Personalised External Aortic Root Support Project (PEARS)

PEARS: Engineering in Cardiac Surgery

Scientific and Technological Advances
in Cardiac and Vascular Surgery,
Ettore Majorana, Erice, Sicily, April/May, 2015

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&
Prof. John Pepper MA MChir FRCS

Personalised External Aortic Root Support Project (PEARS)

PROJECT TEAM - Technical

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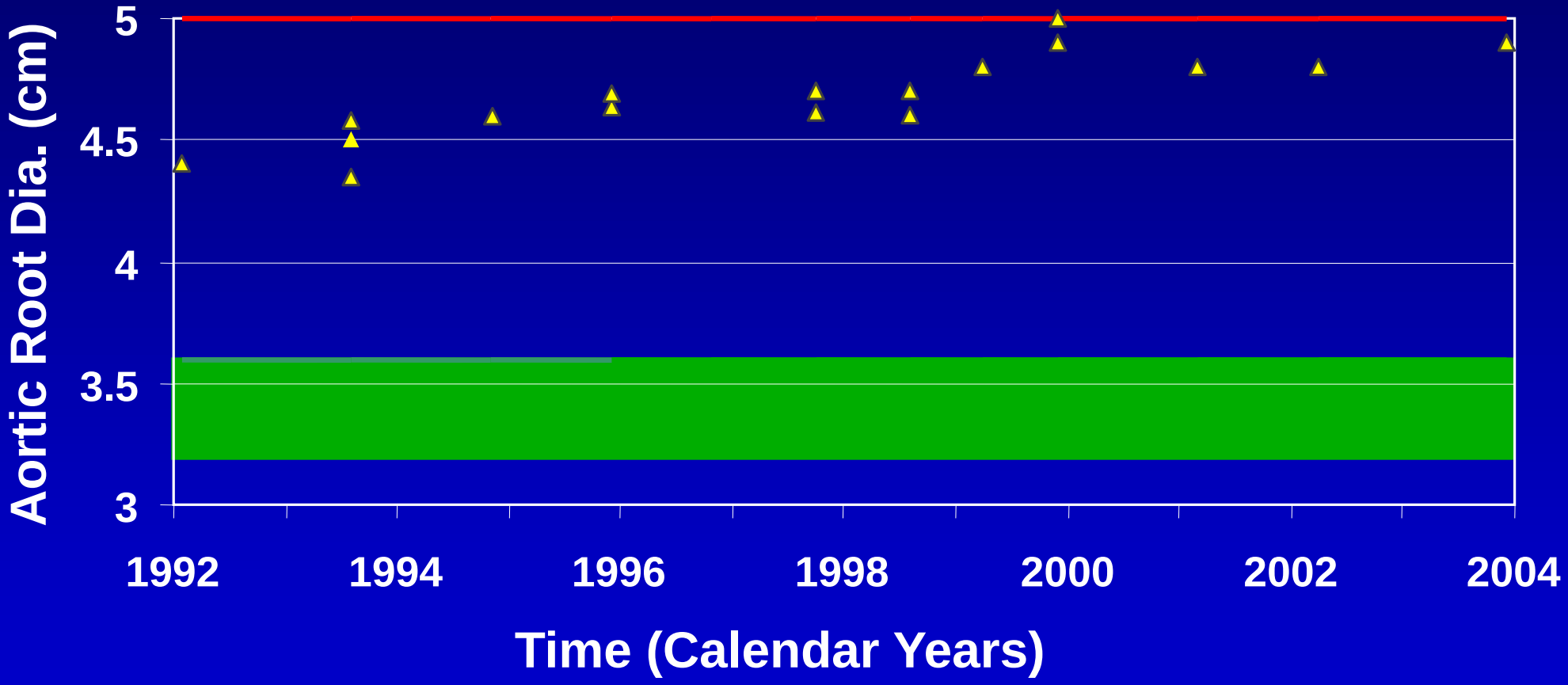
What is an APC engineer doing in surgery?



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CULTURE?

TG: "You know what the problem with you surgeons is?"

TT: "What's that?"

TG: "You are facing engineering problems but you're *NOT* engineers"

TT: "Yes, you're right……"

Bob Anderson's lab, Gt Ormond St, summer 2000

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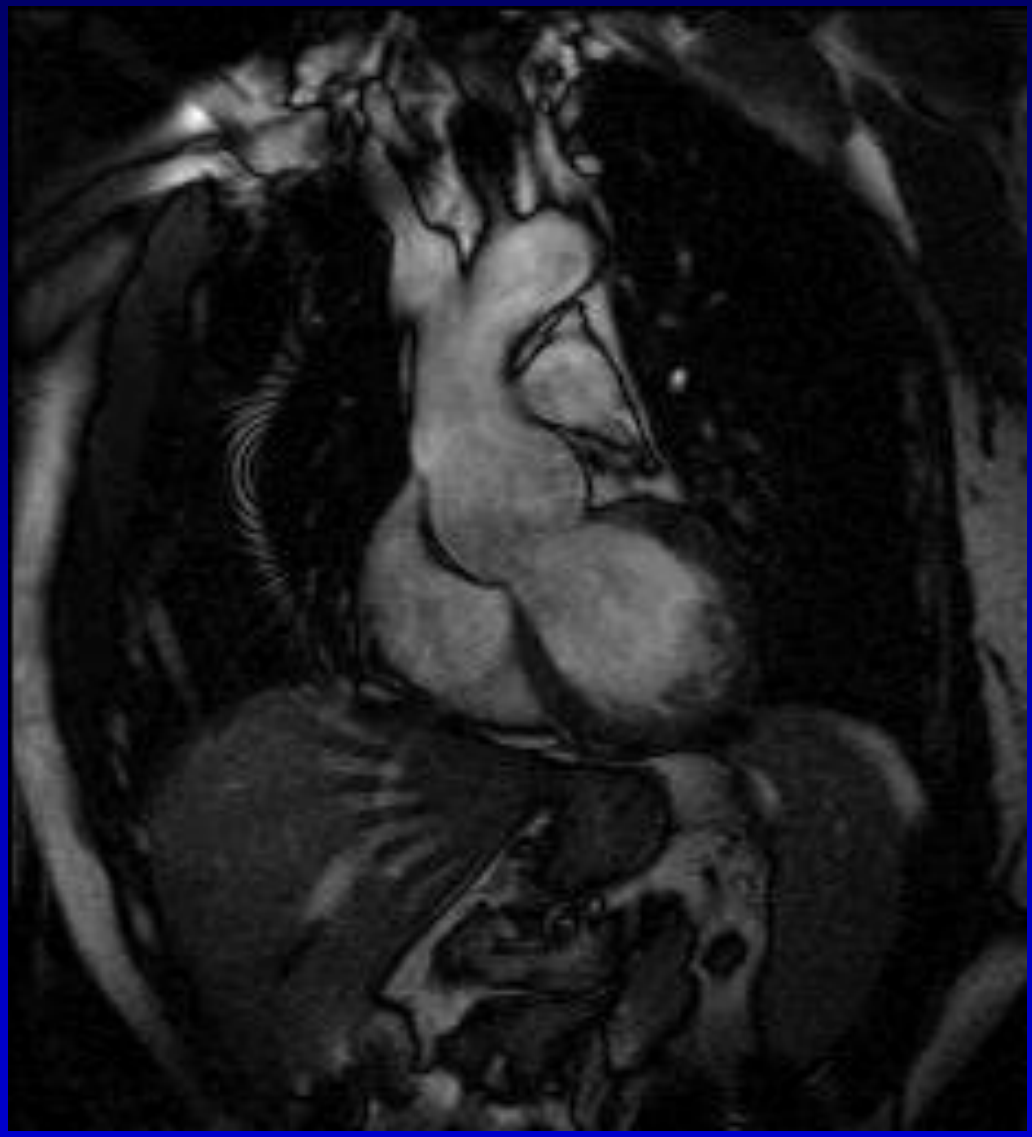

