Why Should You Not limit your Expertise To A Single Stent Graft

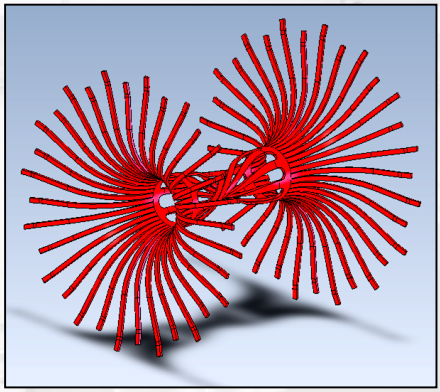
Pourquoi je n'utilise pas qu'un seul modèle d'endoprothèse ?

Claude MIALHE
Cardio Thoracic Centre - MONACO

CONFLICT OF INTEREST

Vascular mind

- IP owner:
  - HQS
  - Xcath
  - USD
  - Twister
  - Dilatulip



- Vasular Mind owner:

incubator of innovative technologies

No support from industry

Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators*

Summary

Background Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

Methods We used data from the EVAR randomised controlled trial (EVAR trial 1), which enrolled 1252 patients 37 centres in the UK between Sept 1, 1999, and Aug 31, 2004. Patients had to be aged 60 years or older, have aneury of at least 5·5 cm in diameter, and deemed suitable and fit for either EVAR or open repair. Eligible patients randomly assigned (1:1) using computer-generated sequences of randomly permuted blocks stratified by cent receive either EVAR (n=626) or open repair (n=626). Patients and treating clinicians were aware of group assignm no masking was used. The primary analysis compared total and aneurysm-related deaths in groups until mid-2015 in the intention-to-treat population. This trial is registered at ISRCTN (ISRCTN15703451).

Findings We recruited 1252 patients between Sept 1, 1999, and Aug 31, 2004. 25 patients (four for mortality outcome) were lost to follow-up by June 30, 2015. Over a mean of 12·7 years (SD 1·5; maximum 15·8 years) of follow-up, we recorded 9·3 deaths per 100 person-years in the EVAR group and 8·9 deaths per 100 person-years in the open-repair group (adjusted hazard ratio [HR] 1·11, 95% CI 0·87–1·27, p=0·14). At 0–6 months after randomisation, patients in the EVAR group had a lower mortality (adjusted HR 0·61, 95% CI 0·37–1·02 for total mortality; and 0·47, 0·23–0·93 for aneurysm-related mortality, p=0·034), but beyond 8 years of follow-up open-repair had a significantly lower

The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture

Interpretation EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and re-intervention if necessary.

Funding UK National Institute for Health Research, Camelia Botnar Arterial Research Foundation.

Group, Imperial College London, London, UK (R Patel PhD, Prof J T Powell MD, Prof R M Greenhalgh MD); and Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK (M J Sweeting PhD)

Correspondence to:

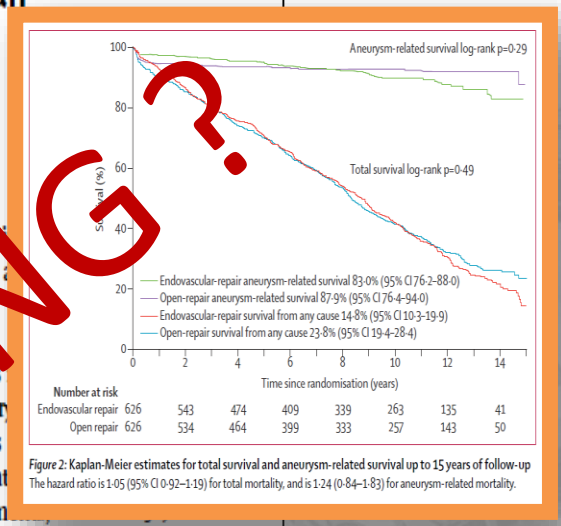


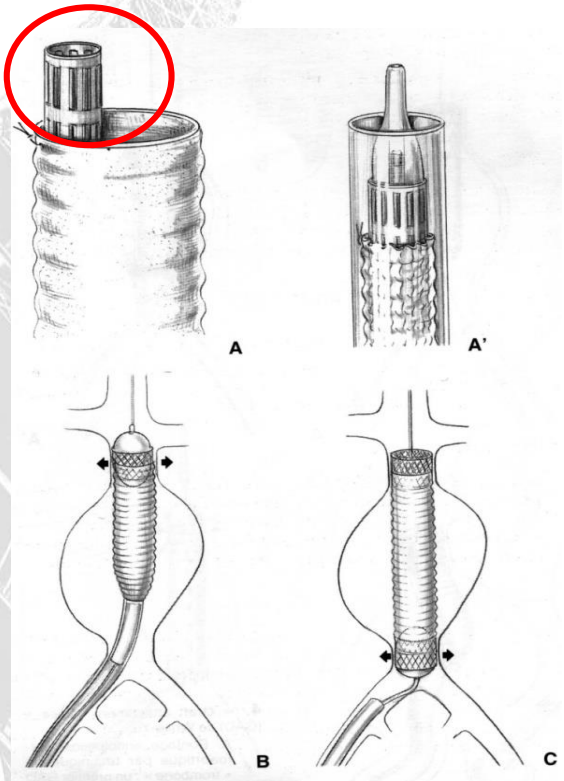
Figure 2: Kaplan-Meier estimates for total survival and aneurysm-related survival up to 15 years of follow-up
The hazard ratio is 1·05 (95% CI 0·92–1·19) for total mortality, and is 1·24 (0·84–1·83) for aneurysm-related mortality.

