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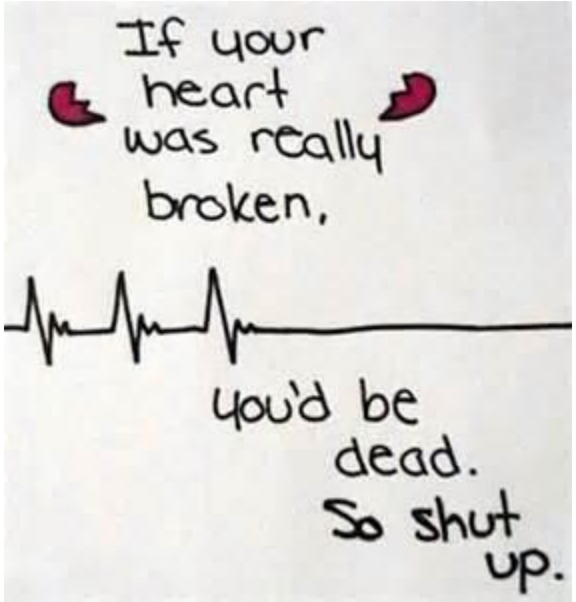
ROOM NAME:

BIOM1010HEARTS

“MENDING BROKEN HEARTS”

BIOM1010 – BIONIC HEARTS – S2 2018



Dr Michael Stevens
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Learning outcomes for today

- Demonstrate the basic operating principles of ventricular assist devices (VADs) and total artificial hearts (TAHs).
- Describe the differences between first, second and third generation VADs.
- Identify which type of ventricular assist device is being used in a clinical situation.
- Describe the limitations of currently used ventricular assist devices.
- Identify which situation you would use a TAH instead of a VAD.

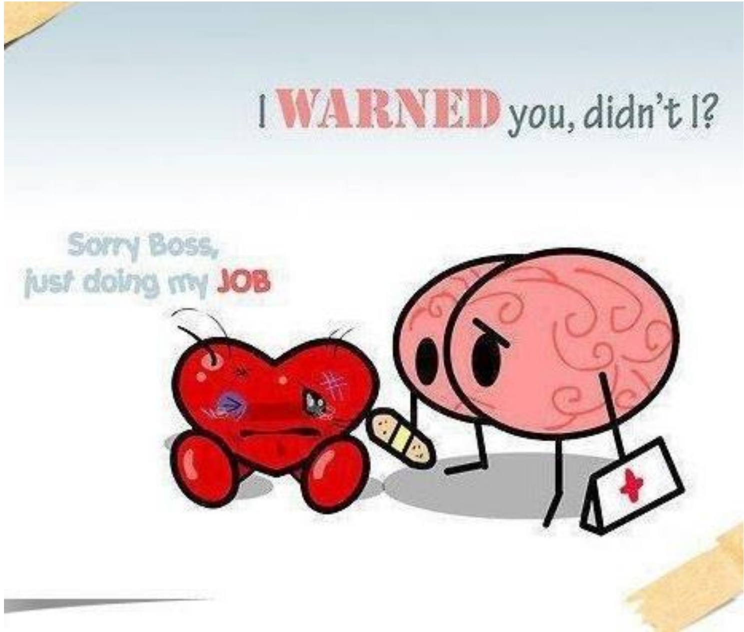
Contents

Part 1 – Cardiovascular Physiology

- What is it?
- What happen when your heart breaks?
- Some treatments
- **NOT EXAMINABLE**

Part 2 – Mechanical Therapy

- Ventricular Assist Devices
- Total Artificial Hearts
- **EXAMINABLE**



NOTE: This lecture contains some graphic content (open heart surgery, animal surgery etc).

But first, about me

Education

- BEng (Medical Engineering) QUT 2010
- PhD Biomedical Engineering UQ 2014
- UNSW Graduate School of Biomedical Engineering (GSBmE) 2015 – present.

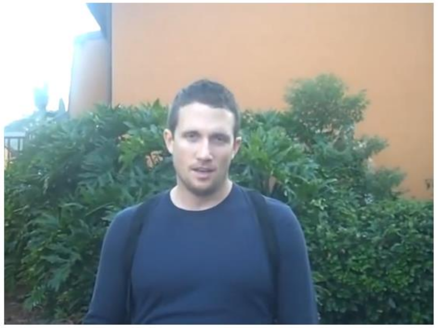
Work

- Innovative Cardiovascular Engineering Technology (ICET) Laboratory, Brisbane – Researcher.
- BiVACOR (Artificial Heart Startup) - consultant

Take-away message from those pre-lecture videos?

My LVAD "Gus"
19,858 views

The Fitness Model Without a Pulse
5,626,832 views



Life with a LVAD

- Very specific issues with each of them – I'll talk about later in lecture
- Young people (< 30 years old)
- Pre-heart failure: active, outdoorsy, sport-loving
- Heart failure was sudden
- Kept alive long enough to receive a transplant (all 3 have now had a HTx)
- Also had a high quality of life with their device
- Engineering is very interesting – but never forget the patients!

Part 1 – Cardiovascular Physiology**

Ask yourself: "What anatomy and functions will a bionic heart have to replace?"

What is the purpose of the Cardiovascular System?

Transportation

- brings oxygen to body cells and takes away carbon dioxide (a waste product)
- carries nutrients from the gastrointestinal tract (gut) to body cells
- carries hormones from endocrine glands to body cells

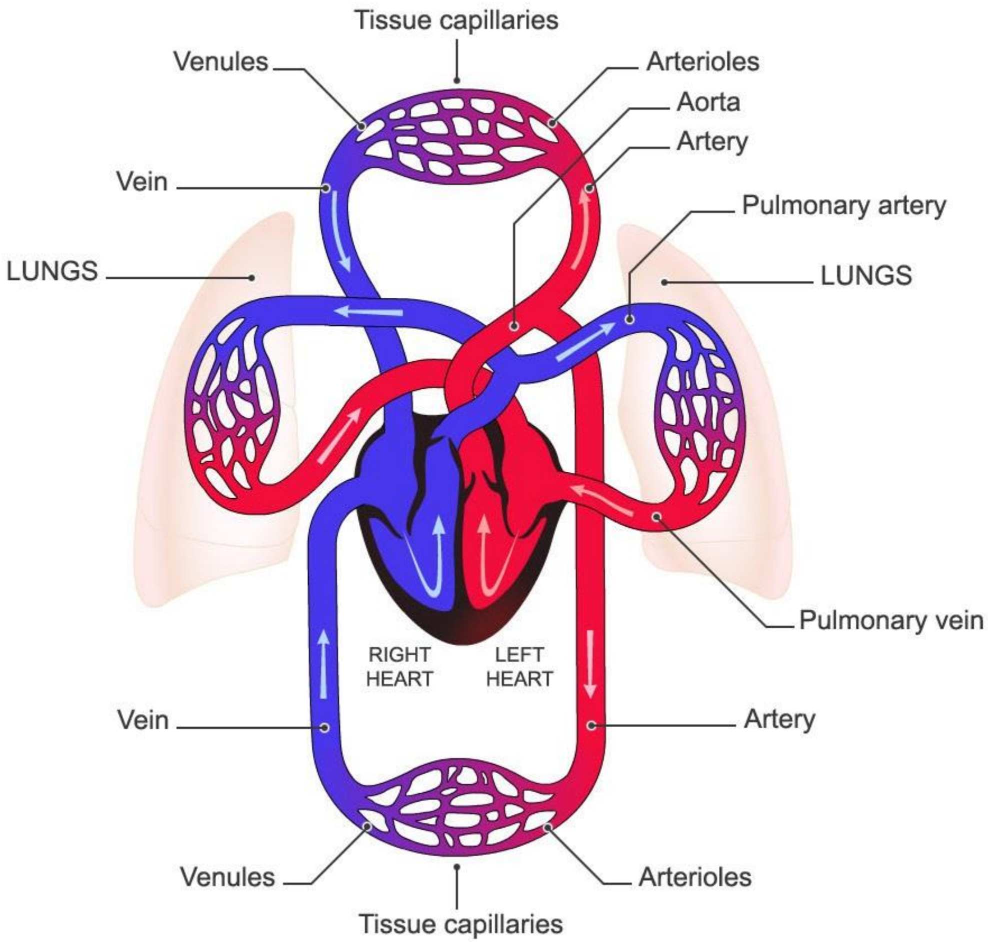
Regulation

- helps regulate the pH of body fluid
- helps regulate body temperature
- regulates water content of cells

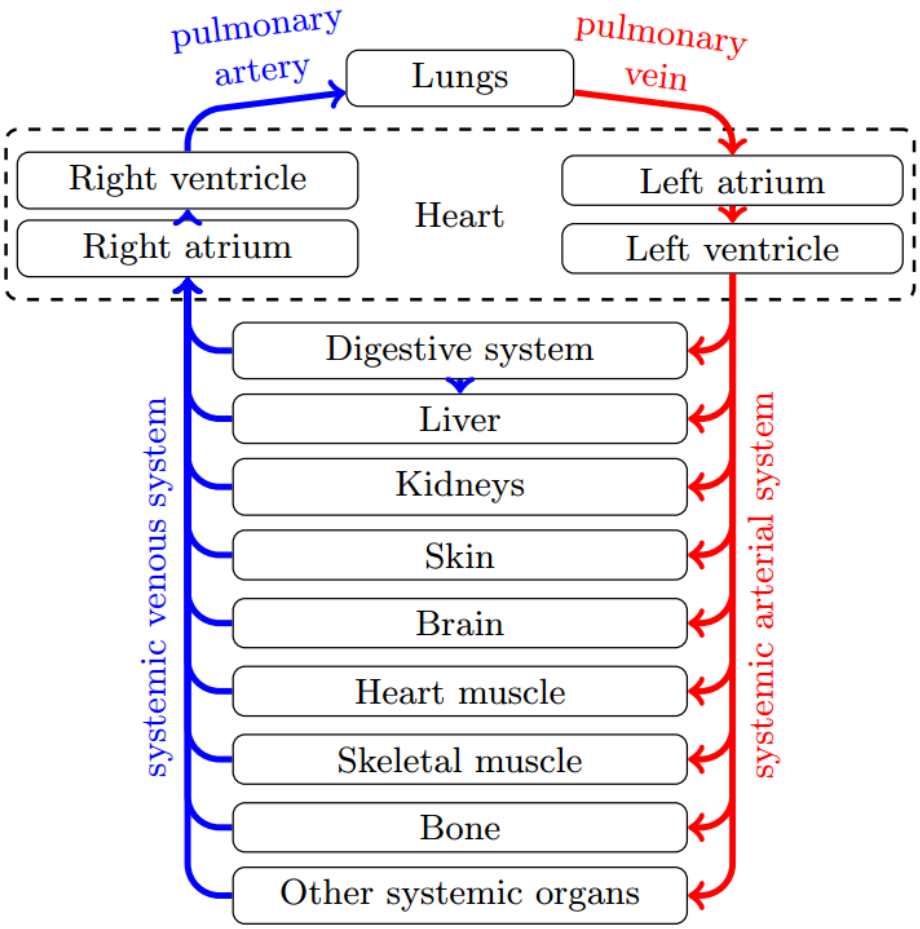
Protection

- carries white blood cells, antibodies, and interferons that protect against disease

