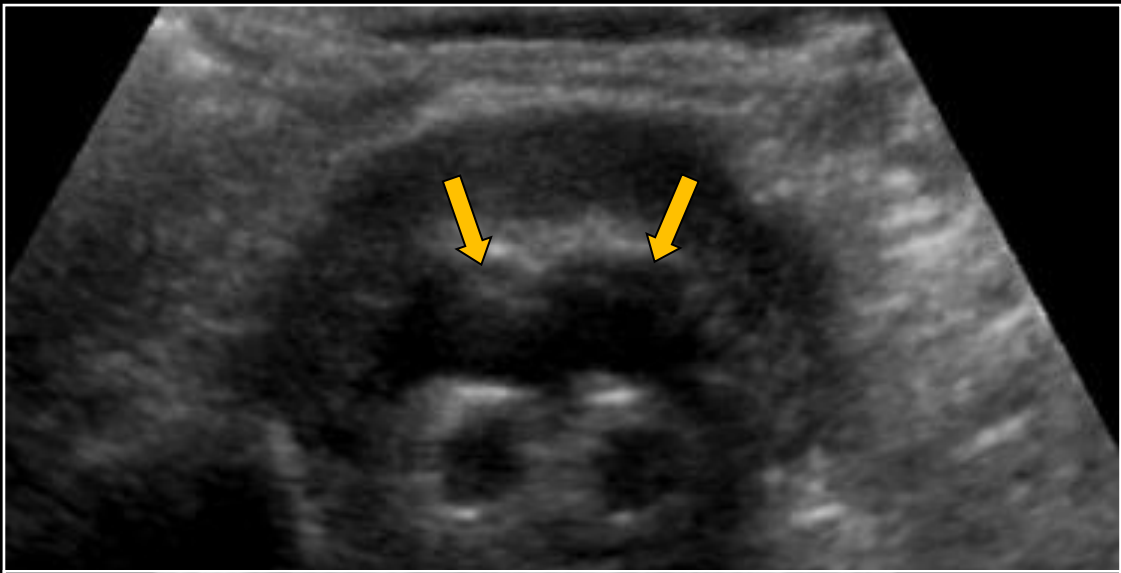
# Stent design: *Paradigm Shift*

- Generations of EVAR: subtle design change
- Technological innovation to produce endograft with:
  - Reduced incidence of graft failure and endoleak
  - Reduced need for surveillance
  - Improve long term outcomes