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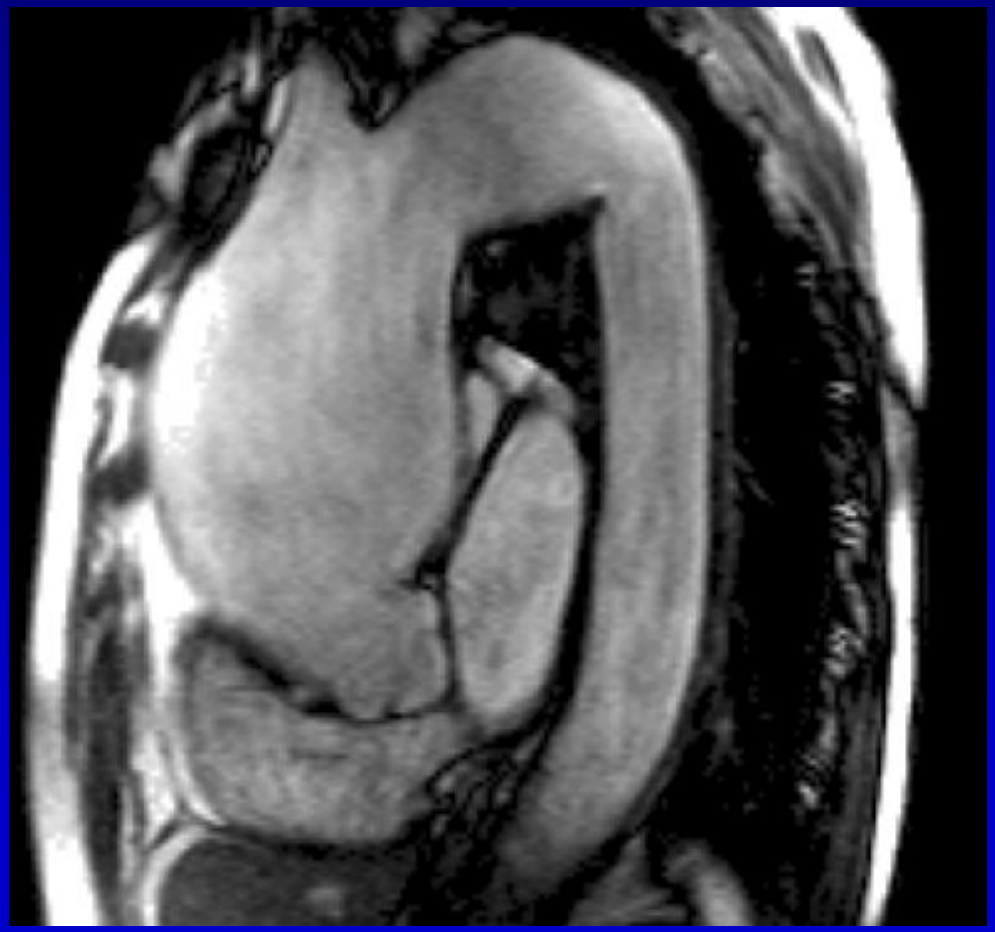
Dilation of the Ascending Aorta – valve malfunction / dissection / rupture



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Management of aortic wall stress

$$\text{Tensile load}_{(wall)} = \frac{P \times D}{2t}$$

Where:

P = Internal hydraulic Pressure

D = Diameter of tube

t = tube wall thickness

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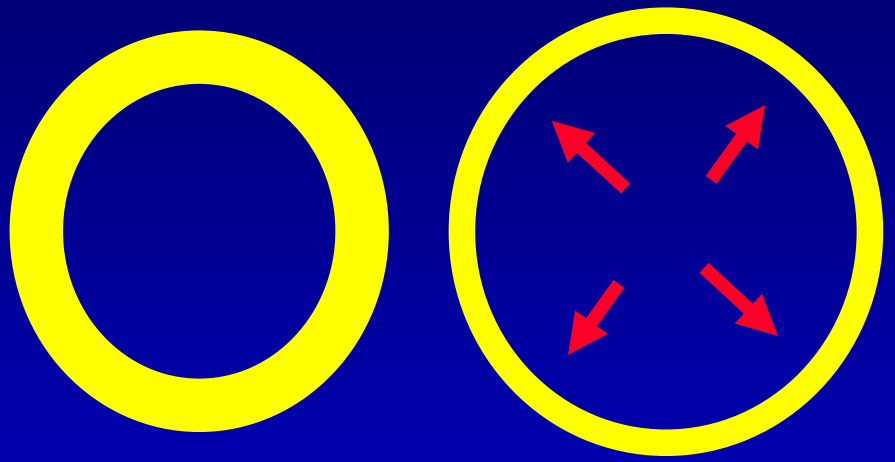
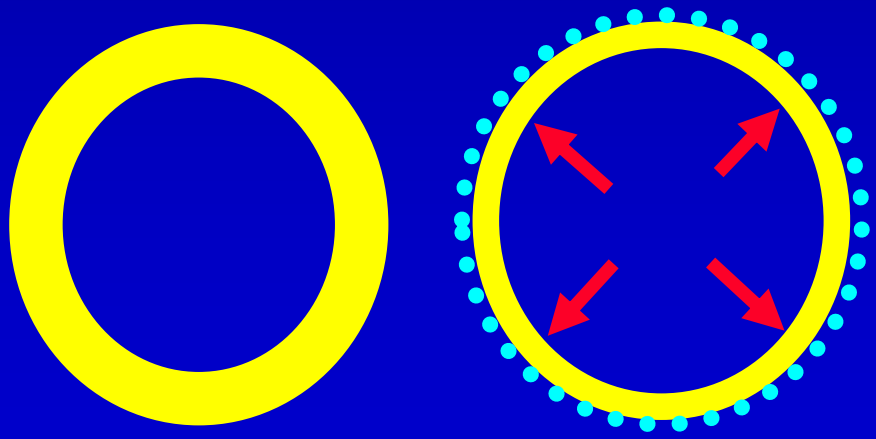
Management of aortic wall stress

