LECTURES 2-3: ARTIFICIAL HEART AND LUNG ASSIST DEVICES

2.1 Ventricular Assist Devices

A ventricular assist device (VAD) is a mechanical pump that's used to support heart function and blood flow in people who have weakened hearts. The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would.

Ventricles are the lower chambers of your heart. A VAD can help support your heart:

• During or after surgery, until your heart recovers.

• While you're waiting for a heart transplant.

• If you're not eligible for a heart transplant.

• A VAD has several basic parts. A small tube carries blood out of your heart into a pump. Another tube carries blood from the pump to your blood vessels, which deliver the blood to your body.

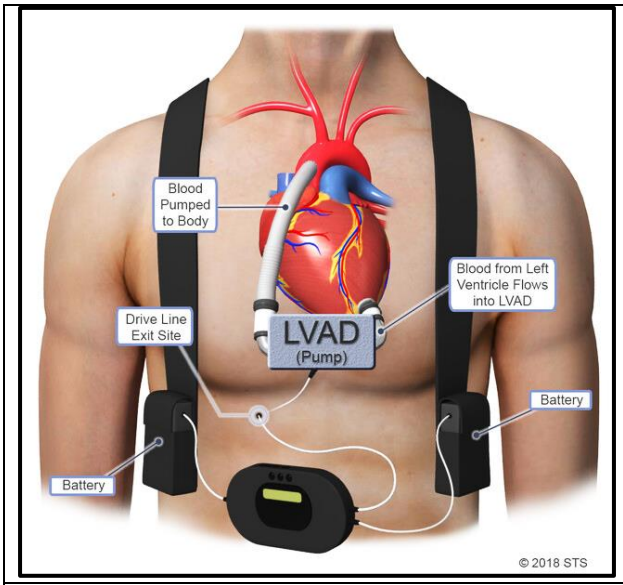
• A VAD also has a power source that connects to a control unit. This unit monitors the VAD's functions. It gives warnings, or alarms, if the power is low or the device isn't working well.

• Some VADs pump blood like the heart does, with a pumping action. Other VADs keep up a continuous flow of blood. With a continuous flow VAD, you might not have a normal pulse, but your body is getting the blood it needs.

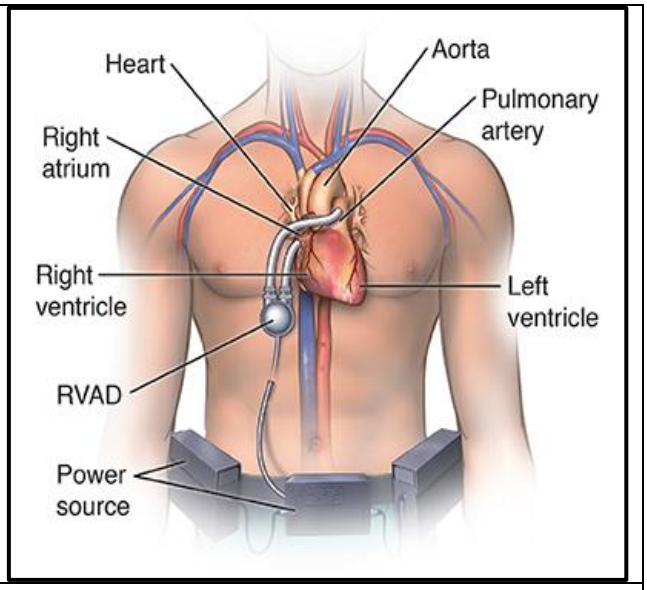
• Research has shown that, compared with other VADs, continuous flow VADs may decrease hospital stays and complications and improve survival. However, more research is needed.

