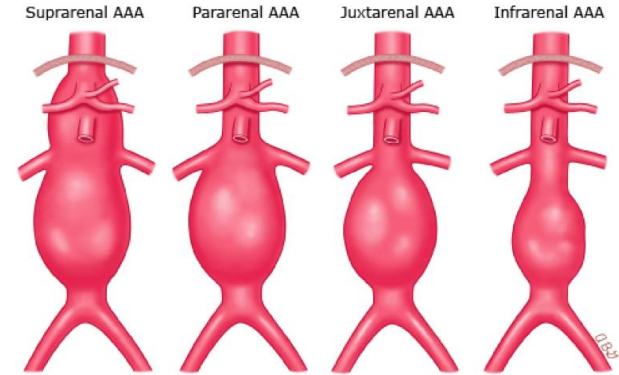


Artificial Grafts for Endovascular Aneurysm Repair (EVAR)

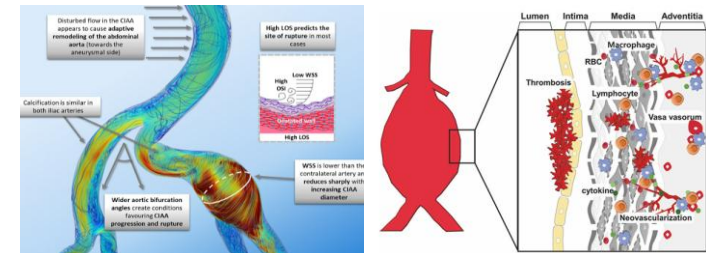
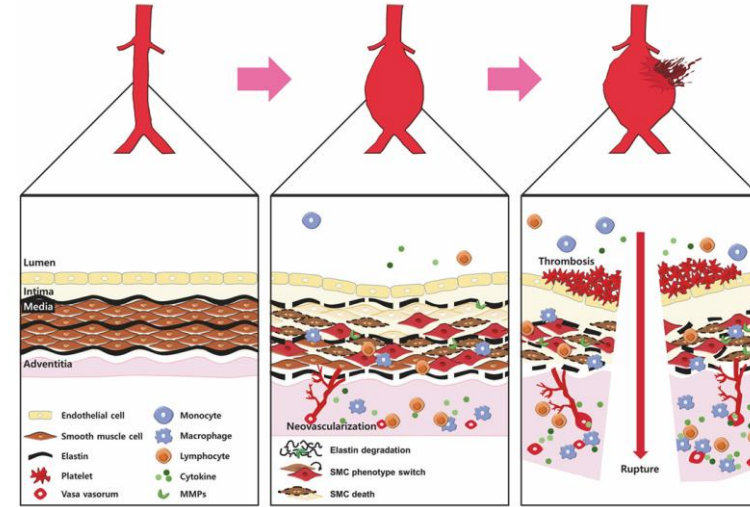
Pietro Boiardi
LSE, MA 3

MICRO-568 Seminar
20/11/2025

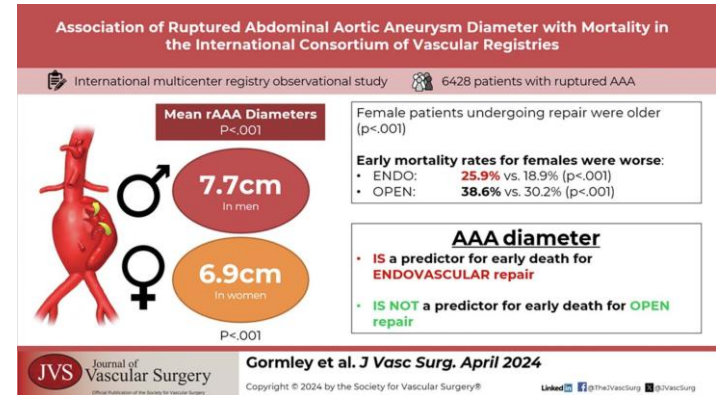
- An aneurysm is a chronic disease with permanent, localized **dilatation** due to adverse wall remodelling
- According to European society of vascular surgery (ESVS) diagnosis is made for **d > 3cm** (≈ 2 SD above mean in men)
- **Abdominal Aortic Aneurysms** (AAA) account for 80% of all cases affecting the main arterial vessel
- Usually **infrarenal** and progressive; the mortality upon rupture >80%, accounting for 150,000–200,000 deaths/year worldwide
- Pathogenesis linked to **matrix degradation**, inflammation, and vascular smooth muscle cells (VSMCs) dysfunction



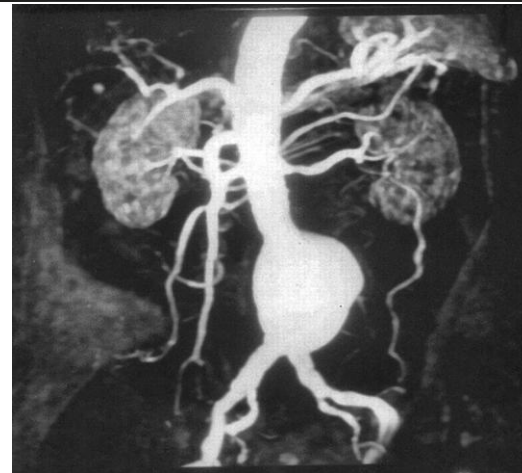
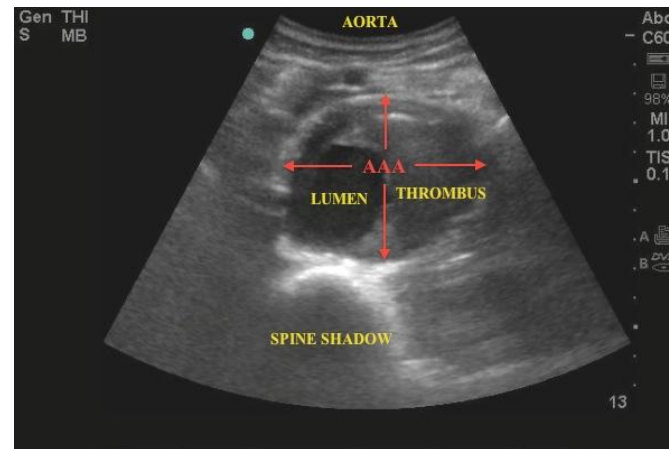
- **Atherosclerotic** and inflammatory processes degrade the extra-cellular matrix (ECM) starting from a lesion
- **Intra-luminal thrombus (ILT)** drives matrix metallo-proteases (MMPs) and cytokines activation
- The chronic and uncontrolled **remodeling** lead to loss of elasticity and elastin/collagen **structures weakening**
- Can originate from infectious, autoimmune or post-traumatic aetiology
- AAA typically **asymptomatic** until rupture; detected incidentally or via screening
- Infrarenal aorta is most susceptible: site of disturbed flow & pressure reflections, high wall shear stress gradients promote **endothelial injury & inflammation**