Unsupported:- Tensile load (wall stretching and thinning)



Supported:- Compressive load (wall compressing and notionally thinning)



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PROJECT AIM

To prove the feasibility of an engineered, bespoke external support sheath for the ascending aorta retaining all of the patient's native tissues thus avoiding the need for prosthetic components in contact with the blood and anti-coagulation therapy.

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STEP 1: Functional Specification

1. ***What MUST the "external stent" do?***
2. ***What must the "external stent" NOT do?***
3. ***What will the impact of the stent be on the aortic/pericardial environment?***
4. ***What will the impact of the aortic/pericardial environment be on the stent?***

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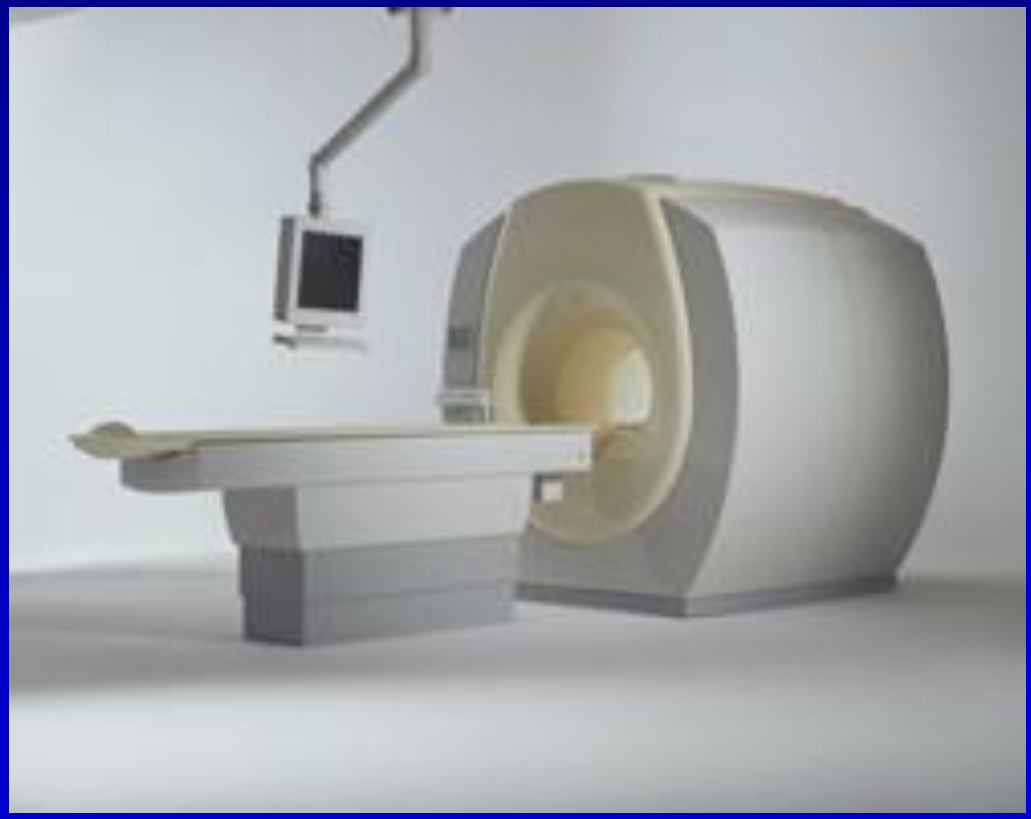
STEP 2: Imaging the Ascending Aorta

CT scanner – gated to 65% R-R (Ventricular diastole) – contrast agent enhanced – LVOT to top of arch.



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Pre-Operative MRI section through Ascending Aortic

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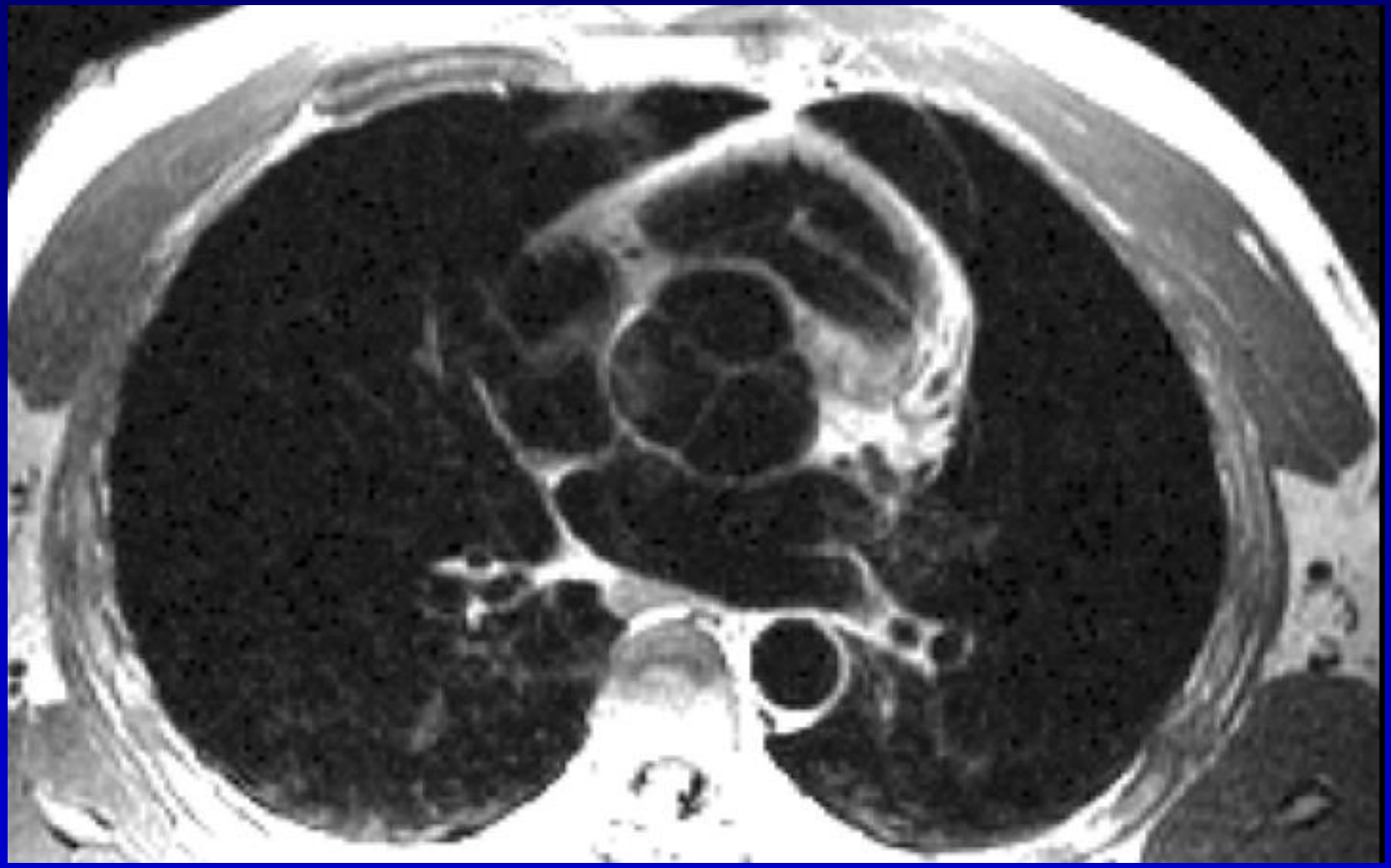
Pre-Operative MRI section through Aortic Valve