2.1.1 Types of Ventricular Assist Devices

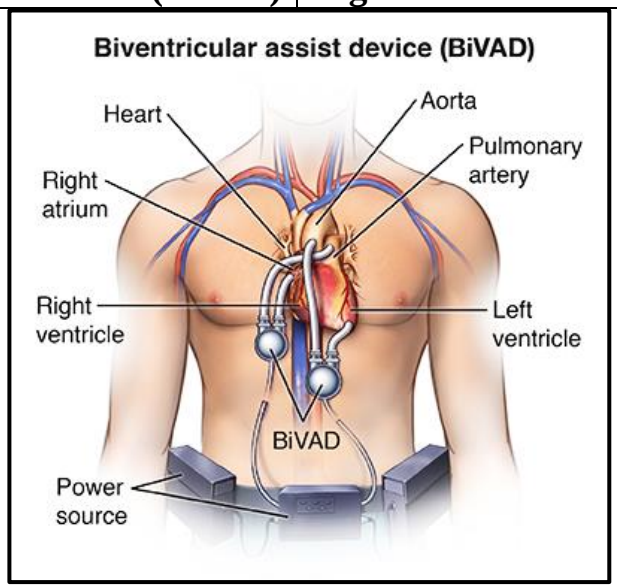
- The two basic types of VADs are a left ventricular assist device (LVAD) and a right ventricular assist device (RVAD). If both types are used at the same time, they're called a biventricular assist device (BIVAD).



Left ventricular assist device (LVAD)

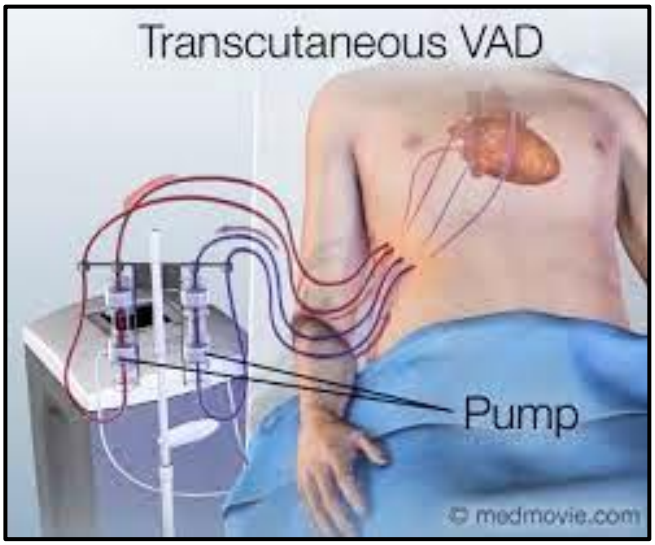


Right ventricular assist device (LVAD)



- The LVAD is the most common type of VAD. It helps the left ventricle pump blood to the aorta. The aorta is the main artery that carries oxygen-rich blood from your heart to your body.

- RVADs usually are used only for short-term support of the right ventricle after LVAD surgery or other heart surgery. An RVAD helps the right ventricle pump blood to the pulmonary artery. This is the artery that carries blood from the heart to the lungs to pick up oxygen.
- A BIVAD might be used if both ventricles don't work well enough to meet the body's needs. Another treatment option for this condition is a total artificial heart (TAH). A TAH is a device that replaces the ventricles.
- VADs have two basic designs. A transcutaneous VAD has its pump



An implantable VAD has its pump located inside of the body and its power source located outside of the body. A cable connects the pump to the power source through a small hole in the abdomen.

Implantable VADs are used mainly for people who are waiting for heart transplants or as a long-term solution for people who can't have heart transplants. Until recently, VADs were too big to fit in many people's chests, especially women and children. Only people who had large chests could get them.

In the past, VADs mostly were used for people who had end-stage heart failure. Now VADs also can help people who have earlier stages of heart failure. Also, the Food and Drug Administration recently approved a VAD designed for smaller children.