- AAA prevalence: ~1% of men aged 65–79 (**≈35 M cases globally in 2019**) and **mortality on rupture ≈ 80%** (often pre-hospital)
- Prevalence rises steeply with age: up to 2,270/100,000 in men aged 75–79 years
- Main risk factors: **age, male sex, smoking, hypertension, dyslipidaemia, family history and genetic predispositions**
- Women: **lower incidence** but higher rupture risk for same diameter
- Rupture risk increases **exponentially with size**: 12%/year at 5.5 cm → 35%/year at 6.5 cm
- Rupture mortality: 100 % if untreated, **~50 % 30-day mortality** even after prompt surgery



- **Diameter is the main predictor** of rupture and index of disease progression, continuous monitoring is essential
- Imaging modalities include: ultrasonography (screening-wise), **computed tomography angiography** (CTA) or magnetic resonance angiography (MRA) for finer investigations and post-op follow-up
- **Early detection** enables personalized management and pre-rupture intervention
- **Conservative management** for small aneurysms; **repair indicated ≥ 5.5 cm** or symptomatic
- Ongoing translational advances improving risk stratification and treatment timing
- Public health challenge to provide **systematic screening** and prevention



Hoop Stress with Thin-Wall Approximation: Effect of Aneurysmal Dilatation

- Thin-wall cylindrical approximation:

$$\sigma_{\theta} = \frac{pr}{t}$$

- Worst-case systolic pressure: $p = 160 \text{ mmHg} \approx 21.3 \text{ kPa}$
- Axial and residual stresses neglected; isotropic homogeneous wall.
- Thin-wall criterion: $t/r \lesssim 0.1$

Case	D (cm)	t (mm)	r (cm)	σ_{θ} (MPa)
Infrarenal healthy aorta	2.0	1.8	1.0	0.118
Fusiform aneurysm (4.5 cm)	4.5	1.2	2.25	0.399
Fusiform aneurysm (6.5 cm)	6.5	0.9	3.25	0.769



- Hoop stress increases by approximately $\times 3.4$ (4.5 cm) and $\times 6.5$ (6.5 cm) compared to healthy.
- Since $\sigma_{\theta} \propto \frac{r}{t}$, both lumen dilation and wall thinning amplify wall stress.
- Healthy aorta: $t/r \approx 0.18$ — borderline for the thin-wall assumption.
- Aneurysms: $t/r \approx 0.053$ and 0.028 — suitable for membrane approximation.

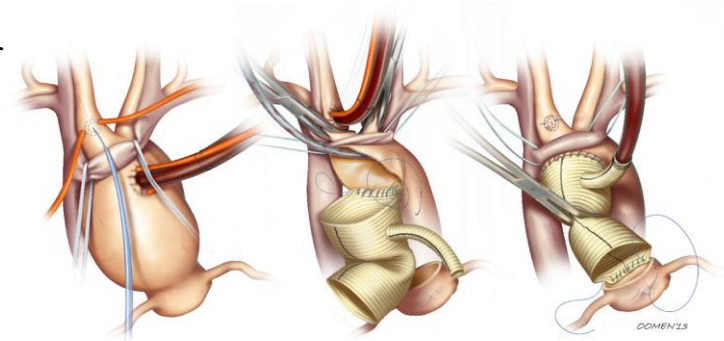
1950s to 1990s: highly invasive Open Surgical Repair (OSR), non-specific standard care for decades

Volodos (1986) first conceptual endograft → Parodi (1990) performs first successful human EVAR using PTFE graft on stent.

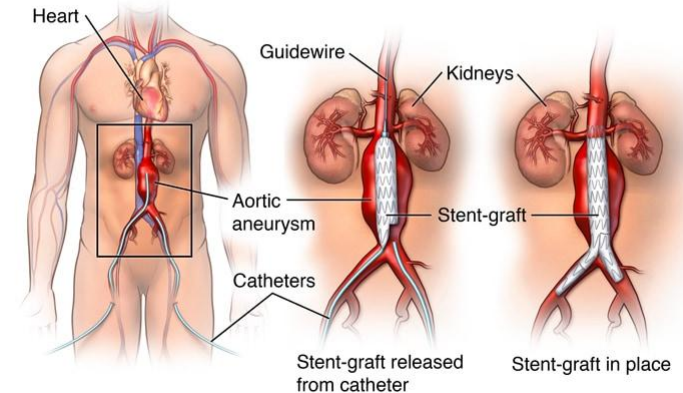
FDA approvals (**late 1990s**) mark transition to clinical use, **initially reserved for high-risk or inoperable patients** due to comorbidities

By 2003, EVAR was used for nearly **half of all elective** AAA repairs in the USA.