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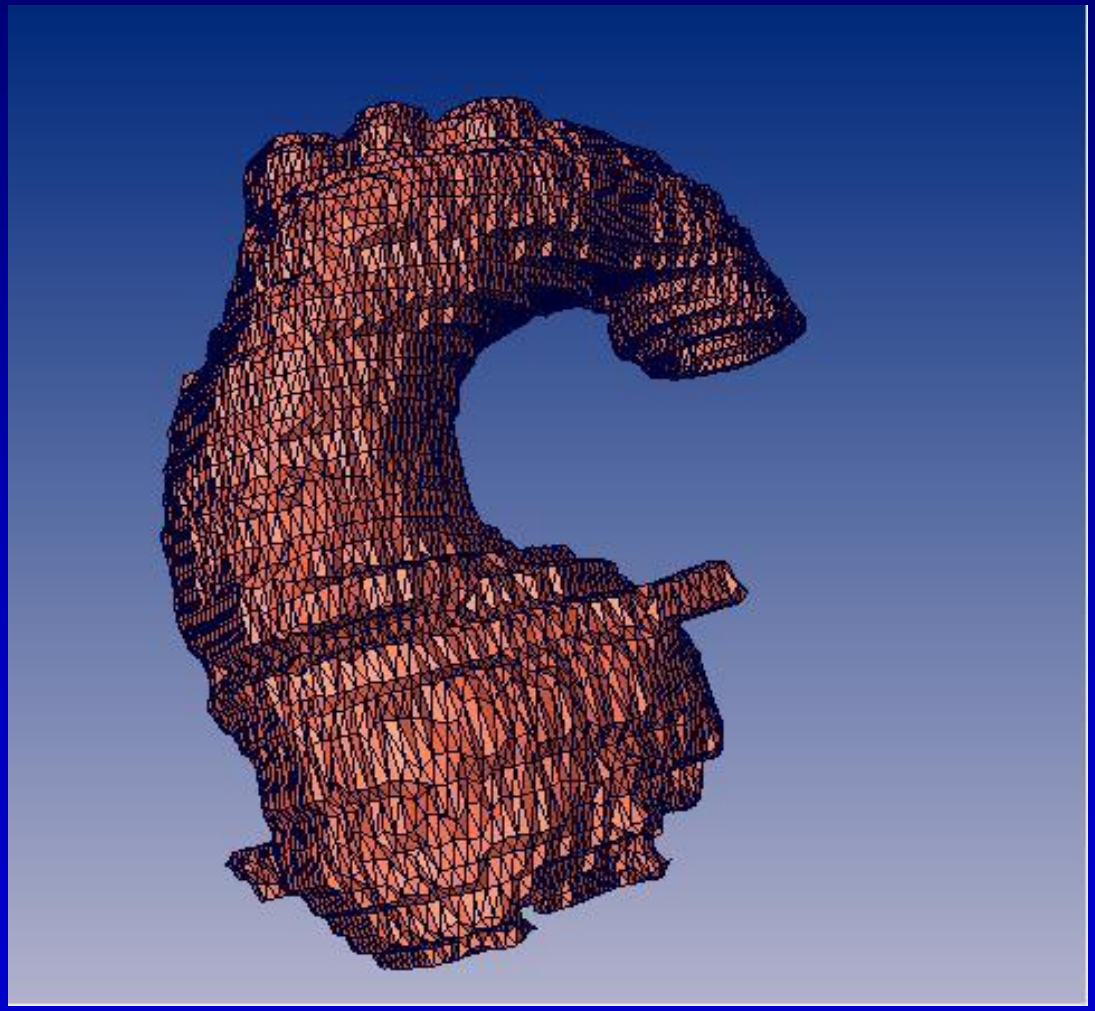
STEP 3: Creating a 3D computer model



