

# Do Adjuncts Improve Durability of POSE?

Robert Fisher

**LiVES** 

Royal Liverpool University Hospital

#### Disclosures

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- Education Honoraria from GORE, Endologix, Medtronic

#### Irresponsible Mavericks!



Critical Issue 2019

### Predictors of Abdominal aortic aneurysm sac enlargement after endovascular repair.

Schanzer et al. Circulation 2011

- Compliance with anatomic guidelines
- 10228 pts 1999-2008
- 42% met conservative IFU
- 5yr sac enlargement 41%
  - Neck>28mm, CIA>20mm, neck angle >60%

Poor IFU compliance, high rate of sac enlargement Irresponsible insertion of EVAR?

### Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival.

O'Donnell TFX et al. JVS 2019

- 2003-2017 EVAR in 14,817 pts with 1 yr CTA
- 40% sac regression, 35% stable, 25% expanded
- Expansion associated with new endoleak (OR1.23)
- Increased long term mortality with:
  - Sac expansion (HR 1.6)
  - Failure to regress (HR 1.2)

Patel R et al. The UK EndoVascular Aneurysm Repair (EVAR) randomised controlled trials: long-term follow-up and cost-effectiveness analysis. Health Technol Assess 2018;22(5).

- EVAR 1 trial: 15yrs
- >8yrs: EVAR > open
  - 1.25 HR total death
  - 5.8 HR AAA death
- EVAR:open
  - AAA rupture 7:1
  - Increased cancer

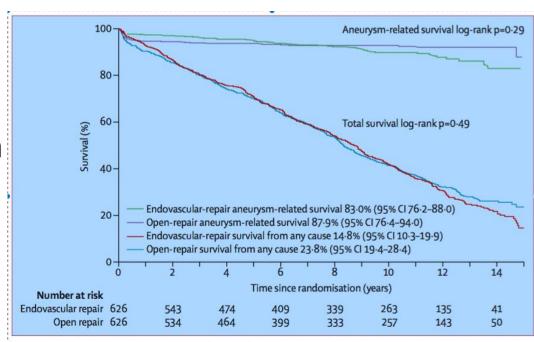


Figure 2: Kaplan-Meier estimates for total survival and aneurysm-related survival up to 15 years of follow-up The hazard ratio is 1.05 (95% CI 0.92-1.19) for total mortality, and is 1.24 (0.84-1.83) for aneurysm-related mortality.

EVAR cost £3798 more

### Abdominal aortic aneurysm: diagnosis and management

NICE guideline

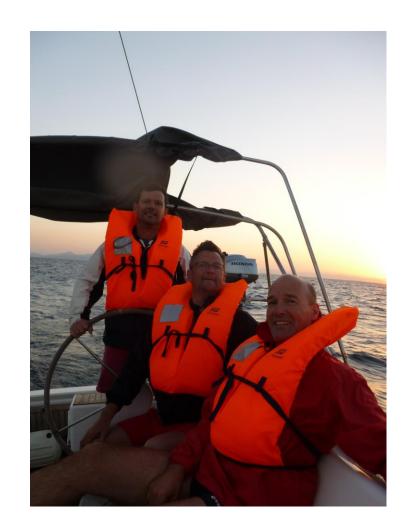
Draft for consultation, May 2018

**Recommendations:** 

If fit: Open surgical repair NOT EVAR

If unfit: conservative NOT EVAR

EVAR not cost effective

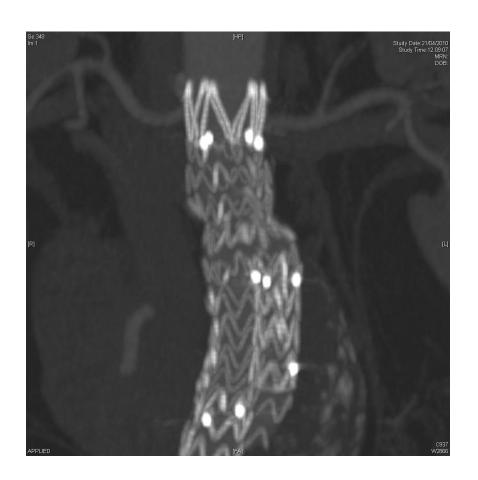


#### Take Home Message?

- EVAR not durable
- EVAR expensive

#### How to improve:

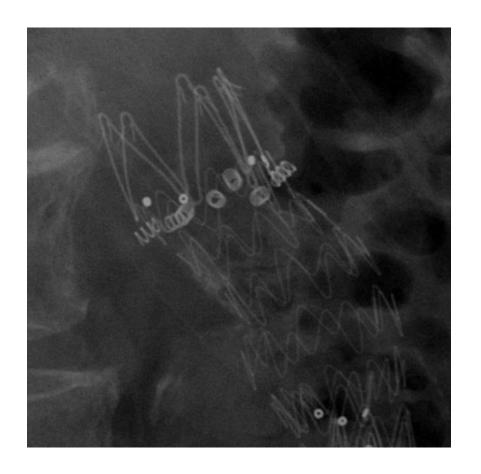
- Get it right first time
- Case selection
- Device selection
- Device delivery
- Effective AAA exclusion
  - Sac regression



