What is wrong with EVAR and how would a perfect device overcome the problems?

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INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES in aortic endografting

Disclosures

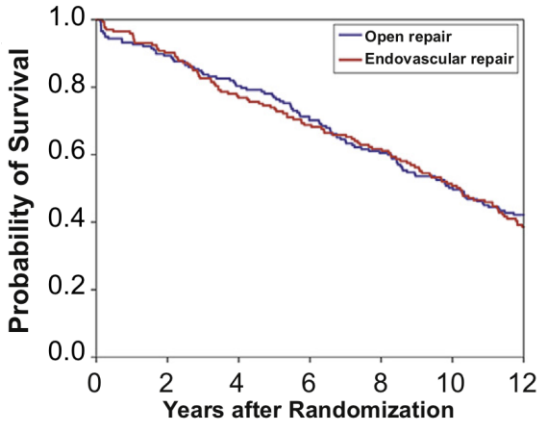
Cook:

Proctoring, Speaker's fees, Grant support, Consulting

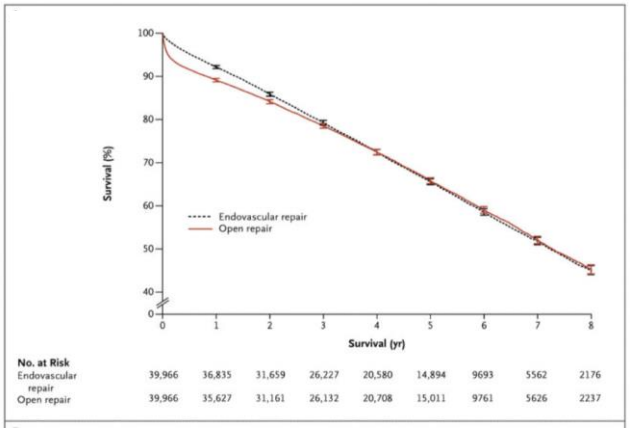
Cydar Medical:

Scientific advisory board

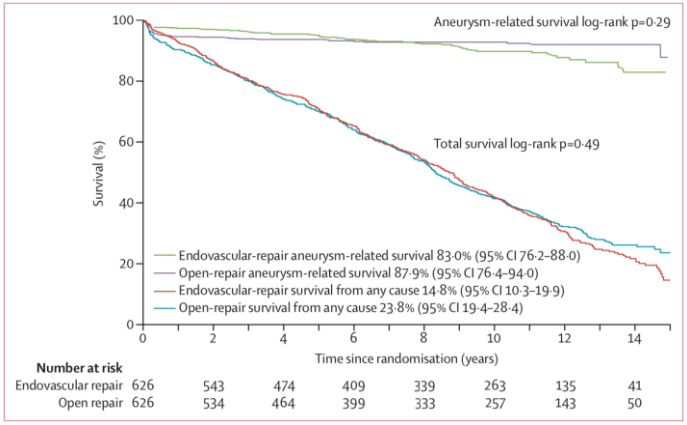
DREAM



Medicare Data



EVAR 1



Schermerhorn et al. N Eng J Med 2015
Van Schaik et al. J Vasc Surg 2017
Patel et al. Lancet 2016

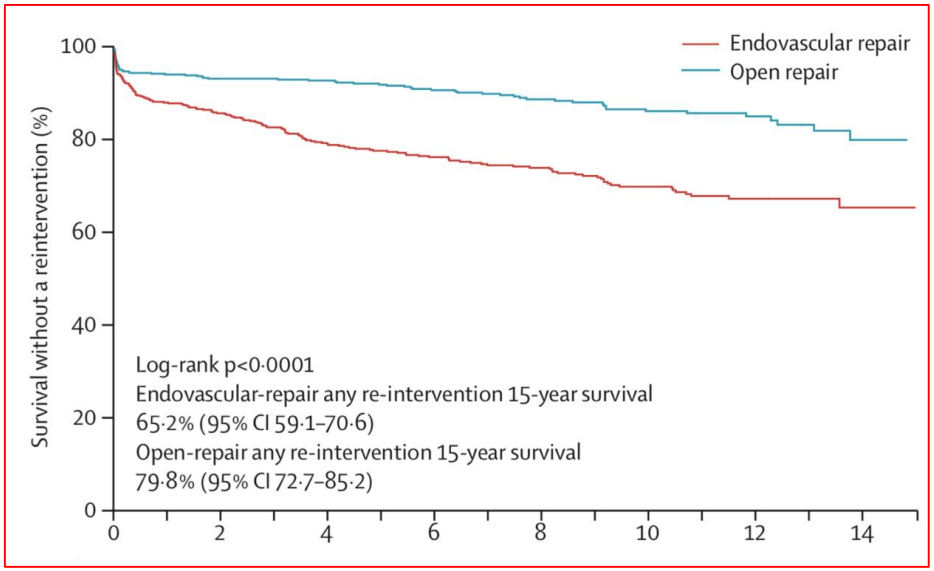
DREAM

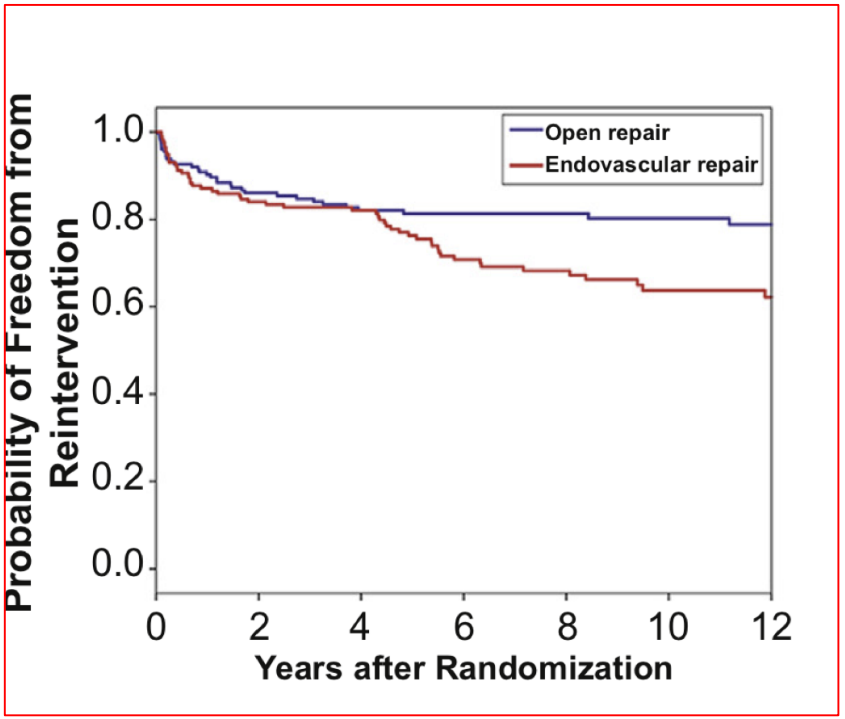
Medicare Data

~50% survival at 10 years

EVAR 1

Schermerhorn et al. N Eng J Med 2015
Van Schaik et al. J Vasc Surg 2017
Patel et al. Lancet 2016