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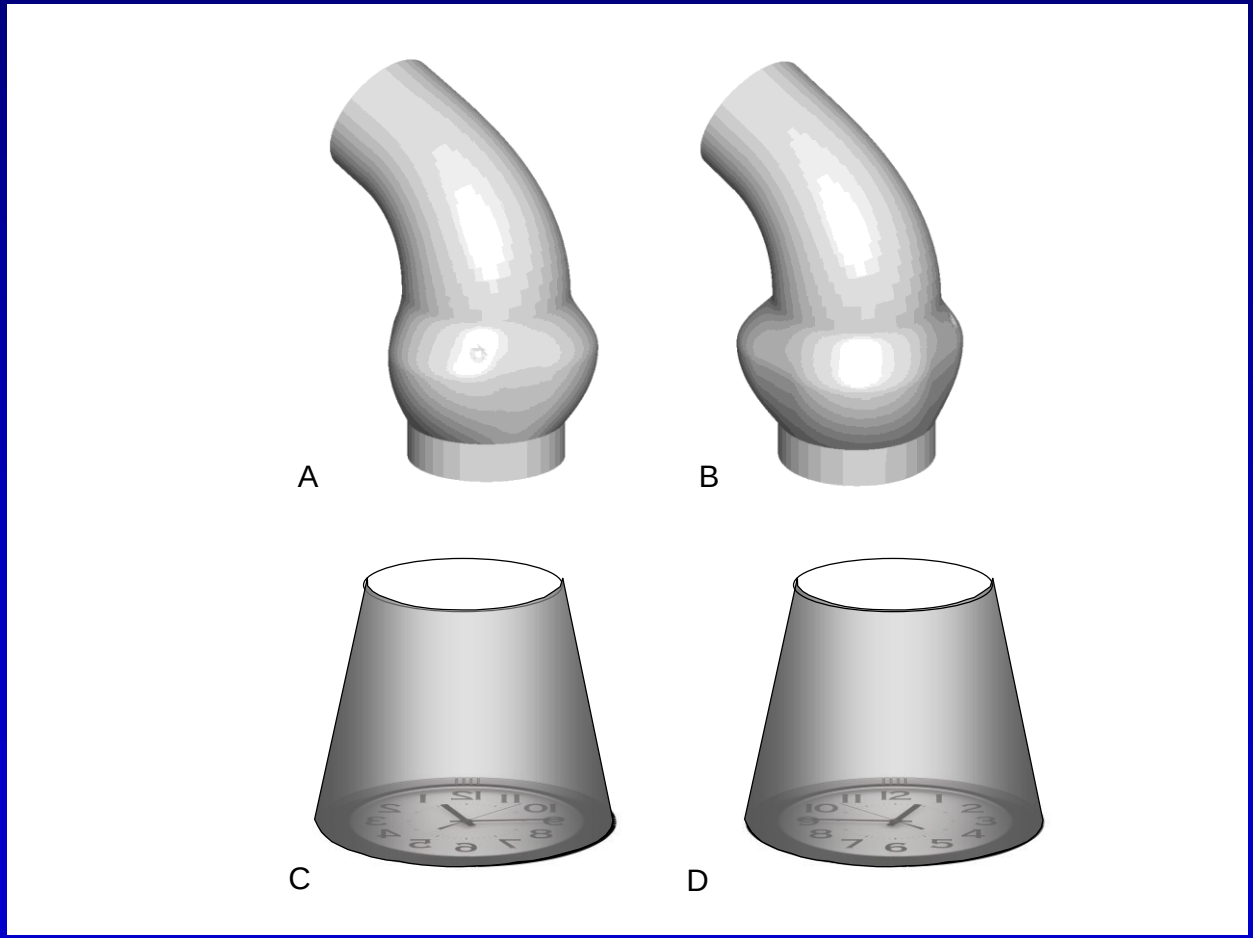
Viewing transaxial images: bottom up or top down?



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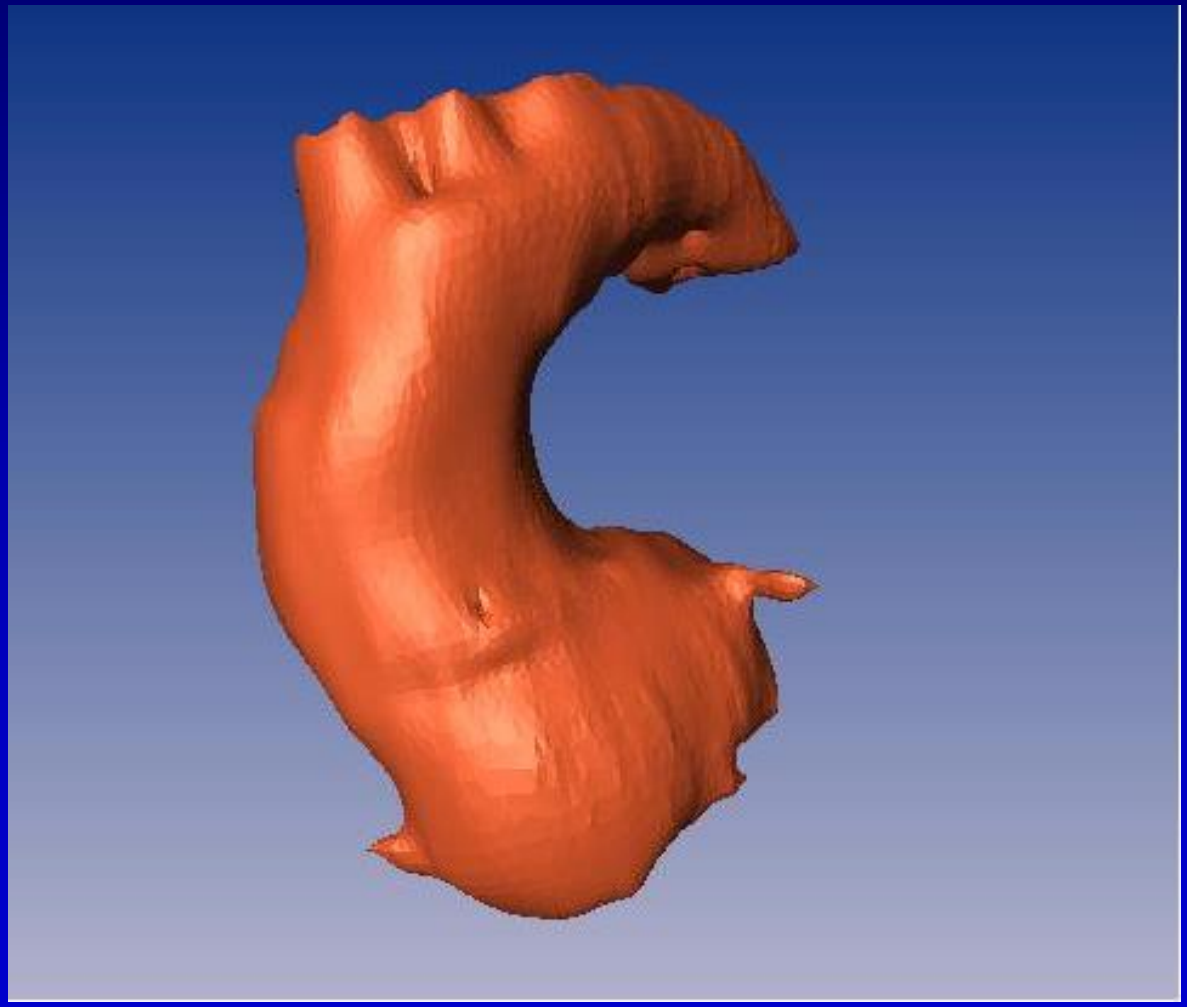