WHAT'S WRONG ?:

http://dx.doi.org/10.1016/S0140-6736(16)31135-7

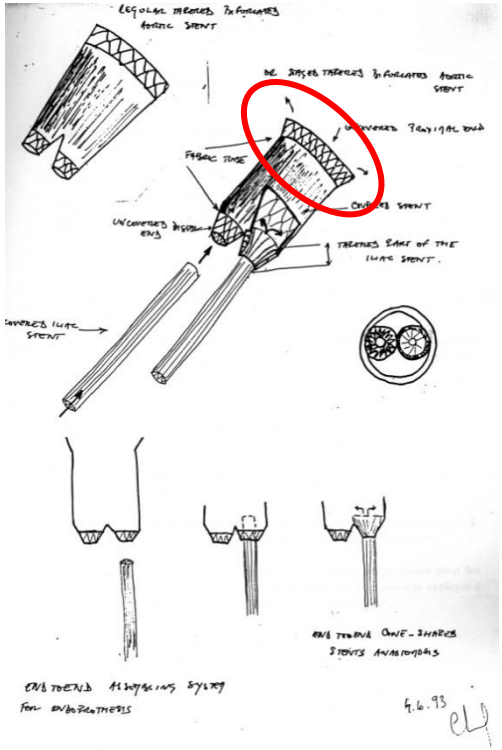
EAG FEASABILITY

« STENT GRAFT »
Juan PARODI 1989

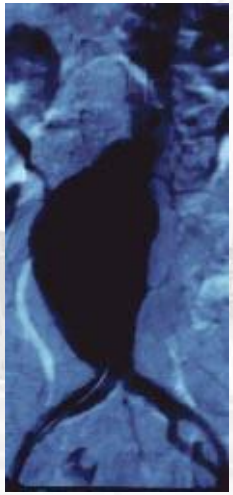


Ann Vasc Surg. 1991; 491-499

MODULAR BIFURCATED EAG
Claude MIALHE 1993



US Patent, 609,627

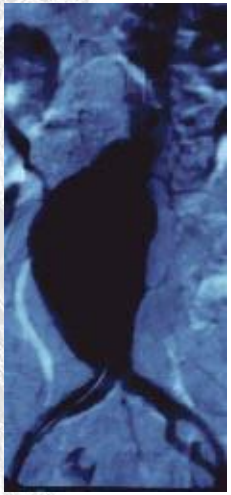


J Vasc Surg 1997; 26:199-209

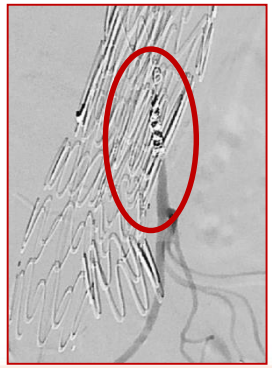
MODULARITY
SUPRARENAL FIXATION

POST EAG PRIMARY FAILURE

- Aneurismal sack exclusion related -



C. Mialhe, C. Amicabile, JP Becquemin
J Vasc Surg 1997; 26:199-209

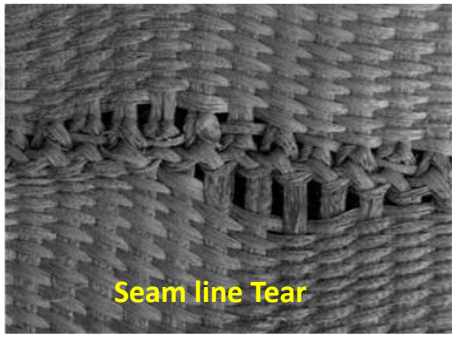


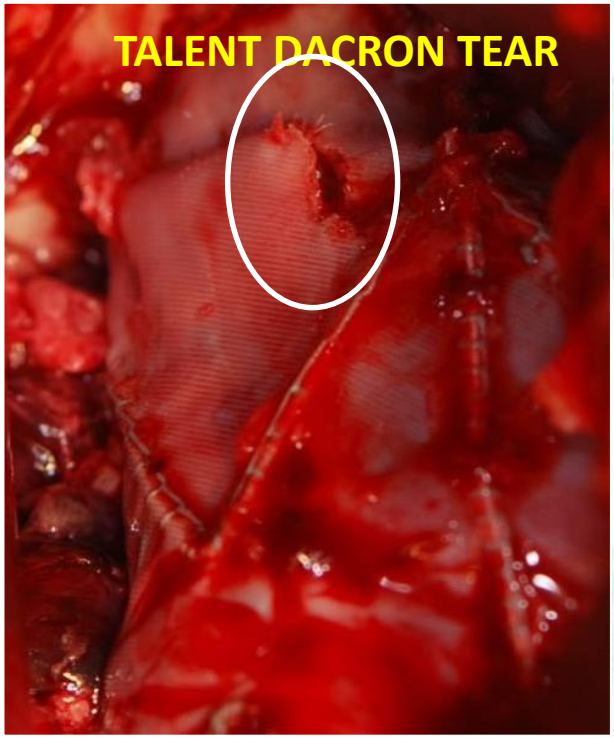
POST EAG PRIMARY FAILURE

- Device structure related -

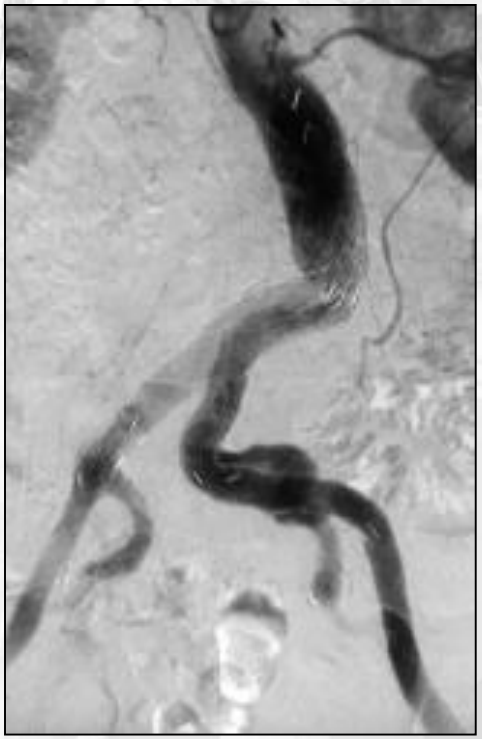
First-Generation Aortic Endografts: Analysis of Explanted Stentor Devices From the EUROSTAR Registry
Robert Guidoin et al.
Endovasc Ther 2000;7:105–122