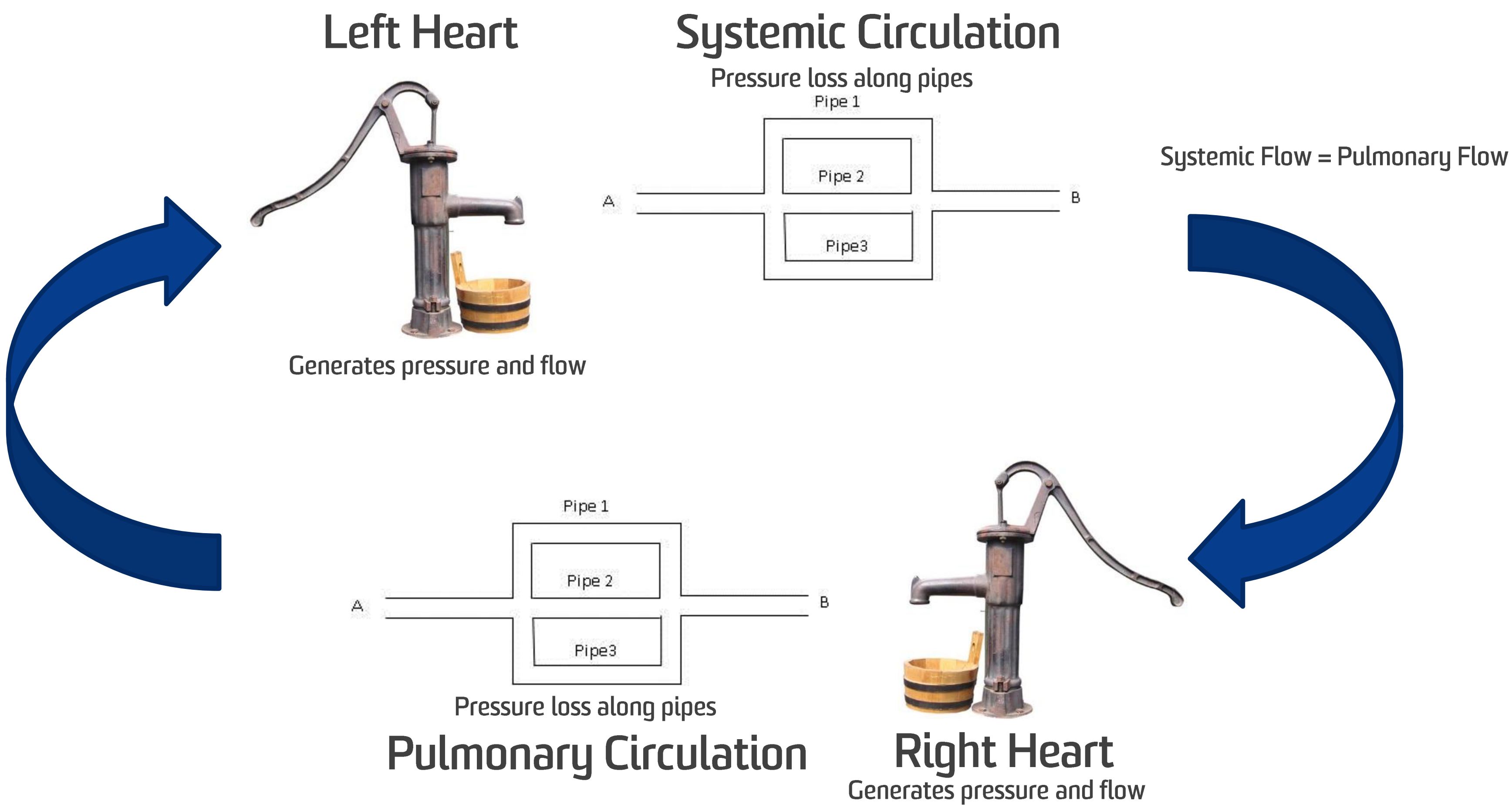
The Circulation



The Circulation



The Circulation – Simplified Plumbing Equivalent



The Heart

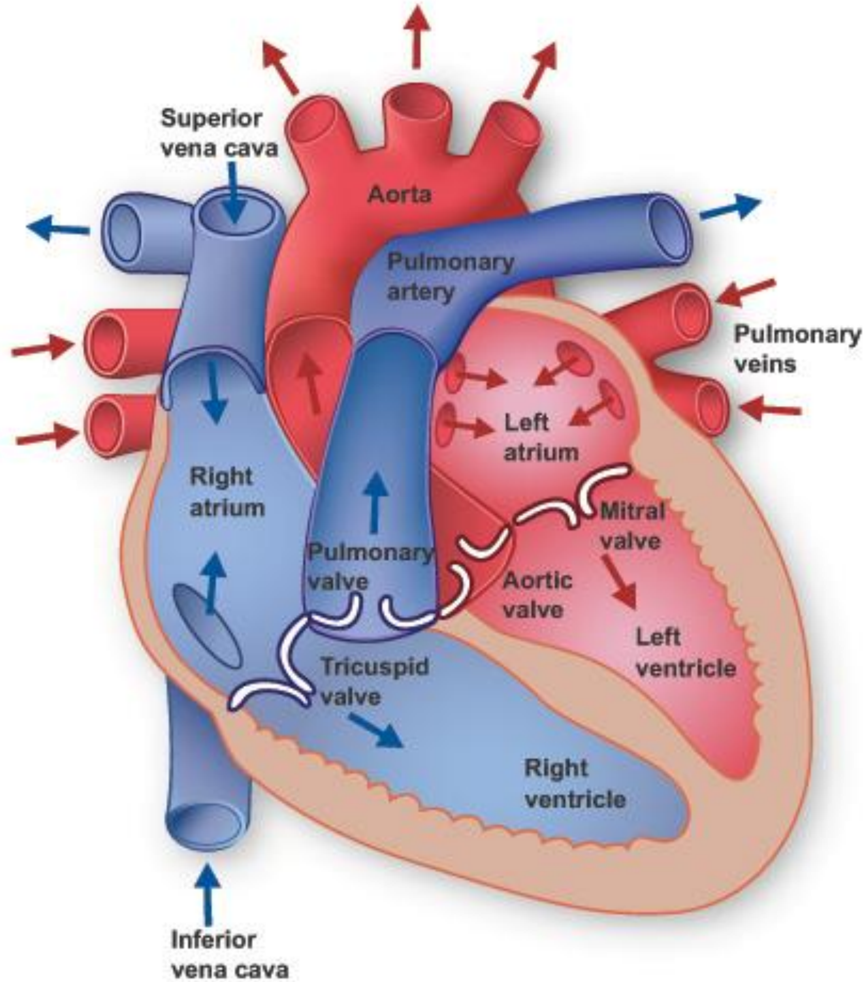
Left and right sides

Heart valves

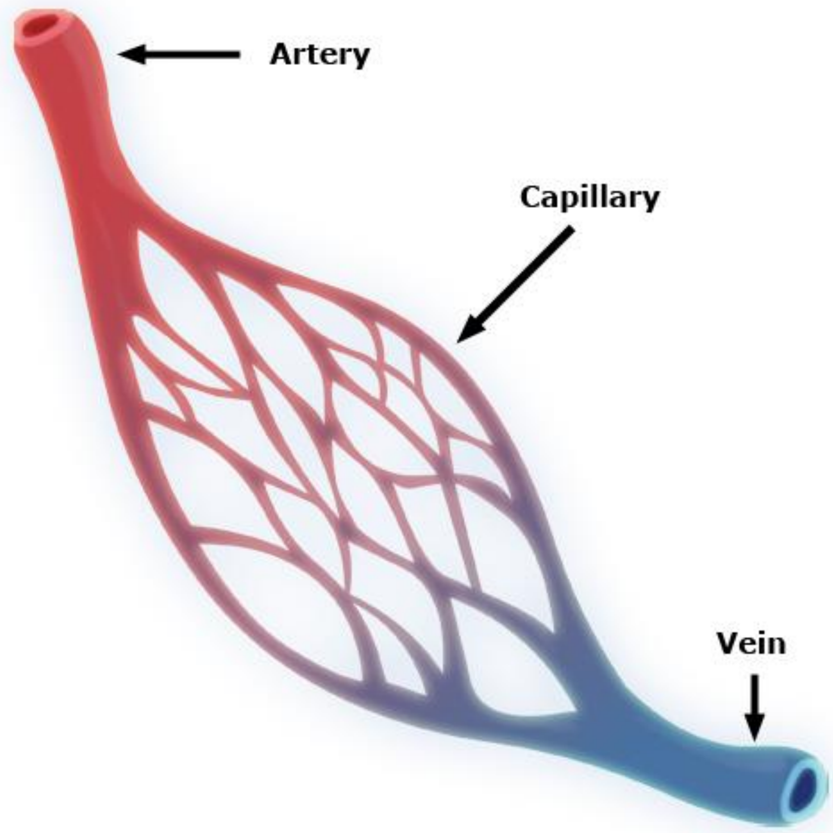
Atria

Ventricles

- 2.5 **billion** beats / lifetime



Blood Flow Control:
Tissues control local blood flow at capillary level



E.g. Exercise!

- Lack of oxygen in muscles results in dilation of capillaries
- Capillaries in non-essential regions (e.g. digestive system) are constricted
- Muscles squeeze veins, return more blood to the heart, which responds by increasing output

Effect is more blood flow is diverted to muscles requiring more oxygen.

Circulatory System Summary

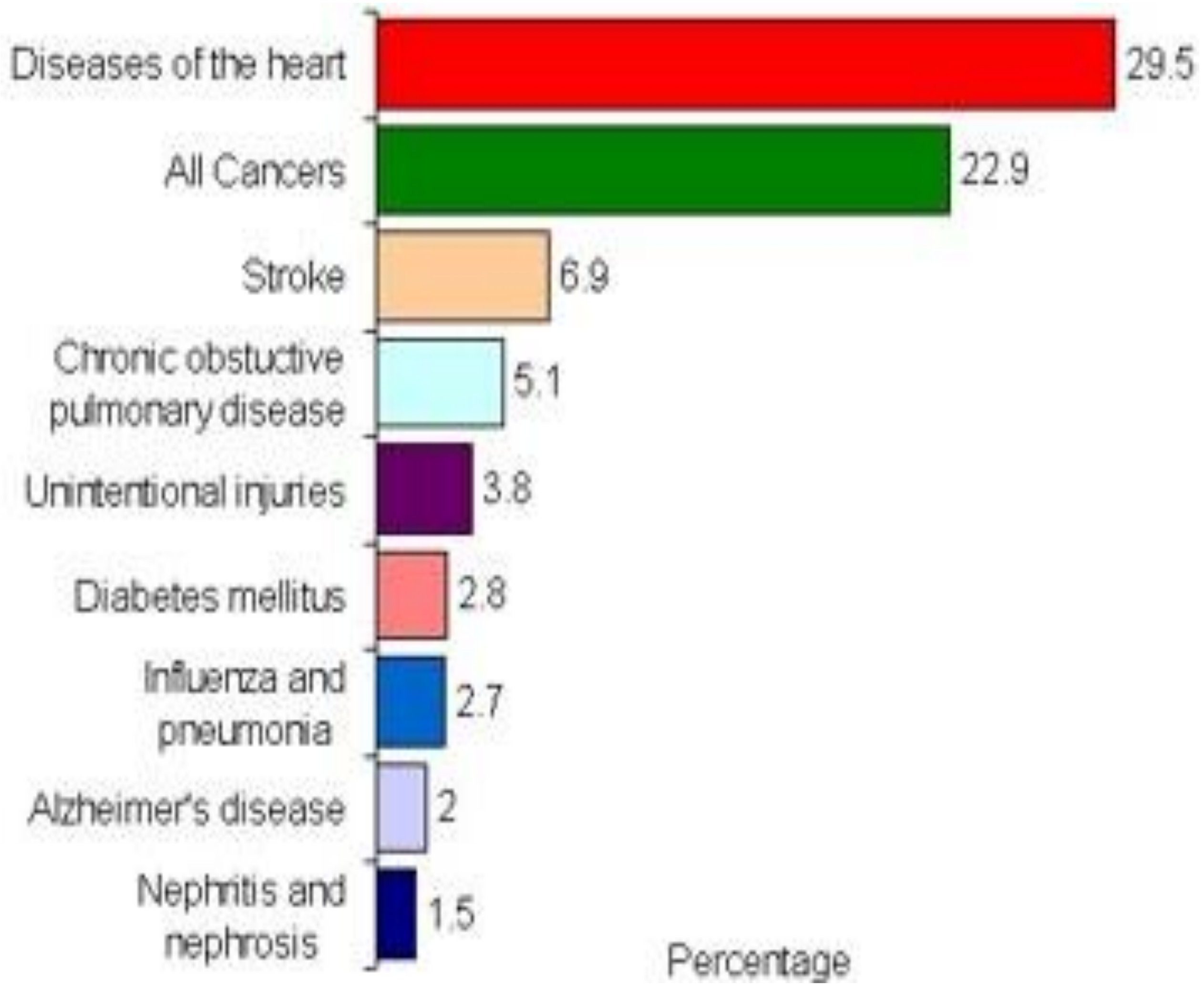
- Circulatory system: conduit (“Plumbing”) for blood
- Heart – pump, billions of beats per year. Ventricles main driving force
- Increased contraction, decreased resistance = more cardiac output

UNSW SYDNEY

Heart Disease

- Prevalence: About 3% of population
- Worlds biggest killer
- Kills one Australian every 10 minutes
- Over 1M US hospital admissions per year
- Cost $35B USD per year in USA alone
- Projected cost by 2030 in USA alone: $95B!!!!

Heart Disease



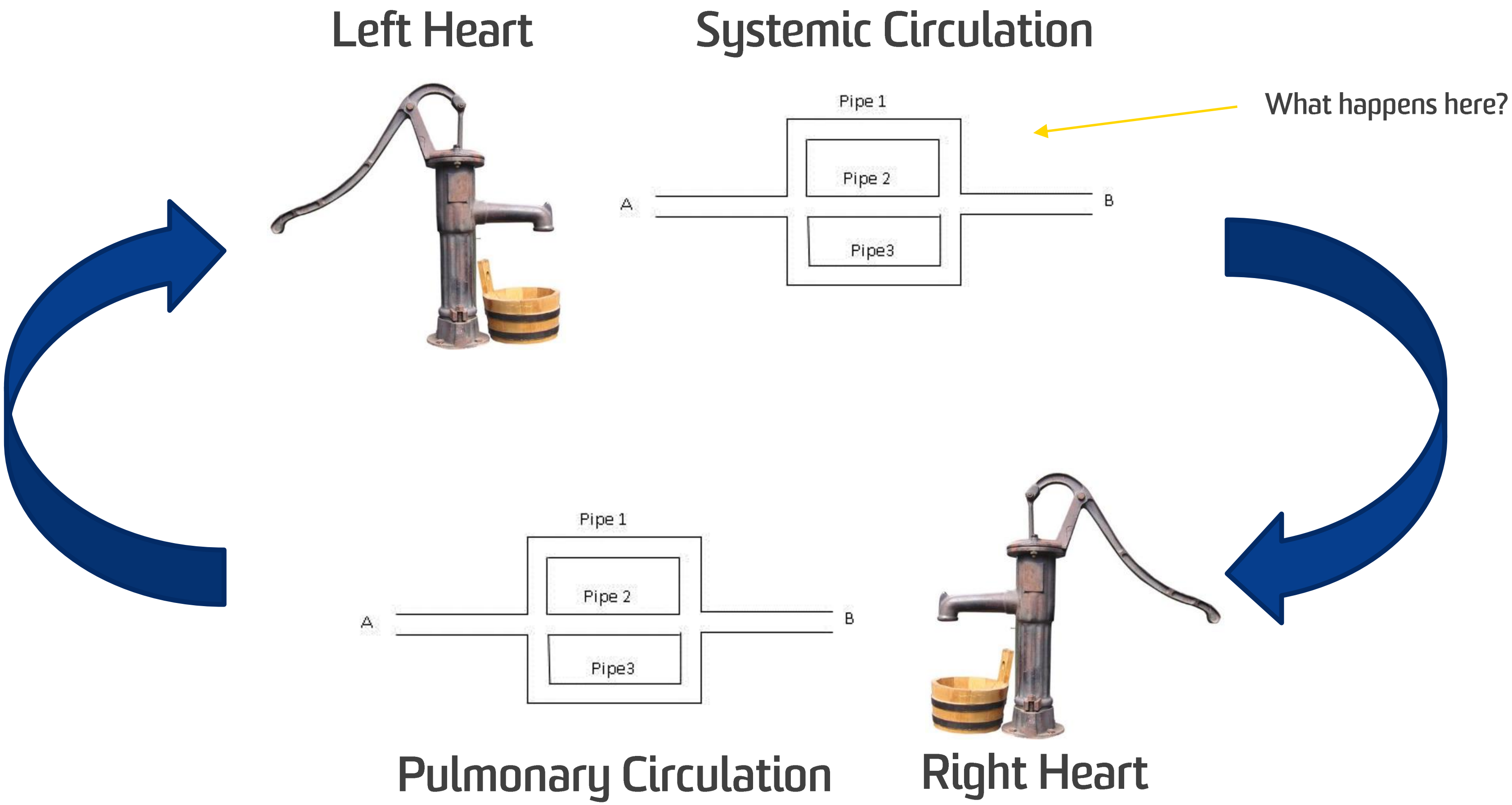
Heart Disease - Causes

Often develops slowly over years

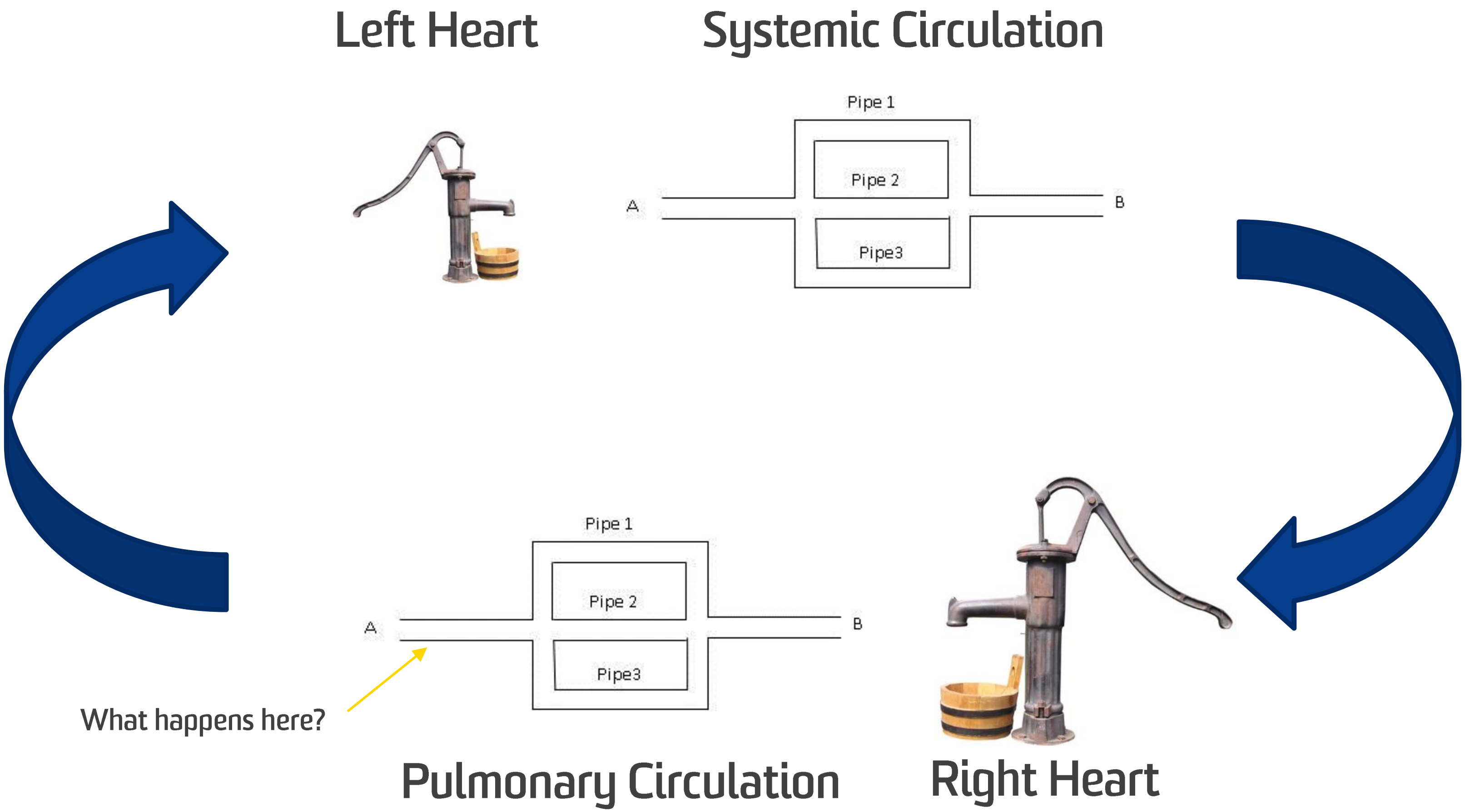
Many causes exist, such as

- Birth defects
- Coronary artery disease
- Cardiomyopathy
  - Dilated
  - Ischemic
- Heart valves
- Virus