Van Schaik et al. J Vasc Surg 2017
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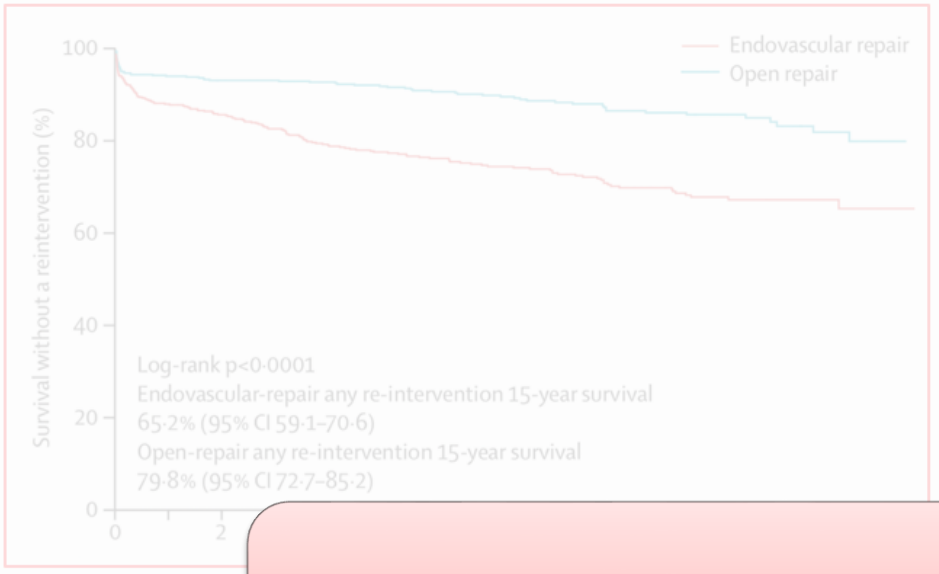
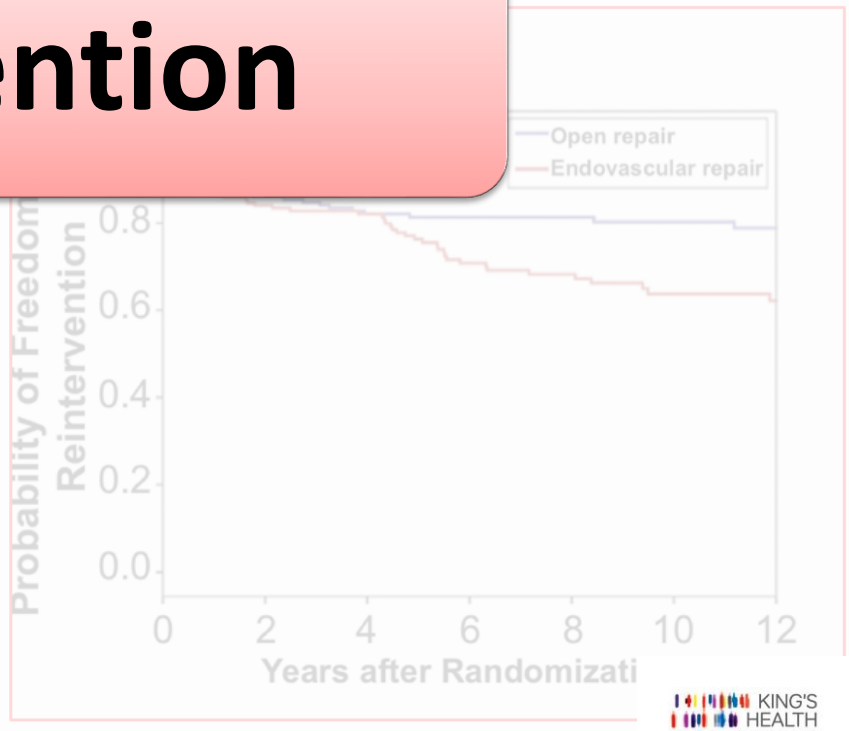


Reintervention

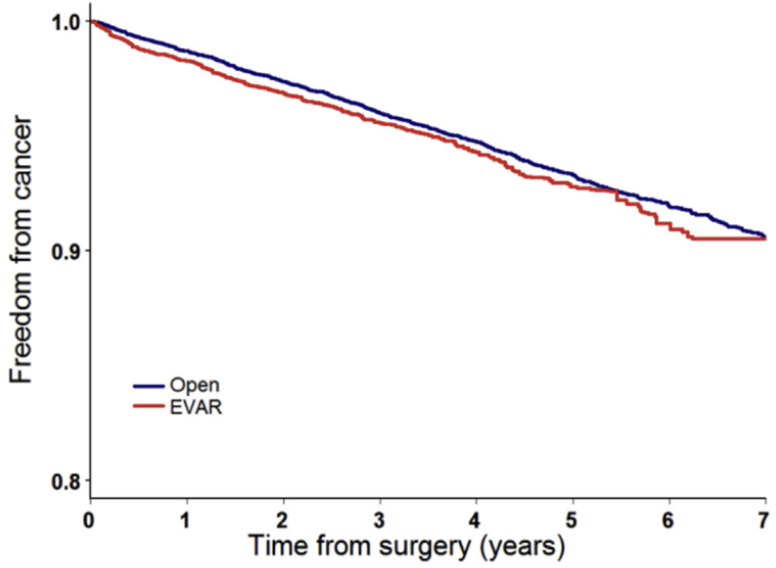


l. J Vasc Surg 2017
cet 2016

A population-based cohort study examining the risk of abdominal cancer after endovascular abdominal aortic aneurysm repair

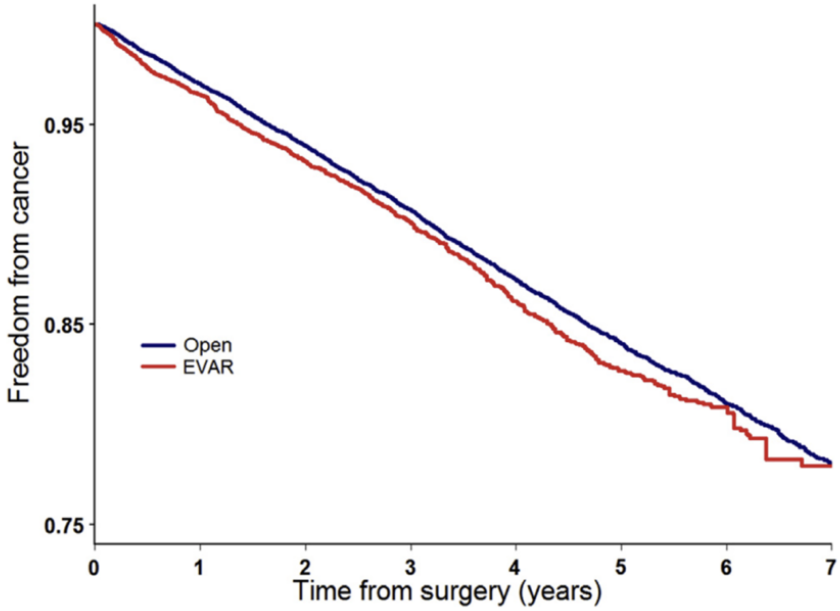
Sheraz R. Markar, PhD, MA, MSc, MRCS,[a] Alberto Vidal-Diez, PhD,[b,c] Viknesh Sounderajah, MRCS,[a] Hugh Mackenzie, PhD, MRCS,[a] George B. Hanna, PhD, FRCS,[a] Matt Thompson, PhD, FRCS,[b] Peter Holt, PhD, FRCS,[b] Jesper Lagergren, PhD, MD,[d,e] *and* Alan Karthikesalingam, PhD, MA, MSc, MRCS,[a,b,c]
London, United Kingdom; and Stockholm, Sweden

Abdominal cancer



HR 1.14 (CI 1.03-1.27, P=0.02)

All cancers



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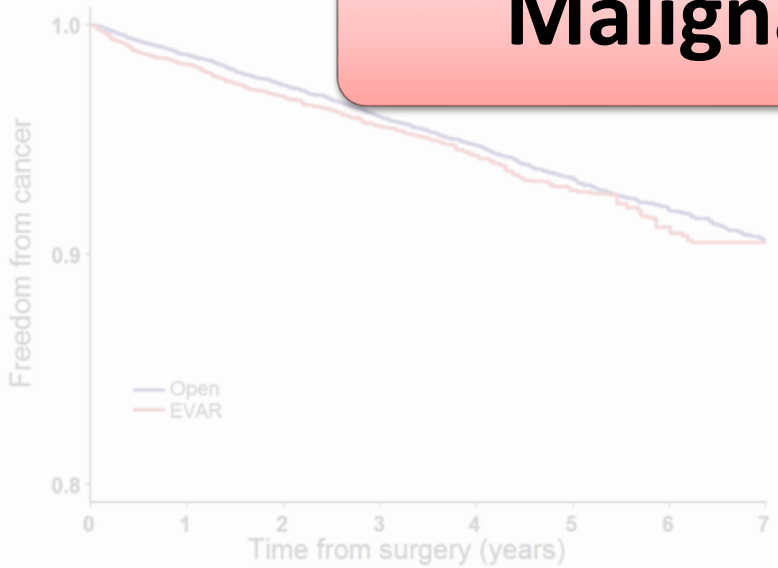
Abdominal cancer

All cancers

Malignancy Risk?



