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Design and Development Artificial Heart Valve

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Annotation: Design of an artificial heart valve (case study) using (SOLIDWORKS) based on international standards and measurements. The type of valve was chosen from among the many known types based on several studies, including the study of characteristics and the uses of each type. The studies included field visits to the specialized cardiology centers, including Ibn al-Bitar Hospital, and to see the cases of common injuries and damage that occur in the natural heart valves. We achieved several answers from them. Type of artificial valve (Mechanical bileaflets valve) was chosen according to the mentioned studies. These studies also included (study of the blood flow in each type and the effect of the material on the body on the body and its compatibility with the daily routine of the person). the material was strong, durable, fatigue resistant and biocompatible. Also, other properties like the hydrophobic property and others. It is worth noting that our choice of this type does not mean the inefficiency of the other heart valves. However, this valve was chosen based on its special characteristics and its need in the daily routine of the patient. According to the experts, Mitral Valve damage is the most common in Iraq, and the best choice for replacement is the (Mechanical Bileaflet Valve).

1. Overview

INTRODUCTION

The development of the heart lung machine and safe ways to stop and restart the heart raised the possibility of replacing defective heart valves. From the 1950s onwards there were many attempts to build artificial valves, that mimicked the anatomy of heart valves, from artificial materials [1].

Many problems and diseases can occur inside the heart of human and all these problems consider dangerous and deadly diseases, so that lead the specialists to think for solutions may be through medicine or through surgery.

2. Anatomy and Function of the Heart Valves

1. What are heart valves?

The heart consists of 4 chambers, 2 atria (upper chambers) and 2 ventricles (lower chambers). Blood passes through a valve before leaving each chamber of the heart. The valves prevent the backward flow of blood. Valves are actually flaps (leaflets) that act as one-way inlets for blood coming into a ventricle and one-way outlets for blood leaving a ventricle. Normal valves have 3 flaps (leaflets), except the mitral valve, which only has 2 flaps. The 4 heart valves include:

1. **Aortic valve:** The aortic valve is located between the left ventricle and the aorta.
2. **Pulmonary valve:** The pulmonary valve is locating between the right ventricle and the pulmonary artery.
3. **Tricuspid valve:** This valve is located between the right atrium and the right ventricle.
4. **Mitral valve:** This valve is located between the left atrium and the left ventricle. It has only 2 leaflets.

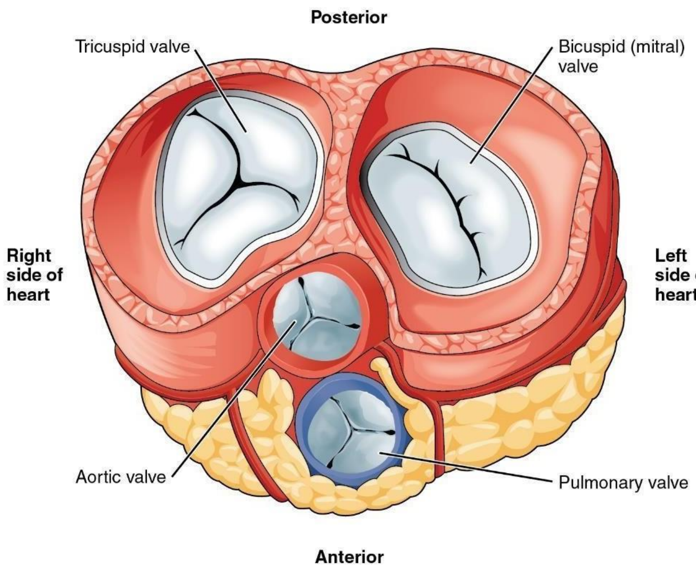


Fig (1.1): Heart Valves

2. *How do the heart valves function?*

As the heart muscle contracts and relaxes, the valves open and shut, letting blood flow into the ventricles and atria at alternate times. The following is a step-by-step description of how the valves function normally in the left ventricle:

- When the left ventricle relaxes, the aortic valve closes and the mitral valve opens, to allow blood to flow from the left atrium into the left ventricle.
- The left atrium contracts, allowing even more blood to flow into the left ventricle.

- When the left ventricle contracts again, the mitral valve closes and the aortic valve opens, so blood flows into the aorta.