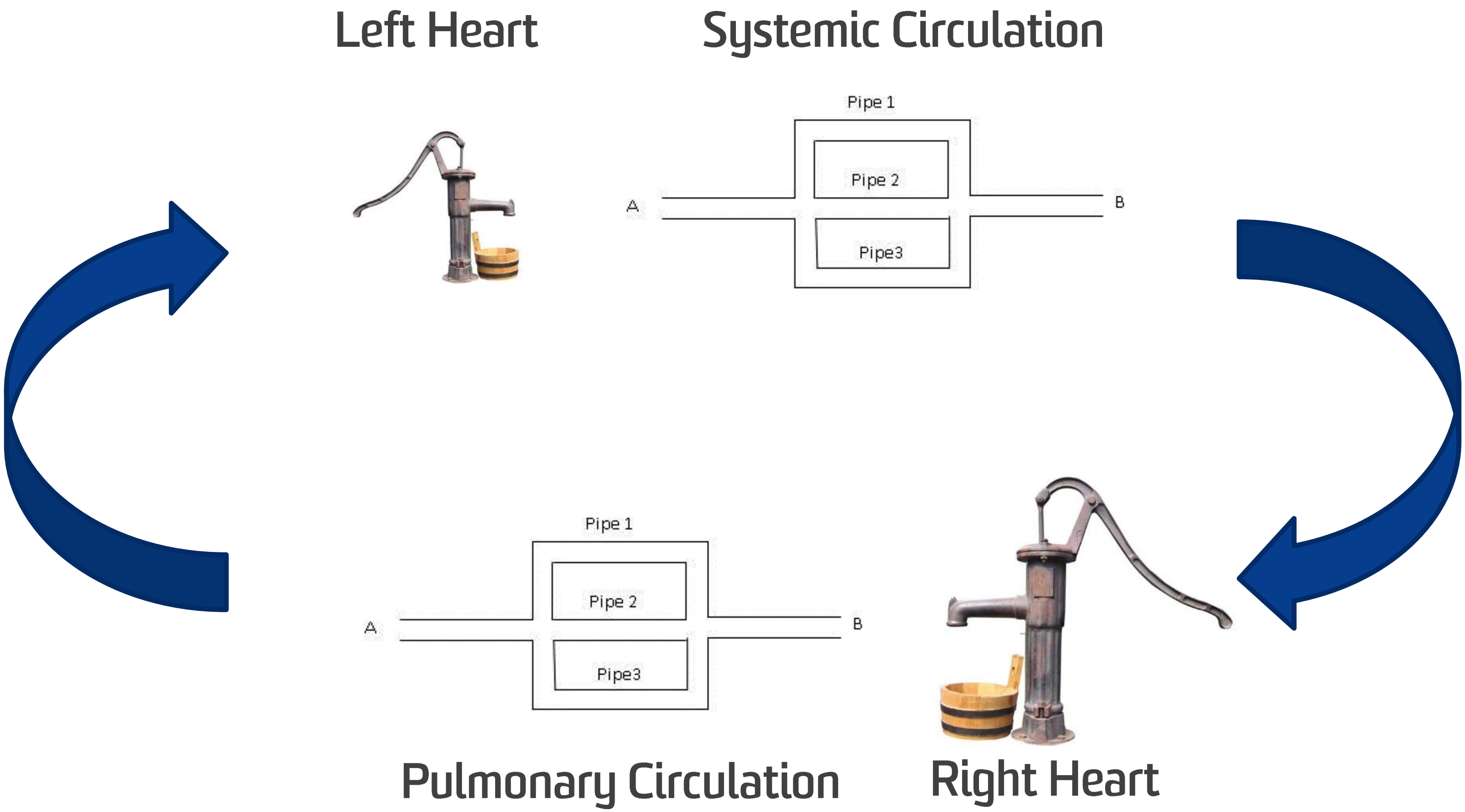
Question: What happens to pressure and flow in the *systemic* circulation when the left ventricle fails?



Question: What happens to pressure and flow in the *pulmonary* circulation when the left ventricle fails?



Question: Do you think that the body compensates for LV heart failure? Yes/No?



Heart Failure

Pumping ability decreases, causing:

- Lower SV and CO
- Damming of blood in veins.
- Increase of RAP

Compensation:

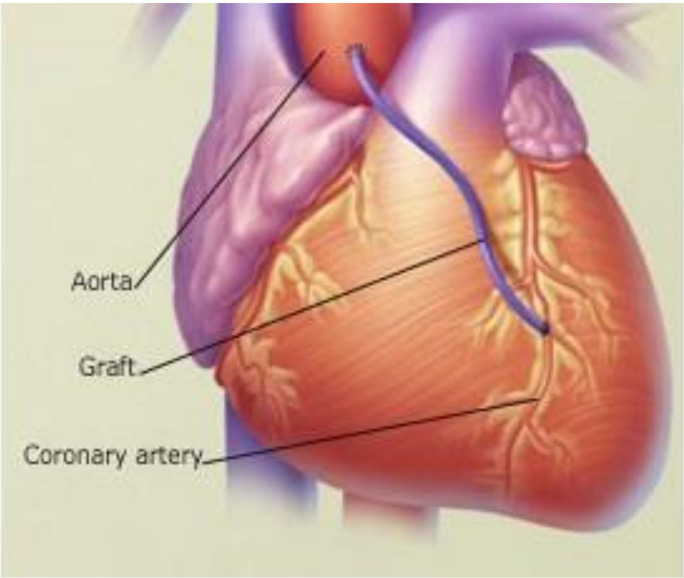
- Sympathetic stimulation: HR, contraction, venous tone
- Fluid retention by kidneys

Return resting CO to normal – but no capacity to increase CO in exercise.

Heart Disease - Treatment

Medical management

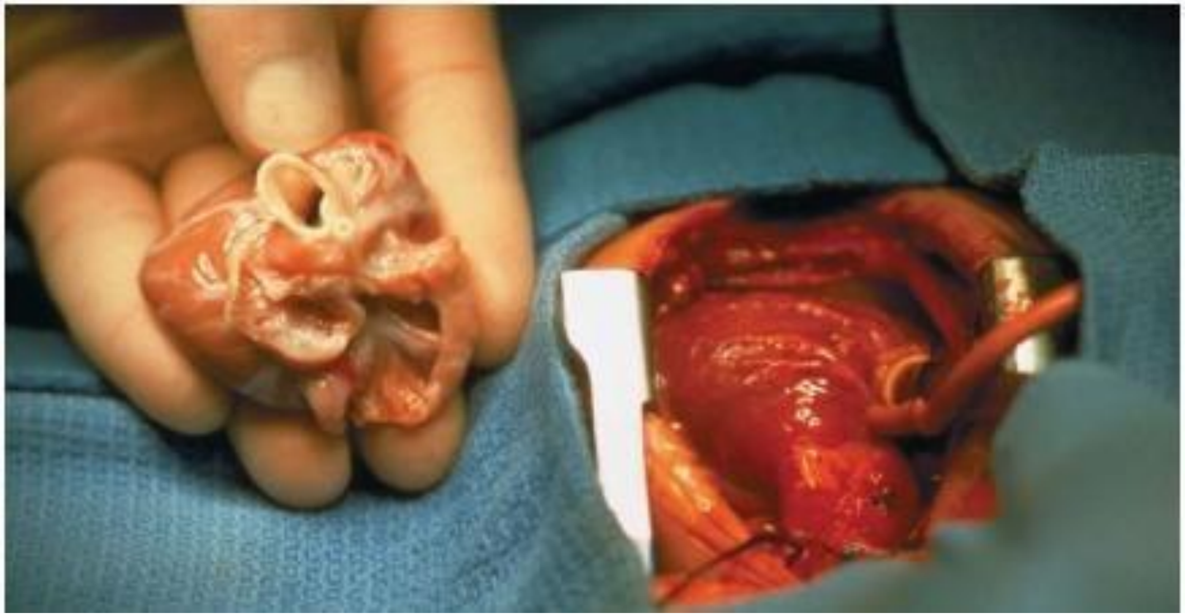
- Medicinal
  - Beta blockers (function)
  - ACE inhibitors (dilation)
- Surgical
  - Stents
  - Valve corrections
  - CABG



Heart Disease - Treatment

Heart transplant

- Gold standard treatment for heart failure
- First performed in South Africa in 1967 – Dr. Christiaan Barnard.
- Survival rates – 1 year (85%), 5 years (75%), 10 years (60%)



Heart Disease - Treatment

Severe lack of donor hearts

About 65-70 heart transplants per year in Australia

Less than 4000 worldwide each year

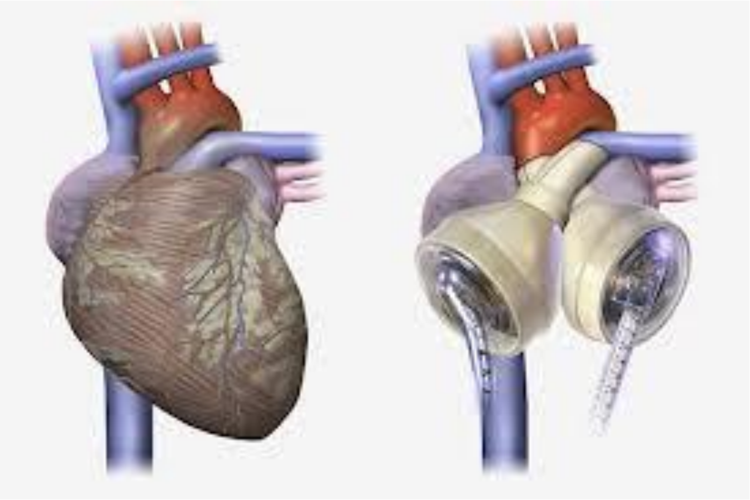
20-40% mortality rate while waiting

Need for mechanical support

Cardiovascular Devices

Four main devices used to increase cardiac output:

- Intra-aortic balloon pumps
- **Ventricular assist devices**
- **Total artificial hearts**
- Extra-corporeal membrane oxygenation (ECMO)

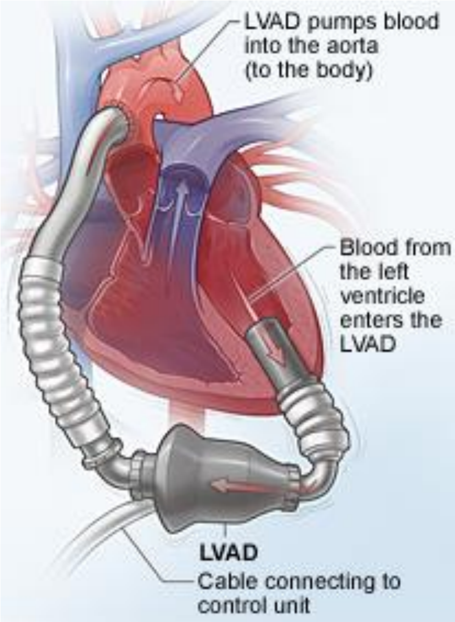


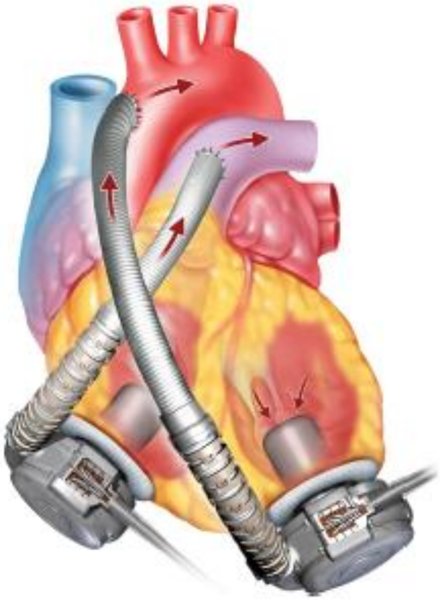
Ventricular Assist Devices (VADs)

Leaves the heart in place

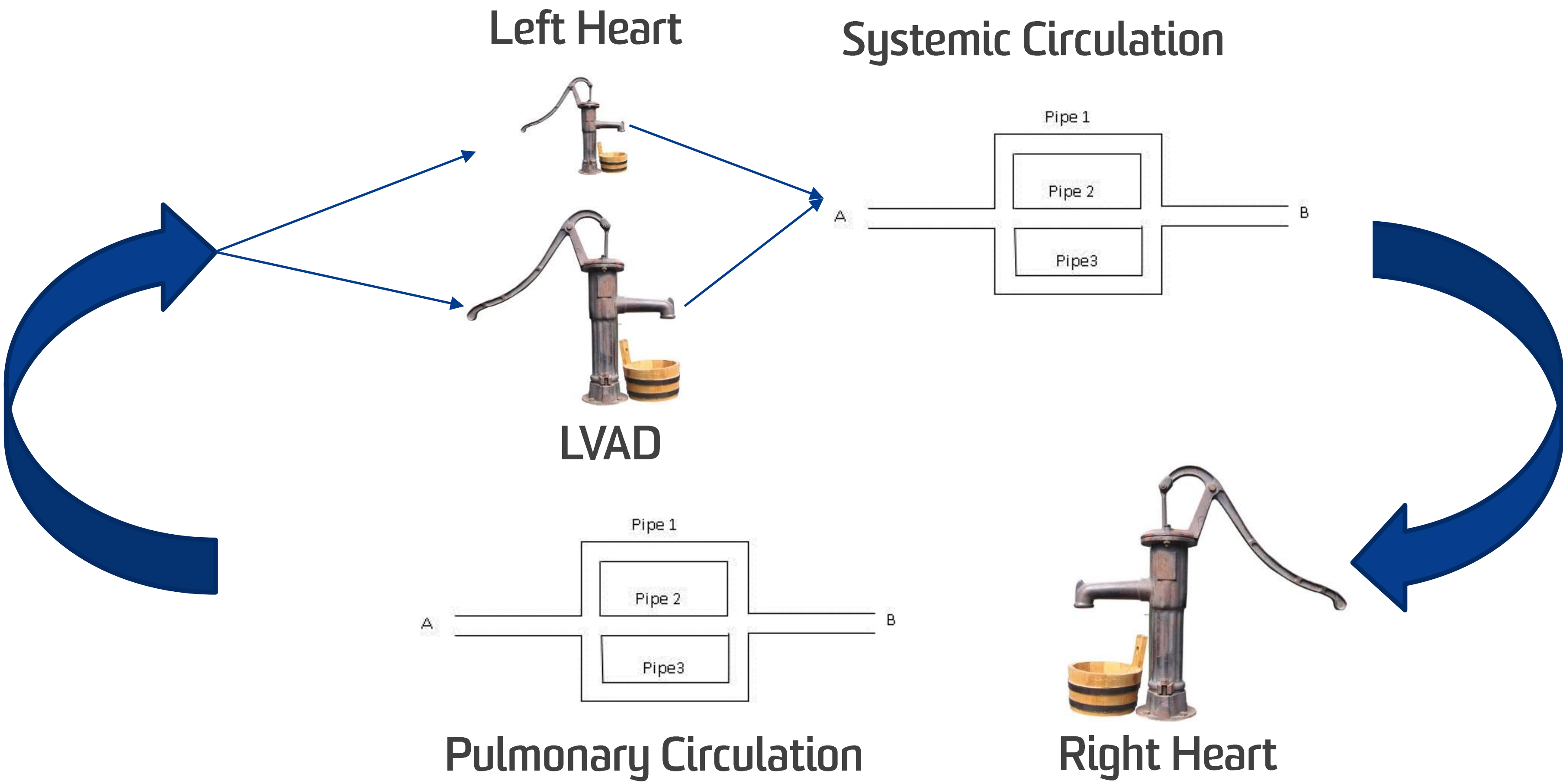
Supports the failing ventricle in parallel

Bridge to decision, transplant, destination, recovery.