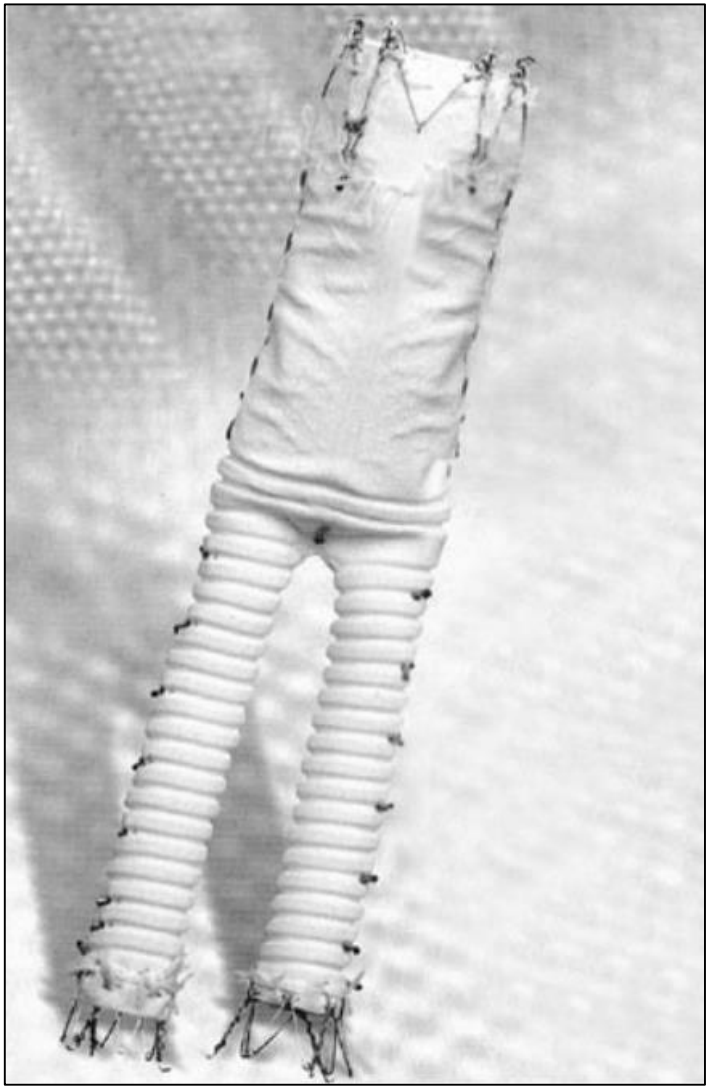
1.14 (CI 1.03-1.27, P=0.02)

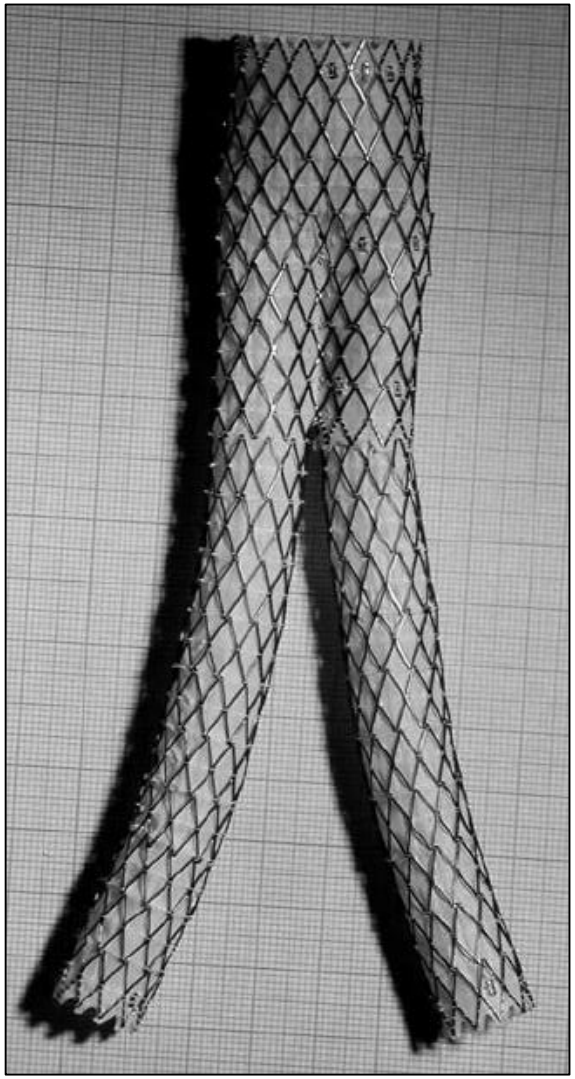
HR 1.09 (CI 1.02-1.16, P=0.