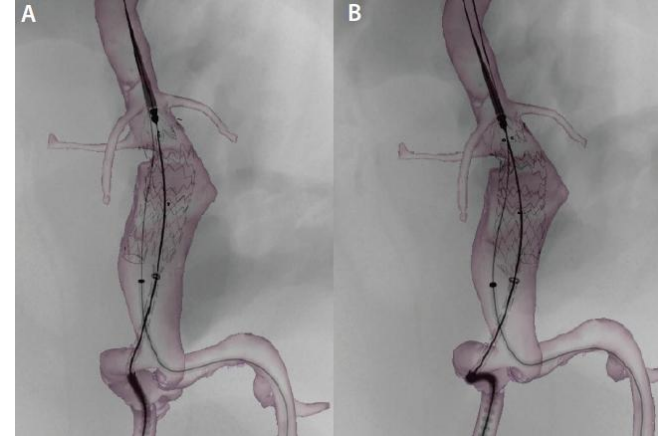
In 2008, EVAR accounted for 77% of all intact AAA repairs, retrospective studies illustrate



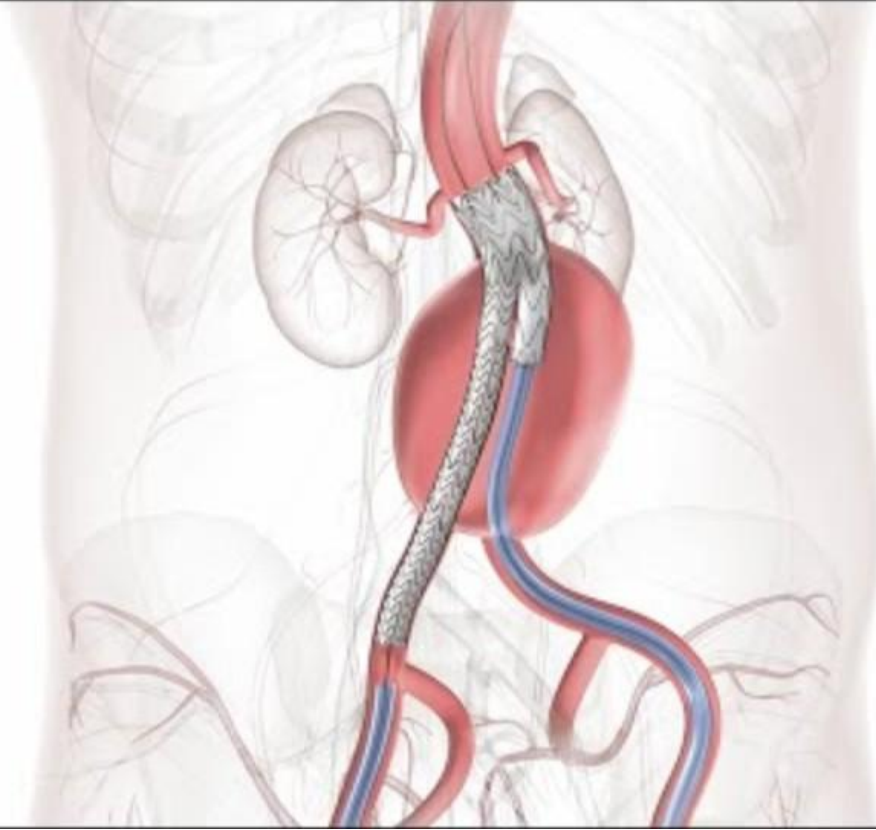
Endovascular aneurysm repair (EVAR),
abdominal aortic aneurysm (AAA)



- **Pre-op imaging** to assess neck sizes, lengths and to evaluate tortuosity, anatomical complexity, calcification
- Double **femoral percutaneous access** under fluoroscopy
- **Hydrophilic and stiff guidewires navigation**, should not buckle or kink, advanced up to site, angiography defines renal arteries and aneurysm neck
- Main graft delivery via **self-expansion** of stent after sheath retraction, anchors to aortic wall
- **Contralateral limb cannulation**, second wire from opposite femoral access enters the gate of main body
- A **molding compliant balloon** is inflated at seal zones to improve wall apposition and prevent endoleaks

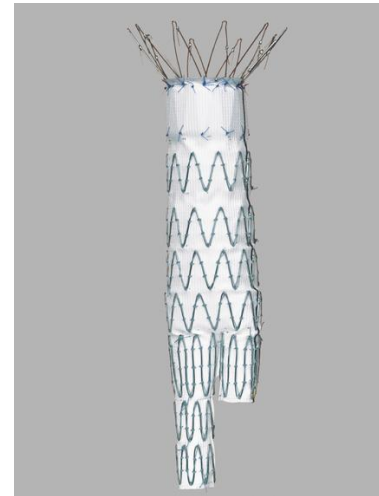
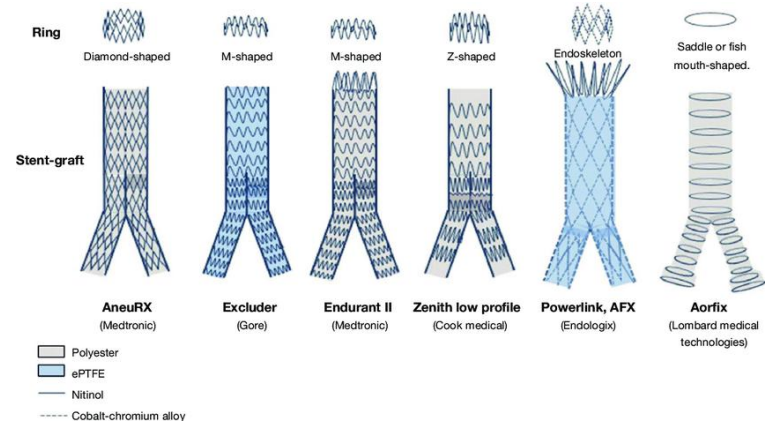