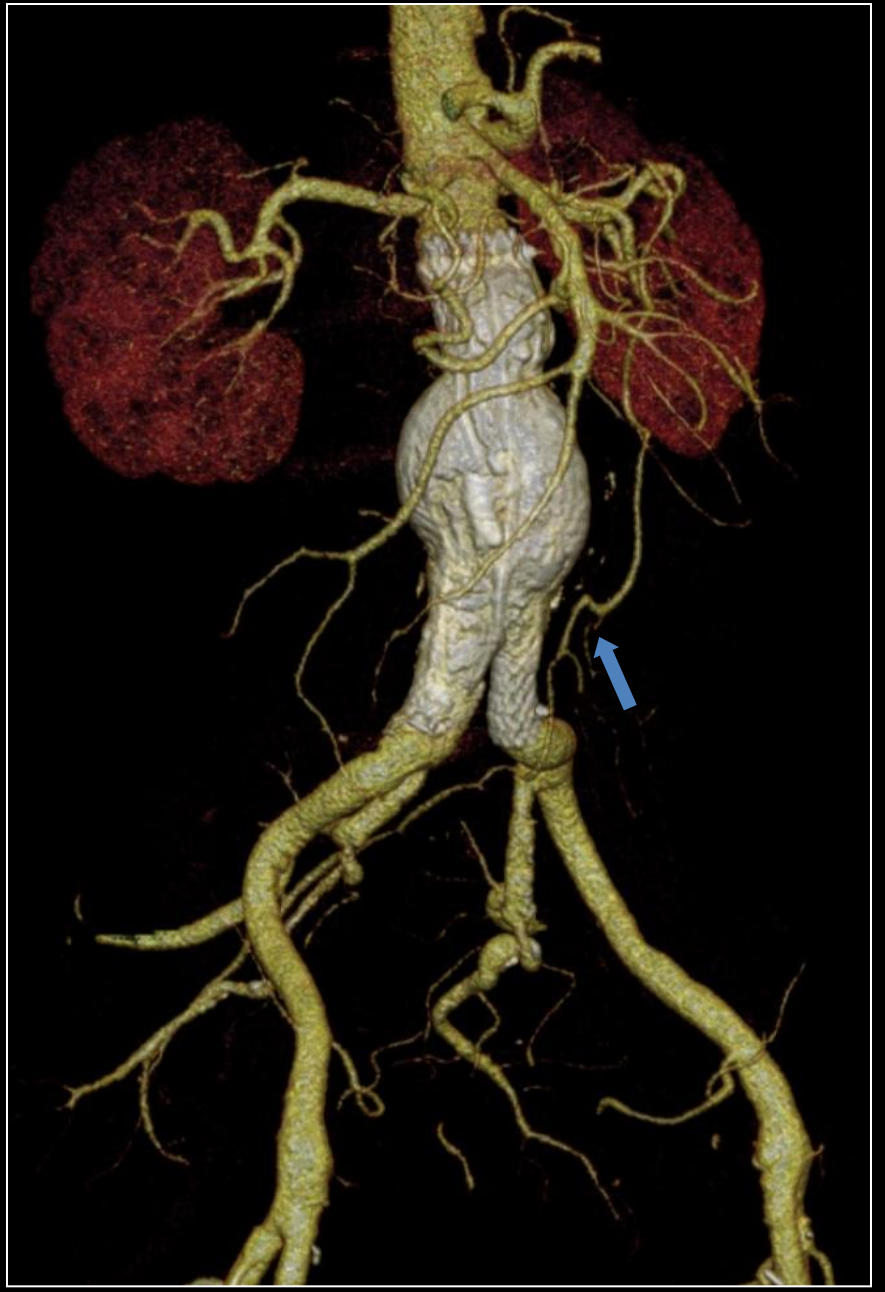