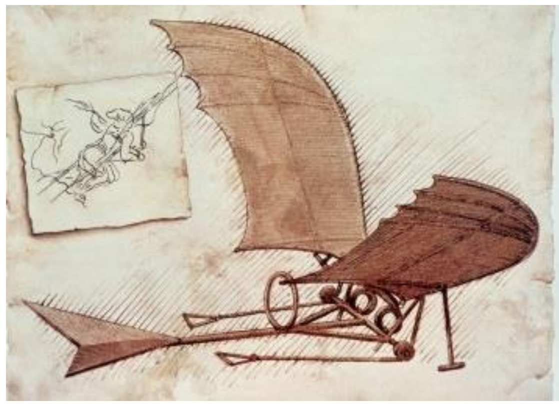


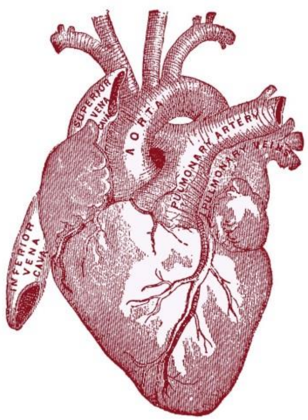
Where do VADs fit into our plumbing analogy?

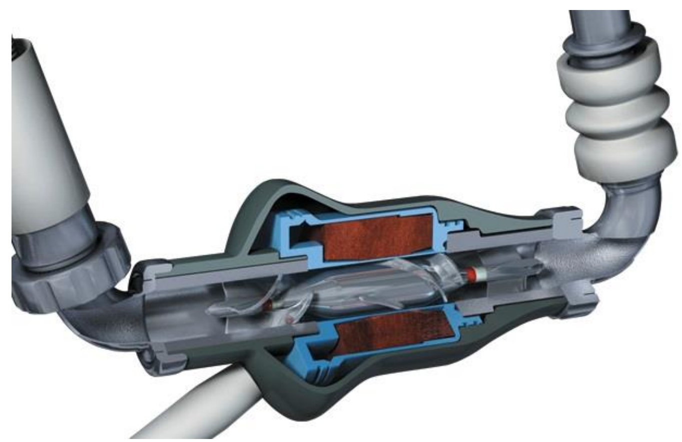


Ventricular Assist Devices (VADs)

Device Generations







Ventricular Assist Devices (VADs)

1st Gen.	2nd Gen.	3rd Gen.
		

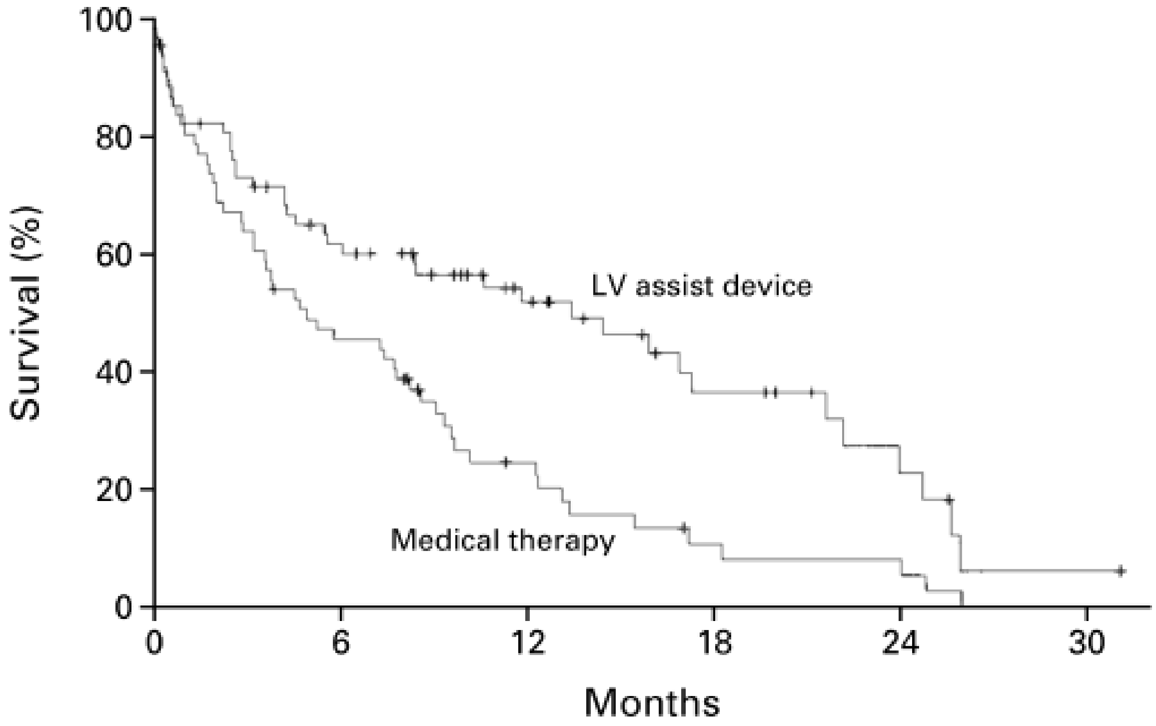
Ventricular Assist Devices (VADs)

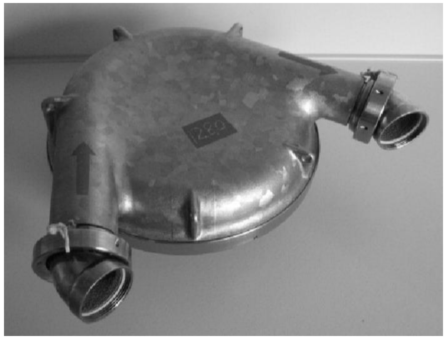
1st Gen.

- Pulsatile
- Pneumatic or electric
- Sit outside the body (usually)
- Infection
- Blood clots
- Large drive consoles
- Short term support
- No longer used in developed countries

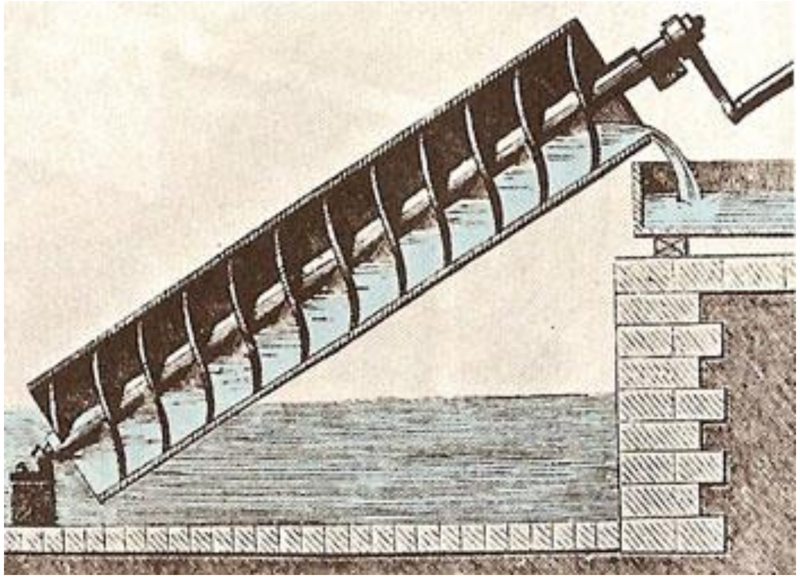
2001 - The REMATCH Trial

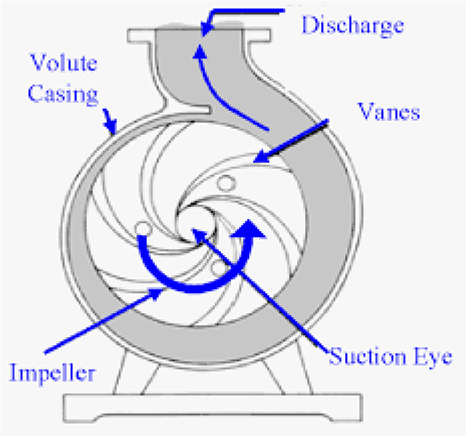
- Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure.
- 129 patients, randomized between LVAD vs conventional medical treatment





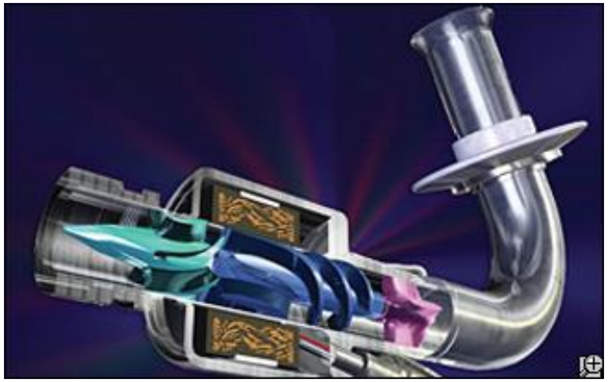
Humans have been pumping fluids for a LONG time…





1998 – Second Generation VADs

2nd Gen.



Centrifugal ⟵ Continuous flow ⟶ Axial

Ventricular Assist Devices (VADs)

Smaller

Electrically driven

Small external components

Mechanical contact

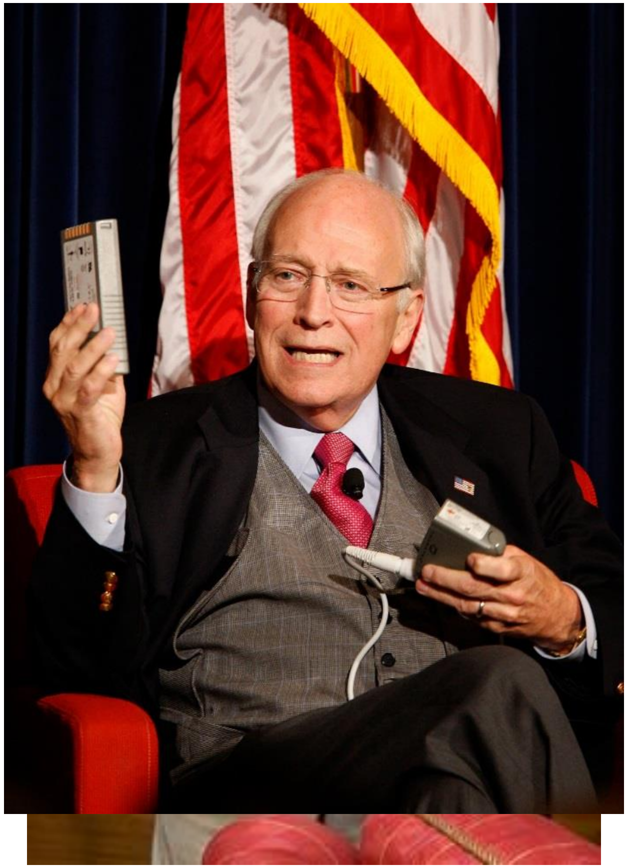
Blood damage

Infection

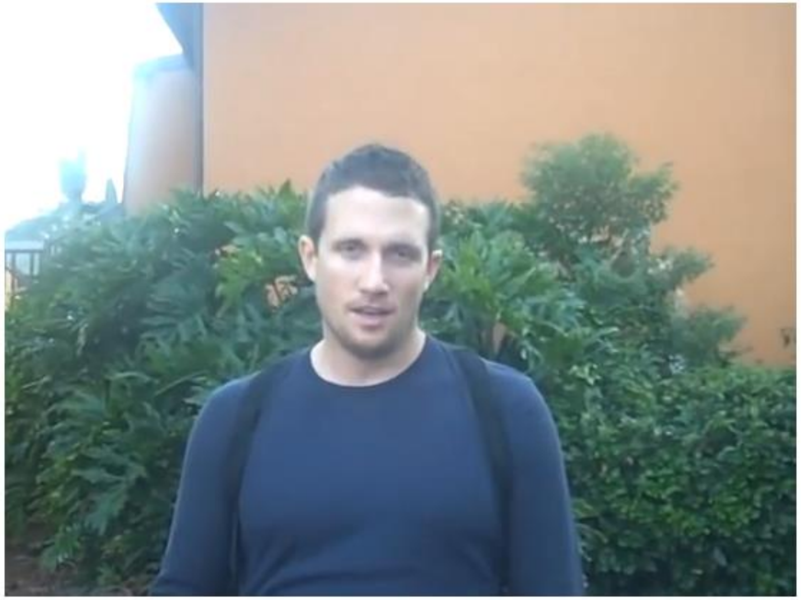
First implanted in 1998

Longest support over 8 years

2nd Gen.