FATIGUE LESIONS



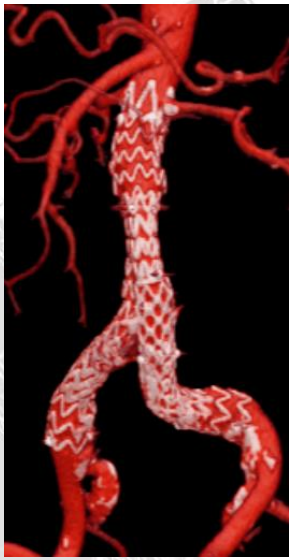


SHRINKAGE EFFECT



SACK EXCLUSION

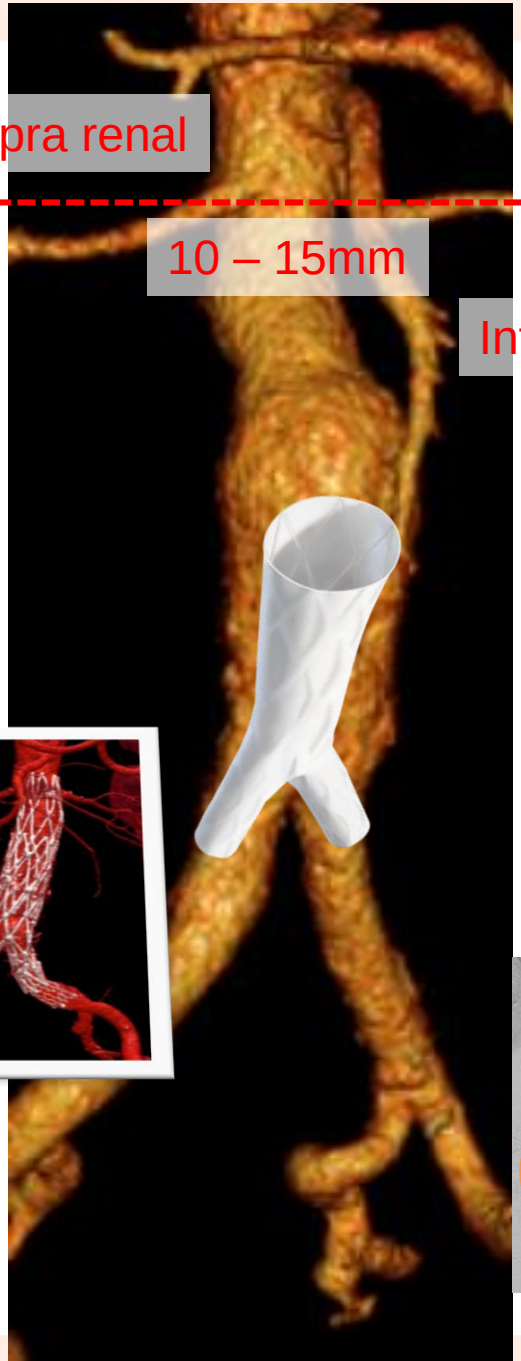
NECK FIXATION

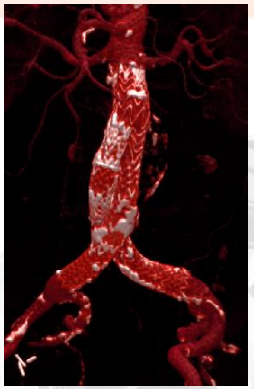


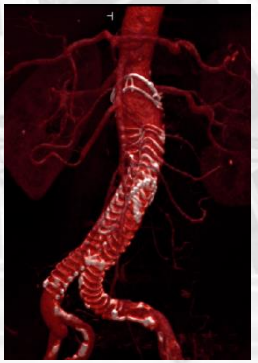
Supra renal

10 – 15mm

Infra renal

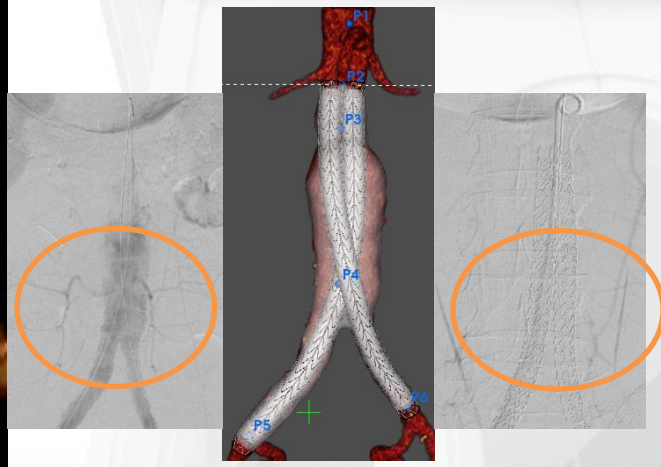






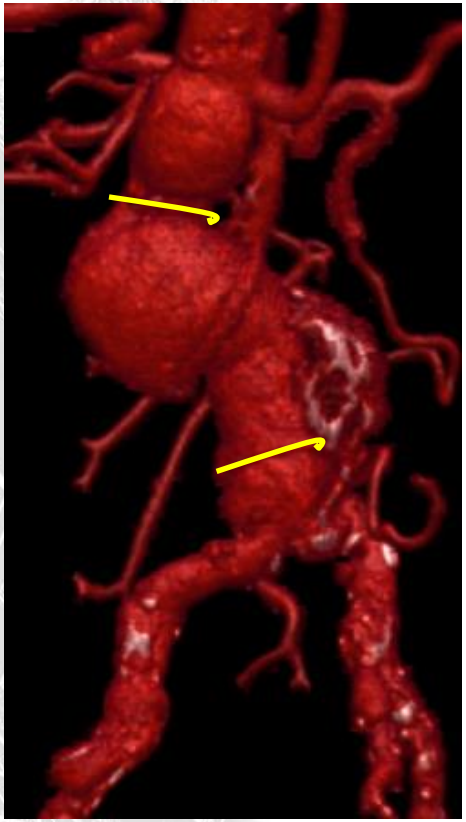
BIFURCATION SUPPORT

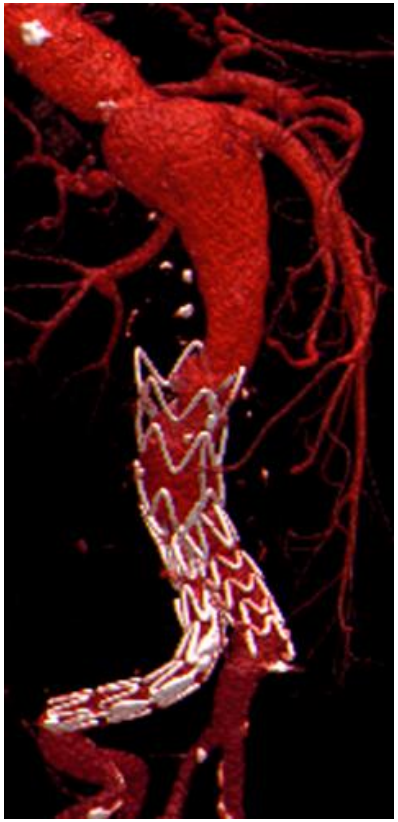
SACK SEALING