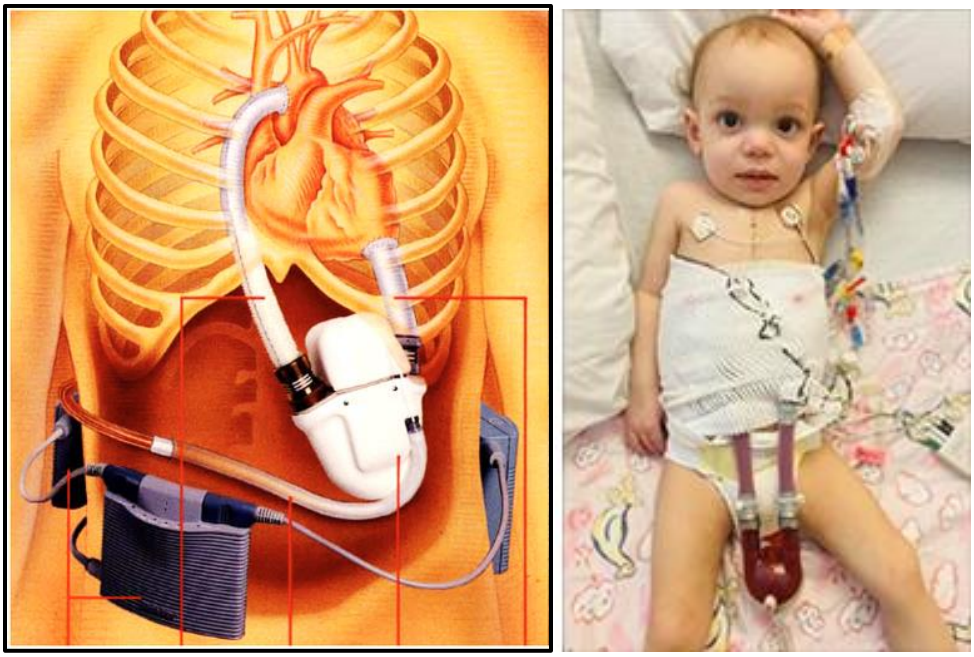
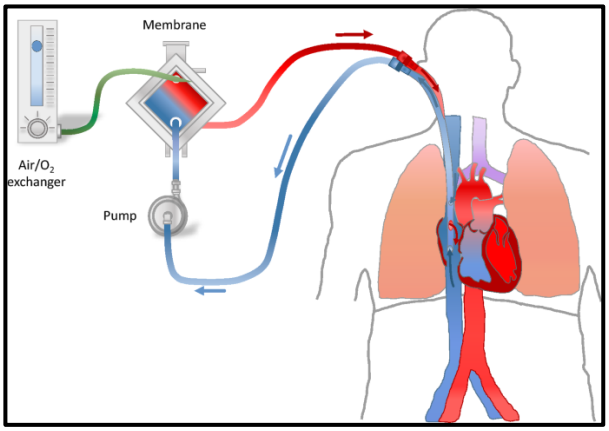


FIGURE 1. The implantable system. Blood enters the device through the inflow conduit from the left ventricle, and pumps blood to the body through the outflow conduit to the ascending aorta.

2.2 LUNG ASSISTING DEVICES

The Nova lung Interventional Lung Assist device is a membrane ventilator that allows for oxygen and carbon dioxide gas exchange to occur by simple diffusion. It has been used in patients with severe acute lung failure due to ARDS, inhalation injury, severe pneumonia, chest injury, foreign body aspiration, and after thoracic surgical interventions.



The use of extracorporeal CO2 removal in acute respiratory failure

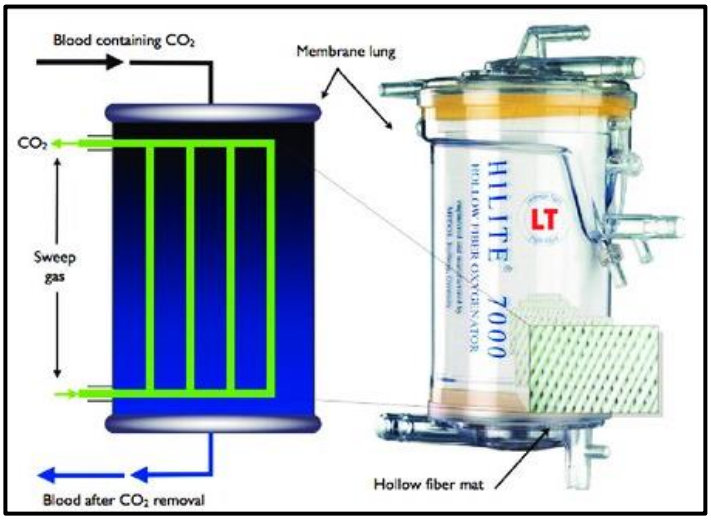


Figure 2. Diagram showing the basic principle of a membrane lung. Sweep gas passes through the hollow fibres