Demo from GORE Medical EXCLUDER®⁹

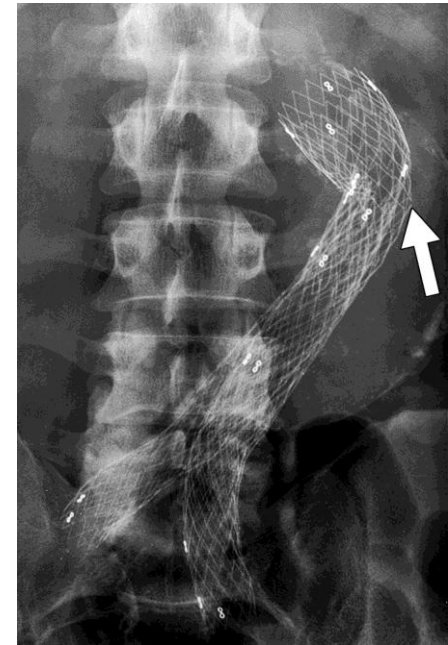


Credits: [EXCLUDER® AAA Endoprosthesis | Gore Medical](#)

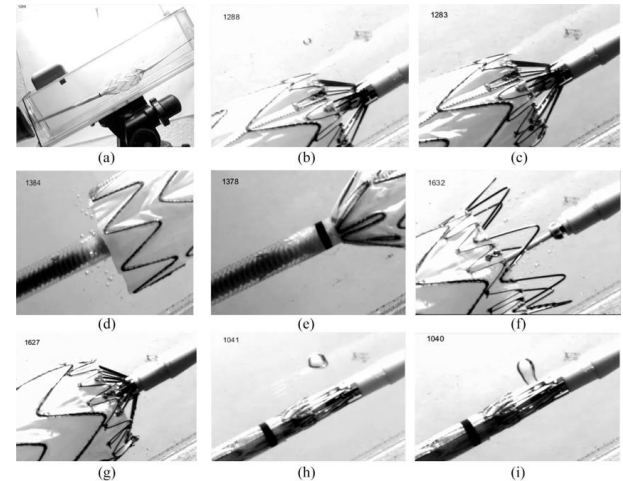
- Frame of passivated laser cut rings, **Nitinol superelastic shape memory alloy (SHA)**, **sutured pleated** synthetic fabric graft
- Titanium oxide surface prevents Ni ion release and corrosion, non-ferromagnetic, **safe for imaging**
- Fixation ensured by radial force due to 10-20% **oversizing** for proper fit at landing zones, barbs/hooks to prevent migration grip on *intima*
- Modular bifurcated devices, main aortic body and **contralateral limb extension** for iliac sealing
- Maintains **luminal patency**, adapts to curvature and **resists kinking**. **Radiopaque markers** for traceability
- Provides blood-proof isolation of aneurysmatic sac
- **Low profile** for catheter delivery, self-expandable, high fatigue endurance, good pushability



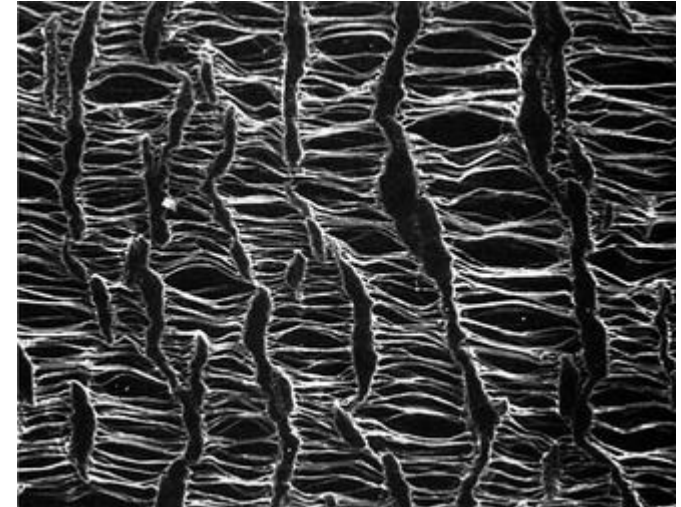
- Must be **hemocompatible**, minimizing platelet adhesion and thrombus formation, **biologically inert, biocompatible**
- Controlled porosity for sealing and controlled tissue ingrowth
- Must resist **radial collapse**, keep outward sealing pressure. Must also withstand bending, kinking, torsion
- Should limit **endoleaks** and not suffer from **migration**
- Ensure **long-term fatigue endurance** under pulsatile aortic loading ($> 4 \times 10^8$ cycles/year)
- Should maintain apposition and seal integrity in the long run with **minimal compliance mismatch**.
- Some relevant **standards** include for example *ASTM F3067-14* and *ASTM F2606-08* protocols
- ***In vitro* testing** to replicate physiologic pressures



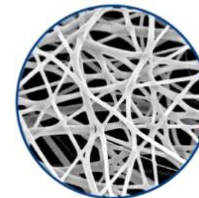
- **Hydrophilic** and kink resistant outer sheath for **friction-free** navigation, low friction inner polyimide catheter for **torque control**
- 14-26 Fr profiles (1 Fr=0.33 mm), **crimped** device
- Stiff guidewires as **stable rail** for advancement and then retraction
- Compliant balloon catheters for molding, tapered polymeric tip for **atraumatic** insertion
- **Endoanchors** can make fixation more robust
- Compatibility with standard **fluoroscopic** imaging
- **Pleated fabric covering** (tiny «wrinkles») allows controlled expansion, lower tensile strains, avoid kinking and **stress concentration**