3. Types of Valves and Their Diseases

1. The Aortic Valve

Is located between the aorta and the heart's left ventricle. The pulmonary vein delivers oxygenated blood to the heart's left atrium. Then it passes through the mitral valve and into the left ventricle. With each of the heart muscle’s contractions, oxygenated blood exits the left ventricle through the aortic valve. In most cases, three flaps comprise the valve. Namely the right coronary cups (R), the lift coronary cusp (L), and the non-coronary cusp (N). [2]

The bicuspid aortic valve is the most common cardiac valve abnormality. Due to a congenital (present at birth) condition. Here are two leaflets fused during the development. A bicuspid aortic valve occurs in 1-2% of the population and twice as often in men compared to women.

A bicuspid aortic valve can be hereditary, both familial clustering and isolated valve defects are documented. The incidence of bicuspid aortic valve may reach 10% in certain families. A bicuspid aortic valve is often associated with other congenital heart defects, including coarctation of the aorta. Usually there is a fusion between the LCC and RCC (70%). In many cases, the bicuspid aortic valve does not cause any problems. Later in life, the valve will calcify early causing a stenosis and possibly also regurgitation through maladaptation of the affected crisps.

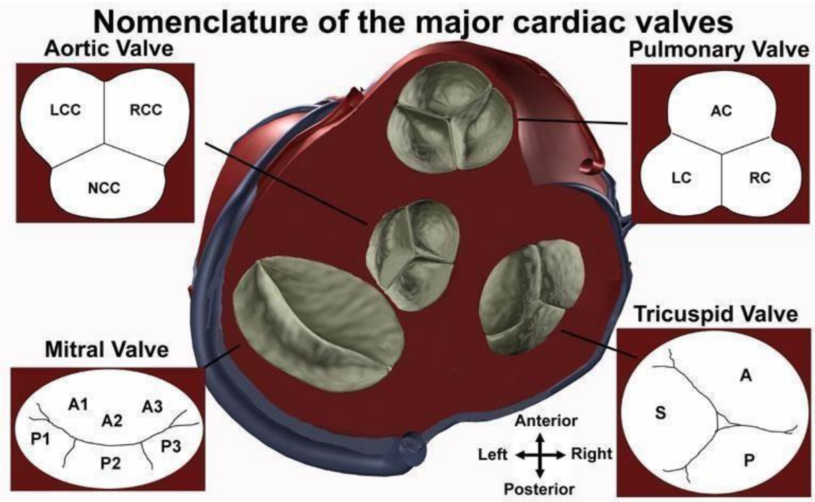


Fig (1.2): Names of heart valves

Diseases of Aortic Valve

- **Aortic valve regurgitation**: occurs when blood flows backward through the aortic valve into the left ventricle each time the ventricle relaxes rather than in the normal, one-way direction from the ventricle to the aorta. Back flow may be caused by a dysfunctional or leaky valve. This may be due to deterioration of the valve, an abnormal valve shape present at birth (congenital heart disease) or by a bacterial infection. [3][4][5]

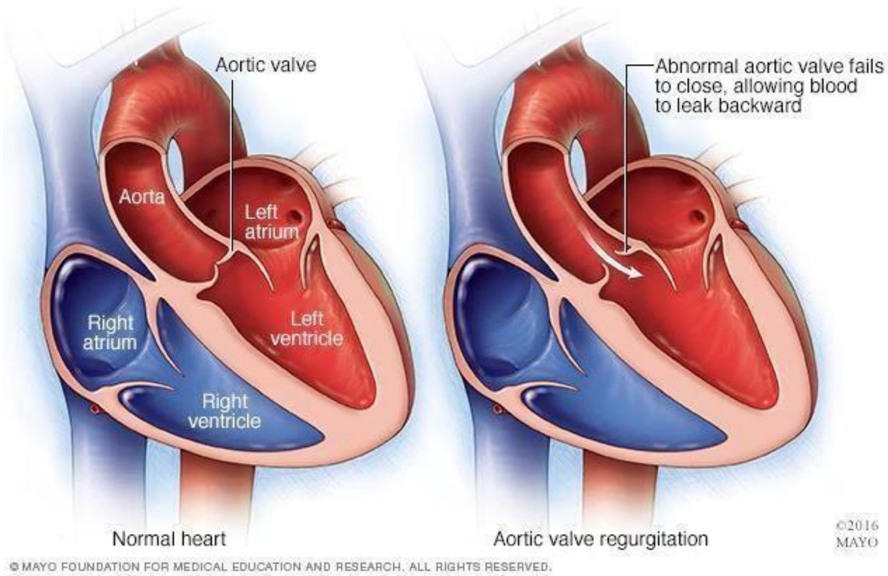


Fig (1.3) Aortic valve regurgitation

- **Aortic valve stenosis:** causes the aortic valve to become narrowed or obstructed, which makes it harder for the heart pump blood into the aorta. This may be caused by congenital heart disease, thickening of the valve's closure flaps (cusps) or post-inflammatory changes, such as those associated with rheumatic heart disease. [5]