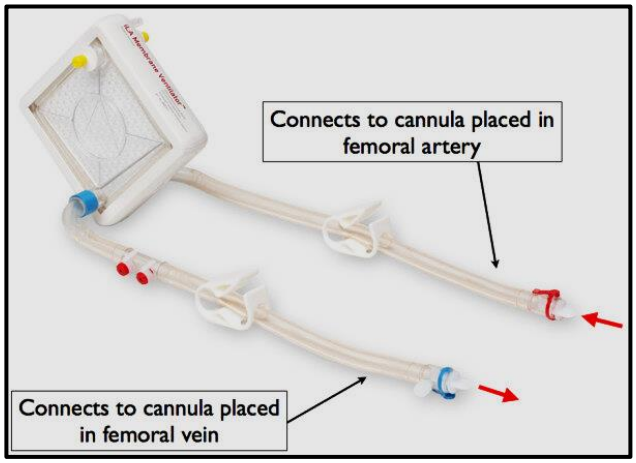


Image of the interventional lung assist (iLA), blood is propelled through the circuit by arterial pressure. Image courtesy of Novolung (GmbH, Hechingen, Germany).

The iLA consists of a plastic gas exchange module with diffusion membranes made from polymethyl pentene (PMP). These PMP fibers are woven into a complex configuration of hollow fibers, which provides maximum blood/gas mixing. Gas transfer takes place without the direct contact with blood. In addition, the PMP membrane surface in contact with blood is treated with a heparin coating to provide a biocompatible and non-thrombogenic surface.

Blood flows over the exterior surface of the device's fibers; the ventilating gas (commonly O_2) flows inside these fibers. In this way the Novalung iLA mimics the native lung. This allows for the blood exiting the device to have the normal amount of oxygen and carbon dioxide that exits the normal lung.

Recently reported on the successful use of the Novalung iLA as a bridge to lung transplantation in patients with severe ventilation-refractory respiratory acidosis and hypercapnia. The use of the device allows for a safer form of ventilation (protective ventilation), because the patients' carbon dioxide levels and pH can be adjusted to normal levels with the device.

2.3 ARTIFICIAL HEART VALVE

An artificial heart valve is a device implanted in the heart of a patient with valvular heart disease. When one of the four heart valves malfunctions, the medical choice may be to replace the natural valve with an artificial valve. This requires open-heart surgery.

There are three main types of artificial heart valves: the mechanical, the biological, and the tissue engineered valves.

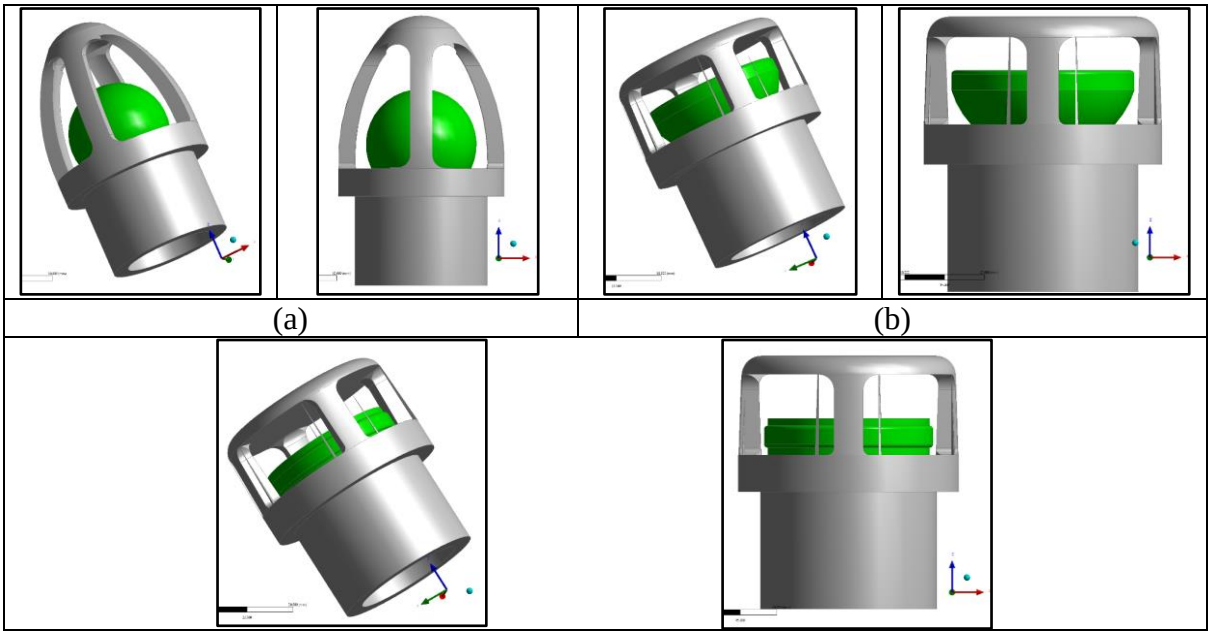
- **Mechanical heart valve**
  - o Percutaneous implantation
    - -Stent framed
    - -Not framed
  - o Sternotomy/Thoracotomy implantation