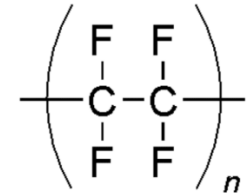
- **Chemically inert fluoropolymer** and **hydrophobic**, $-\text{CF}_2-\text{CF}_2-$ backbone
- Manufacturing involves **paste-extrusion**, multi-axial stretching expansion, **thermal sintering**, can also be **electrospun** for anisotropy
- **Node-fibril** microstructure, 30–60 μm to balance **impermeability** and cell infiltration, high flexibility
- Minimal protein adsorption, excellent **resistance to creep** and long-term dilation ($\approx 19\%$ over 6 yrs)
- **Lower platelet adhesion** and lower post-implantation syndrome (PIS) incidence
- On the other hand, radiolucent (Pt-Ir or Tantalum markers), **costly manufacturing**



SOLARIS
(Electrospinning PTFE)



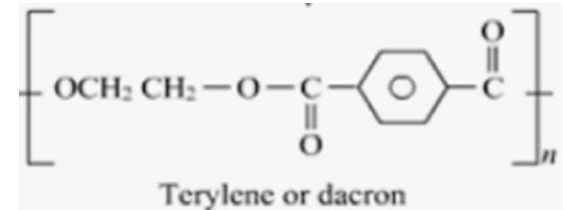
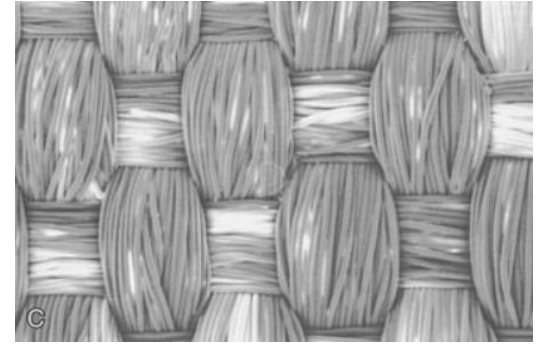
Solaris Covering
Multidirectional Strength



Credits: [Solaris BX](#) > [SCITECH Medical](#)

Polyester Dacron®

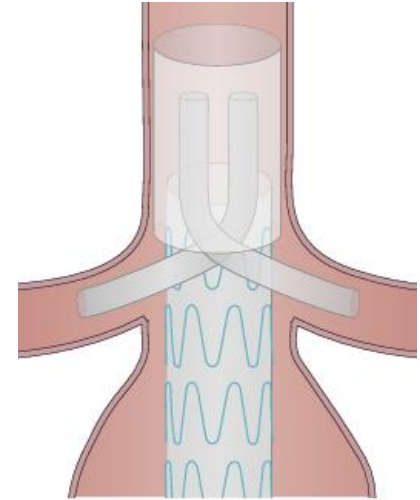
- **Woven PET** is tight, high-burst and tensile strength, lower compliance and porosity, **over-and-under pattern** in the lengthwise and circumferential directions
- **Knitted PET** shows bigger pores, normally impregnated with gelatin, fibers looped in an **interlocking chain** for higher stretchability
- Strong longitudinally, subject to **gradual dilatation** (~20–30 %) over years
- Slightly higher compliance than ePTFE (1.8 % vs 1.2 % per 100 mmHg) but still stiffer than native aorta (5–10 %)
- Requires **pre-clotting or coatings for hemostasis**
- **Cost-effective**, widely available, customizable weaving/knitting patterns



Comparative Analysis of Properties

Property / Material	ePTFE	Dacron©
Mechanical Behavior	microporous node–fibril matrix for high flexibility, low creep, minimal long-term dilatation	woven/knitted textile for a very high burst and tensile strength, but stiffer and prone to gradual enlargement
Hemocompatibility & Surface Interaction	hydrophobic, smooth surface less thrombogenic, no coating needed	requires gelatin/collagen coatings for early hemostasis, more protein adsorption
Tissue Integration & Healing	limited transmural ingrowth unless high porosity (>60 μm); lower infection risk	macroporous structure allows fibrovascular ingrowth and firm fixation, but higher bacterial adherence potential
Manufacturing	More costly manufacturing process, high melting point, needs extrusion and sintering, yields higher porosity to material ratio but smaller voids (20% node-fibril)	Tuneable textile properties according to knitting or weaving configurations, control on mechanical properties

- Low profile (≤ 14 Fr) systems for **safer percutaneous** access and negligible trauma
- Need for **off-label** EVAR due to short neck length, excessive **neck angulation**, tiny access vessel diameter
- **Polymer sealing rings** (ALTO™): adaptive sealing without rigid barbs, improved performance in short/angulated necks
- **Smart coatings**, heparin or carbon surfaces for antithrombogenicity, antibiotic layers for infection control
- Fenestrated (already FDA-cleared), “chimney”, **sandwiched multi-branch off-the-shelf** tailored configurations (IDE, pre-market approval)



Credits: [ALTO - Endologix](#)

[The Ovation Abdominal Stent Graft Creates a Patient-Specific EVAR Seal in a Variety of Anatomies - Endovascular Today](#)

- Global market size valued at €2.3 billion (2018) → projected **CAGR 8.6 % (2019–2026)**
- Aortic repairs: 219 664 (2021) → projected **> 400 000 by 2030**
- Despite improved diagnostics and devices, the **global economic burden** is rising steadily, high post-treatment resource use
- Increasing share of healthcare spending devoted to aortic repair and follow-up
- Growing demand for low-profile, durable, cost-efficient devices, economic load of aortic disease is **outpacing growth**
- Medtronic, Gore, Cook, etc. lead innovation but face price and regulatory pressure.