#### Do Adjuncts Improve POSE Durability?

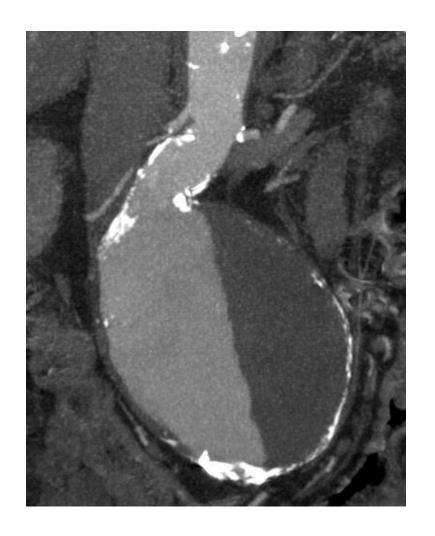
- Primary adjuncts
  - Planned
  - Unplanned

- Indications
- Evidence
- Cost



#### **Aortic Neck**

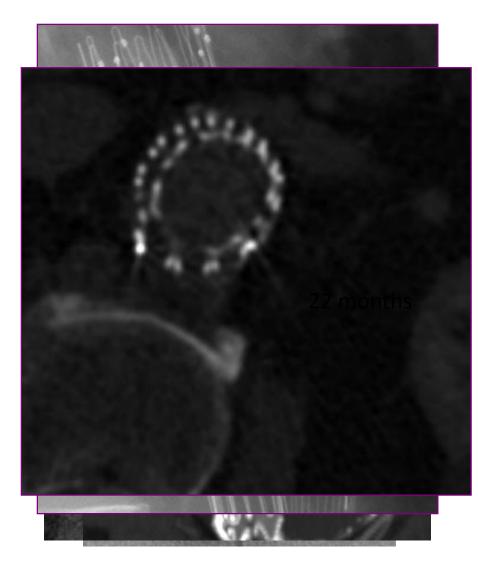
- Compromised seal zone with risk of type Ia endoleak
  - Balloon
  - Giant Palmaz
  - Endoanchors
  - Cuff (+/- chimney or endoanchor)



#### **Aortic Neck Adjuncts**

- Re-ballooning
  - Can eradicate Type Ia
  - Can rupture aorta!

- Giant Palmaz
  - If adequate neck/seal
  - Risk of rupture, emboli, renal compromise
  - Long term neck dilatation



Long-term outcomes of Palmaz stent placement for intraoperative type Ia endoleak during endovascular aneurysm repair. Arthurs ZM et al. Ann Vasc Surg 2011.

- 31 pts between 2000-05; median 53 mths FU
- No type Ia endoleak
- 26% had neck shortening/ 35% loss of seal zone due to aortic degradation
- No stent migration
- 15mm infrarenal: 63% neck diameter >10%
- 55% sac regression; 45% increase

## The Long-term Durability of Intra-operatively Placed Palmaz Stents for the Treatment of Type Ia Endoleaks After EVAR of Abdominal Aortic Aneurysm.

Abdulrasak M et al. EJVES 2017.

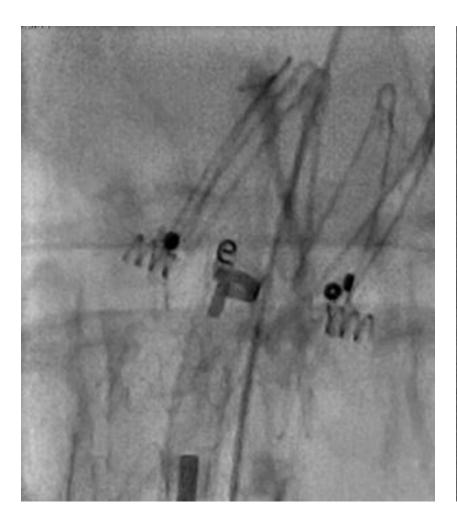
- Malmo 1998-2012; 125 pts (83 elective, 22 rupture, 20 symp)
- 9 died (2 elective, 7 acute)
- Mean 43month FU; 51 re-interventions (7 for Type Ia)
- Io freedom from endoleak at 5 yrs: 89%
  - Elective >acute
- 9mm infra-renal aortic diameter increased 33% over follow up