-Ball and cage
-Tilting disk
-Bi-leaflet
-Tri-leaflet

- **Tissue (biological) heart valves**
  - o Allograft/isograft
  - o Xenograft
- **Tissue-Engineered heart valves**

2.3.1 MECHANICAL VALVES

Mechanical heart valves (MHV) are prosthetics designed to replicate the function of the natural valves of the human heart. The human heart contains four valves: tricuspid valve, pulmonary valve, mitral valve and aortic valve. Their main purpose is to maintain unimpeded forward flow through the heart and from the heart into the major blood vessels connected to the heart, the pulmonary artery and the aorta. As a result of a number of disease processes, both acquired and congenital, any one of the four heart valves may malfunction and result in either stenosis (impeded forward flow) and/or backward flow (regurgitation).



(c)

Figure 2. The designed prosthetic artificial mechanical heart valve; (a) the designed conical caged ball valve; (b); the single hemispherical caged ball valve (c) the single-leaflet valve

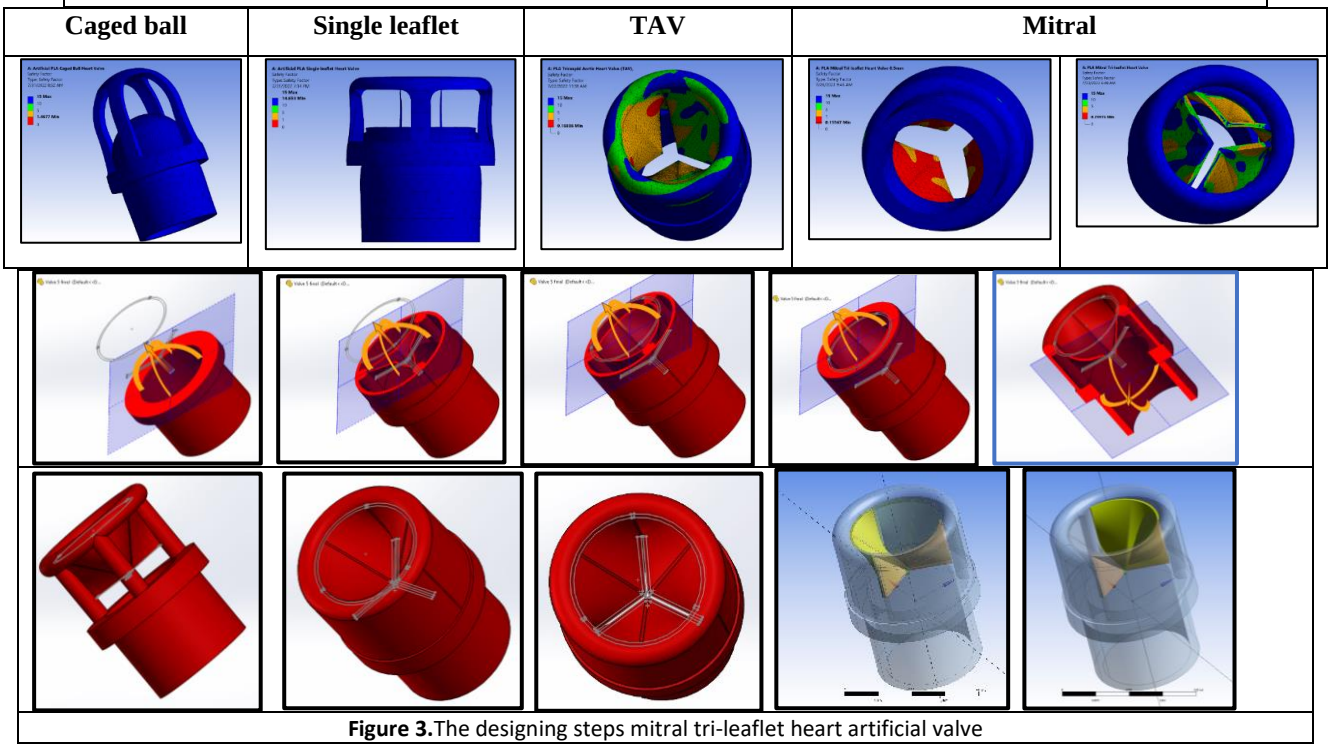


Figure 3. The designing steps mitral tri-leaflet heart artificial valve

Current mechanical heart valves all require lifelong treatment with anticoagulants (blood thinners), e.g. warfarin, which requires monthly blood tests to monitor. This process of thinning the blood is called anticoagulation.