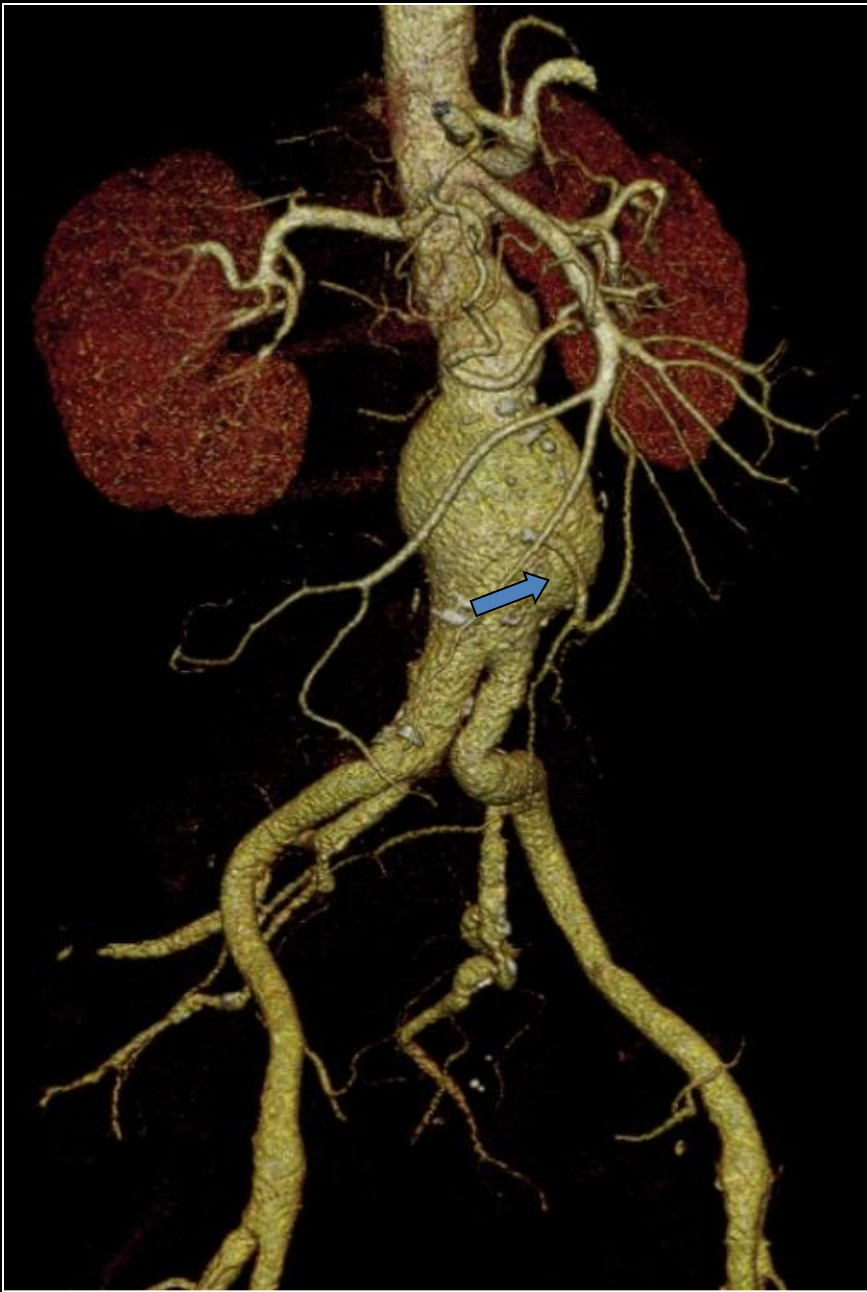