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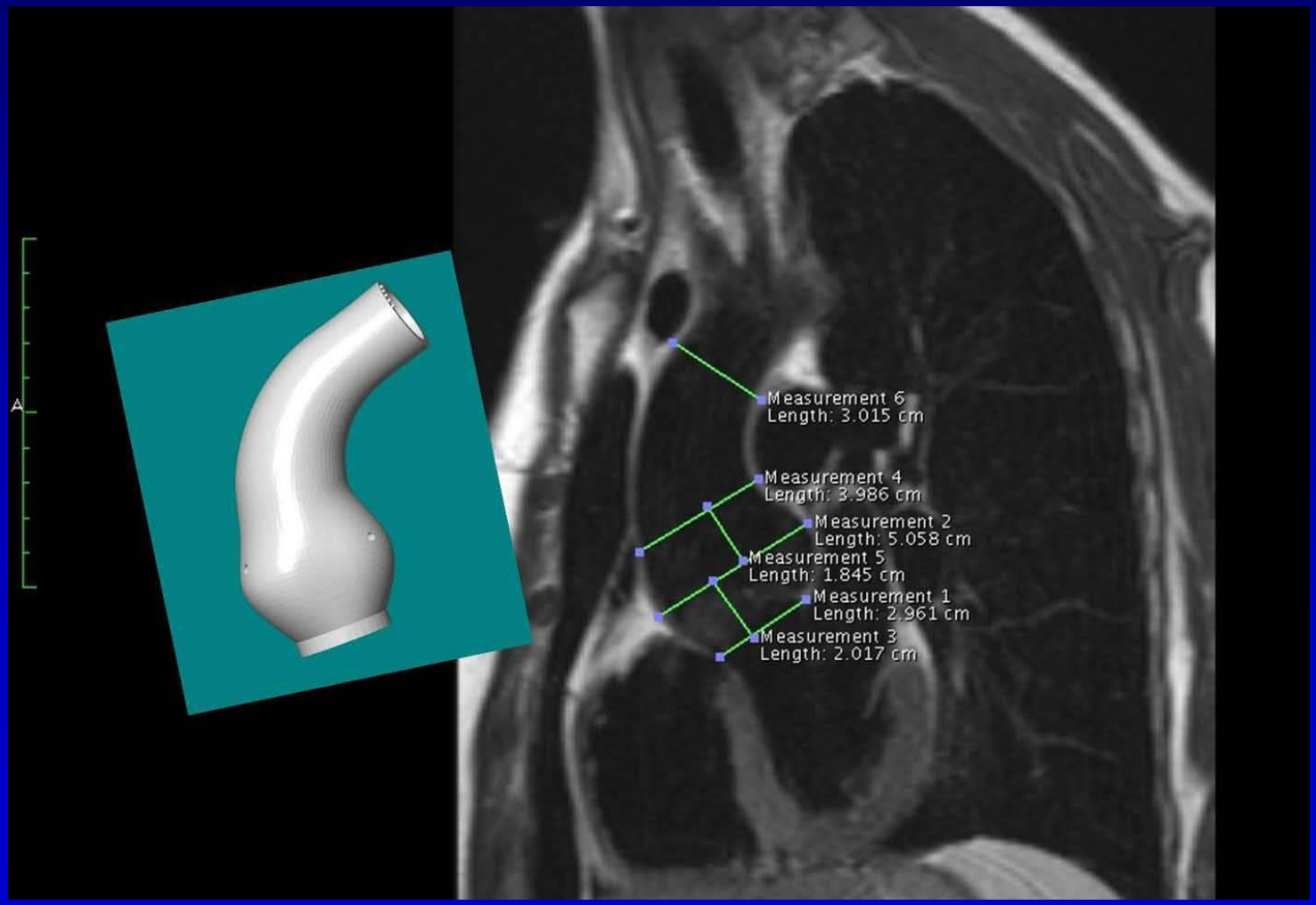

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STEP 4: Manufacturing a former

Rapid Prototyping – Selective Laser Sintering

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STEP 5: Manufacturing an Exovasc

Textile mesh shaped on former – cleaned, sterilised and packed

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Textile Technology

Implant type	T/VS RR	PEARS
Polymer type	**PET**	**PET**
Yarn (mono/multi filament)	Multi fil	Multi fil
Textile type	**Woven**	**Knitted**
Textile stiffness	High	Low
Textile porosity	V.Low	High
Textile edges	hard/sharp	soft/pliant
Textile incorporation	Partial	Total

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STEP 6: Surgical implantation

Beating heart: no circulatory break-in, optional CPB

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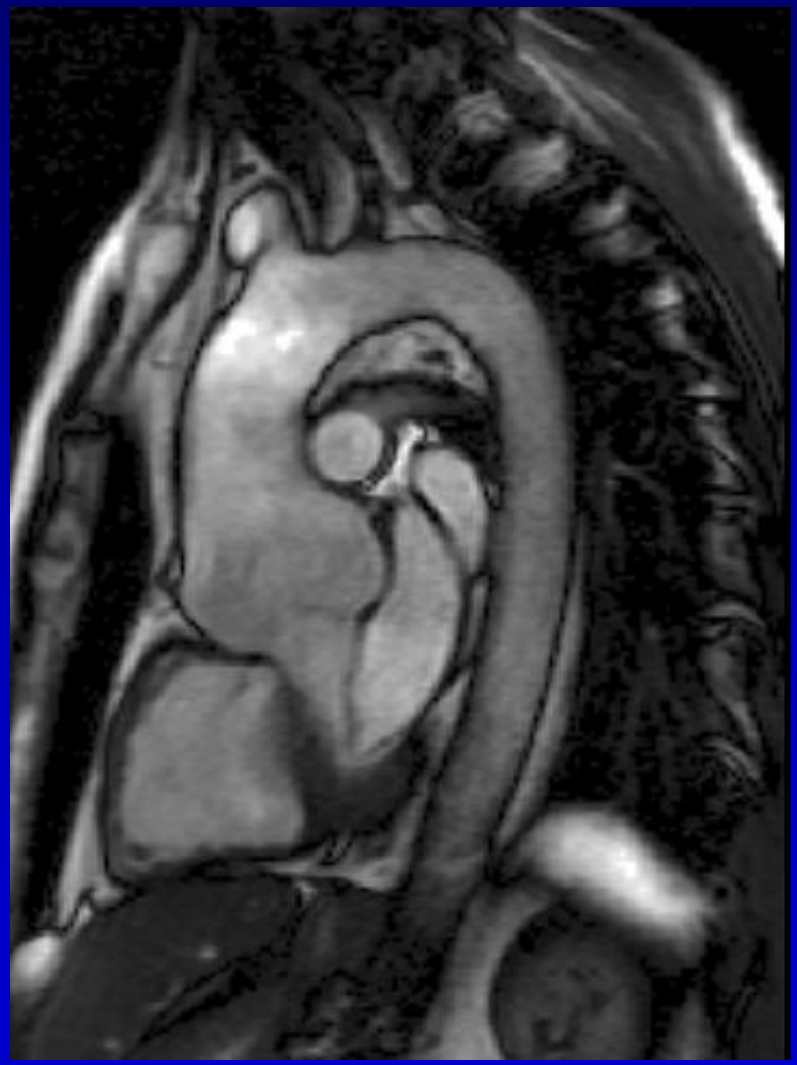
Pre – Op Apr 04