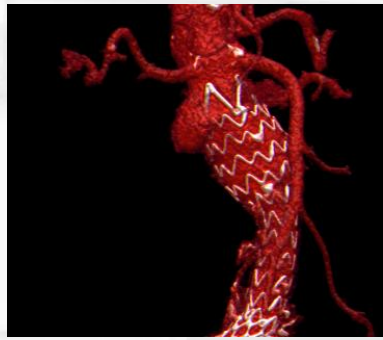


POST EAG SECONDARY FAILURE

- Disease related -



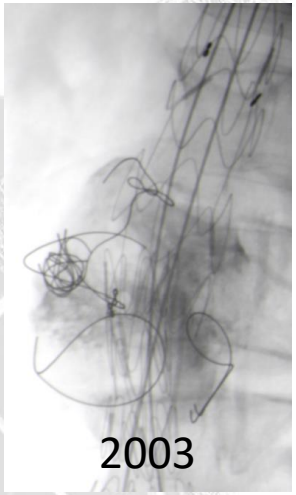


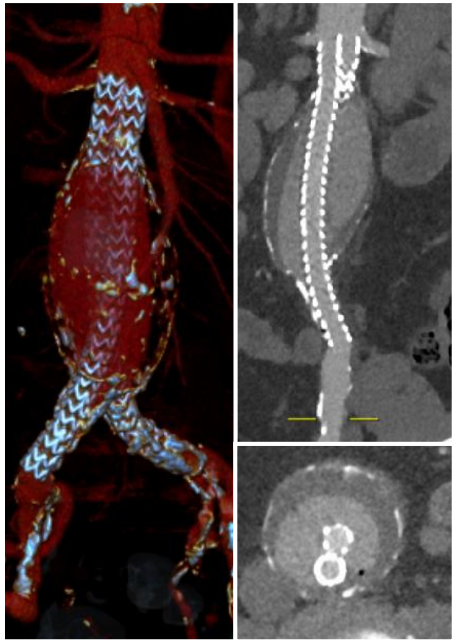


OVER GRAFT ANEURISMAL EXTENSION = NATURAL HISTORY OF DEGENERATIVE DISEASE

SECONDARY FAILURE MODE

TYPE 2 ENDOLEAK

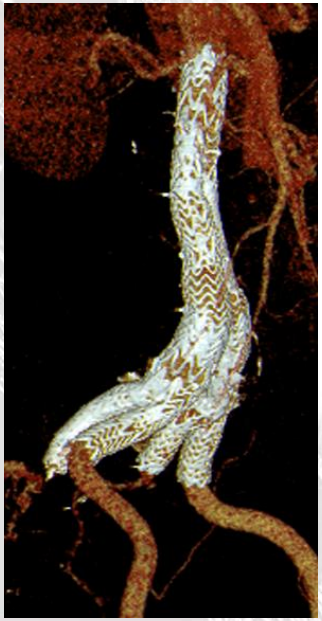




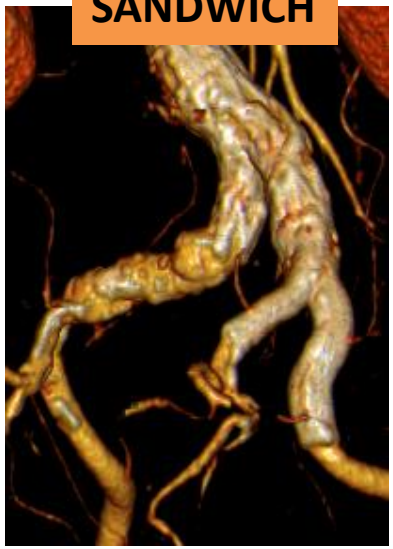
ANEURISMAL DISEASE EXTENSION

ILIAC EXTENSION

IBE



SANDWICH



PERISCOPE