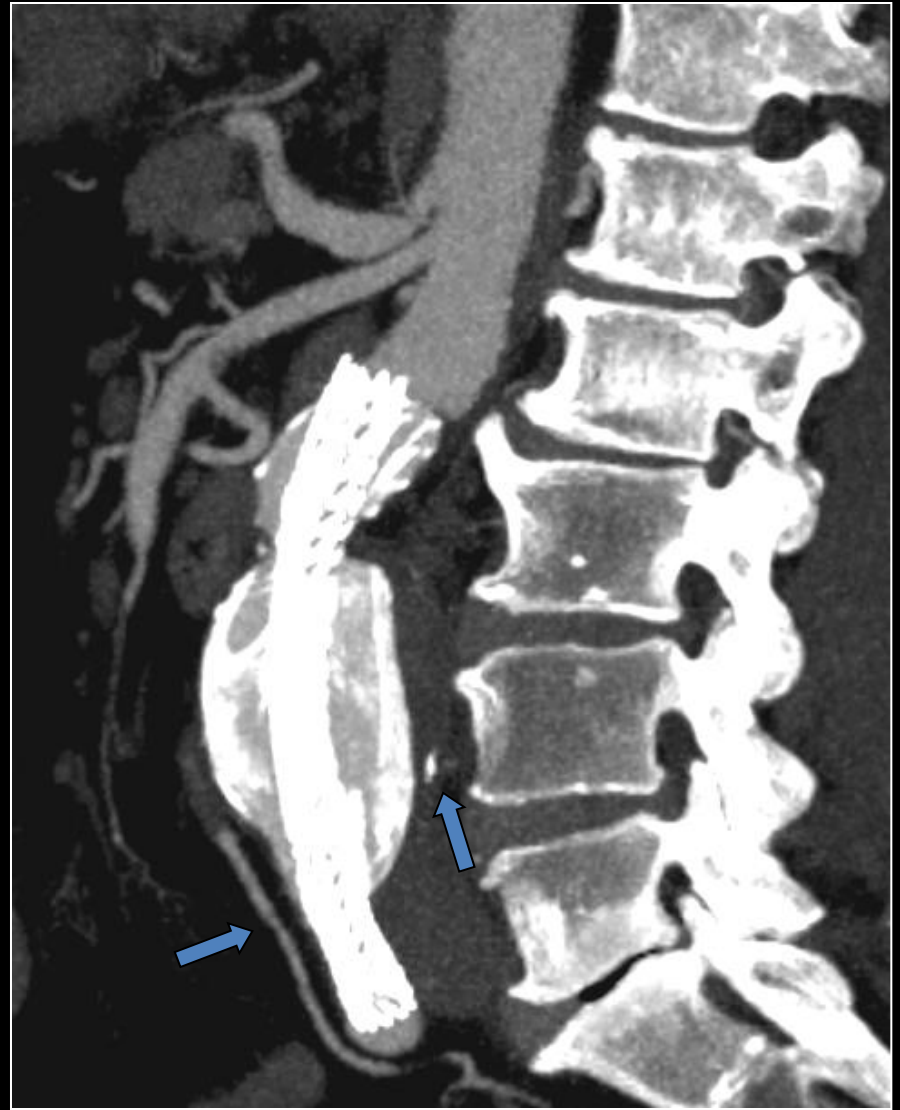
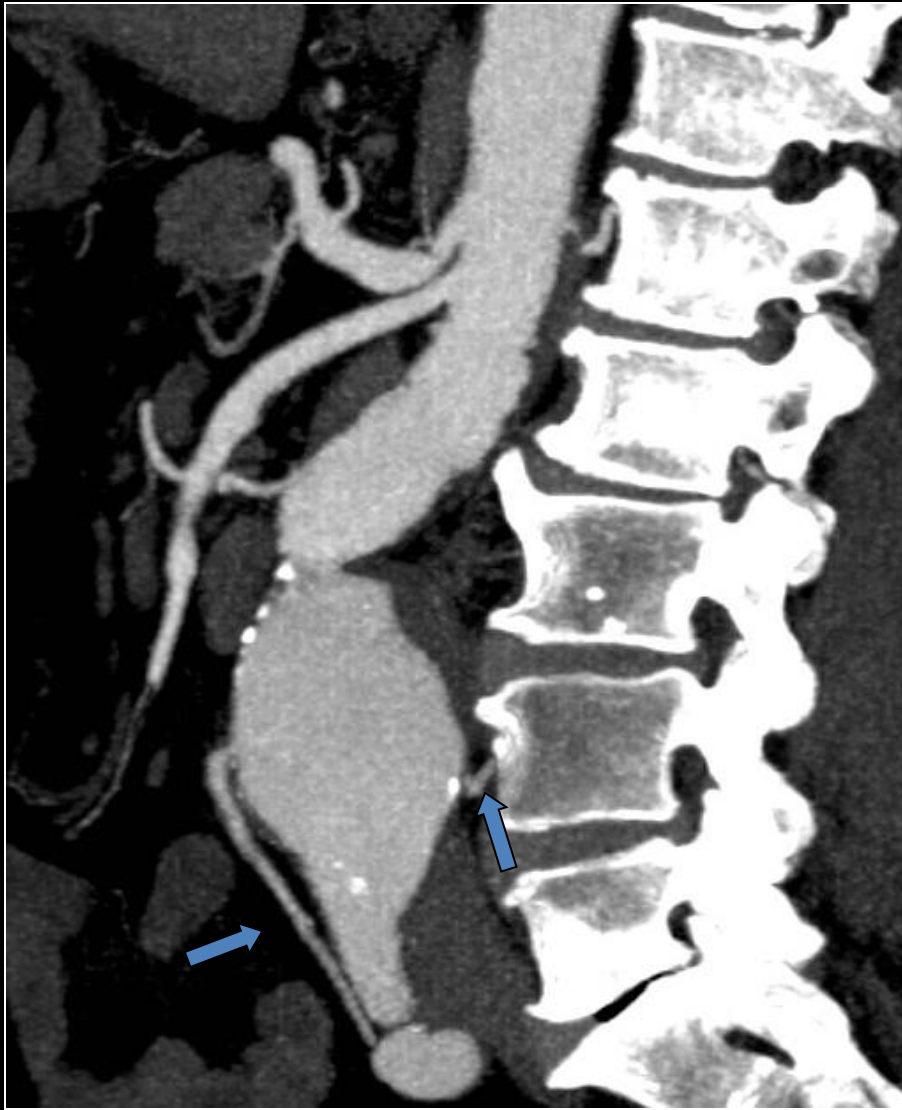