Guy's and St Thomas' NHS Foundation Trust

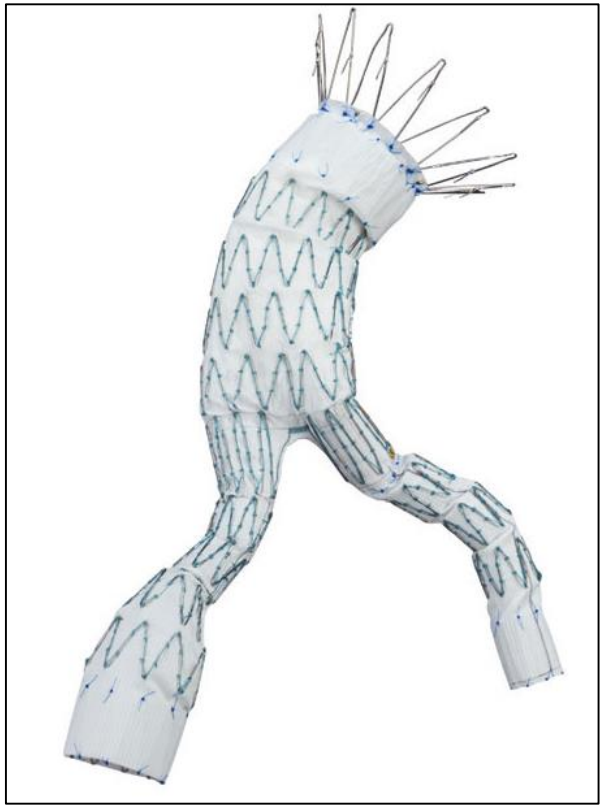
KING'S HEALTH PARTNERS

Stent graft evolution





Stent graft evolution



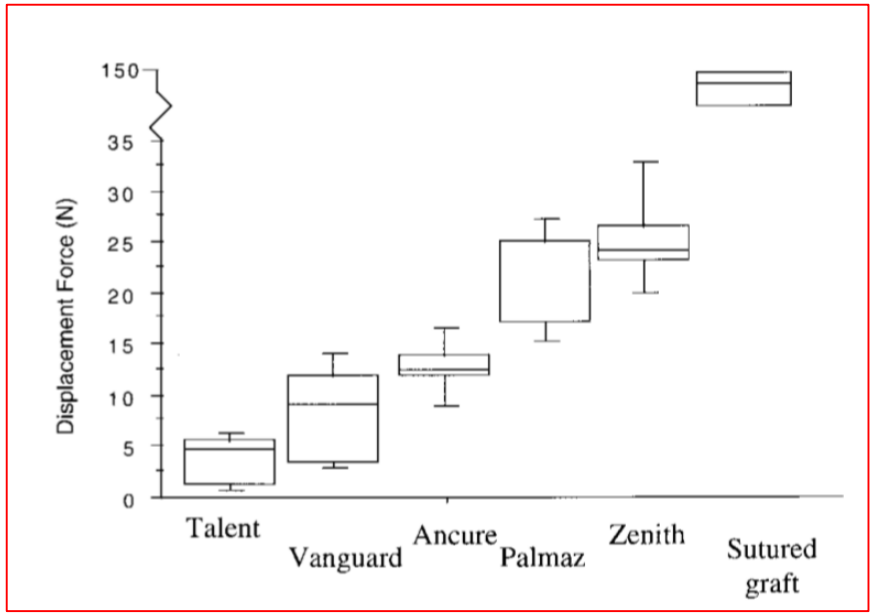
Stent graft evolution

- Materials
- Fixation
- Profile
- Deployment

EVAR Challenges

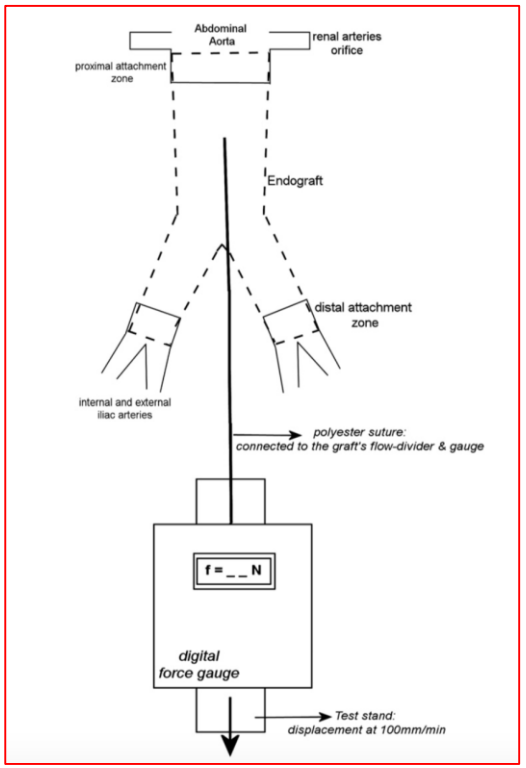
- Device integrity
- Disease progression
- Device fixation
- Case selection
- Endoleak
- Radiation exposure
- Limb occlusion
- Surveillance

Active fixation reduces migration



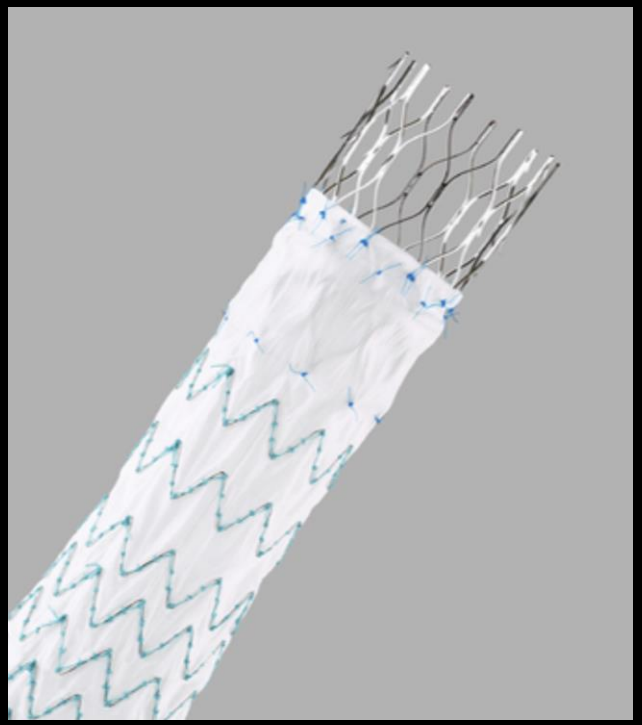
Force to dislodge stent graft 6X less than sutured anastomosis.

Resch et al. EJVES 2000



- Cadaveric model
- Fixation hooks/barbs: Higher DF
- Less migration

Melas et al. EJVES 2010



Systematic review and meta-analysis of migration after endovascular abdominal aortic aneurysm repair

Vascular
2016, Vol. 24(3) 323–336

DOI: 10.1177/1708538115590065
vas.sagepub.com
SAGE

Talent, Excluder, Aneurx, Zenith

Factors associated with migration:

Aneurysm diameter

Neck length

Neck length

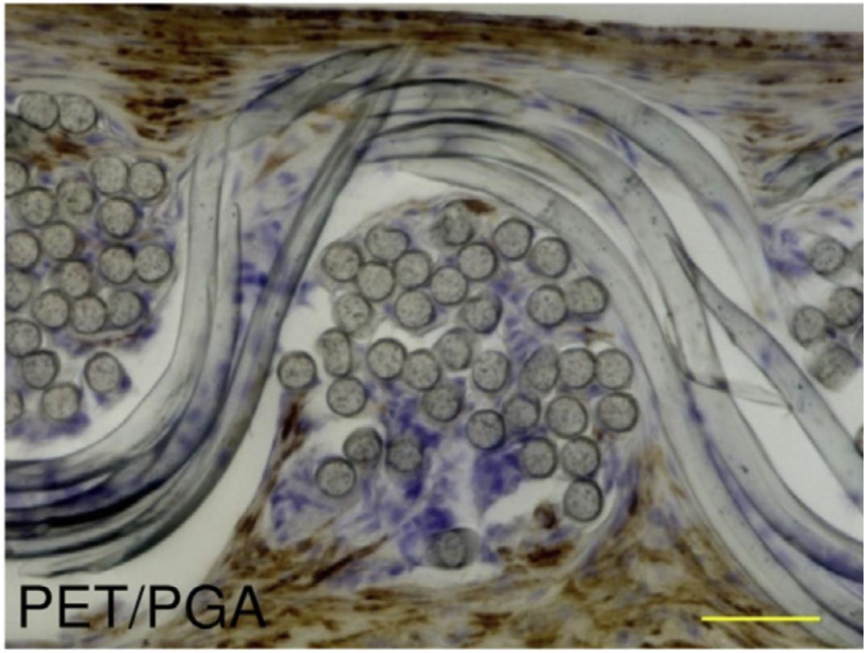
4mm

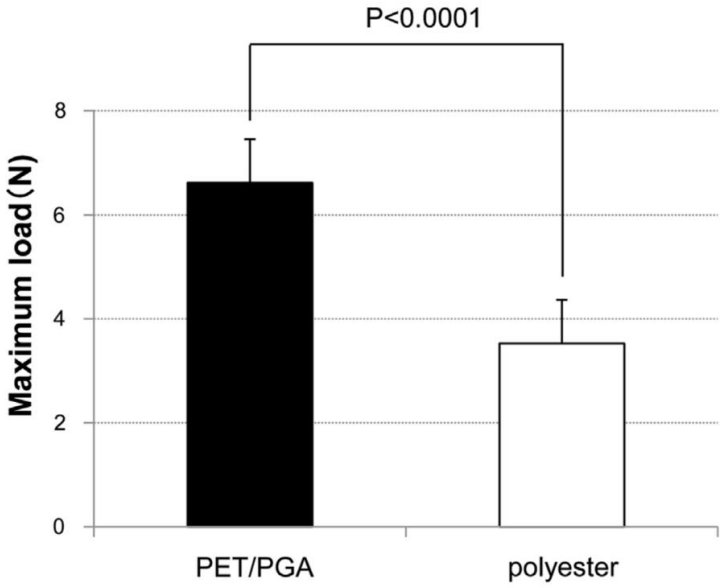
1cm

1.5cm

Current endograft technology relies almost exclusively on mechanical interaction between device and native vessels to afford stability