CHIMNEY COELIAC EXTENSION

NONE BARE STENT CUFF

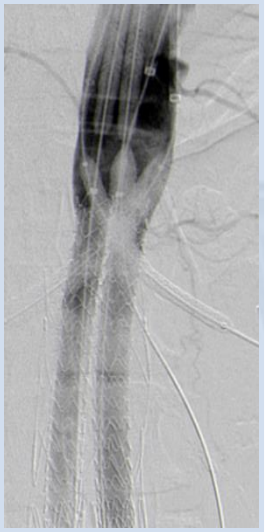
Long aortic segment > 50 mm

EVAS

Short aortic segment < 50 mm

Difficult Access

BE // stents



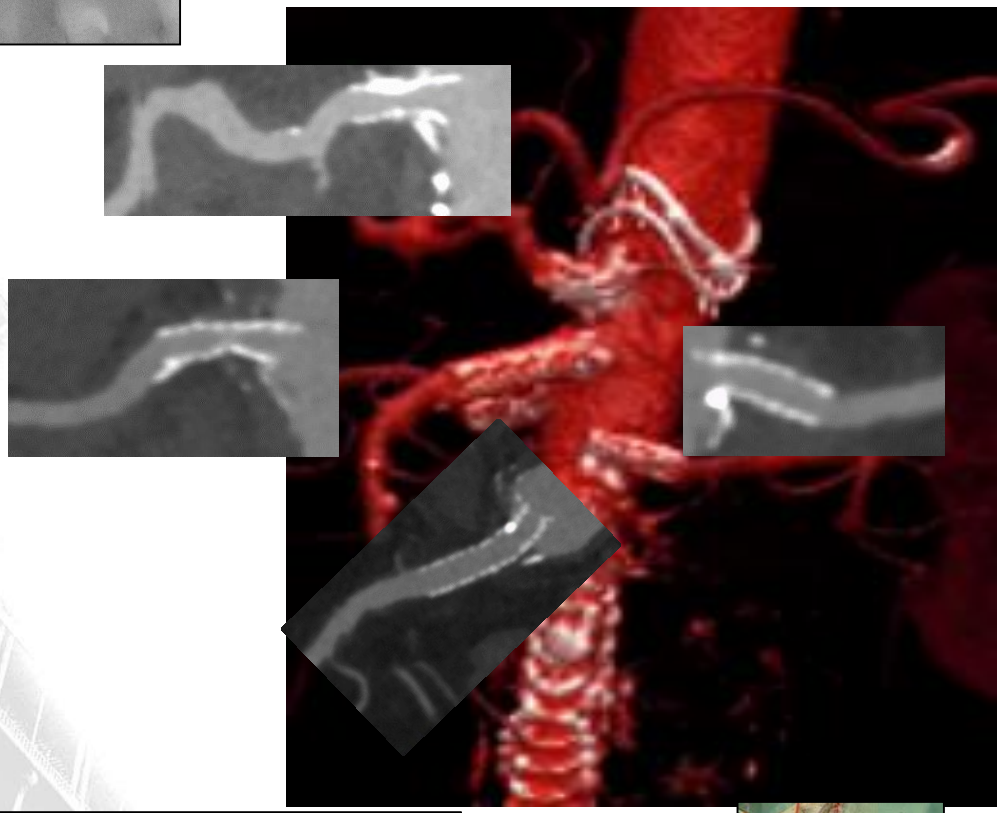
BE // stents

- **Advantages:**
  - Versatile option
  - Delayed large femoral access
  - Single door catheterization
  - Available on shelves
- **Limits:**
  - Potential mechanical Conflict / EAG
  - Stroke risk