Post – Op Sep 04

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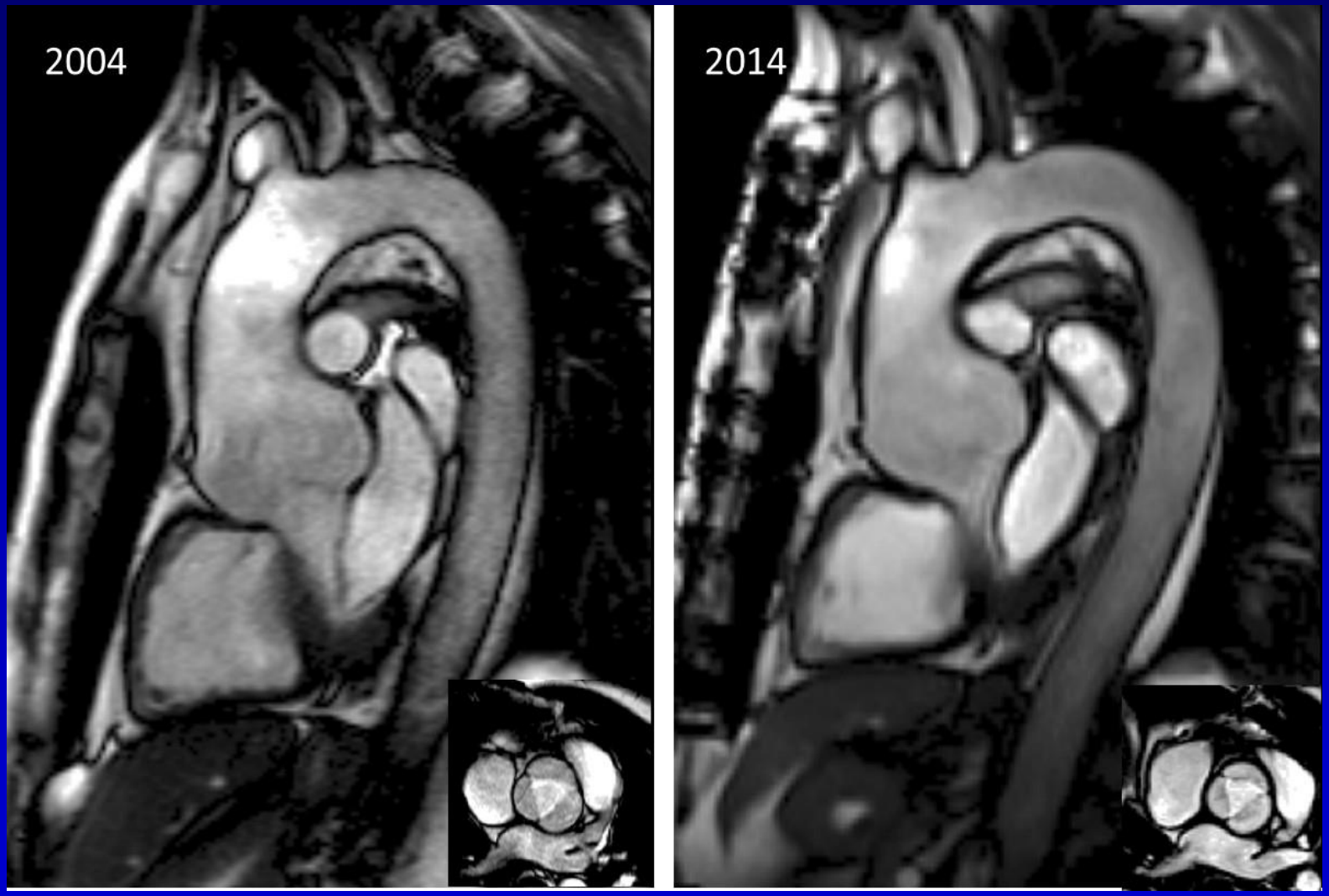
Sep 2004 **Oct 2014**



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Implant Incorporation and neo-vascularisation