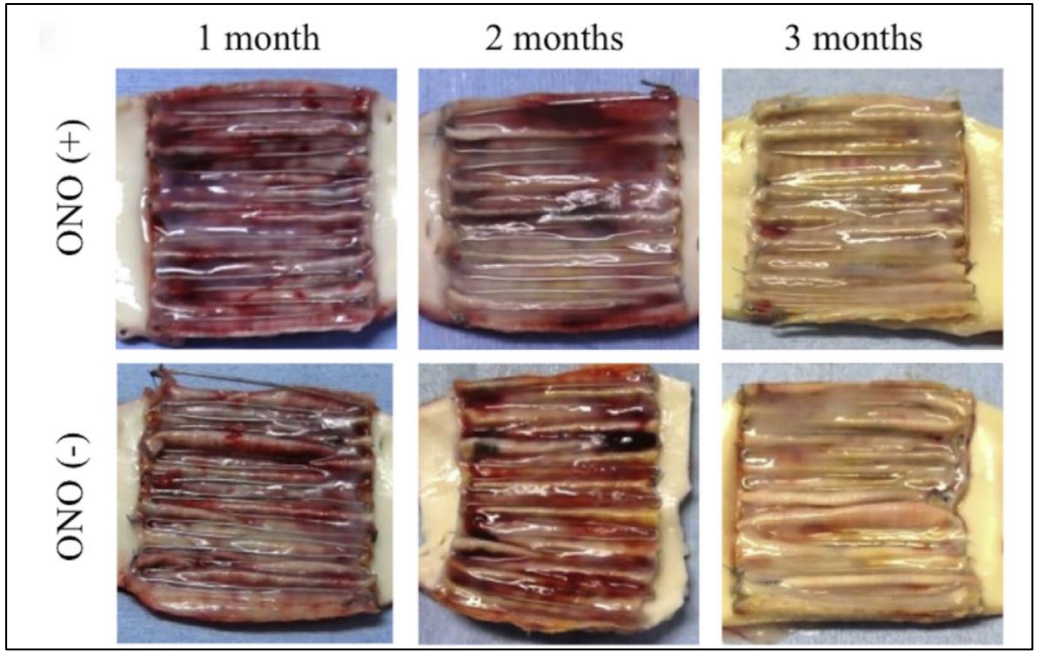
Tissue-engineered stent-graft integrates with aortic wall by recruiting host tissue into graft scaffold





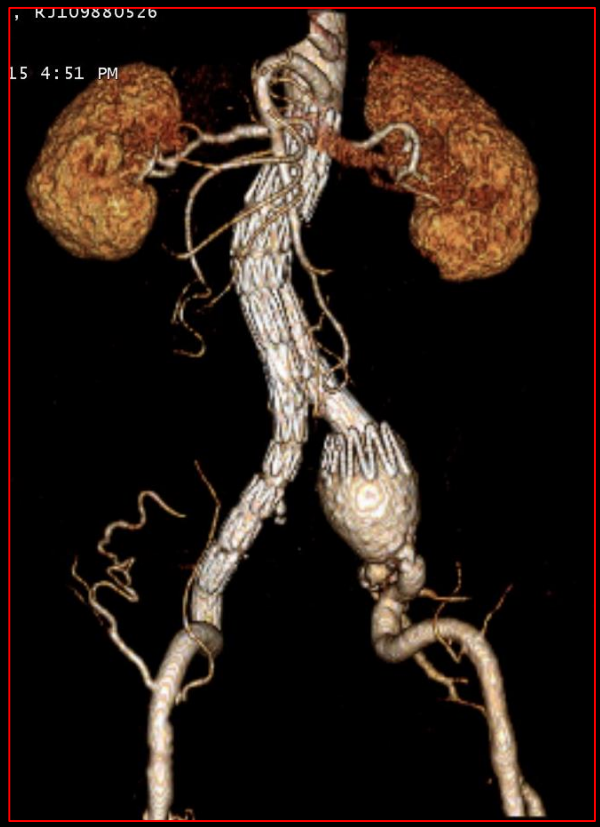
J Thorac Cardiovasc Surg 2014;148:1719-25

Development of a prostacyclin-agonist–eluting aortic stent graft enhancing biological attachment to the aortic wall



- Canine model
- Enhanced neointimal formation and fibrous tissue
- Strengthening the mechanical force of attachment graft/aorta.

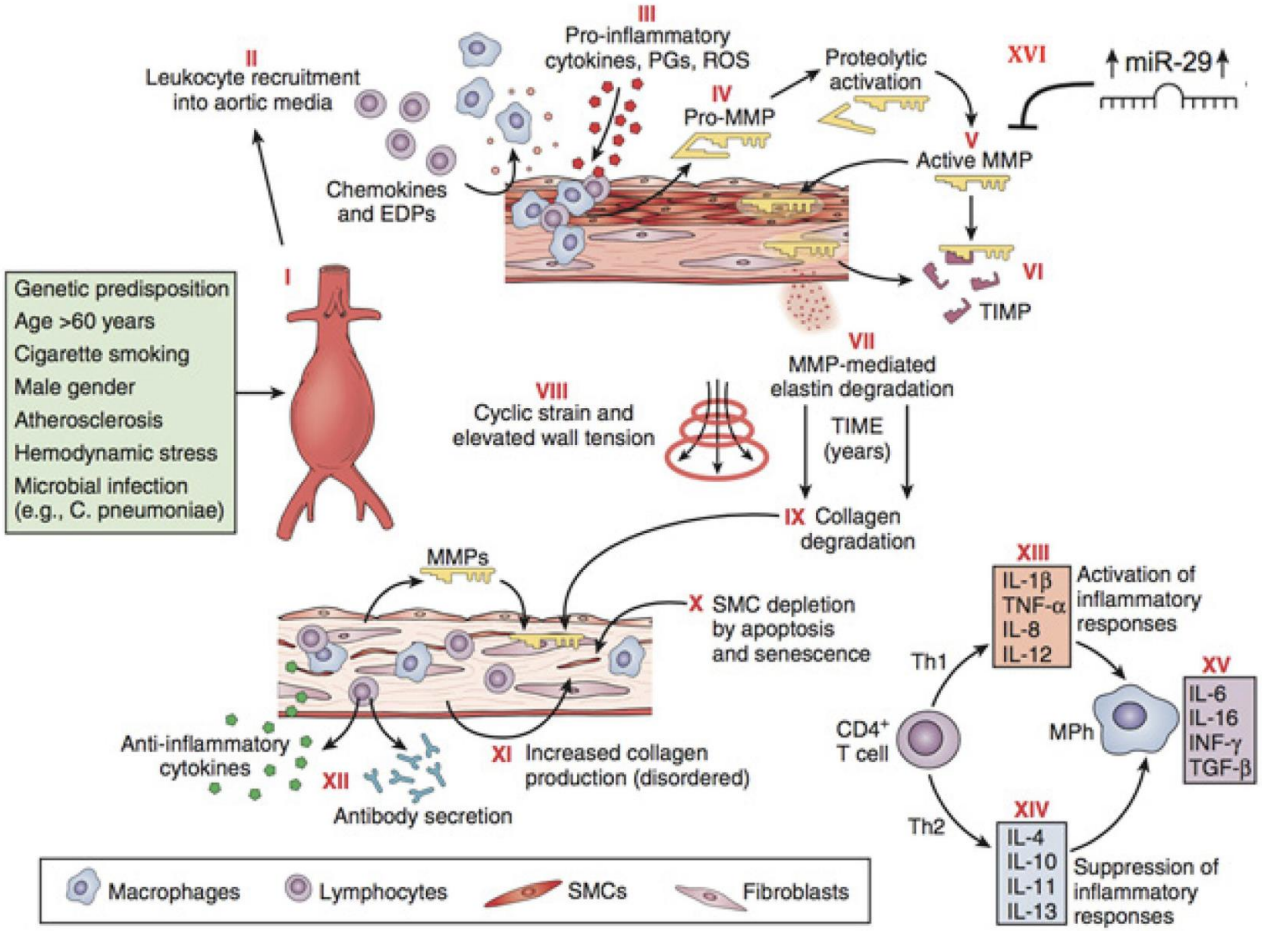
J Thorac Cardiovasc Surg 2014;148:2325-34



- Maintenance of aortic integrity at seal zones……
- Risk factors: thrombus, ectasia, synchronous aneurysms
- Occult underlying genetic factors?
- Oversizing promotes degeneration

Stent grafts that "fail well"