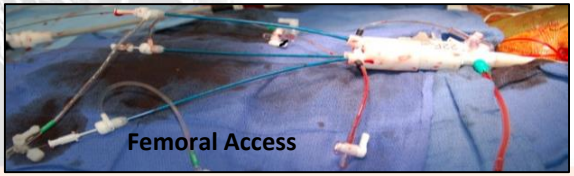
FEVAR COELIAC EXTENSION

ADVANTAGES:
*anatomical option
*neutral mechanical connection

CHALLENGE:
*traffic jump
*multiple doors catheterisation

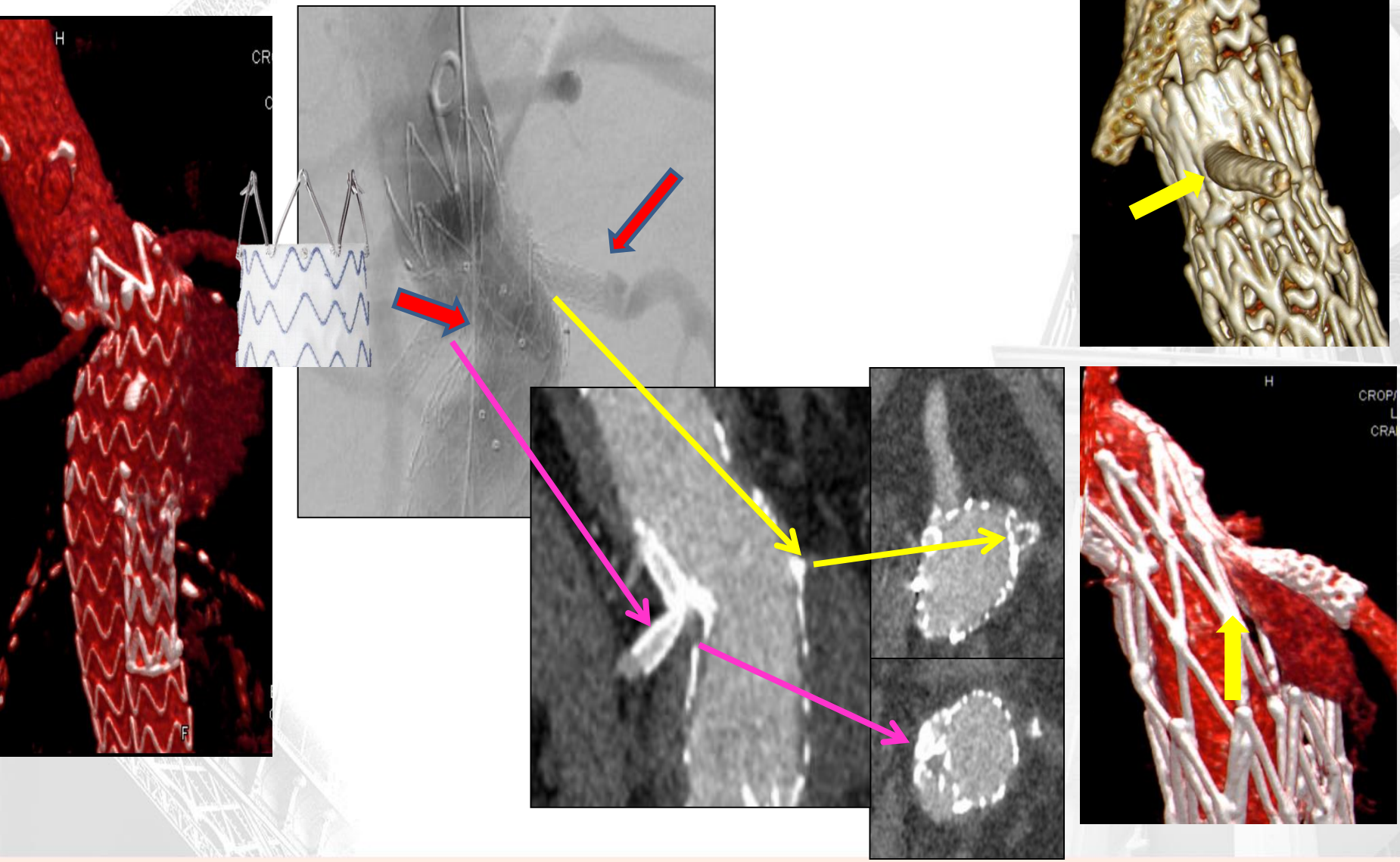


LIMITS:
*customized device
*clamping time



COELIAC EXTENSION LIMITATIONS

OVER BARE STENT COELIAC EXTENSION