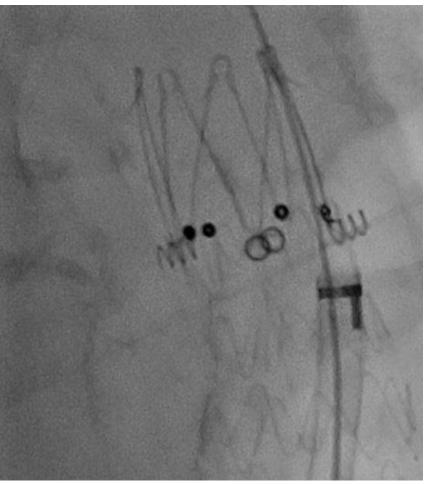
Palmaz effective eradicating Type Ia endoleaks but continued aortic degradation may influence durability.

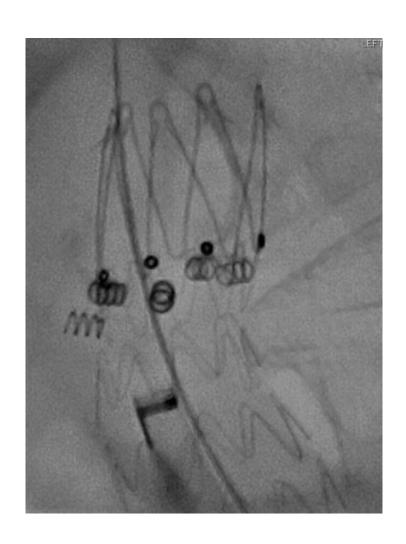
NOT a permit to go off IFU!

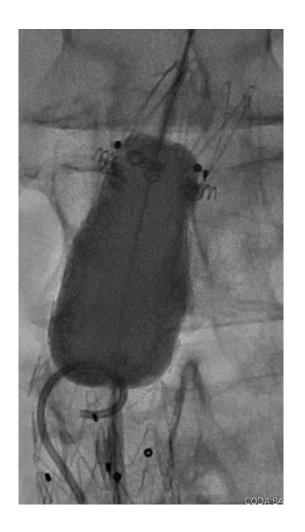


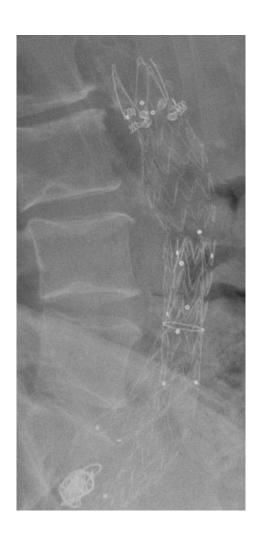








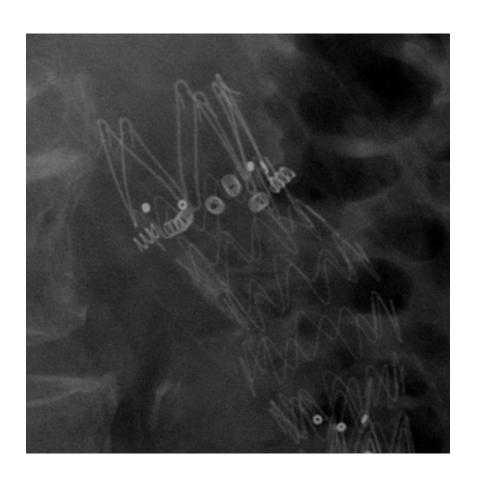






Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy. Jordan WD et al. J Vasc Surg 2014

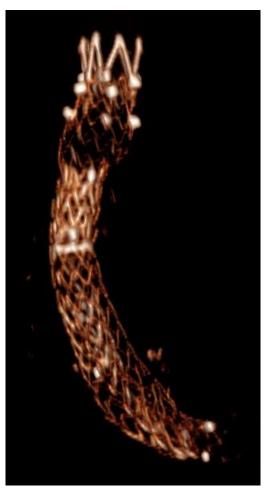
- Multicentre 319 pts
  - 242 primary/77 revision
- Technical success
- Procedural success
- Mean neck length 16mm
  - 43% <10mm/ 43 % conical
- 5.8 endoanchors
- 95% technical success
- Procedural success
  - 90% primary
  - 81% revision



Influence of aortic neck characteristics on successful aortic wall penetration of EndoAnchors in therapeutic use during endovascular aneurysm repair. Goudeketting SR et al. J Vasc Surg 2018.