Tissue heart valves, in contrast, do not require the use of anticoagulant drugs due to the improved blood flow dynamics resulting in less red cell damage and hence less clot formation. Their main weakness however, is their limited lifespan. Traditional tissue valves, made of pig heart valves, will last on average 15 years before they require replacement (but typically less in younger patients).

There are three major types of mechanical valves – caged-ball, tilting-disk and bileaflet valve – with many modifications on these designs.

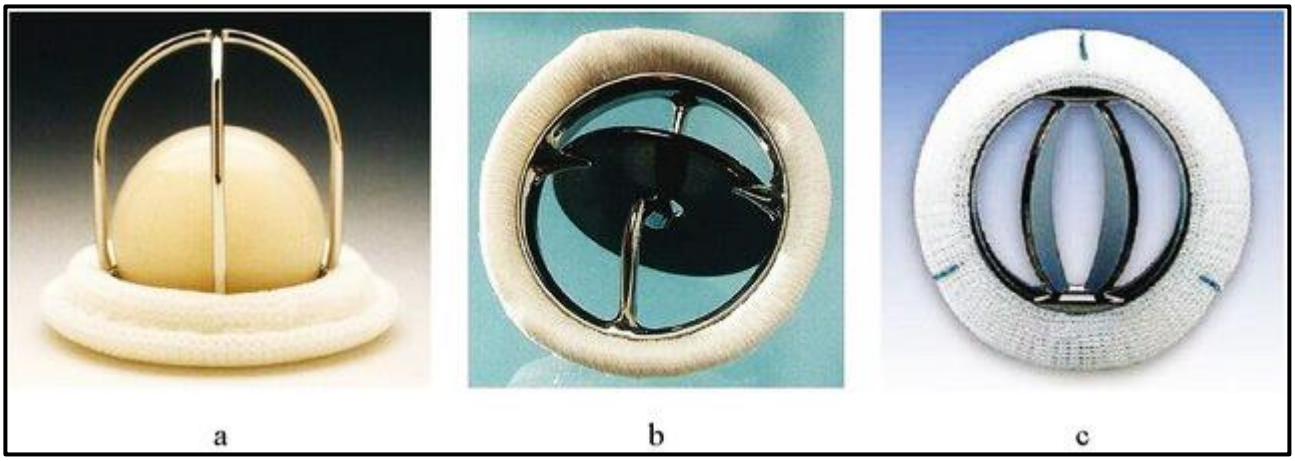


Figure. Three kinds of mechanical valves, a) caged-ball, b) tilting-disc and c) bileaflet

Caged ball valve - The caged-ball utilizes a metal cage to house a silicone elastomer ball. When blood pressure in the chamber of the heart exceeds that of the pressure on the outside of the chamber the ball is pushed against the cage and allows blood to flow. At the completion of the heart's contraction, the pressure inside the chamber drops and is lower than beyond the valve, so the ball moves back against the base of the valve forming a seal.

Tilting-disc valve - Tilting disk valves have a single circular occluder controlled by a metal strut. They are made of a metal ring covered by an ePTFE fabric, into which the suture threads are stitched in order to hold the valve in place. The metal ring holds, by means of two metal supports, a disc which opens and closes as the heart pumps blood through the valve. The disc is usually made of an extremely hard carbon material (pyrolytic carbon), in order to allow the valve to function for years without wearing out. In some models of mechanical valves, the disc is divided into two parts, which open and close as a door.