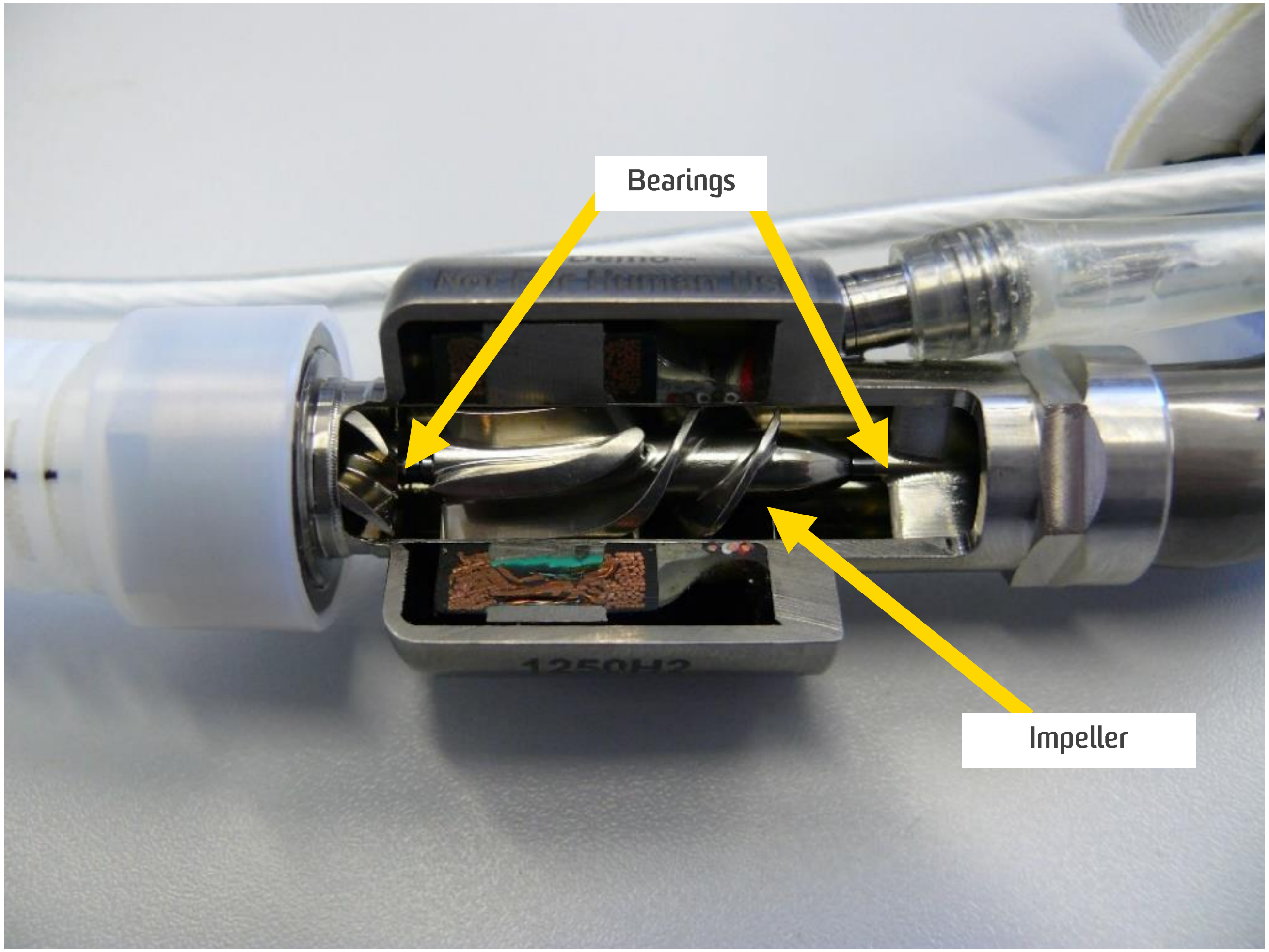


Richard had a second gen LVAD – HeartMate II (Abbott)

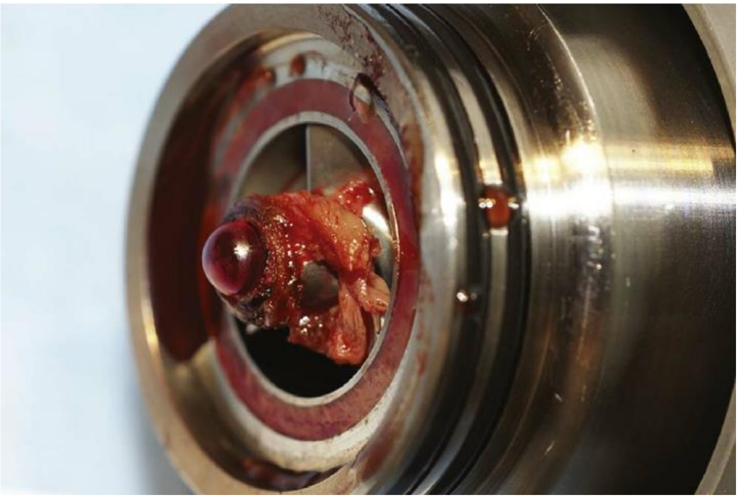


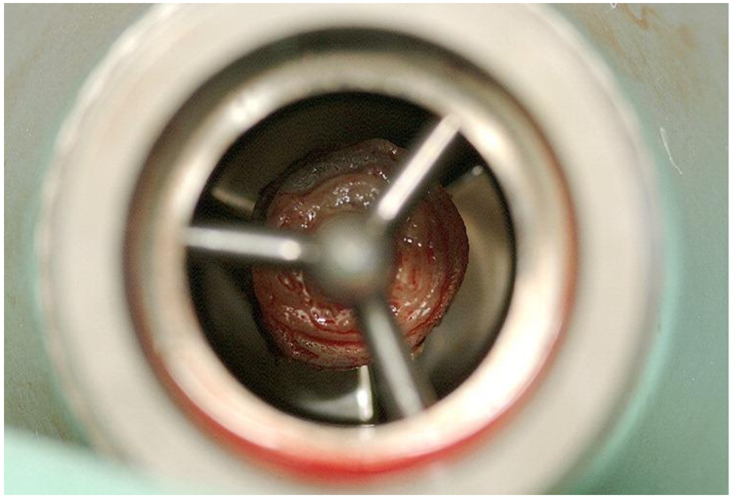
Life with a LVAD

1998 - Second Generation LVADs

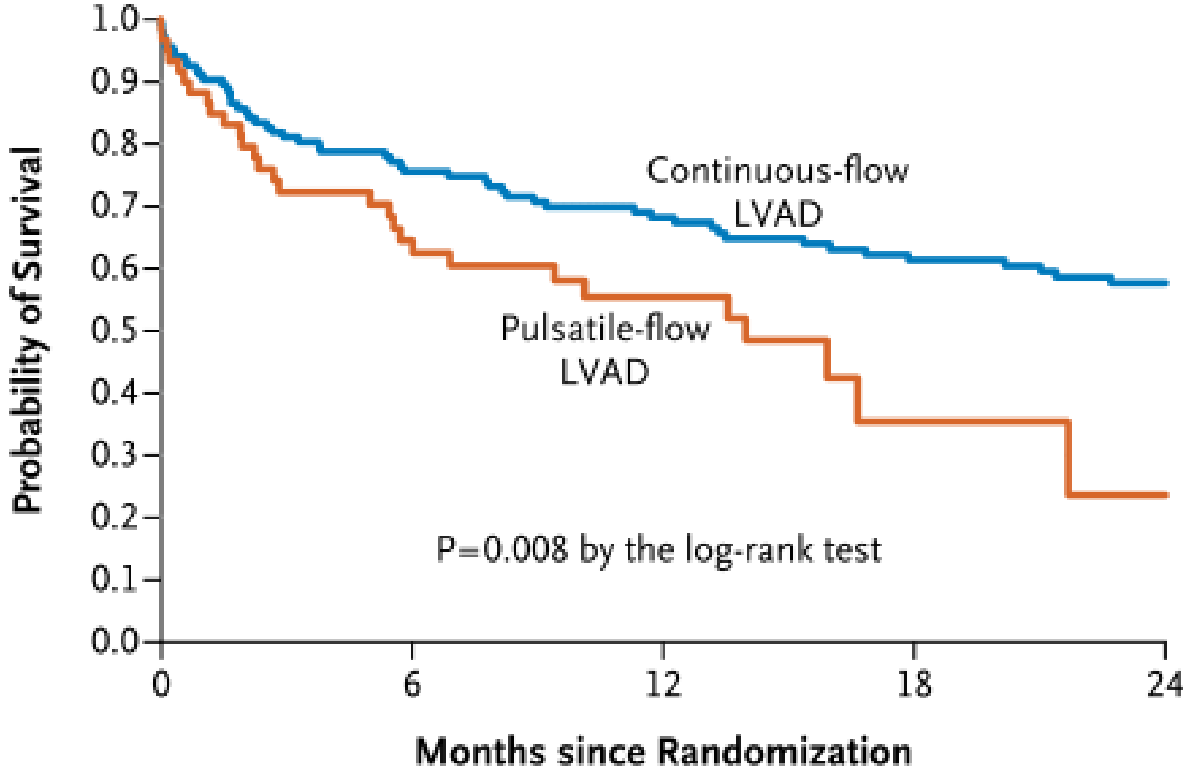


The mechanical bearing causes issues…





Survival on second gen LVADS better than first gen



M. S. Slaughter et al"Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device," *N Engl J Med*, vol. 361, no. 23, pp. 2241–2251, Dec. 2009.

3rd Generation VADs

Continuous flow

- Centrifugal
- Axial

Completely implantable

3rd Gen.

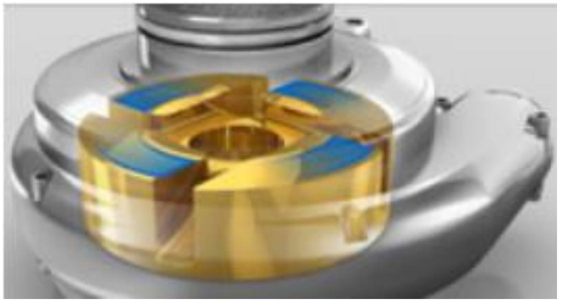
- **No mechanical wear**

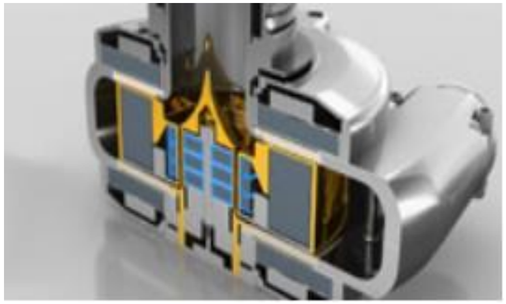
HOW?

3rd Generation LVADs have no mechanical contact between impeller and housing.

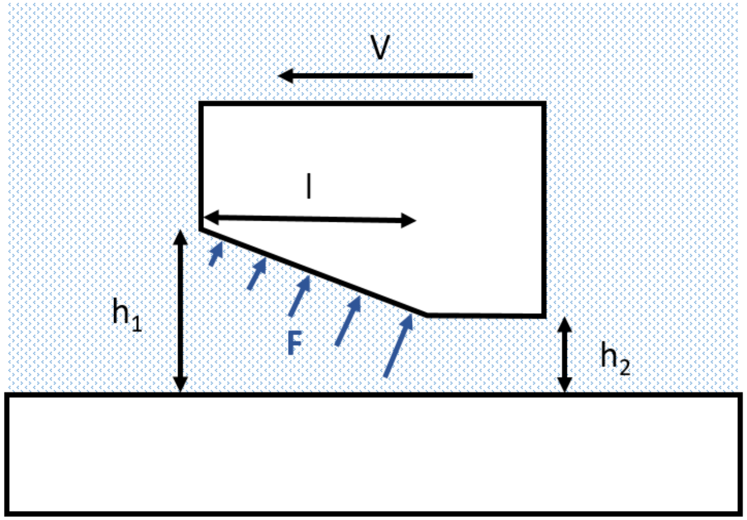
Achieved through different types of bearings:

- Hydrodynamic Bearings
- Electromagnetic Bearings





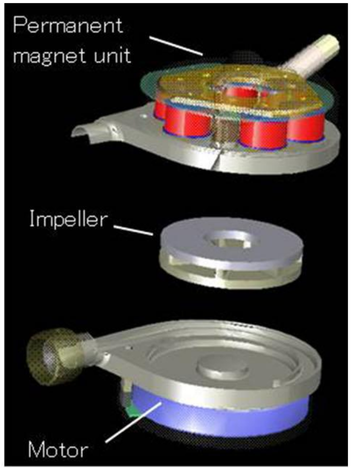
Hydrodynamic Bearings

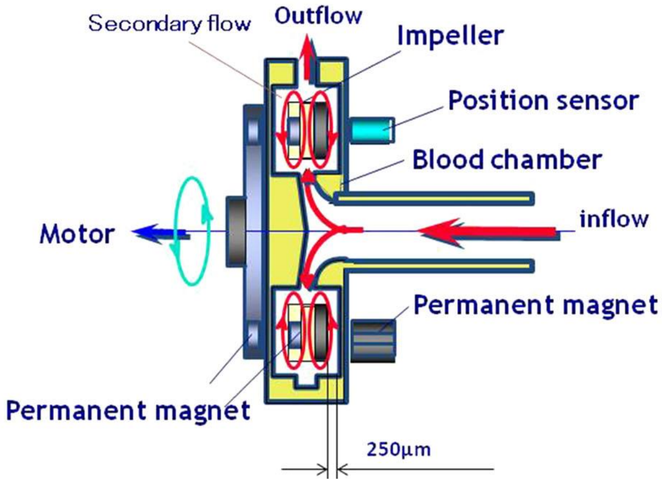


$$F = 0.1602 \frac{\mu V l^2}{h^2}$$

- High pressure fluid (blood) underneath rotor
- Rotor “surfs” on top of blood
- Clearance (h) needs to be large enough to prevent blood trauma
- Small clearance (h) required to generate pressure.
- Changes in clearance require change in speed or surface area -> knock-on effects to size and hydraulic characteristics
- Minimum start up speed required

Electromagnetic bearings





- Impeller magnetically suspended
- Large gaps ok – great for blood!
- Magnets are large and bulky – makes device bigger and harder to implant
- Requires sensors (eddy current) for active control of rotor position

Ash and AJ had 3rd Gen devices – HeartWare HVAD (Medtronic)

Not just the pump!

Image from heartware.com

Question

You see a patient in the intensive care unit implanted with a single left ventricular assist device. You can only see a small cable exiting the patient's skin, attached to a tiny console on the patient's bedside table. You overhear the doctors discussing that there may be some blood clots forming around the mechanical bearing. The device most likely implanted is a:

a) First generation LVAD

b) Second generation LVAD

c) Third generation LVAD

d) Total artificial heart

Ventricular Assist Devices (VADs) - Complications

The Major Complications

Adverse event	[redacted]
Bleeding	
Right heart failure	
Myocardial infarction	
Cardiac arrhythmia	
Pericardial drainage	
Hypertension	
Arterial non-CNS thrombosis	
Venous thrombotic event	
Hemolysis	
Infection	
Neurologic dysfunction	
Renal dysfunction	
Hepatic dysfunction	
Respiratory failure	
Wound dehiscence	
Psychiatric episode	
Total burden	

Question: Which complication do you think is the most prevalent?