- 86 ANCHOR pts
  - 61 primary/ 25 revision
- 62% without Type Ia
  - More endoanchors with good penetration (4vs3)
- Multivariate analysis
  - Good penetration with Endurant graft
- Poor penetration in large, short and calcified necks

Selection and deployment paramount

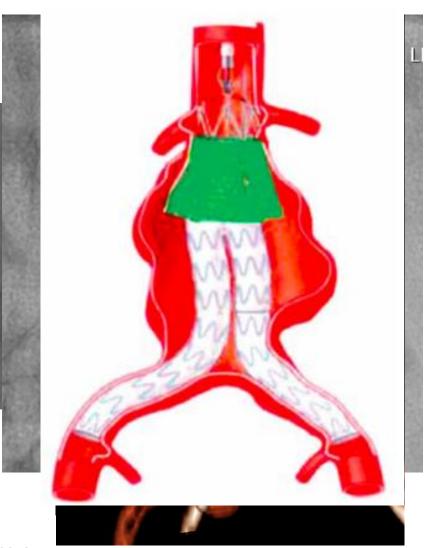


#### **Aortic Neck Adjuncts**

Aortic Cuffs

Cuff + APTUS

• The endowedge and kilt techniques to achieve additional juxtarenal seal during deployment of the Gore Excluder endoprosthesis. Minion DJ et al. Ann Vasc Surg 2006.



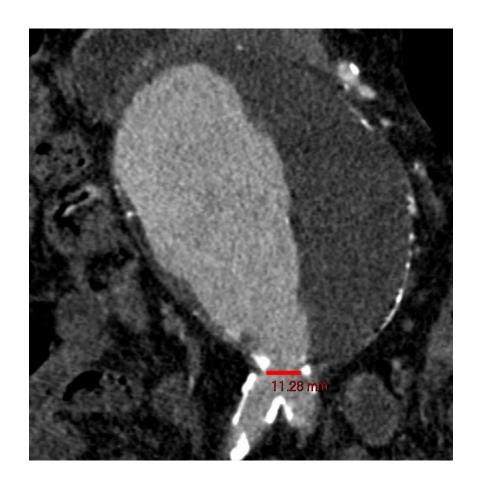
## Short-term outcomes of the C3 excluder for patients with abdominal aortic aneurysms and unfavorable proximal aortic seal zones. Smeds MR et al. Ann Vasc Surg 2013

- 77 pts with C3 or regular Excluder
- 44 pts (57%) unfavourable neck morphology
- 16/44 (36%) needed cuff
- 13% in C3 group vs 65% in Excluder
- 2month FU- no type Ia endoleaks

Repositional grafts may reduce need for cuffs

#### Aneurysm morphology

- Stent stenosis/compression
  - Distal neck
    - Bilateral angioplasty
    - Stent relining
  - Iliac origin morphology
    - Angioplasty
    - Stent relining
  - External Iliac extension
    - Stent relining



#### **Adjunctive Iliac stents**

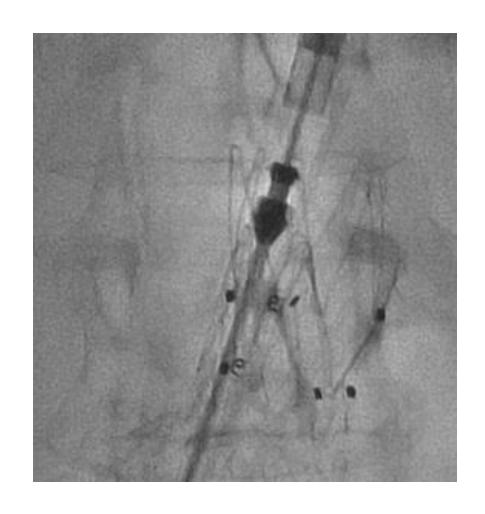
- Adjunctive iliac stents reduce the risk of stent-graft limb occlusion following endovascular aneurysm repair with the Zenith stent-graft. Oshin et al. JEVT 2010
- Self expandable stent application to prevent limb occlusion in external iliac artery during endovascular aneurysm repair. Lee JH et al. Ann Surg Treat Res 2016.
- Adjunctive stents (Wall stent/SMART stent) reduce incidence of external iliac limb occlusions



### Cost impact of extension cuff utilization during endovascular aneurysm repair. Chandra V et al. Ann Vasc Surg 2012.

- 218 elective EVAR
- No extensions (98)
- Prox/distal extension (120)
- Similar morphology
- Similar outcomes
- Median 1 (1-4) pieces
- 30% uplift in costs

?per-case costing



# Irresponsible Mavericks Getting what they Deserve?

- Poor case selection fuelled by
  - Fnthusiasm?
  - Adjuncts?
- Poor durability and cost effectiveness of current EVAR practice
- NICE retribution?
- Appropriate case selection
  - Supported by adjuncts to improve durability

NOT adjuncts to extend indications for EVAR