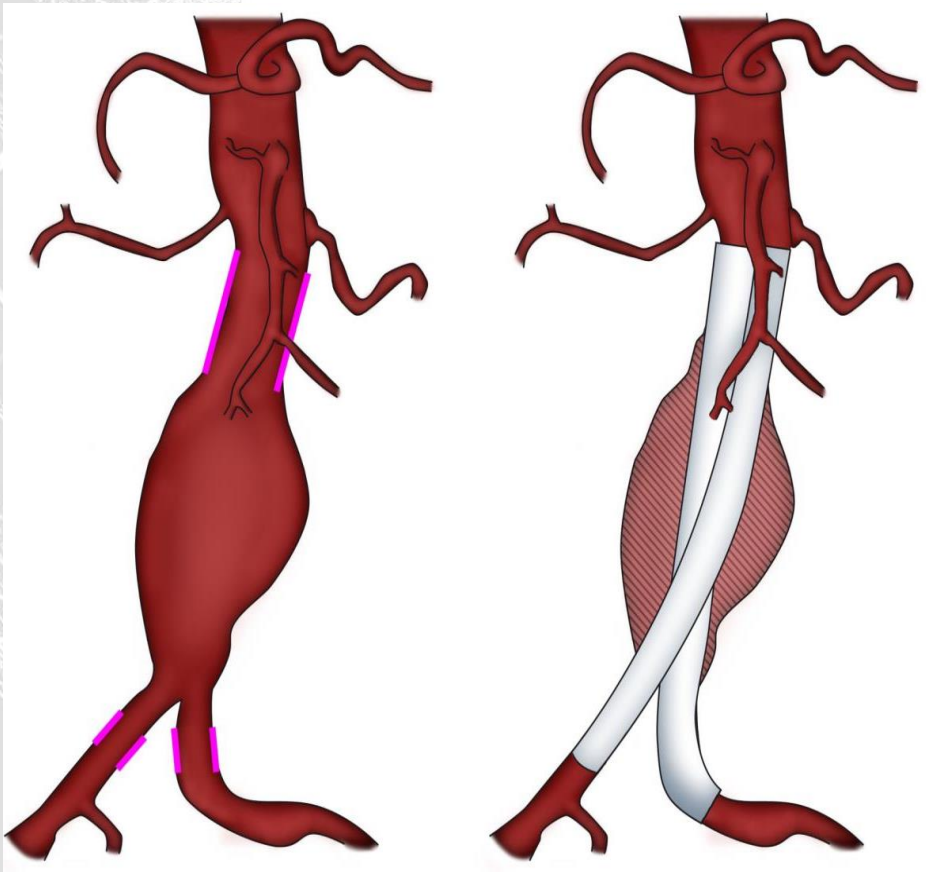


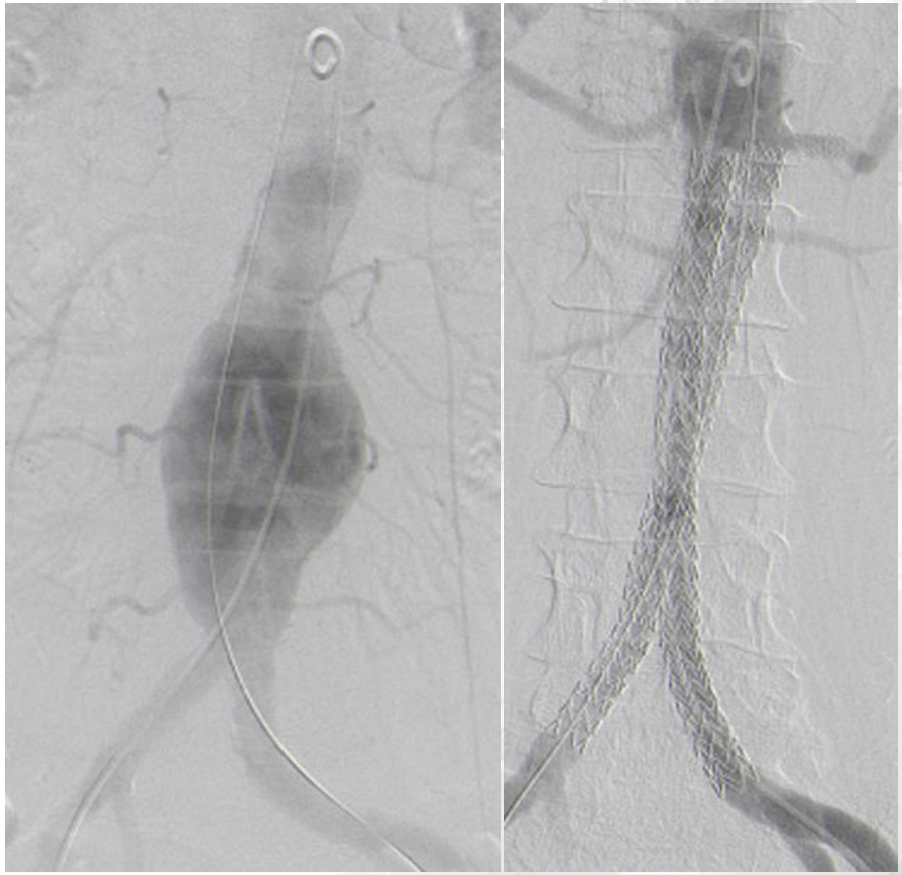
AAA EVOLUTION RELATED CLASSIFICATION

ERC 1

DISEASE FREE INFRA RENAL NECK

Potential type 2
SACK STABILISATION





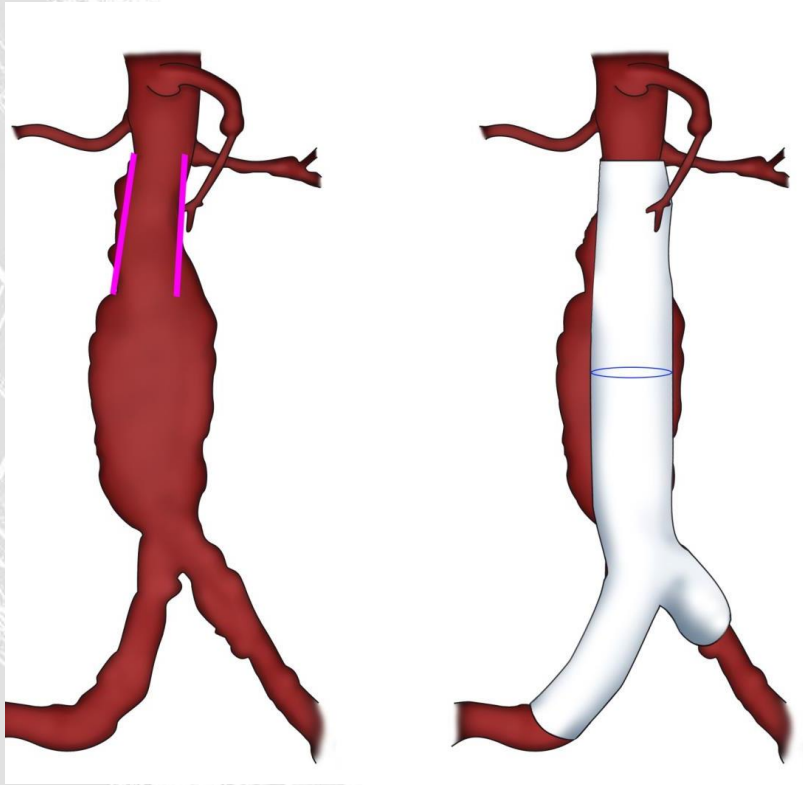
EVAS / ERC 1: 50 cases (4 years)– mean F.U.: 14+/- 13mths –Type1=0, Type2=0