The Major Complications

Adverse event	[redacted]
Bleeding	
Right heart failure	
Myocardial infarction	
Cardiac arrhythmia	
Pericardial drainage	
Hypertension	
Arterial non-CNS thrombosis	
Venous thrombotic event	
Hemolysis	
Infection	
Neurologic dysfunction	
Renal dysfunction	
Hepatic dysfunction	
Respiratory failure	
Wound dehiscence	
Psychiatric episode	
Total burden	

Bleeding

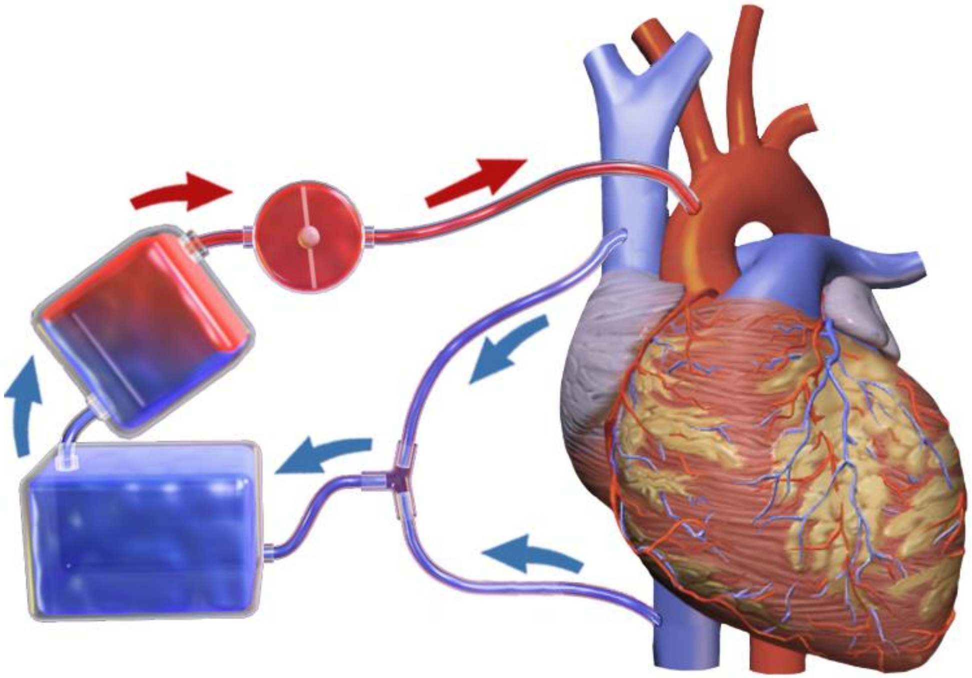
Major cause of mortality with VADs

Blood thinners required – decreases blood viscosity and doesn't clot

Coagulopathy issues in sick patients

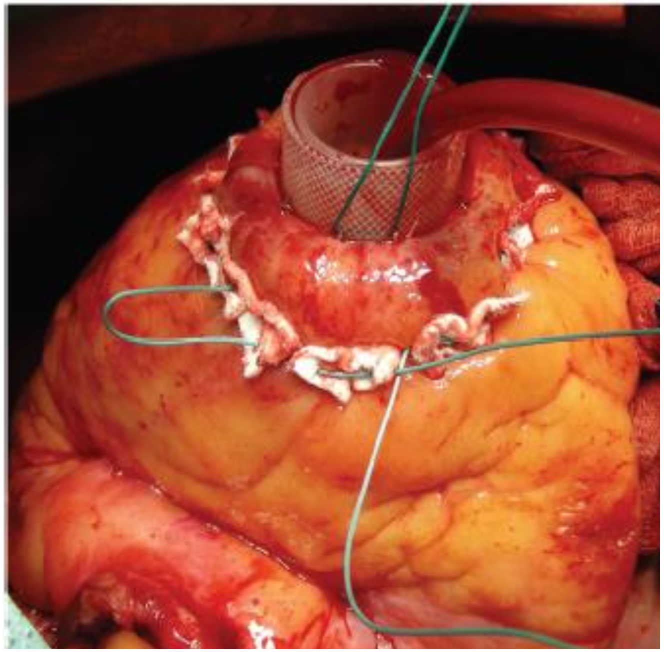
Cardiopulmonary bypass

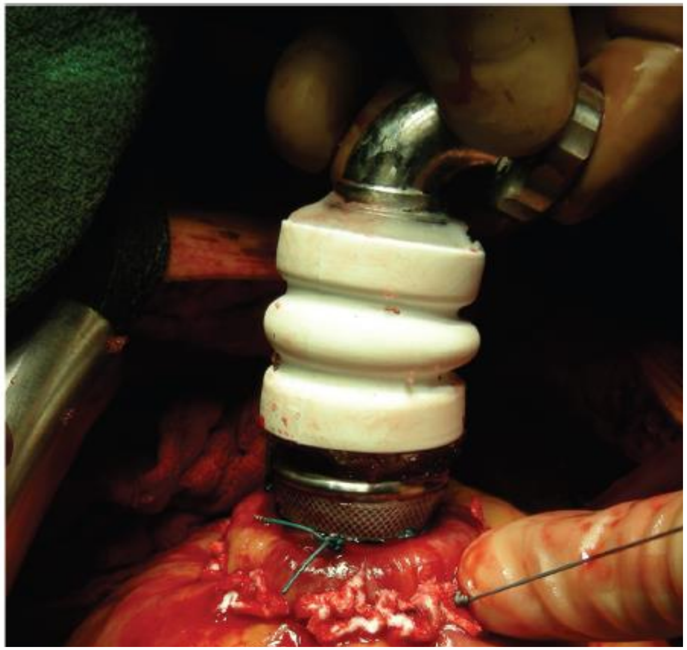
Cannula fixation



Bleeding

Bleeding





Operative time ≈ 40 mins.

Ash talked about GI (Gastrointestinal) Bleeding with her device

- Common, possibly due to continuous flow
- Can be managed with medication

Infection

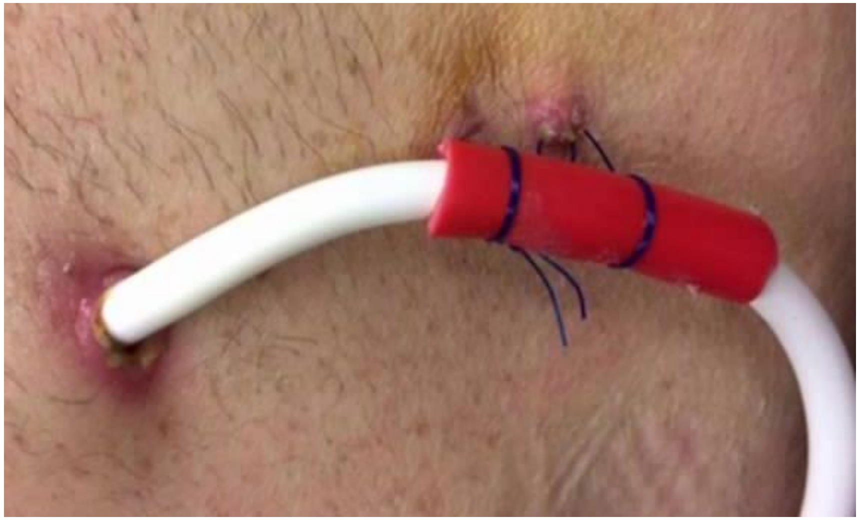
Most significant short- and long-term complication with VADs

Can spread all the way to VAD and require urgent transplant

VERY difficult to treat

Potentially due to trauma at exit site

Driveline design and coating can influence VAD infection

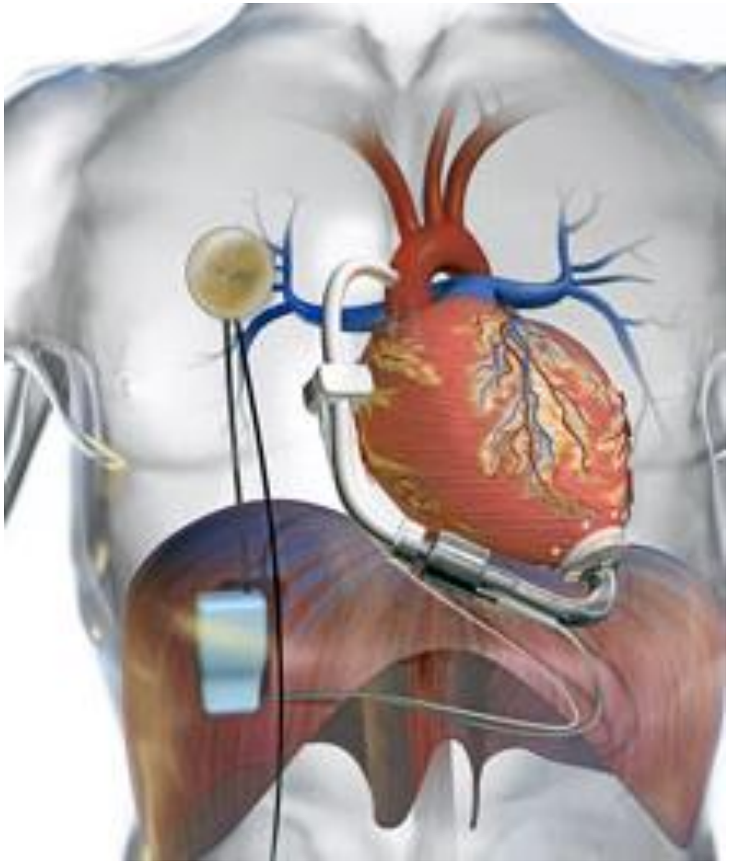


You saw AJ changing the dressing around the exit site of the driveline.

- Has to do it every two days
- doesn’t need the face mask (that’s “creative licence” from the directors!)

Infection

Transcutaneous Energy Transfer

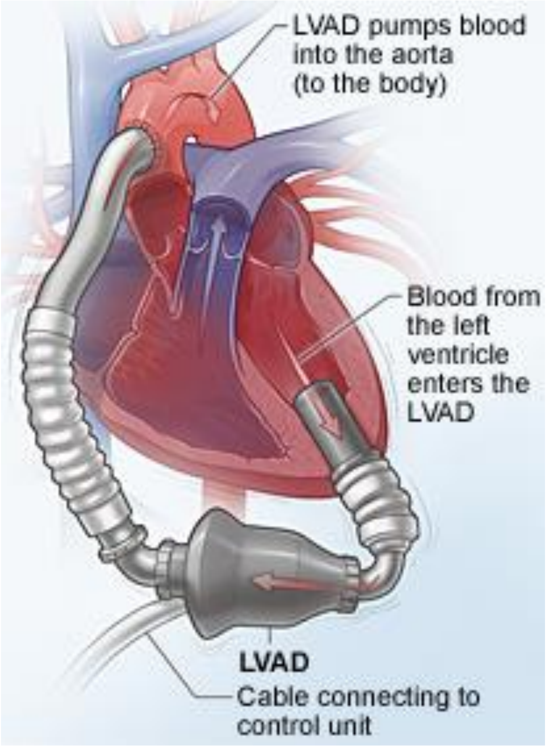


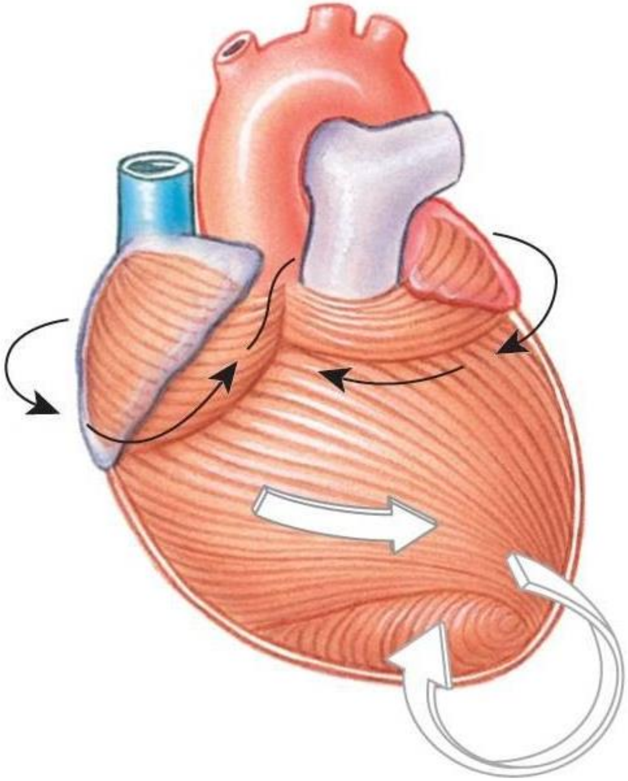
Right Heart Failure

Right ventricle now needs to keep up with the left side

Septal position influence

Remodelling of LV and RV (and spiral muscle shape)





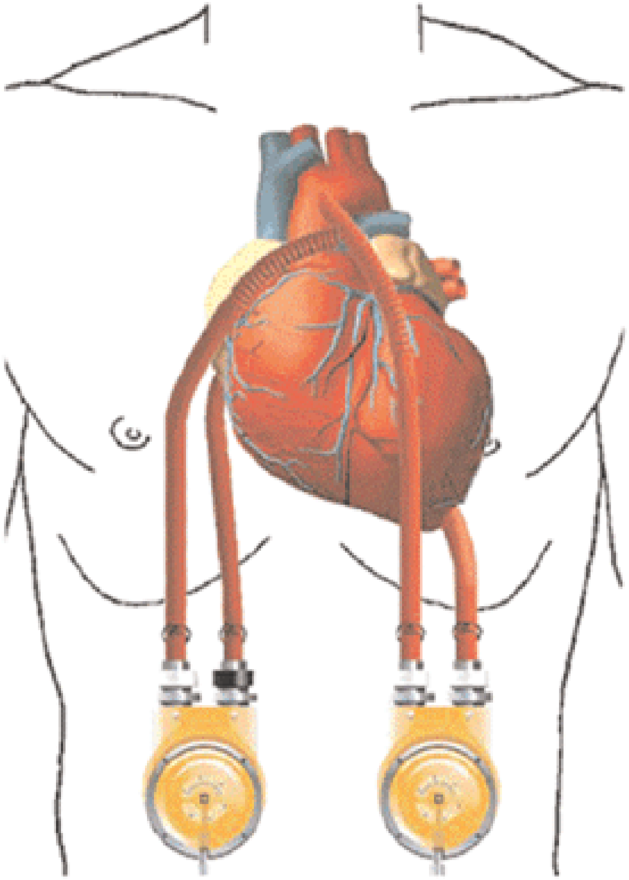
Left and / or Right Heart Support

LVAD support more common

LVAD support often unmasks right heart failure in up to 40% of patients .