Bileaflet valve - Bileaflet heart valves consist of two semicircular leaflets that rotate about struts attached to the valve housing. Bileaflets are vulnerable to backflow and so they cannot be considered as ideal. Bileaflet valves do, however, provide much more natural blood flow than caged-ball or tilting- disc implants. One of the main advantages

of these valves is that they are well tolerated by the body. Only a small amount of blood thinner is needed to be taken by the patient each day in order to prevent clotting of the blood when flowing through the valve.

Mechanical heart valves are today very reliable and allow the patient to live a normal life. Most mechanical valves last for at least 20 to 30 years

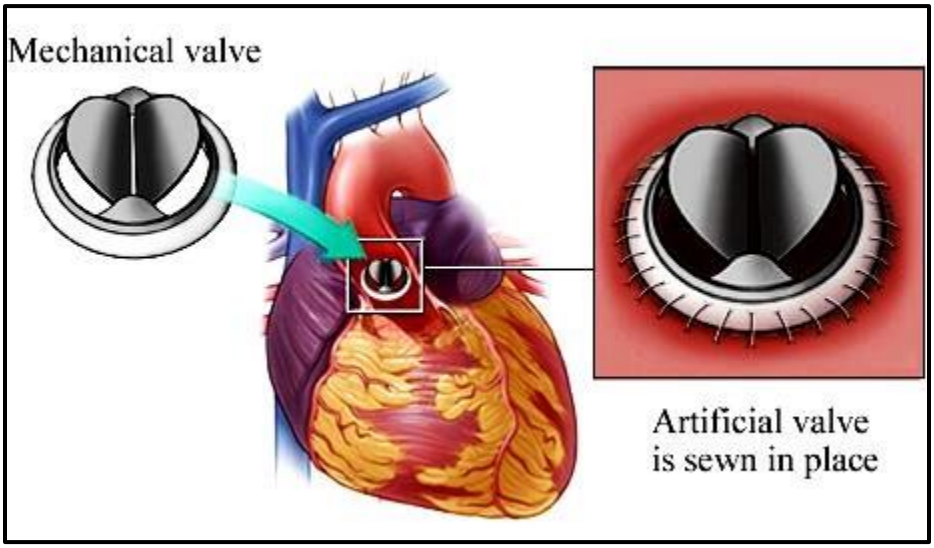


Figure. Schematic picture of using bileaflet valve as aortic valve

Durability of the Mechanical heart valves

Mechanical heart valves have been traditionally considered to be more durable in comparison to their bioprosthetic counterparts. The struts and occluders are made out of either pyrolytic carbon or titanium coated with pyrolytic carbon, and the sewing ring cuff is Teflon (PTFE), polyester or Dacron. The major load arises from transvalvular pressure generated at and after valve closure, and in cases where structural failure does happen, it is usually as a result of occluder impact on the components.

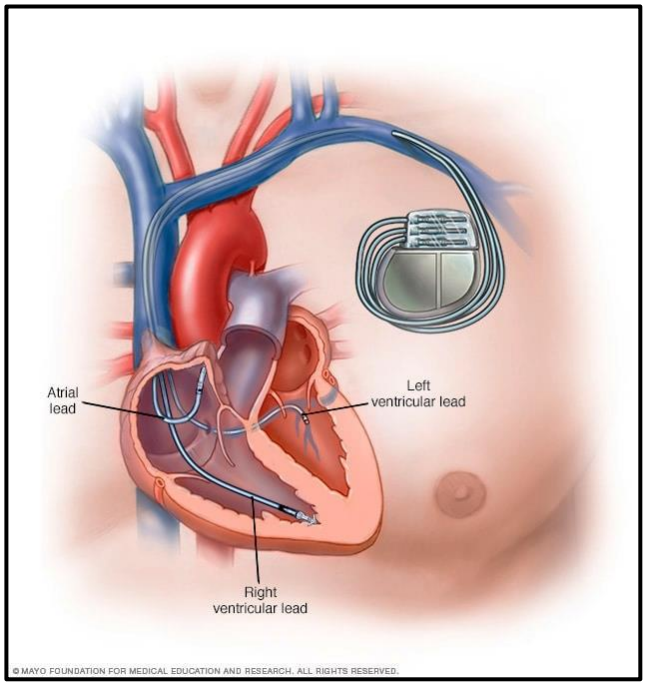
Impact wear and friction wear dictate the loss of material in MHV. Impact wear usually occurs in the hinge regions of bileaflets, between the occluder and ring in tilting-discs, and between the ball and cage in caged-ball valves. Friction wear occurs between the occlude and strut in tilting-discs, and between the leaflet pivots and hinge cavities in

bileaflets. MHV, made out of metal are also susceptible to fatigue failure owing to the polycrystalline characteristic of metals, but this is not an issue with pyrolytic carbon MHV because this material is not crystalline in nature