AAA EVOLUTION RELATED CLASSIFICATION

ERC 2

DISEASED CYLINDRICAL INFRA RENAL NECK

Potential type 1
NBS ENDOGRAFT / INFRA RENAL FIXATION



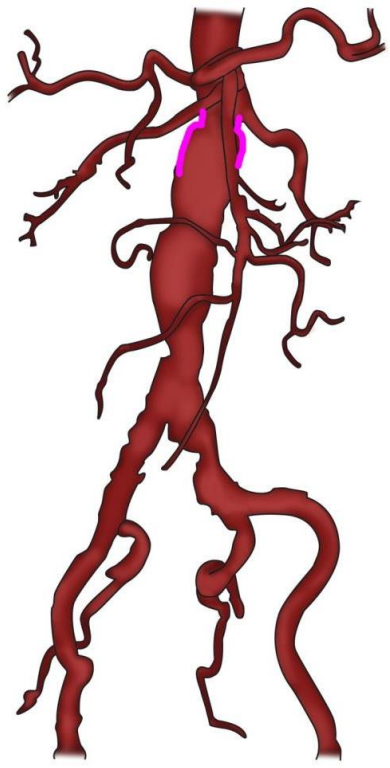
INFRA RENAL EAG / ERC 2 (5years): 50 cases – mean F.U.: 7+/- 7mths

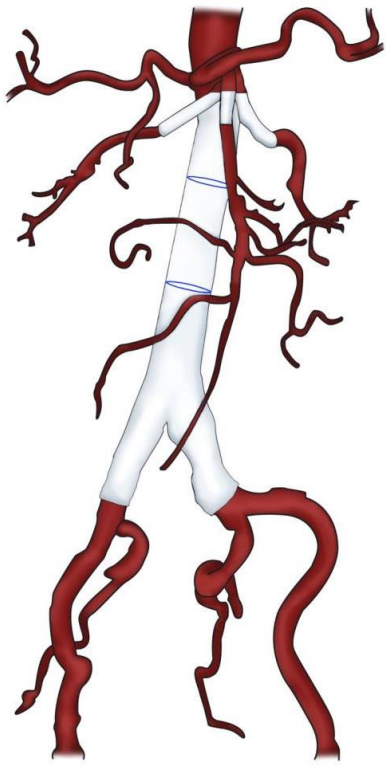
AAA EVOLUTION RELATED CLASSIFICATION

ERC 3

NO INFRA RENAL NECK

PRIMARY 3 CHIMNEYS / 3 FEVAR





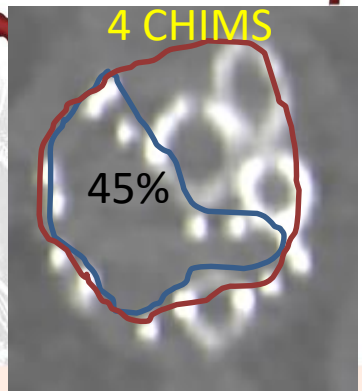
CHIM/CUFF / ERC 3 (4 years): 50 cases – mean F.U.: 14+/- 11mths

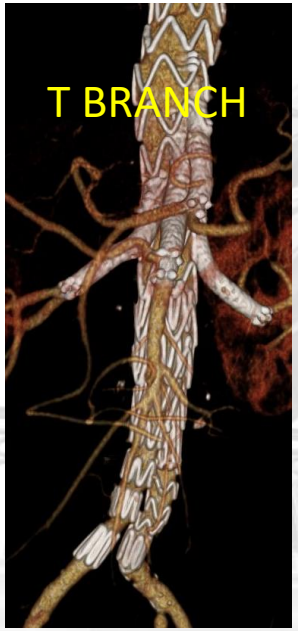
Renal stent occlusion: 11% - Secondary Patency: 94%

AAA EVOLUTION RELATED CLASSIFICATION

ERC 4

COELIAC ANEURISM





By Courtesy of Stephan HAULON

CONCLUSION

- Aneurismal extension over EAG is part of the natural history of degenerative disease
- Primary EAG indication has to anticipate AAA long term evolution and correlated device extension
- Mid and Long Term Evolution of Infra Renal Neck Leads to Reconsider the Use of BS Supra Renal Fixation

Then the ideal EAG concept would associate sack stabilisation, infrarenal fixation, modularity for retrograde and antegrade extension