RVAD options:

- First gen devices
- Short term 3rd gen devices
  - < 30 days
- 2 x long term LVADs



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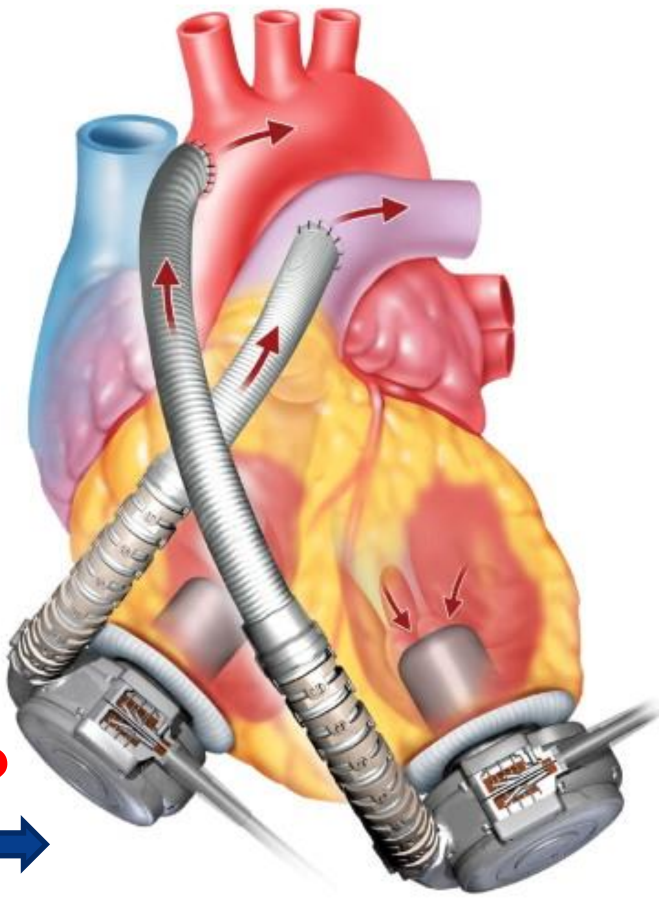
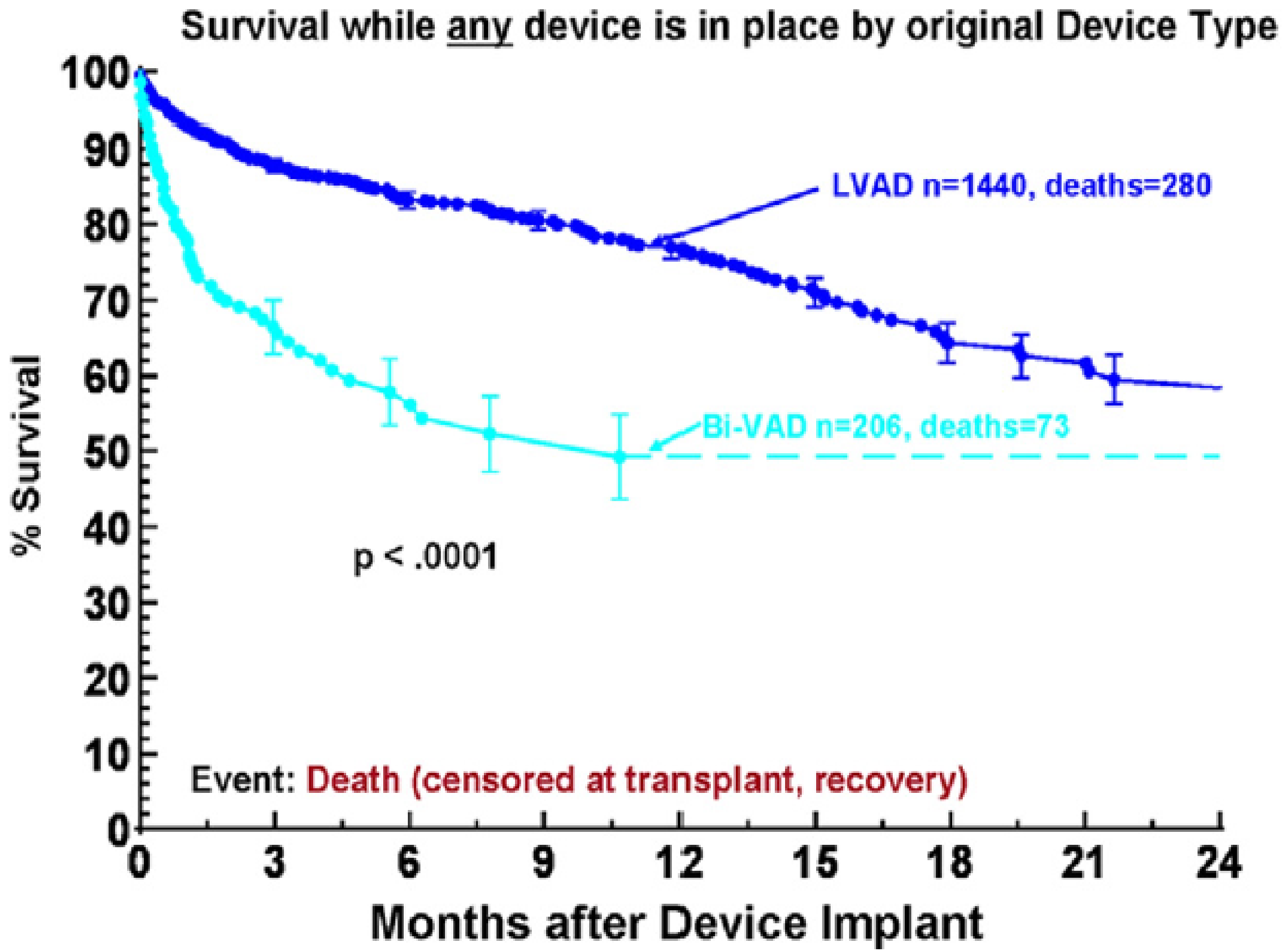
HOW?



Left and / or Right Heart Support



Respiratory Failure

Some patients require prolonged ventilation after LVAD

Associated with poor outcomes and high cost

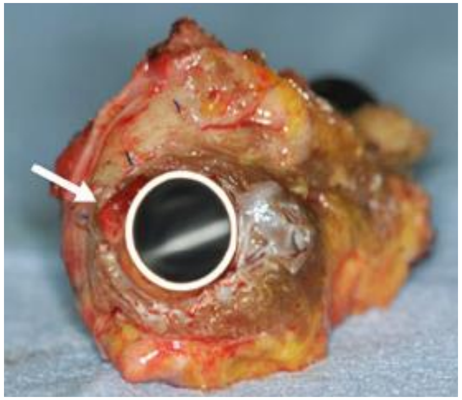
Alternative options such as extracorporeal membrane oxygenation (ECMO)

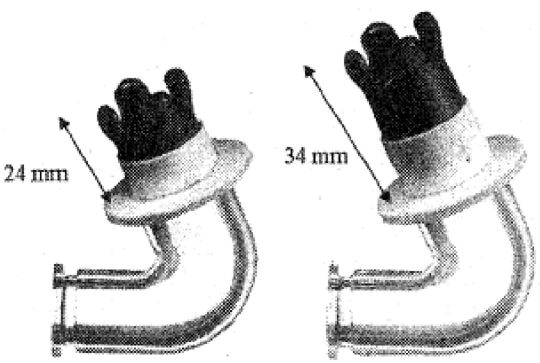
Neurologic Dysfunction

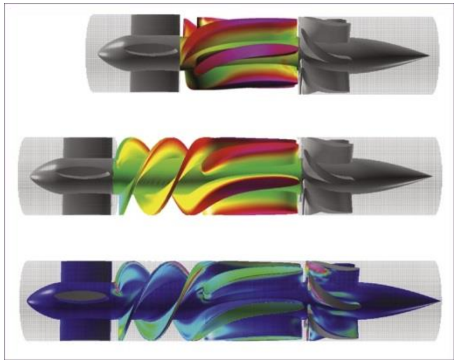
Can be due to thrombus (clots) which form in the ventricle or LVAD

Crucial to optimise LVAD and ventricular flow dynamics

Studies have shown cannula design can reduce neurologic complications from ~23% to ~4%





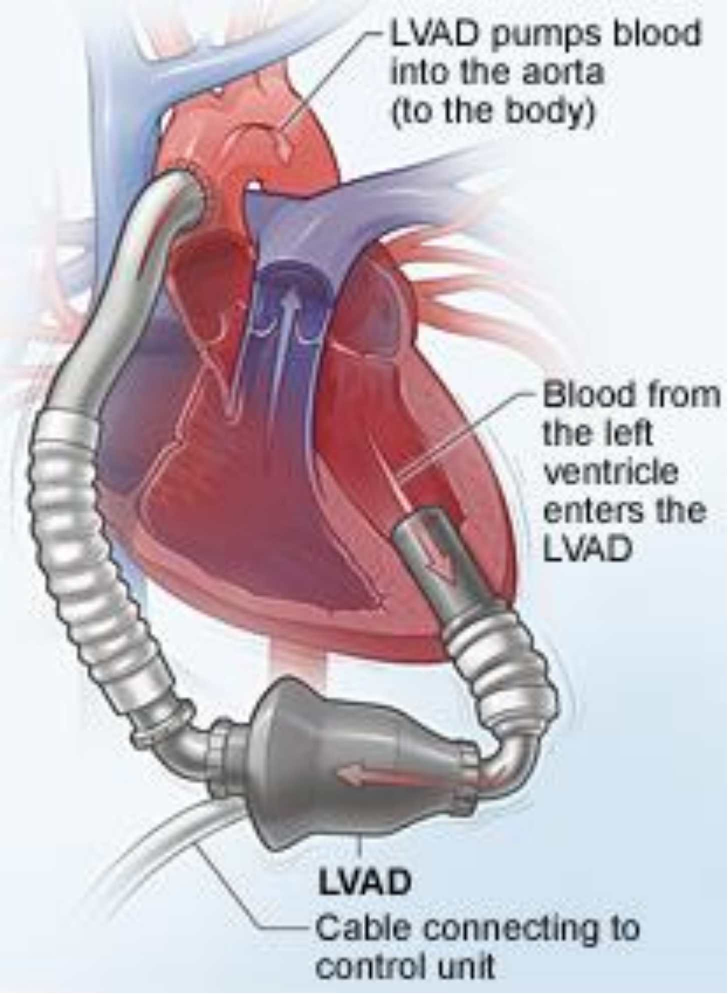


Cardiac Arrythmia

May cause reduced flow, right heart failure, thrombus

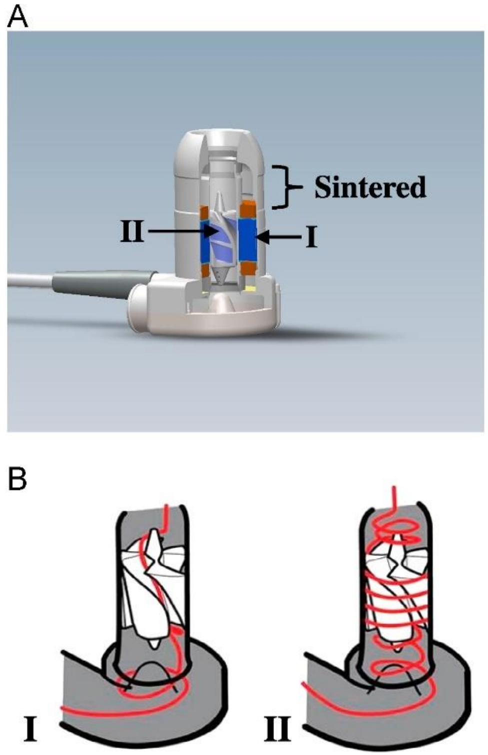
Can be caused by cannula – heart interference

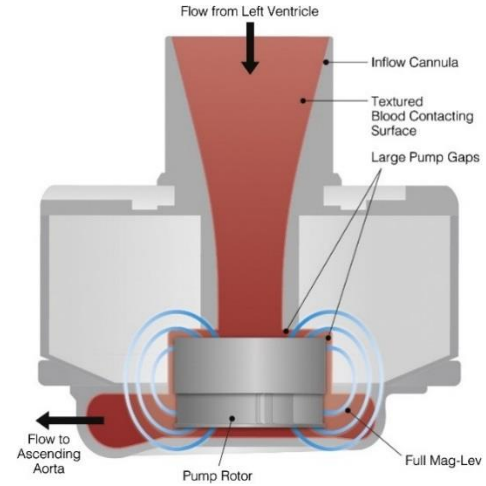
Heart can be sucked onto the cannula by negative pressure created by LVAD



UNSW SYDNEY

VADs are getting smaller – is this a good thing?





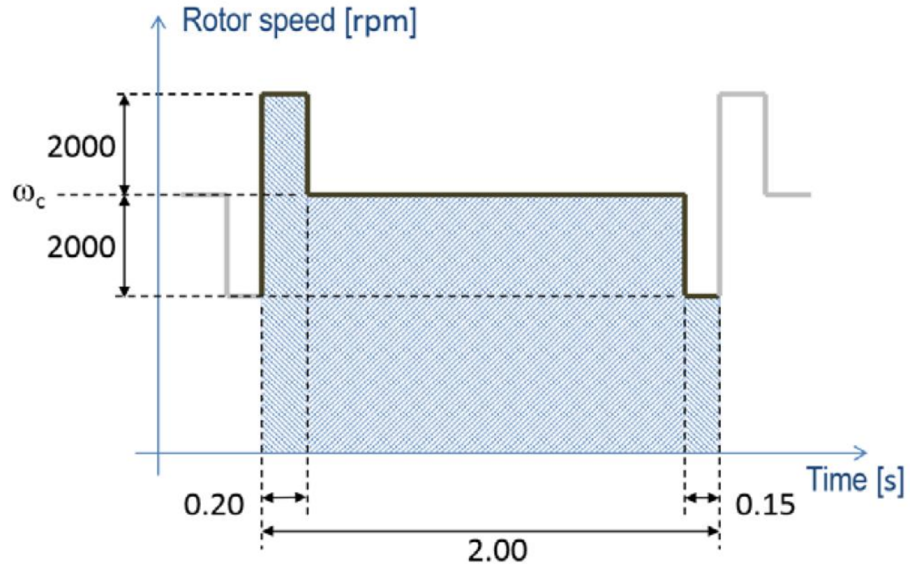
Question:

LVADs are getting smaller - is this a good thing? Give one reason for your argument.

Example answer:

"Yes: I have tiny hands"

Generating an artificial pulse…sort of…



Total Artificial Hearts (TAH)

Completely replaces the heart

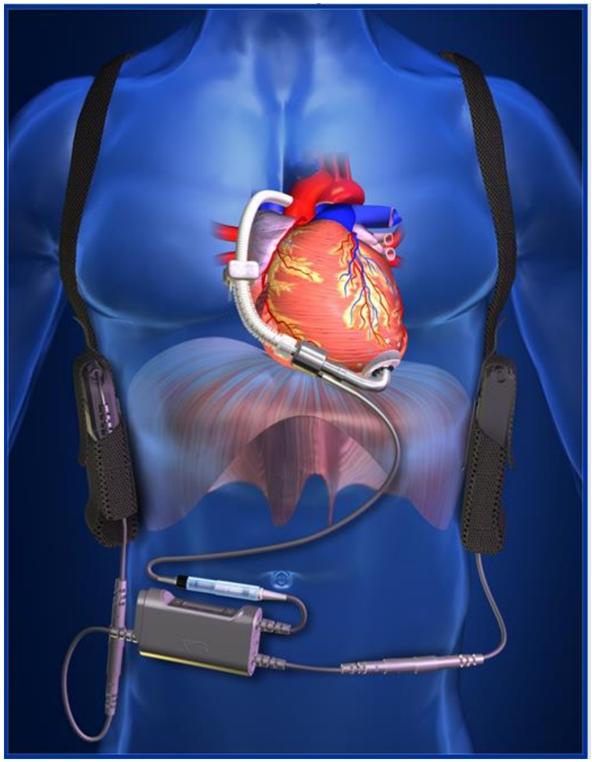
Used if –

- Native heart cannot support life
- Usually ineligible for transplant

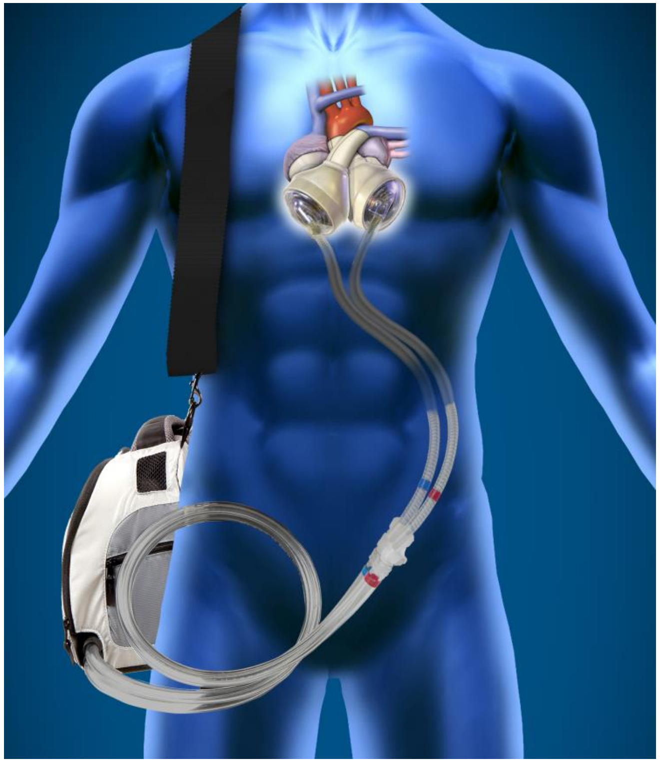
Large size – needs a large patient

(Some women and children ineligible)