2.4 CARDIAC PACEMAKER

A pacemaker or artificial pacemaker is a medical device which uses electrical impulses, delivered by electrodes contracting the heart muscles, to regulate the beating of the heart.

The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's natural pacemaker is not fast enough, or because there is a block in the heart's electrical conduction system. Modern pacemakers are externally programmable and allow a cardiologist to select the optimum pacing modes for individual patients. Some combine a pacemaker and defibrillator in a single implantable device. Others have multiple electrodes stimulating differing positions within the heart to improve synchronization of the lower chambers (ventricles) of the heart



LECTURES 2-3: ARTIFICIAL HEART AND LUNG ASSIST DEVICES

A pacemaker is a small, battery-operated device that senses when the heart is beating irregularly or too slowly. It sends a signal to your heart that makes your heart beat at the correct pace.

Most pacemakers have 2 parts:

- The generator contains the battery and the information to control the heartbeat.
- The leads are wires that connect the heart to the generator and carry the electrical messages to the heart.

A pacemaker must be implanted under the skin. This procedure takes about 1 hour in most cases. You will be given a sedative to help you relax. You will be awake during the procedure. They are not permanent pacemakers

When the heart beats too slowly, your body and brain may not get enough oxygen. Symptoms may be light-headedness, tiredness, fainting spells, and shortness of breath.

How does a pacemaker work?

A pacemaker consists of a battery, a computerized generator, and wires with sensors at their tips. (The sensors are called electrodes.) The battery powers the generator, and both are surrounded by a thin metal box. The wires connect the generator to the heart.

A pacemaker helps monitor and control your heartbeat. The electrodes detect your heart's electrical activity and send data through the wires to the computer in the generator.

If your heart rhythm is abnormal, the computer will direct the generator to send electrical pulses to your heart. The pulses travel through the wires to reach your heart.

Newer pacemakers can monitor the blood temperature, breathing, and other factors. They also can adjust your heart rate to changes in your activity. The pacemaker's

computer also records your heart's electrical activity and heart rhythm. Your doctor will use these recordings to adjust your pacemaker so it works better for you.

The doctor can program the pacemaker's computer with an external device. He or she doesn't have to use needles or have direct contact with the pacemaker.

Pacemakers have one to three wires that are each placed in different chambers of the heart.

- The wires in a single-chamber pacemaker usually carry pulses from the generator to the right ventricle (the lower right chamber of your heart).
- The wires in a dual-chamber pacemaker carry pulses from the generator to the right atrium (the upper right chamber of your heart) and the right ventricle. The pulses help coordinate the timing of these two chambers' contractions.
- The wires in a biventricular pacemaker carry pulses from the generator to an atrium and both ventricles. The pulses help coordinate electrical signaling between the two ventricles. This type of pacemaker also is called a cardiac resynchronization therapy (

2.5 ARTIFICIAL SKIN

Artificial skin refers to a collagen scaffold that induces regeneration of skin in mammals. The term was used in the late 1970s and early 1980s to describe a new treatment for massive burns. It was later discovered that treatment of deep skin wounds in adult animals and humans with this scaffold induces regeneration of the dermis. It has been developed commercially under the name IntegraTM and is used in massively burned patients, during plastic surgery of the skin, and in treatment of chronic skin wounds.

The skin is the largest organ in the human body. Skin is made up of three layers, the epidermis, dermis and the fat layer, also called the hypodermis. The epidermis is the outer layer of skin that keeps vital fluids in and harmful bacteria out of the body. The

dermis is the inner layer of skin that contains blood vessels, nerves, hair follicles, oil, and sweat glands. Severe damage to large areas of skin exposes the human organism to dehydration and infections that can result in death.