# Nellix: *Pilot Study*

- N=34
- 100% procedural success
- No major adverse events to 30 days



## EVAR Using the Nellix Sac-anchoring Endoprosthesis: Treatment of Favourable and Adverse Anatomy<sup>☆</sup>

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### KEYWORDS

Abdominal aortic aneurysm;  
Endovascular aortic aneurysm repair;  
Novel sac-anchoring endoprosthesis;  
Adverse aortic anatomy;  
Clinical results of EVAR with new endovascular device;  
New device for EVAR

**Abstract** *Objective:* The study aimed to review the results of endovascular aneurysm repair (EVAR) using a novel sac-anchoring endoprosthesis in patients with favourable and adverse anatomy.

*Design:* This is a prospective, multicentre, clinical trial.

*Materials:* The Nellix endoprosthesis consists of dual, balloon-expandable endoframes, surrounded by polymer-filled endobags, which obliterate the aneurysm sac and maintain endograft position.

*Methods:* The study reviewed worldwide clinical experience and Core Lab evaluation of computed tomography (CT) scans.

*Results:* From 2008 to 2010, 34 patients (age  $71 \pm 8$  years, abdominal aortic aneurysm (AAA) diameter  $5.8 \pm 0.8$  cm) were treated at four clinical sites. Seventeen patients (50%) met the inclusion criteria for Food and Drug Administration (FDA)-approved endografts (favourable anatomy); 17 (50%) had one or more adverse anatomic feature: neck length  $<10$  mm (24%), neck angle  $>60^\circ$  (9%) and iliac diameter  $>23$  mm (38%). Device deployment was successful in all patients; iliac aneurysm treatment preserved hypogastric patency. Perioperative mortality was 1/34 (2.9%); one patient died at 10 months of congestive heart failure (CHF); one patient had a secondary procedure at 15 months. During  $15 \pm 6$  months follow-up, there were no differences in outcome between favourable and adverse anatomy patients. Follow-up CT extending up to 2 years revealed no change in aneurysm size or endograft position and no new endoleaks.



# Pilot Study: Results

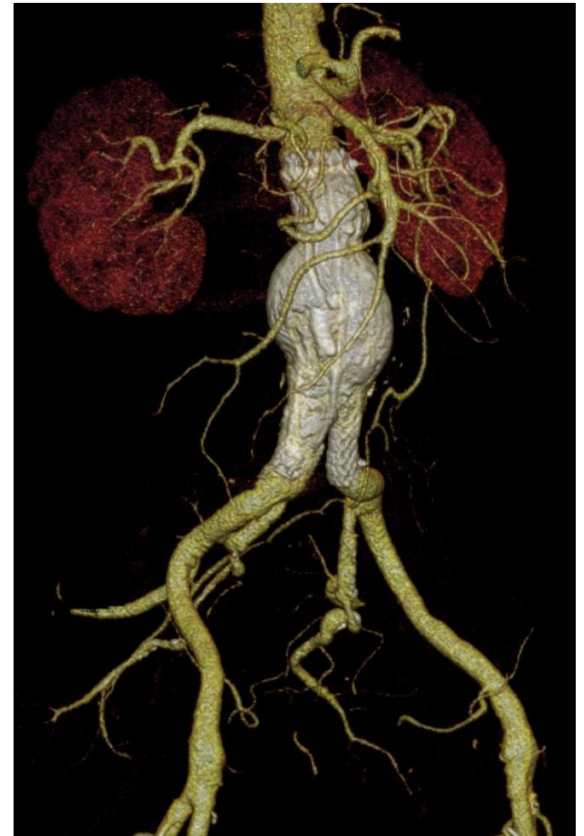
Evaluation	30 Days (N=34)	6 Month (N=33)	1 Yr (N=32)	2 Yrs (N=32)	3 Yrs (N=31)	4yrs (n=?)
Device Migration	0	0	0	0	0	
Endoleak – Type IA	2.9% (1)*	0	0	0	0	
Endoleak – Type IB	2.9% (1) <sup>†</sup>	3.0% (1) <sup>†</sup>	3.1% (1) <sup>†</sup>	0	0	
Endoleak – Type II	0	0	0	0	0	
Endoleak – Type III/IV	0	0	0	0	0	