- Procedure **cost-imbalance**: mean cost: \approx \$31 700 / case, reimbursement: \approx \$27 600 / case \rightarrow \$4 000 loss per EVAR, device cost = $>$ 50 % of total
- Efficient centers (LOS \approx 1.7 days) still face **negative margins**, device pricing bottleneck
- Post-discharge care and **readmission** amplify long-term cost
- EVAR's "less invasive" advantage offsets only acute costs, not **lifecycle costs**.
- Strategies for economic viability include recalibration of **value-based reimbursement**, re-think Diagnosis Related Groups (DRGs)
- Promote patient-specific **pre-operative modeling** to reduce **failure-related** expenses



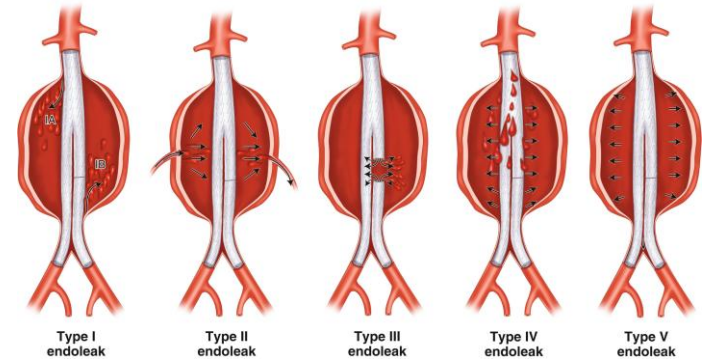
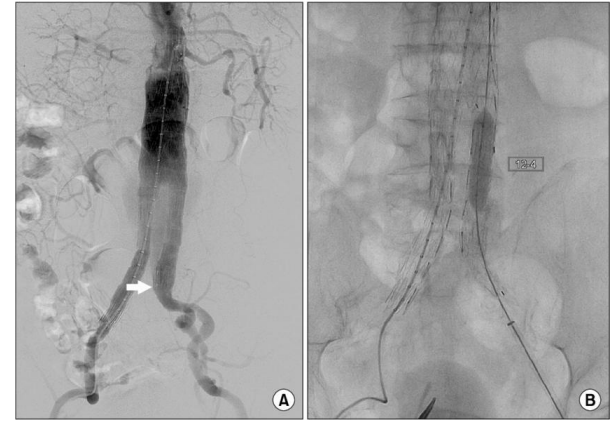
Stone, David H., et al. "The financial implications of endovascular aneurysm repair in the cost containment era." *Journal of vascular surgery* 59.2 (2014)

- EVAR provides **lower peri-operative mortality** and **reduces LOS compared to OSR**
- EVAR shows lower 30-day mortality (1–2 %) vs 4–6 % for open surgical repair (OSR), hospital stay: **EVAR ~1–2 days**, OSR ~7–10 days.
- On the other hand, **re-interventions**: required in up to 20–25 % of EVAR cases, compared with <10 % after OSR
- **Long-term equivalence at 4–5 years**, total mortality and aneurysm-related death rates converge between EVAR and OSR
- Despite clinical maturity, EVAR **remains cost-intensive** due to implant price and reintervention burden
- Sustained cost-effectiveness requires **enhanced durability** and simplified follow-up strategies, main R&D areas

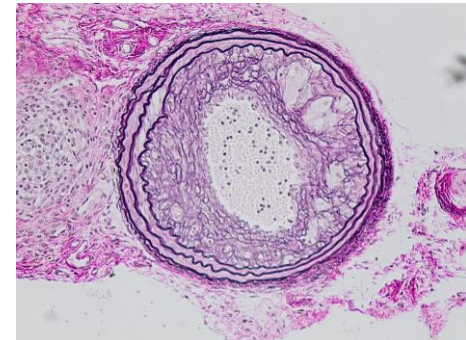


EPFL Device-Associated Complications

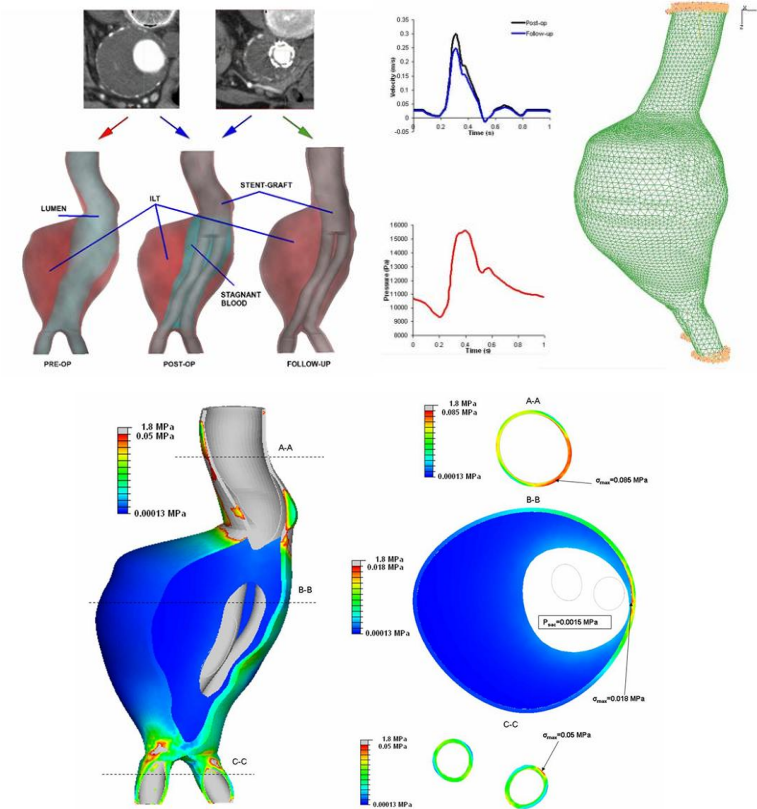
- Endoleak *Type I*: inadequate **proximal/distal seal** or poor apposition in short/angulated necks
- Endoleak *Type II*: **retrograde collateral flow** from lumbar or mesenteric arteries
- Endoleak *Type III*: **leaks through fabric** tears or modular disconnections
- Fixation loss and **migration** from sealing site
- **Fatigue** induced failure upon **stress accumulation**
- **Kinking and partial occlusion**, risk of **pro-thrombotic** conditions, possible in tortuous anatomies
- Counteract optimizing friction on walls, gripping, radial pressure, using conforming polymers
- **Sac re-pressurization** can alter graft positioning