Total Artificial Hearts (TAH)

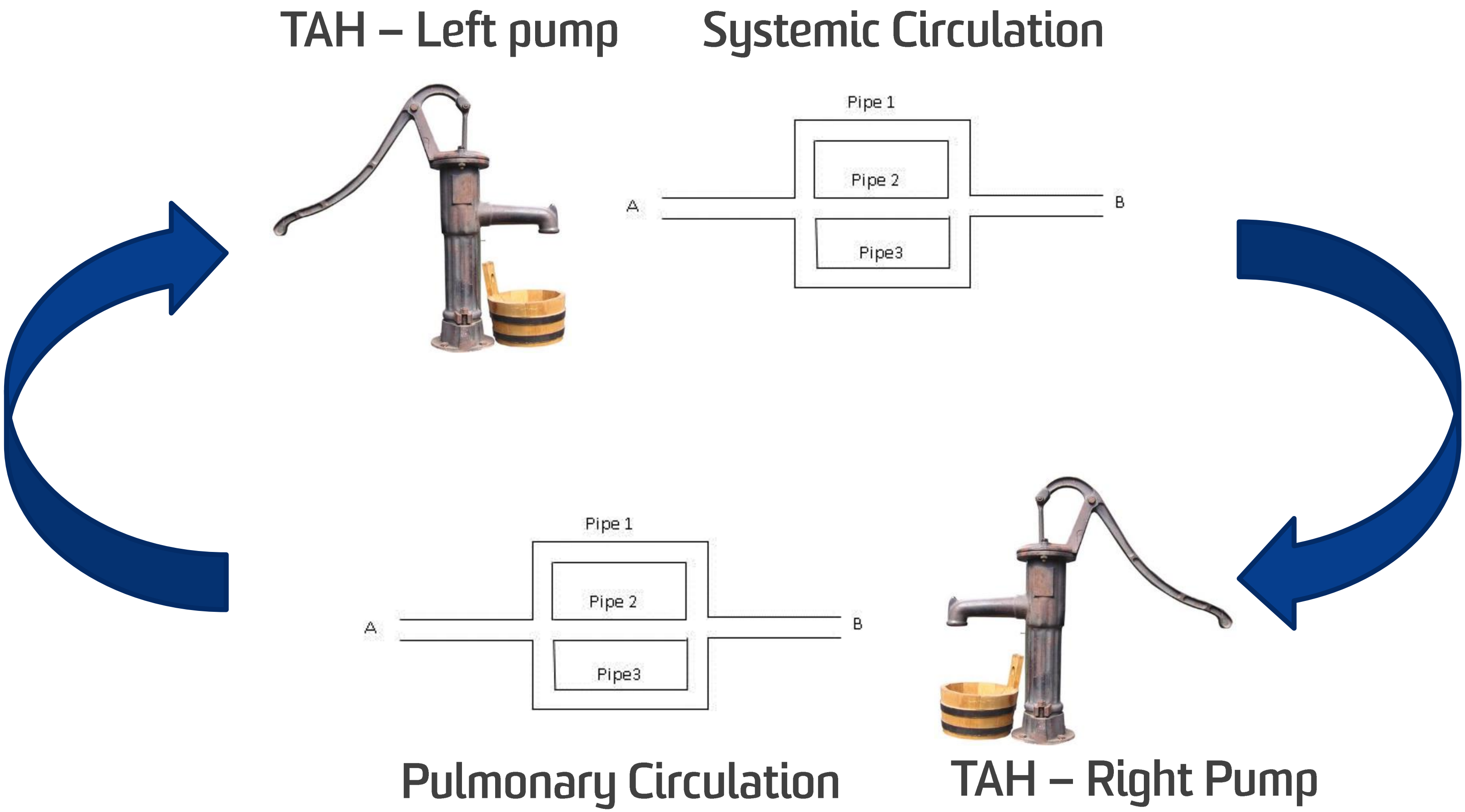


Left ventricular assist device (LVAD)



Total artificial heart (TAH)

How do TAHs fit into the plumbing analogy?



Total Artificial Hearts (TAH)

Syncardia
Pulsatile pneumatics
>1300 implants
4 years support
Infection

Abiocor
Pusher plate
TETS
Blood clots
Taken off market

Carmat
Pusher plate
Biological coating
<5 implants
Limited success so far

1969 – First Human TAH Implant

- Patient: Haskell Karp
- Device: Liotta-Cooley TAH…
- Support duration: 65 hours
- Heart Transplant
  - Died 32 hours later, renal failure and bronchopneumonia

<u>Great milestone in the TAH community?</u>

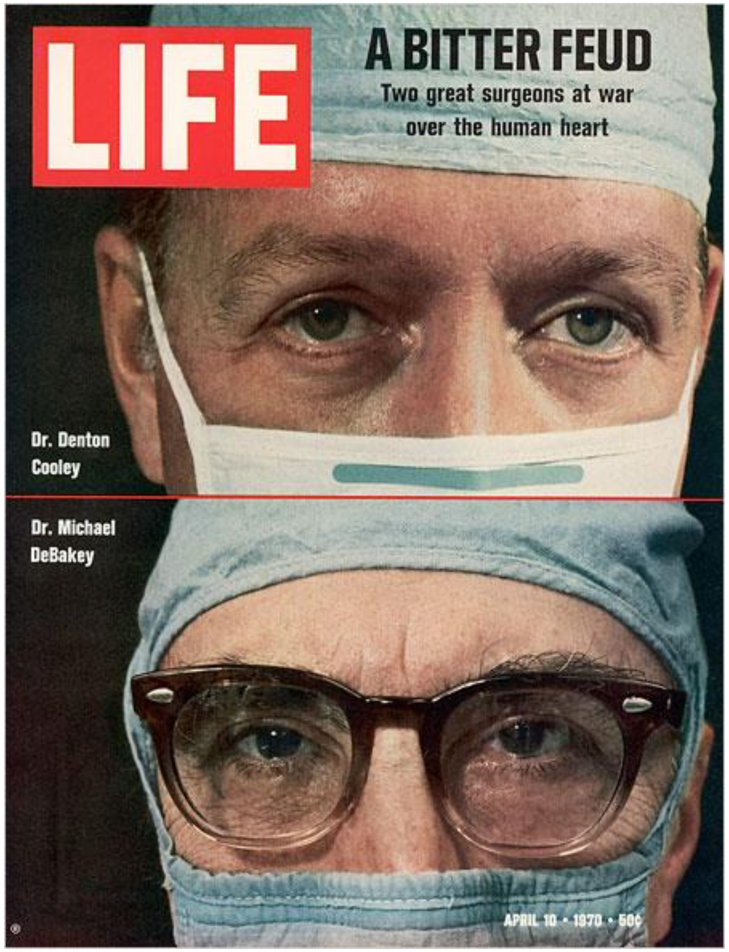
•Shirley Karp (wife): filed a lawsuit against Cooley/Liotta and St Luke's Hospital
•Judge ruled in favour of Cooley/Liotta.

1982 – First Permanent Total Artificial Heart

- Patient: Barney Clarke
- TAH: Jarvik 7 – became Syncardia, still used today!
- Survived 112 days
- Suffered considerably: Infections, discomfort.

1969 - TAHs were at the centre of one of the biggest feuds in medicine

- Denton Cooley, associate of DeBakey
- 1960: Cooley moved out of Baylor and into St Luke's Hospital, establishing famous Texas Heart Institute
- 1969: Cooley commandeered an artificial heart from DeBakey's lab at Baylor and implanted into patient at St Luke's, without permission. First ever human implant.
- Cooley censured by American College of Surgeons
- 40 year feud, reconciled before Debakey died in 2008.



Total Artificial Hearts (TAH)

Longest support to date: Almost 4 years

Recent News: Driver failure has caused increased mortality in TAH patients

https://www.tctmd.com/news/fda-warns-deaths-stroke-due-power-system-problems-total-artificial-heart-system?utm_source=TCTMD

Notice one thing about these TAHs?

They pulse…therefore, they are first generation devices

What about second and third generation TAHs?

Continuous Flow TAHs – Can the human body be supported with only continuous flow?

2 x LVAD as a TAH. – Video (4 min)

WARNING

This video contain graphic content of open heart surgery in humans and animals.

It is also overly-dramatic

https://player.vimeo.com/video/33741794?title=0&byline=0&portrait=0

TAHs Under Development

Cleveland Clinic

Short term in-vivo

BiVACOR

Short term in-vivo

BiVACOR

TAH owned and commercialized by BiVACOR inc, Houston, Texas

Links to international research centres in Australia, Japan, Germany, Taiwan

3rd generation

- Zero mechanical wear

Flow balancing

- Automatically adjusts impeller speed and position to deliver required blood flow

BiVACOR

Image courtesy of bivacor.com

https://www.theaustralian.com.au/news/special-features/bivacor-heart-daniel-timms-stroke-of-genius/news-story/5bf85088fbe2d148b8028db1c7eb3a40?nk=6ba94a6496363b3c2e86978c864d8373-1534804000

Question:

Which do you think is better to implant: a total artificial heart (TAH) or a VAD? Give one reason why

Think about:

- Advantages/disadvantages of leaving the ventricles in
- Size of each device
- Which surgery is easier?
- Cost?

Answer example:

"VAD: They are more shiny"

VAD or TAH?

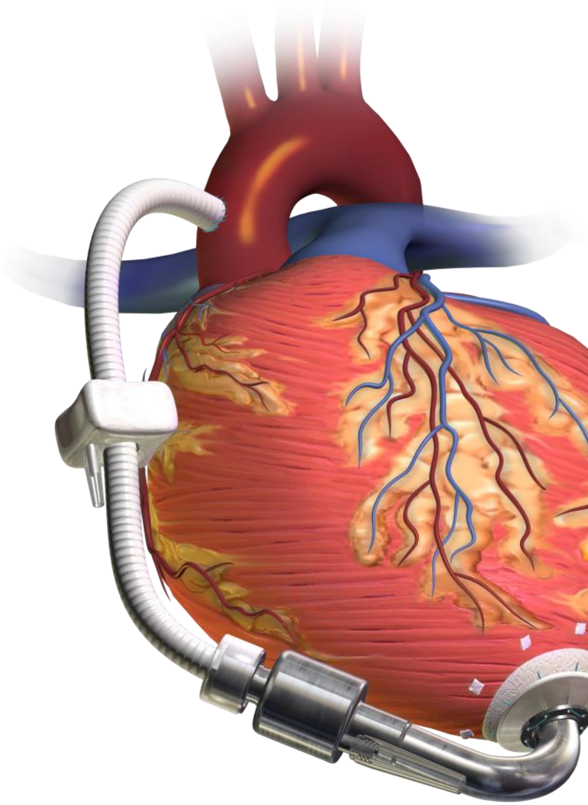
SIZE

VAD	TAH
	

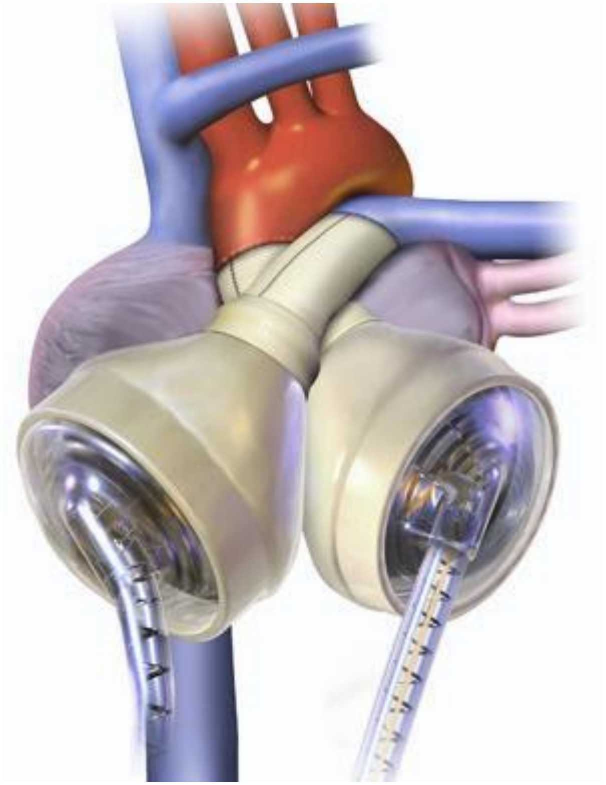
VAD or TAH?

IMPLANTATION

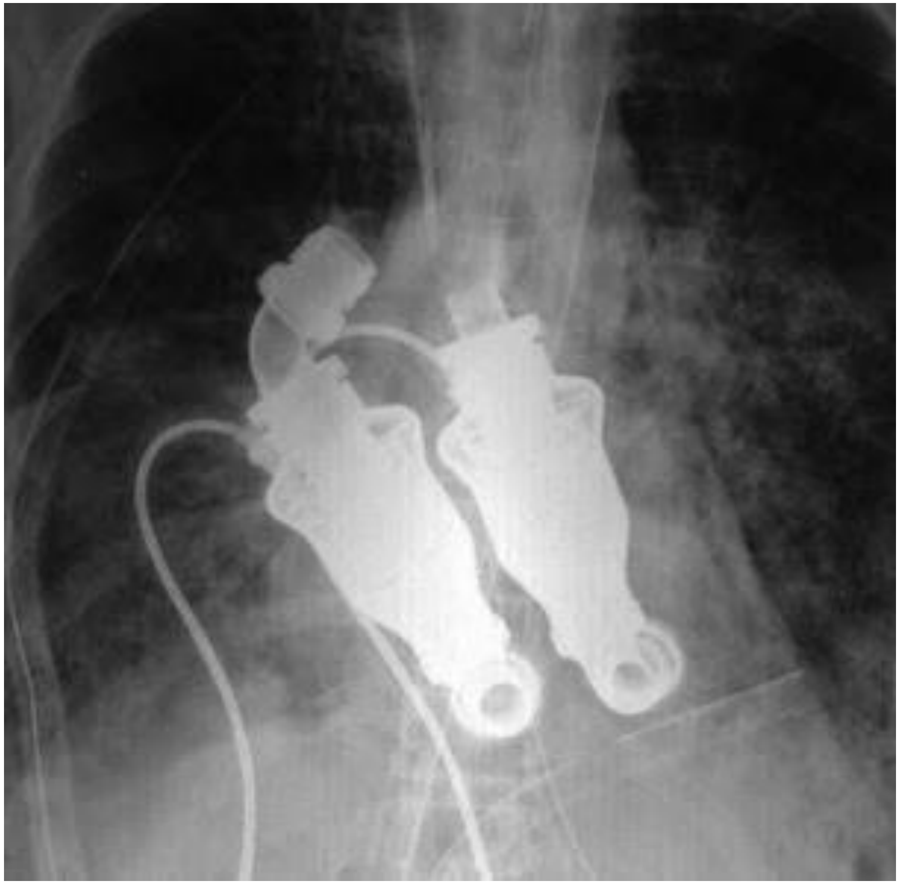
VAD



TAH



VAD AS TAH



Dual HMII LVADs as TAH

What next?

1. Finish the cardiovascular system videos (if you haven't done so already).

2. Watch the two remaining videos on the Moodle page

- "LVAD and its peripherals"
- "LVAD in action"

Before the tutorial

Read the review paper by Samak et al. (2015), located on Moodle (or online here https://basic.medscimonit.com/abstract/index/idArt/895418)

During the tutorial

Work in groups to solve the problems – follow your tutor's instructions

Refer to the lecture notes to answer the questions

Thank you!

- Email me (michael.stevens@unsw.edu.au) if you have any questions!