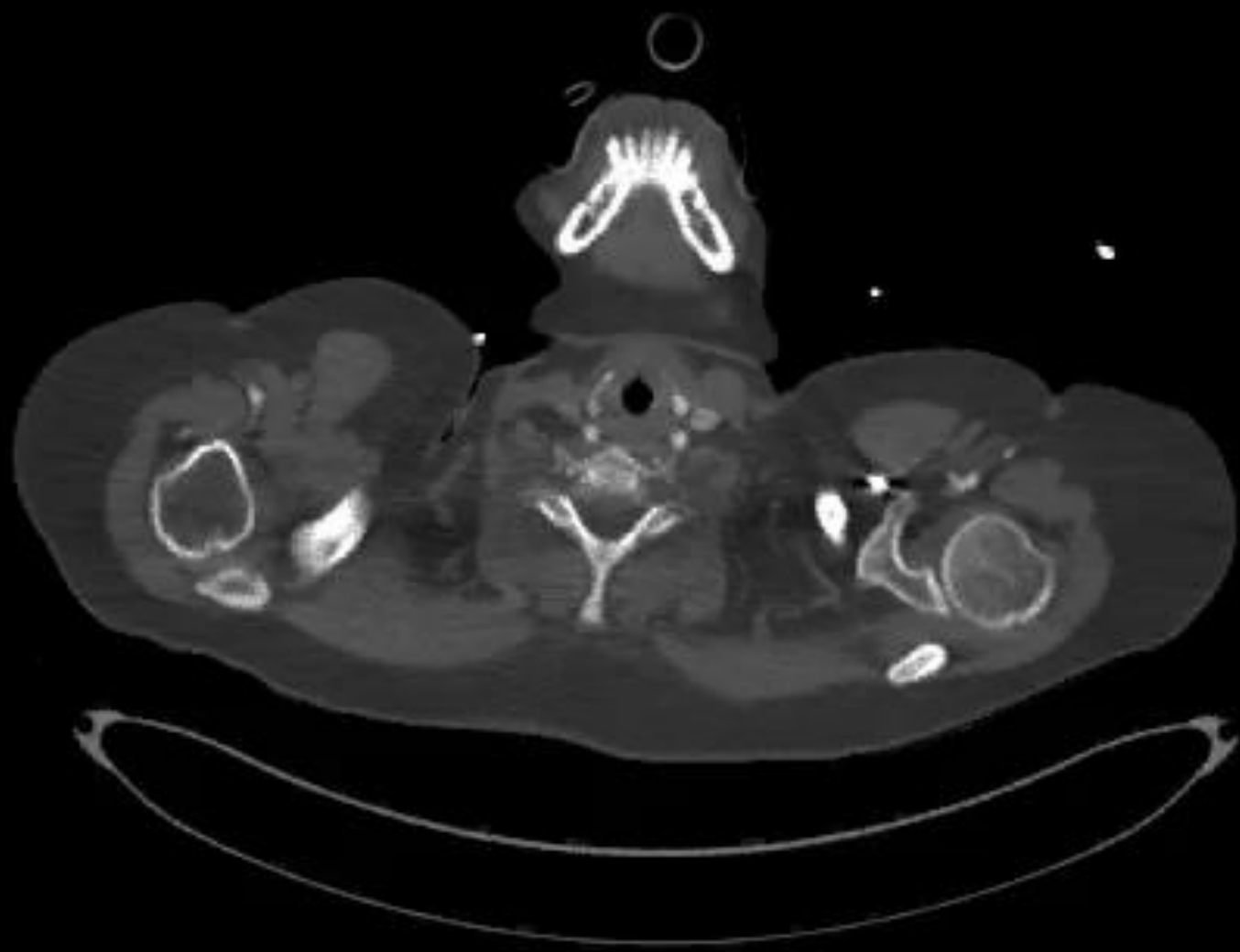
# Clinical Experience Since CE Mark

Observation	Results (number)
<b>Procedural Success</b>	<b>324/324</b>
<b>Intervention for endoleaks</b>	<b>0</b>
<b>Intervention for Rupture</b>	<b>0</b>
<b>Invention for Migration</b>	<b>0</b>
<b>Unilateral in-stent thrombosis†</b>	<b>5</b>
	<b>0 in last 128 pts</b>
<b>Conversion to open repair*</b>	<b>1</b>