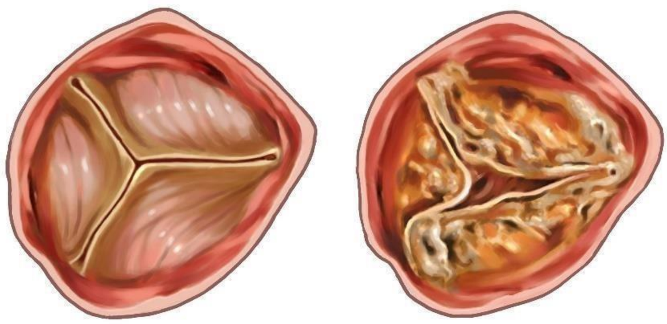


Fig (1.4): Aortic valve stenosis

- **Congenital heart disease** may contribute to aortic valve regurgitation or stenosis as well as result in other problems that prevent the aortic valve from working properly. For example, a person may be born with an aortic valve that doesn't have enough tissue flaps (cusps), the valve may be the wrong size or shape, or there may not be an opening to allow blood to flow normally (atresia) [4][6].

2. *The Pulmonary Valve*

Is one of two valves that allow blood to leave the heart via the arteries. It is a one-way valve, meaning that blood cannot flow back into the heart through it. The valve is opened by the increased blood pressure of the ventricular systole (contraction of the muscular tissue), pushing blood out of the heart and into the pulmonary artery. It closes when the pressure drops inside the heart. It is located in the right ventricle of the heart. The pulmonic valve opens into the pulmonary artery.

The frequency of this cycle depends upon the heart rate. Pulmonary stenosis is a condition where the blood flow out of the heart is obstructed at the pulmonic valve. Its three leaflets, or cusps, are difficult to name because of the oblique angle of the valve. Its nomenclature is therefore derived based on the nomenclature of the aortic valve, which lies in proximity to it. The tow leaflets attached to the septum are named the left and right leaflets, and correspond to the right and left leaflets of the aortic valve, which they face. The third leaflet is called the anterior leaflet or the non-coronary leaflet.

The most common cause of this is congenital heart disease, although rheumatic heart disease and a malignant carcinoid tumor can also initiate the problem. The condition is treated by surgical repair or replacement of the pulmonic valve. [7][8].

Disease of the pulmonary valve

- **Pulmonary valve regurgitation**: is a leaky pulmonary valve. The leaky valve allows blood to flow backward into the heart rather than directly to the lungs for oxygen. The most common cause of pulmonary valve regurgitation is pulmonary hypertension. Other causes of pulmonary valve regurgitation are congenital heart disease (specifically, tetralogy of Fallot or congenital pulmonary valve stenosis), bacterial infection of the heart (infective endocarditis), complications after heart surgery, and rarely rheumatic fever. [8][9].

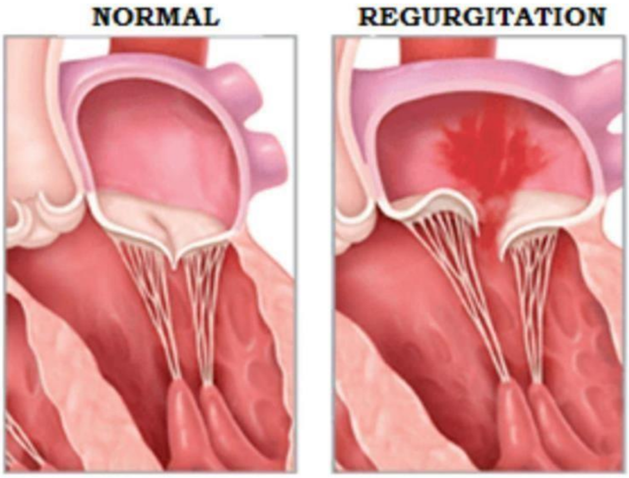


Fig (1.5): Pulmonary valve regurgitation

- **Pulmonary valve stenosis:** occurs when the pulmonary valve becomes thickened or obstructed, which makes it harder for it to open properly and for the heart to pump blood into the pulmonary artery and to the lungs.The cause of pulmonary valve stenosis is usually unknown. It often affects children and may be caused by congenital heart disease or an infection in the mother during pregnancy. It can also occur in adults as a result of a rare type of cancer that affects the heart (carcinoid heart disease) [8][9] [10].