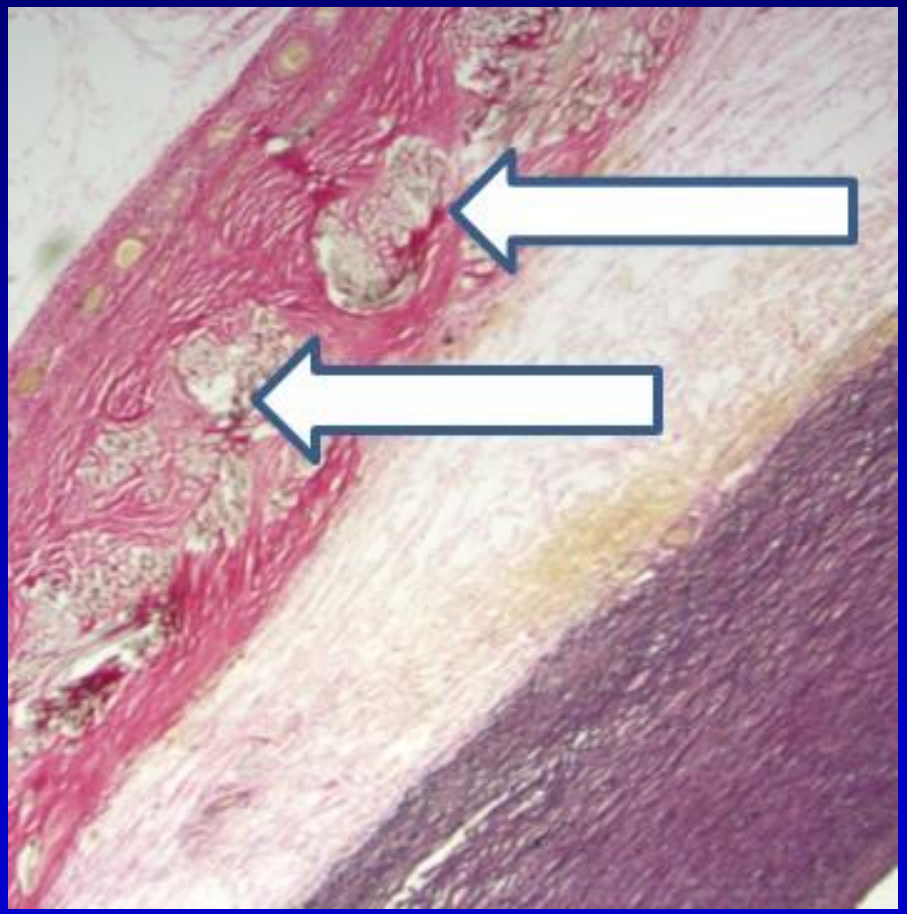

Image courtesy of Martin Goddard et al, Papworth Hospital

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Removal of repetitive tensile loading: Medial repair

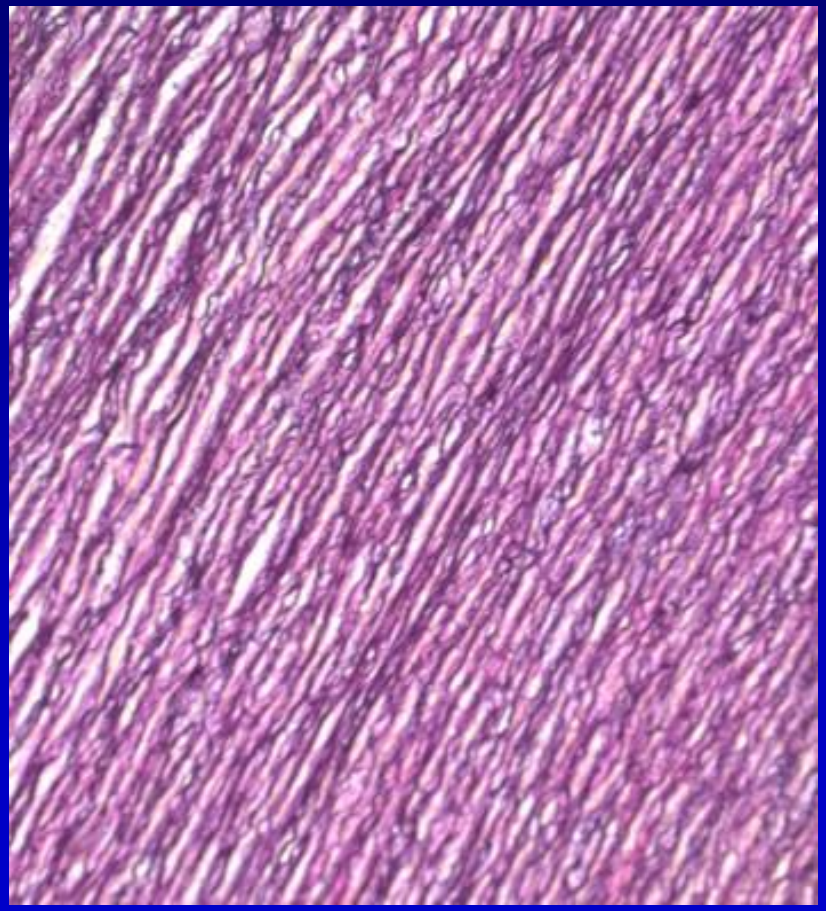

Image courtesy of Martin Goddard et al, Papworth Hospital

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Aortic surgical options

	TRR	VSRR	PEARS
Operation time (hours)	4 – 6.5	4.5 - 7	2 – 3
Heart/Lung bypass (h)	2 – 3	2.5 – 4.5	n.r.u.
Total body cooling	Yes	Yes	No
Circulatory break-in	Yes	Yes	No
Anti-coagulation	Yes	No	No
Re-operation (%/yr)	0.3	1.3	?
Fallback	redo	redo/TRR	VSRR/TRR

A patient's charter?

Every patient is entitled, should he or she wish, to:

1. A clear definition / explanation of what is wrong and the risks associated with this disease / condition (if left untreated) including likely quality of life and life expectancy.
2. A clear, unbiased explanation of ALL the available surgical interventions including the immediate AND long-term risks and benefits.
3. An open and candid discussion with all facts, opinions and conflicts of interests identified and declared.
4. An appropriate interval for reflection and decision on which surgical option to adopt.

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Patient demographic: May 2015

- **54 patients treated (32 M + 22 F)**
- **A cumulative total of 224 post–operative patient years**
- **P1 @ 11 years, 20 patients @ >5 years post-op**
  - **11 x patients treated in their teens**
  - **14 x patients treated in their 20s**
  - **13 x patients treated in their 30s**
  - **12 x patients treated in their 40s**
  - **4 x patients treated in their 50s**

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Surgical

A method for installing the exovasc has been developed:

- **54 patients have been treated**
- **1 patient suffered a left main stem injury during surgery that led to a cranial bleed from which he did not recover**
- **3 patients had peri-operative problems. 2 fully resolved in hospital, 1 substantially resolved**
- **Operating time has been demonstrated at ~ 2 hours**
- **Routine CardioPulmonary Bypass has been demonstrated as unnecessary during the implantation procedure**

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Exovasc: Applications

- **Aortic dilation associated with:**
  - **Marfan Syndrome / Loeys-Dietz Syndrome**
  - **Bicuspid aortic valve disease**
  - **Transposition of the Great Arteries (Arterial Switch Op)**
  - **Tetralogy of Fallot**
- **Recovery of dilation induced Aortic Regurgitation?**
- **Aortic support in long-term LVAD use?**
- **Pulmonary autograft support in the Ross Operation?**

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Acknowledgements

Engineers: Warren Thornton, Peter Gibson

Medical imagers: Raad Mohiaddin, Mike Rubens et al

Surgeons: Tom Treasure, John Pepper, Mario Petrou, Filip Rega, Ulrich Rosendahl, Conal Austin & David Anderson

And various others whose contributions were greater or lesser……..

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Further information at:

www.exstent.com