Aneurysmal disease



Joviliano B J Cardiovasc Surg 2017

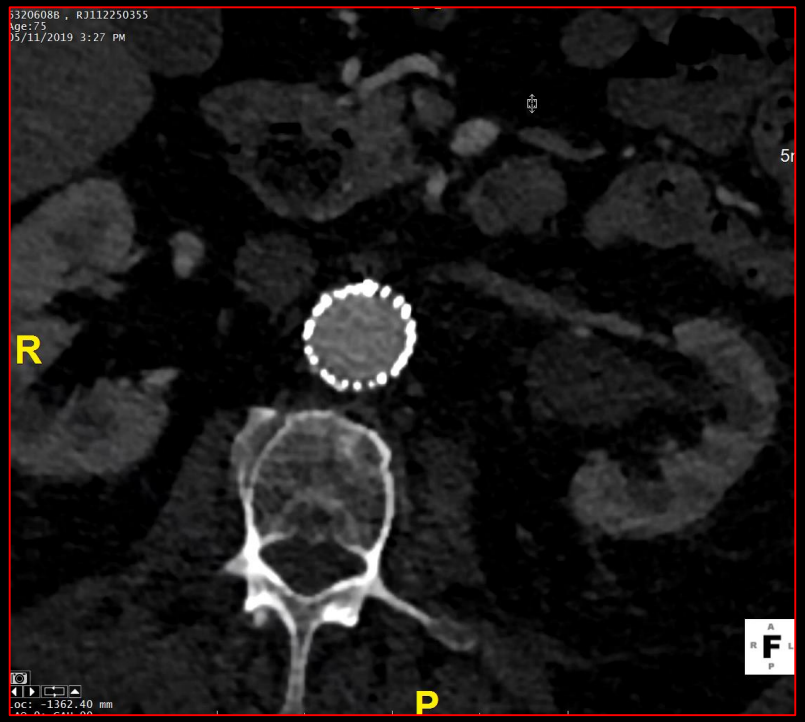
Elastase inhibitor AZD9668 treatment prevented progression of experimental abdominal aortic aneurysms

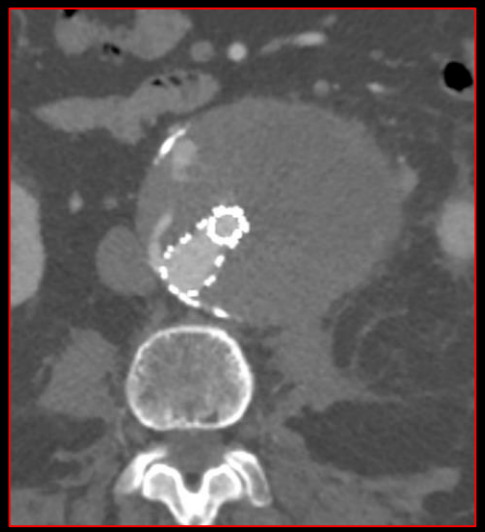
Sandrine Delbosc, PhD,[a,b] Martin Rouer, MD,[a] Jean-Marc Alsac, MD, PhD,[a,c] Liliane Louedec, MsSC,[a,b] Monique Philippe, MsSC,[a,b] Olivier Meilhac, PhD,[a,b] Carl Whatling, PhD,[d] and Jean-Baptiste Michel, MD, PhD,[a,b] *Paris, France; and Molndal, Sweden*

- **Leucocyte produces elastase**
- **Elastase murine model**
- **AZD9668 (AtraZeneca elastase inhibitor)**
- **Inhibits aneurysm progression**