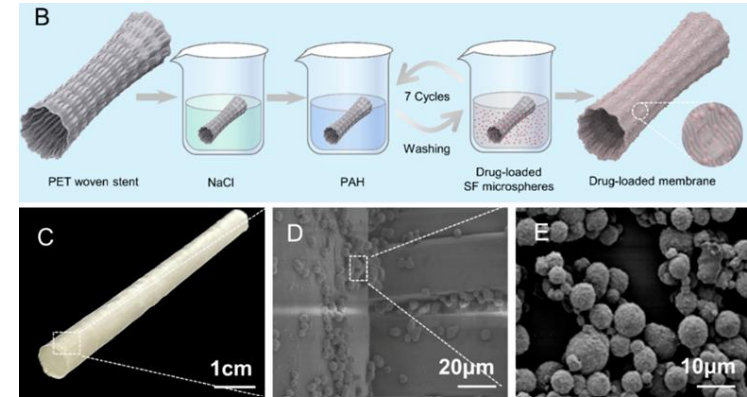
- Graft implantation triggers a **foreign-body reaction** response (FBR) involving coagulation, inflammation and fibrous capsule formation
- Endothelial migration from **anastomotic zones** is inefficient, limited re-endothelialization of mid-graft segments
- **Graft infection incidence: 1–6 %**, often due to bacterial biofilm protecting microbes from immune attack
- Mechanical-biological compliance gap with native artery, observed driver of **PWV elevation, stiffening and surge in cardiac afterload**
- Can lead to **intimal hyperplasia** and pseudoaneurysm formation at anastomoses, key barriers to long-term biocompatibility and healing
- Albumin coating grants lower platelet adhesion and improved **thromboresistance**



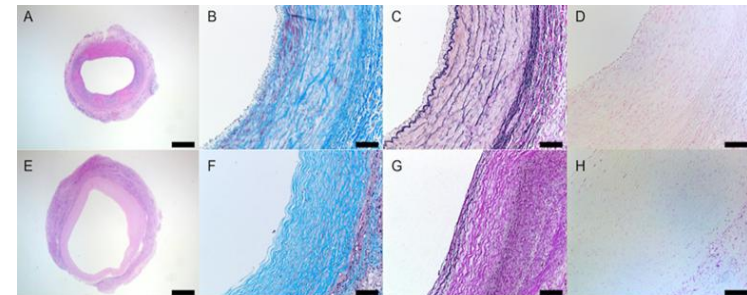
- Design shift towards compliant, hybrid polymers pleated fabric to reproduce **native arterial elasticity**
- **Enhanced biofunctional coatings** (heparin, albumin) to mitigate thrombosis, inflammation and infection risks
- **Adaptive sealing system** (polymer cuffs, etc.), without excessive radial pressure
- **CFD-FSI coupling** and finite element analysis simulations to **run pre-operative planning**
- **Patient specific virtual EVAR** yields tailored predictions of deployment dynamics, sealing efficacy, flow, wall stress and possible failure modalities
- Integration of validated and trustworthy **in silico clinical trial frameworks** to accelerate **regulatory approval** of new devices and to enhance personalised surgery



- Emerging concept of **bio-integrative scaffold**, active in tissue regeneration, allow cell infiltration and expansion
- Exploration of **biodegradable polymer** or decellularized ECM, seeded with autologous cells
- Functionalized coatings to stimulate **endothelial proliferation** and angiogenesis
- Achieve controlled degradation synchronized with **tissue ingrowth and remodeling**
- Preventing early thrombosis while allowing progressive **neo-endothelialization**, integration with host tissue
- Though, most regenerative endograft technologies remain in **preclinical or early translational stages**, with promising results in small animal models
- Barrier of long-term patency, **immune rejection**, scalable manufacturing for clinical adoption