# EVAS Global Registry

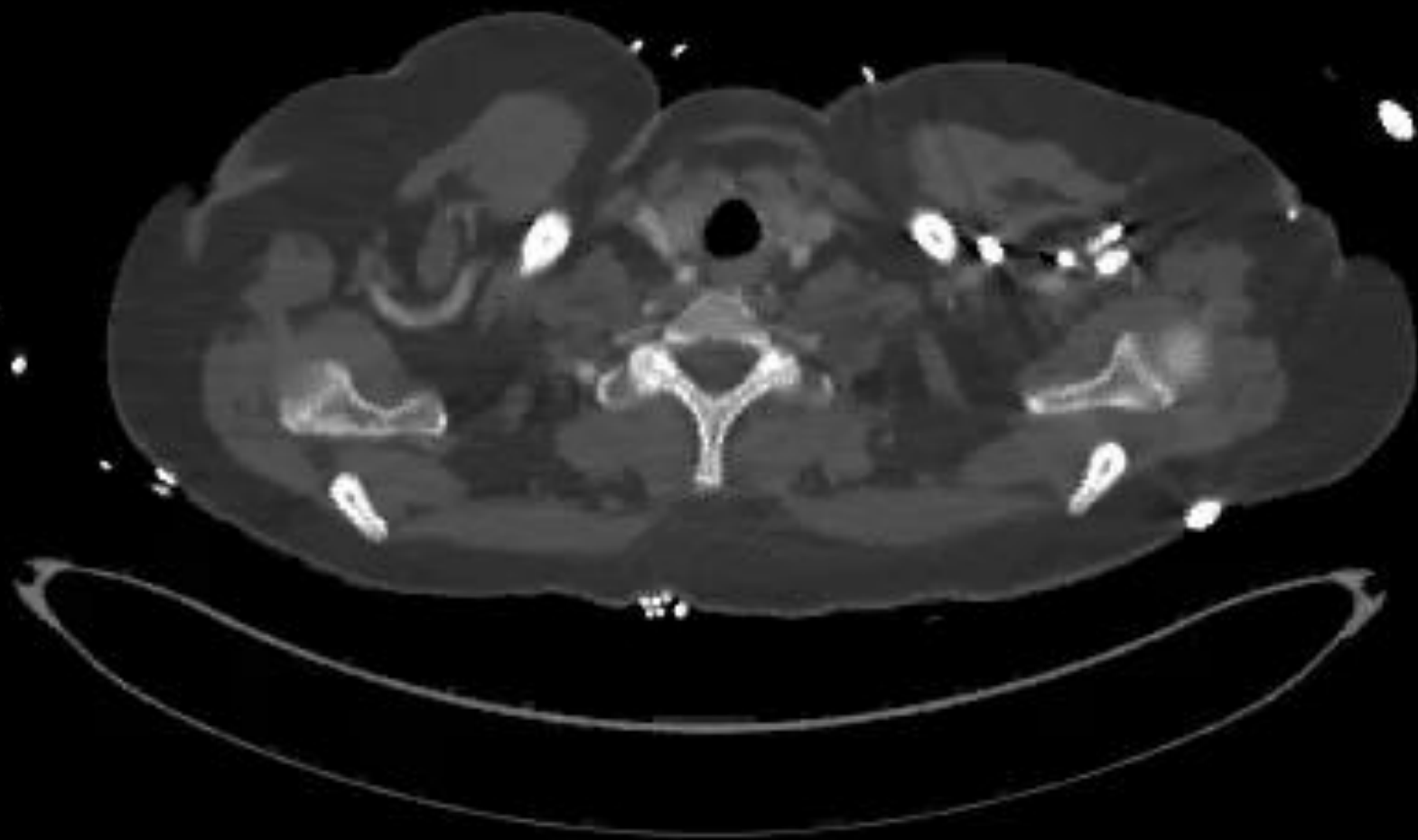
- 5 year prospective registry
- 300 patients
- 30 international sites
- Early and Late Outcomes
  - Re-interventions
  - Aneurysm related mortality