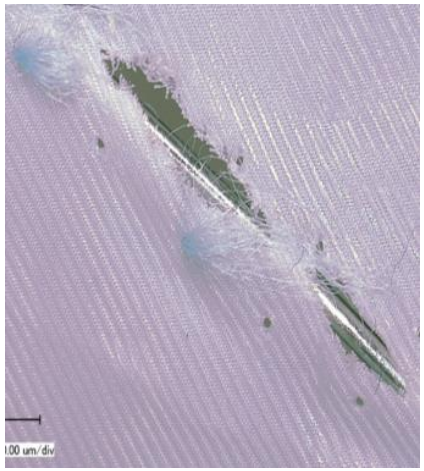
Prior to relining

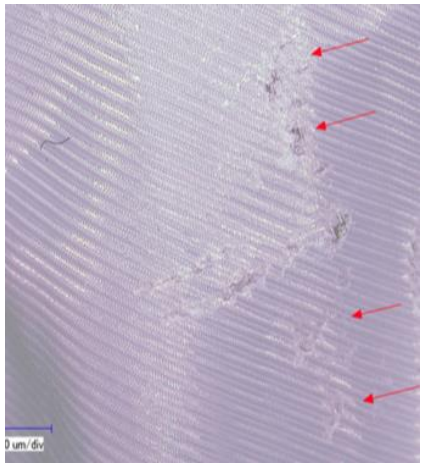
After relining

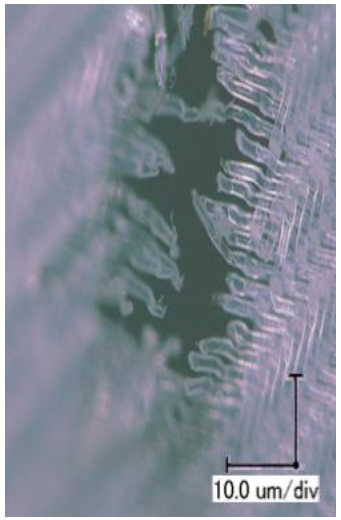


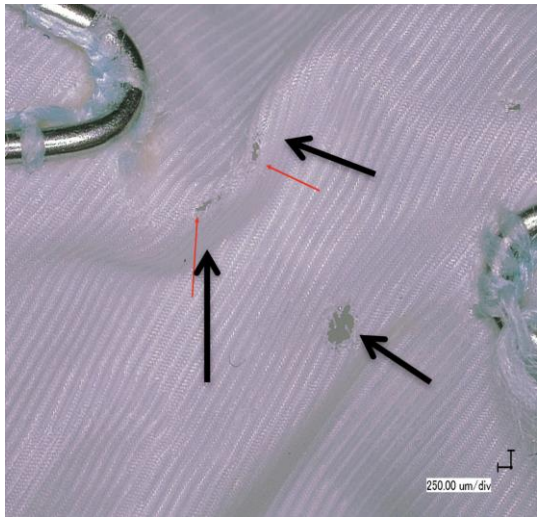


Aging implants

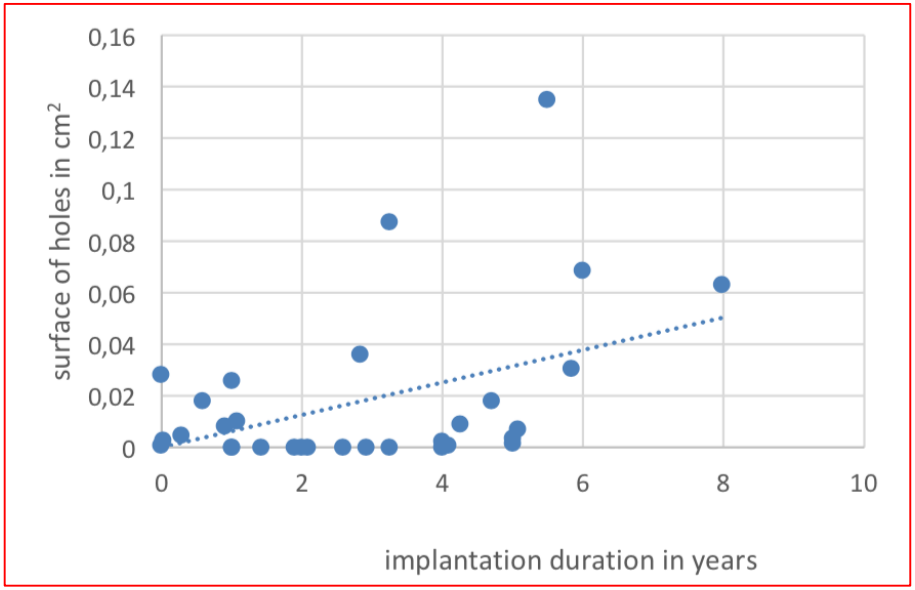






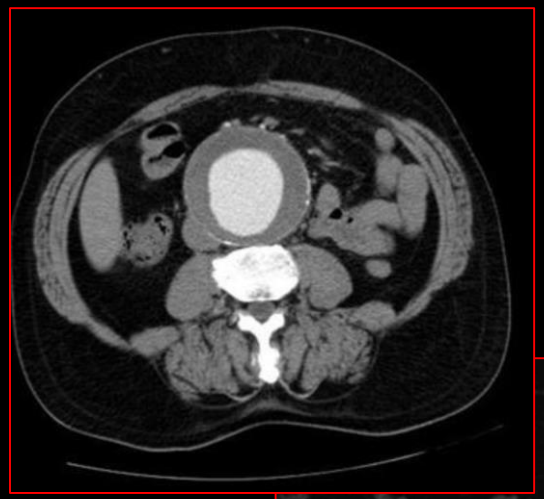


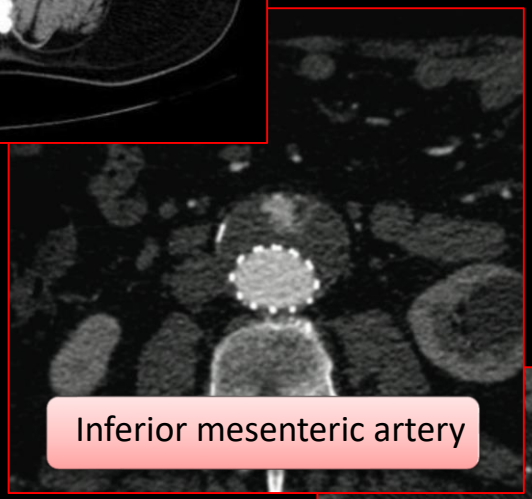
- Fabric/metal wire interaction
- Abrasion: Calcified plaques
- Increase with time?
- New generation materials

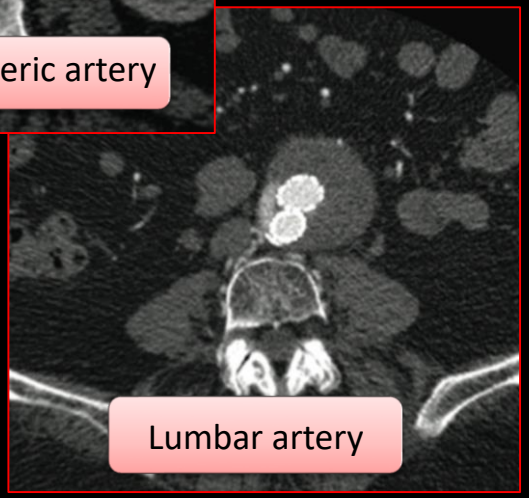


Courtesy of Nabil Chafke/Geprovas

Aneurysm sac management







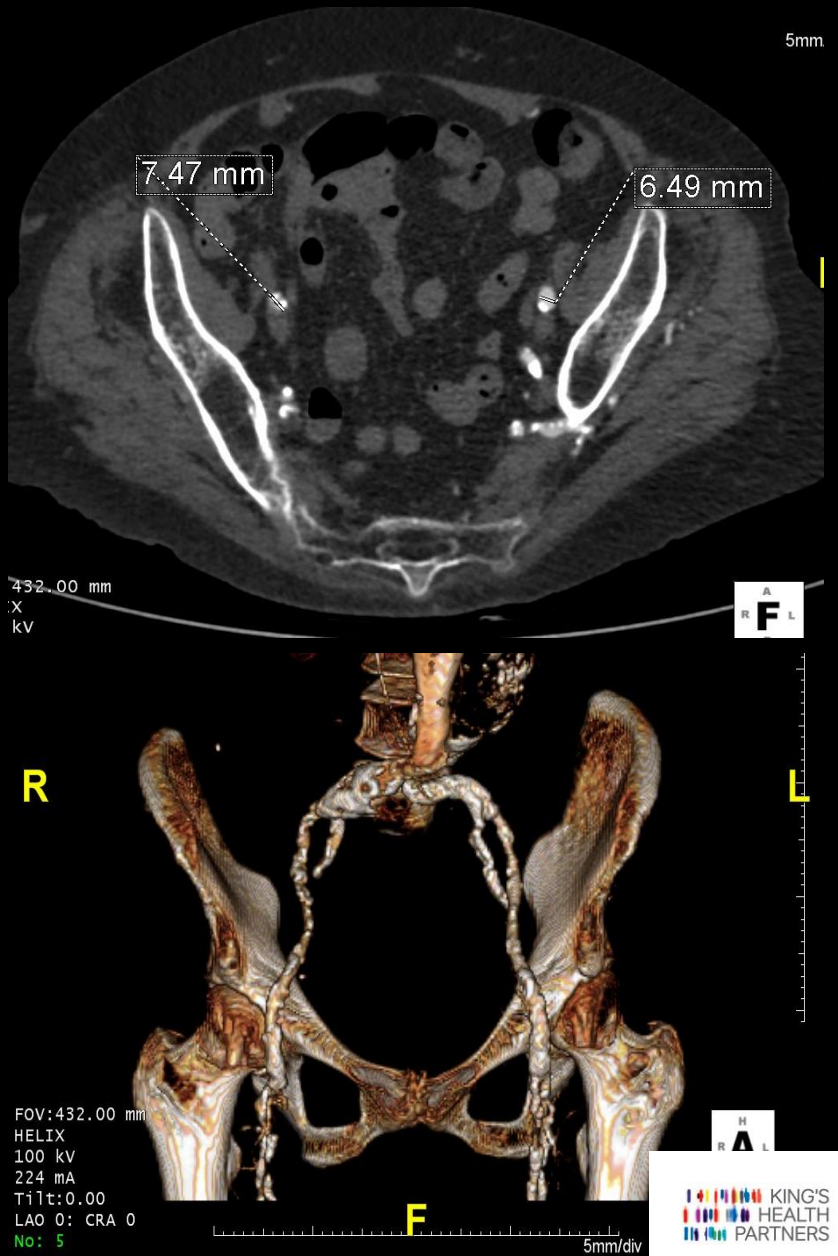
- Endoleak at 30 days:

  Heralds re-intervention
- Malignant type 2 endoleaks
- Endoleaks masquerading as type 2
- Relevance of sac content?
- Advanced imaging of sac/aortic wall
- **Devices that obliterate sac**

Device profile and hostile iliac anatomy

- Ideal system:
  - Low profile
  - Well supported limbs
  - Flexible/compliant
  - Vessel stenosis: Radial force
  - Flexible/hydrophilic delivery system
  - Percutaneous

- Low profile: Compromise on materials?

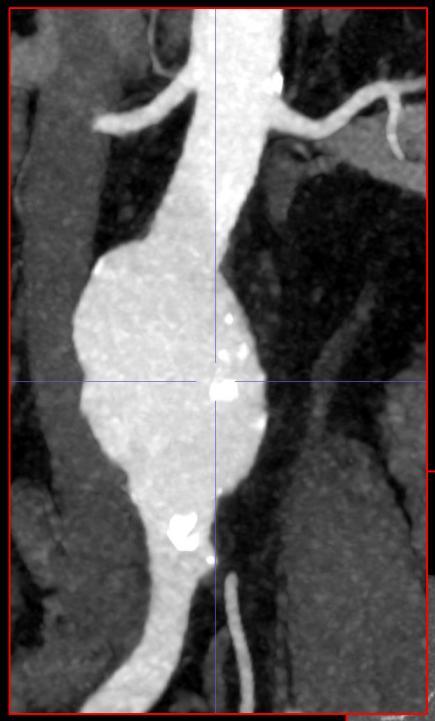


Carefully executed EVAR with conservative IFU performs well

How hard should we strive to increase applicability of devices?