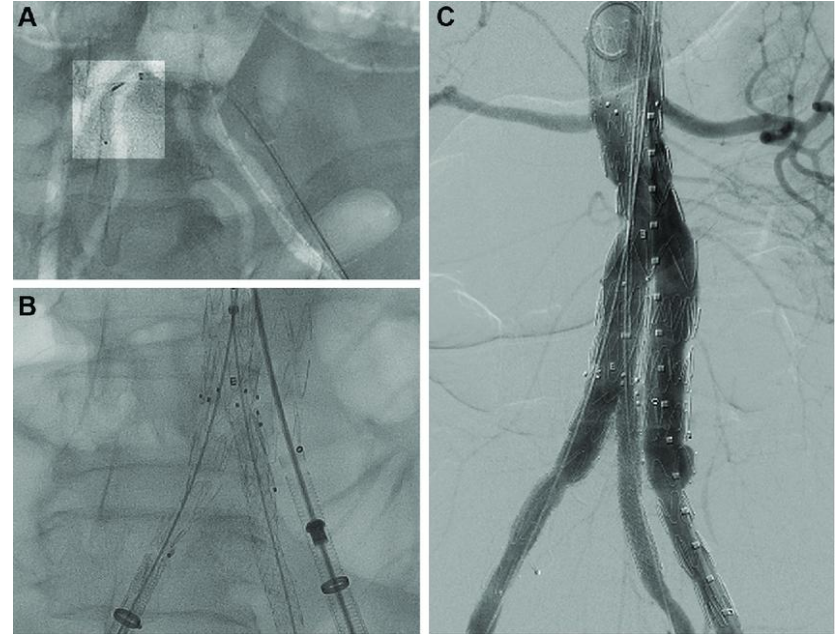


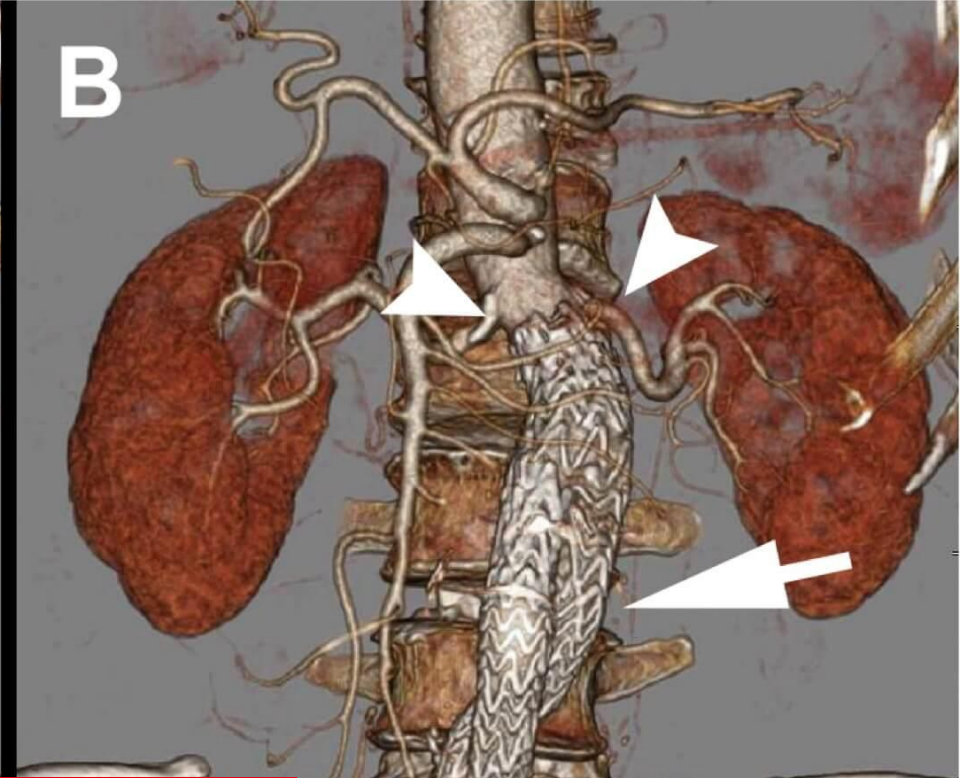
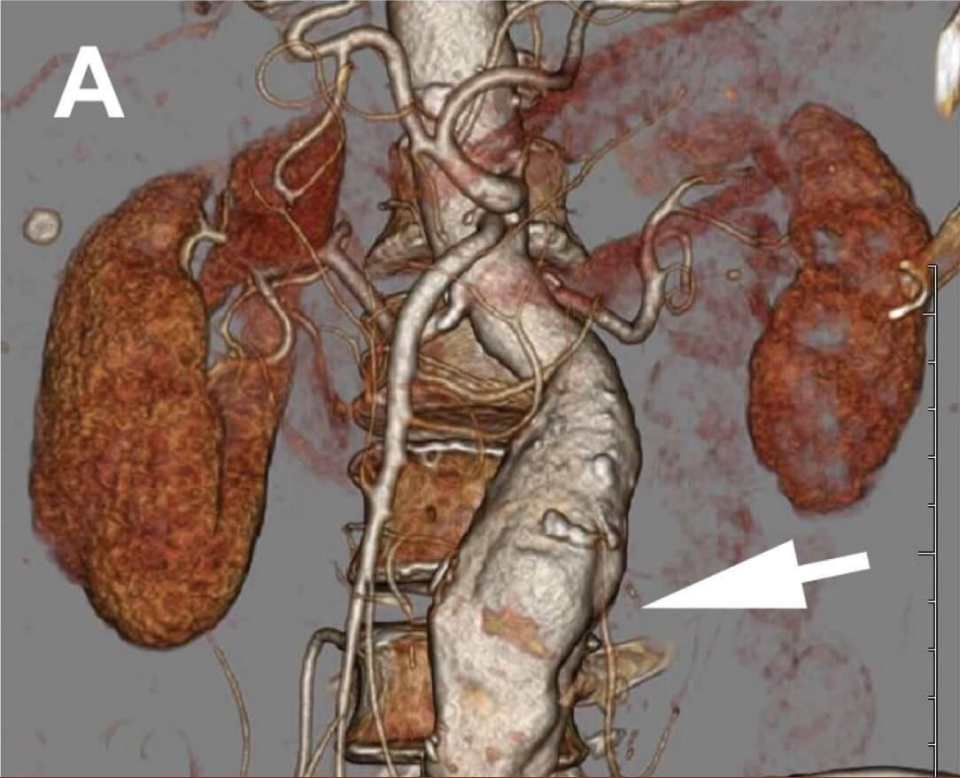
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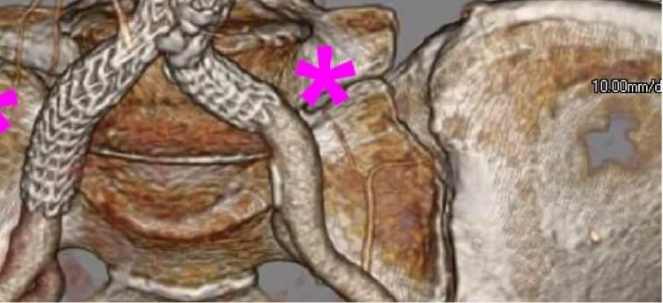
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- EVAR revolutionized AAA management introducing a **minimally invasive transcatheter** surgical approach
- Engineering progress has centered on **materials** (ePTFE, polyester), **flexibility, and miniaturized delivery systems**
- Key limitations, such as endoleaks, fatigue, compliance mismatch, and high device cost persist
- EVAR embodies the convergence of **biomechanics, materials science, and digital medicine**, the pathway from durable to living vascular implants





**Thanks for the attention!
Questions?**



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