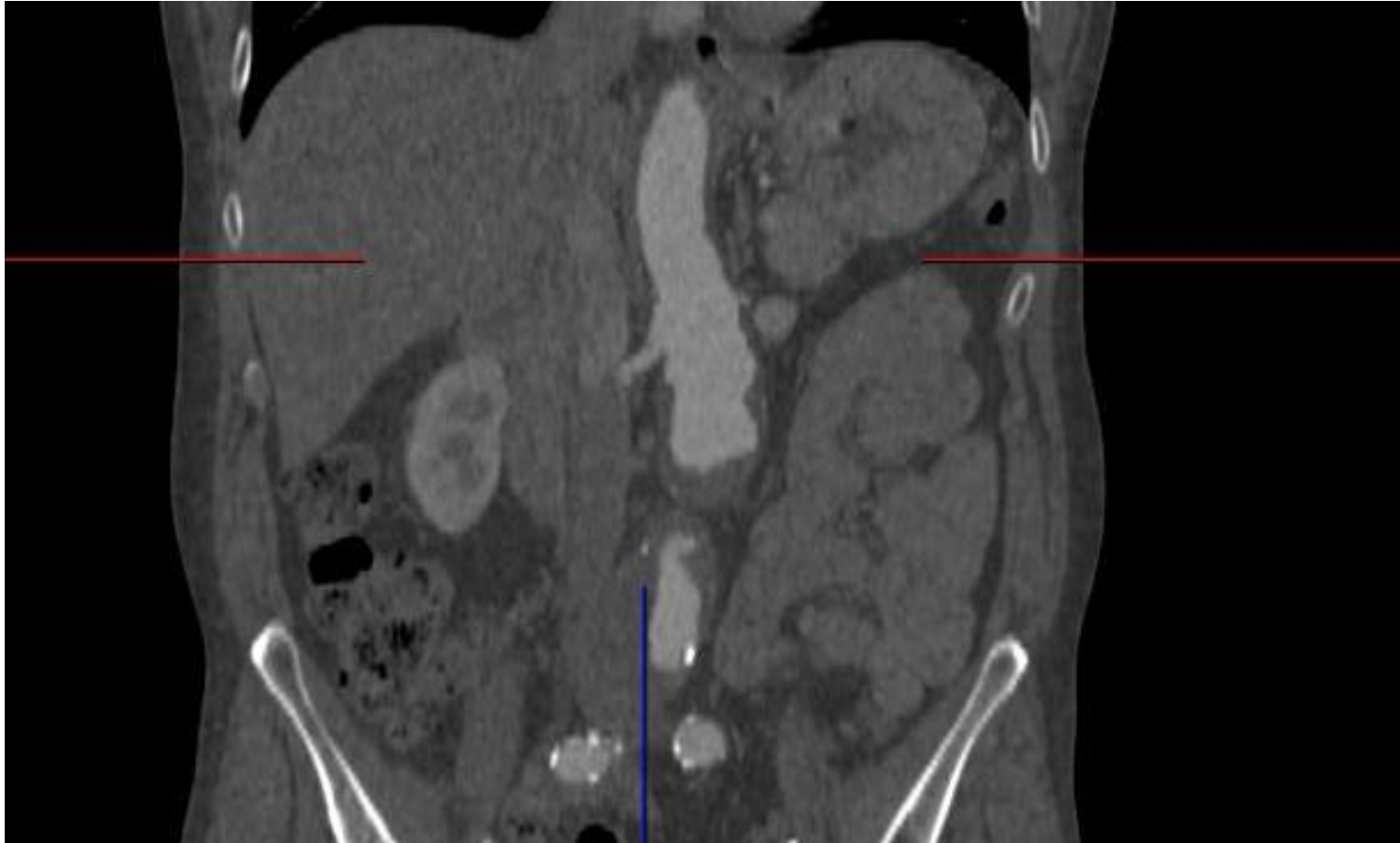




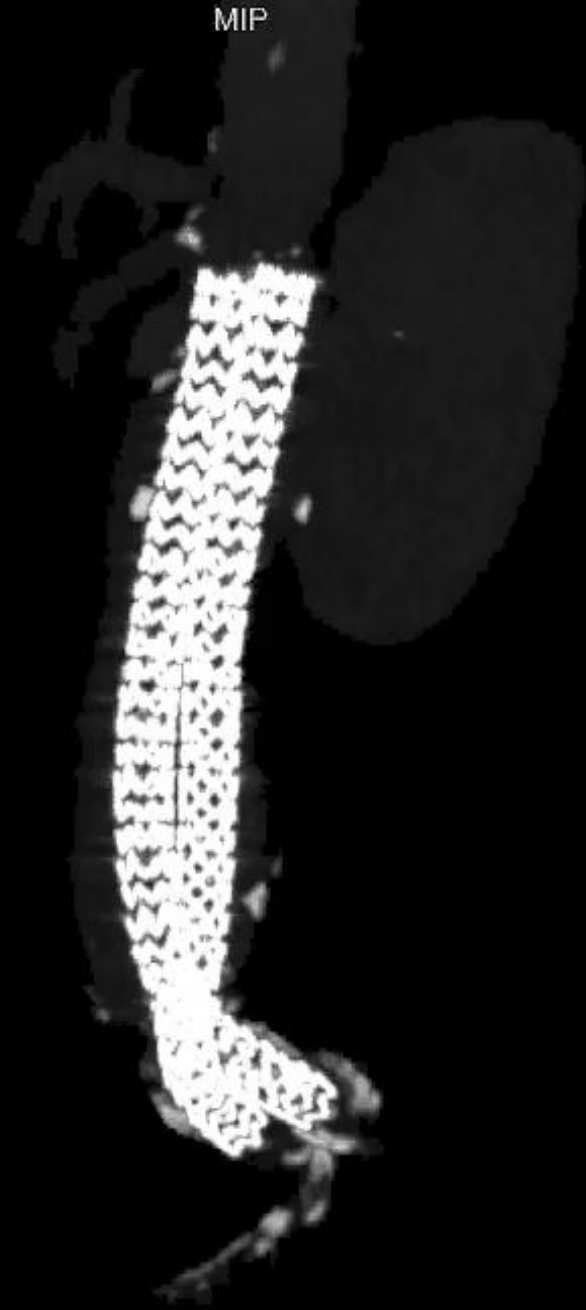




# Chimney Nellix for JRA



MIP



# Conclusion

- Nellix provides an innovative EVAR solution with complete anatomic apposition/seal
- Significant potential to eradicate graft migration and type 2/3 endoleak
- Technical simplicity
- Requires careful long term evaluation (EVAS Registry)