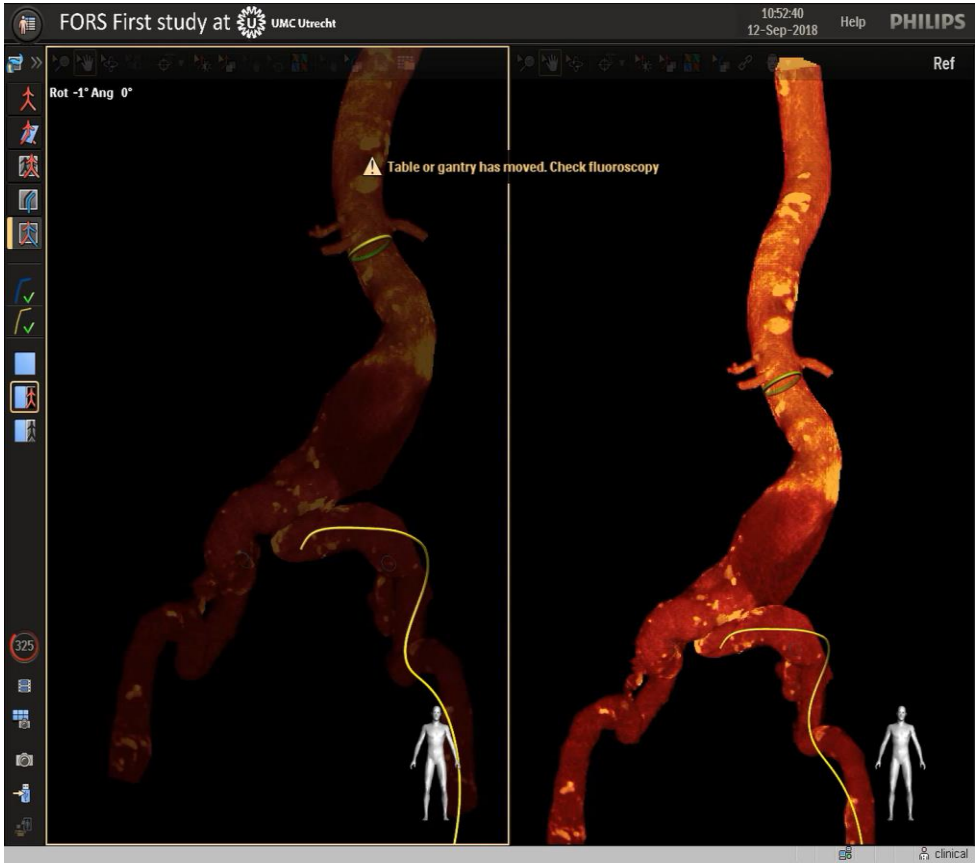
Adverse anatomy → Complications

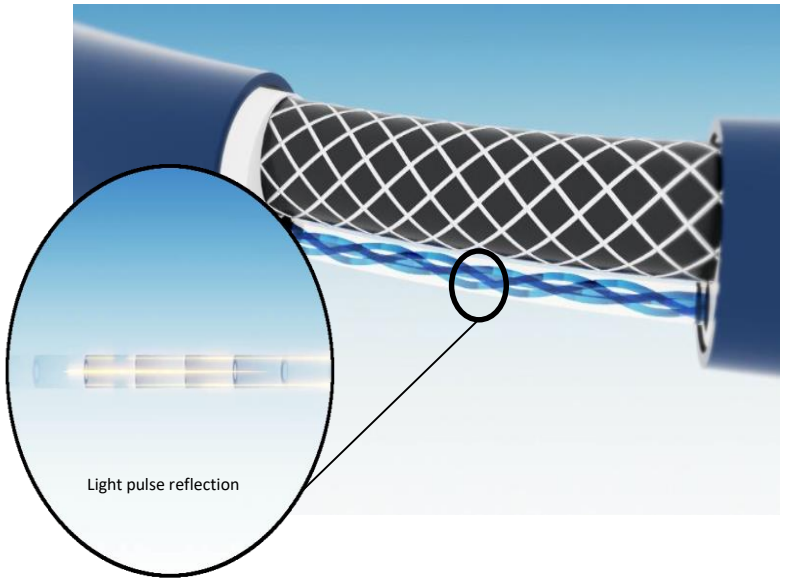
The future: Imaging, AI and machine learning



- **Objective case selection**
  - Accounting for multiple nuances
  - Deformation
  - Available neck length
  - Stent graft conformation
  - Precise deployment
- **Stent graft longevity**
- **Patient longevity**
- **Tailored surveillance**

Fiber Optic RealShape (FORS) technology



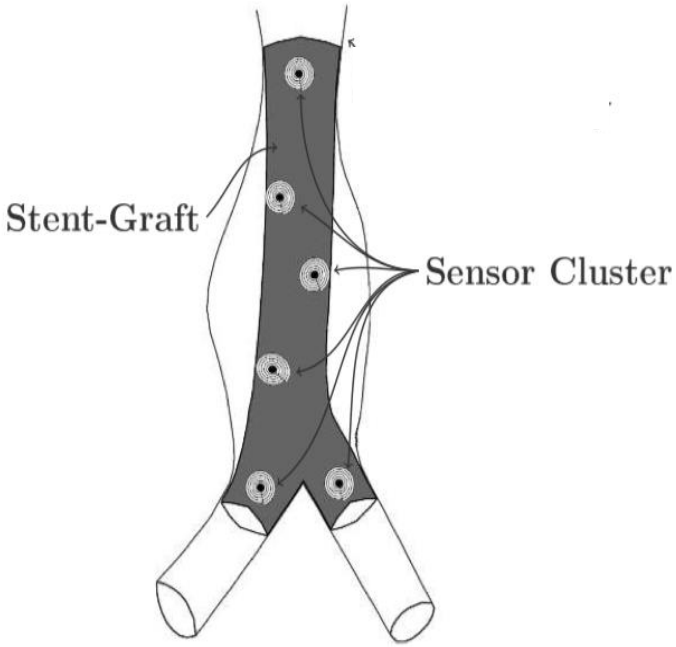


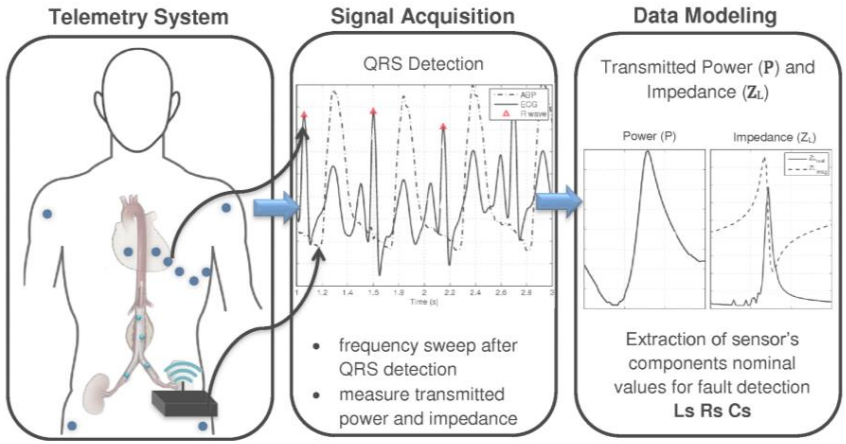
- Real time 3D device visualisation using light
- Multiple unrestricted viewing angles
- Corresponding alignment markers on stent graft?

Courtesy of Dr. Joost van Herwaarden, UMC-U, NL and Philips

2012 IEEE 18th International Mixed-Signal, Sensors, and Systems Test Workshop

Fault Detection System for a Stent-Graft Endoleakage Monitor





Oliveira et al. IEEE 2012

Endovascular Aneurysm Repair (EVAR) Market is growing with $3,580 Million Value Globally by 2023

MARCH 22ND, 2019 ALLIED MARKET RESEARCH RELEASES

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- Iterative improvements from lessons of past
- Paradigm shifts still possible? - Yes
- Novel technology: Increasing regulatory scrutiny

Towards Perfection

Flexibility, strength, support, durable, low profile, precise delivery

Actively prevents disease progression

Incorporates into seals zones

Obliterates aneurysm sac

Facilitates proximal/distal extension

Radiation free implantation/surveillance

Actively warns of malfunction

Perfection

Flexibility, strength, support, durable, low profile, precise delivery

Actively prevents disease progression

Incorporates into seals zones

Obliterates aneurysm sac

Facilitates proximal/distal extension

Radiation free implantation/surveillance

Actively warns of malfunction

Radiation
MRI compatible graft materials - no artefact

FORS and markers on graft that allow you to see exactly where
You are – wire in renal and markers on graft – then you deploy