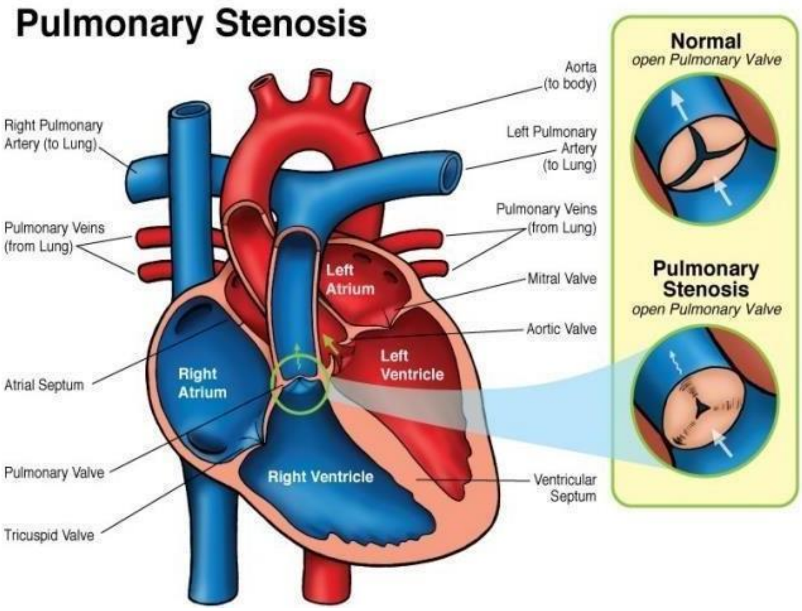


Fig (1.6): Pulmonary valve stenosis

- **Pulmonary atresia**: is a congenital heart defect in which a child is born without a well-defined pulmonary valve. In pulmonary atresia, blood can't flow from the right ventricle into the pulmonary artery. The only blood flow to the lungs is through an open passageway between the pulmonary artery and the main artery supplying blood to the body (aorta). The cause is usually unknown. Children born with pulmonary atresia may also have other heart defects.[9][10]

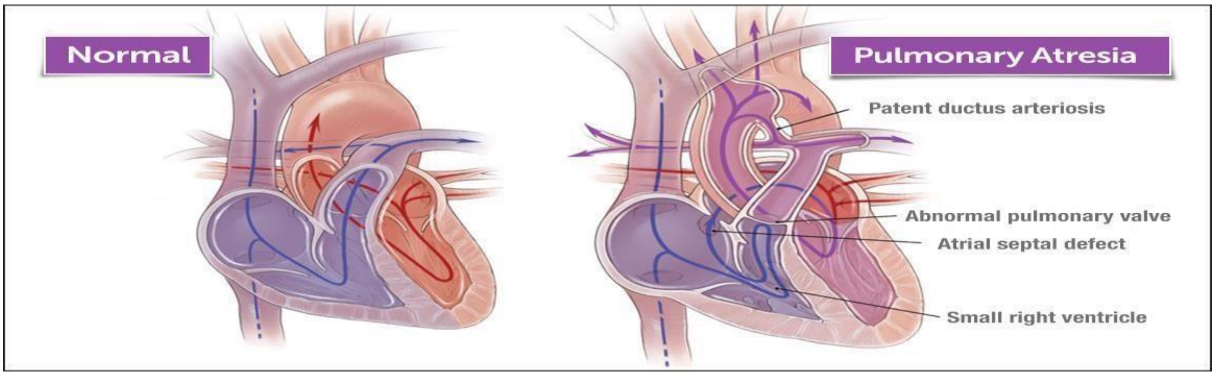


Fig (1.7): Pulmonary atresia

3. *The Tricuspid Valve*

It forms the boundary between the right ventricle and the right atrium. Deoxygenated blood enters the right side of the heart via the inferior and superior vena cava. These are large veins that transport deoxygenated blood from the body back to the heart. Blood collects within the right atrium, and it must flow through the tricuspid valve in order to enter the right ventricle. Then, blood exits the heart via the pulmonary artery, which transmits blood to the lungs for oxygenation. The term 'tricuspid' refers to how the valve is constructed. It contains three flap-like cusps namely, the anterior (A), septal (S), and posterior (P). When closed, keep blood from regressing back into the right atrium [11] [12].

Disease of the tricuspid:

- **Tricuspid valve regurgitation:** occurs when the tricuspid valve doesn't close properly and allows blood to flow back into the right atrium when the right ventricle contracts rather than in the normal, one-way direction from the atrium to the ventricle. [12] [13] [14]

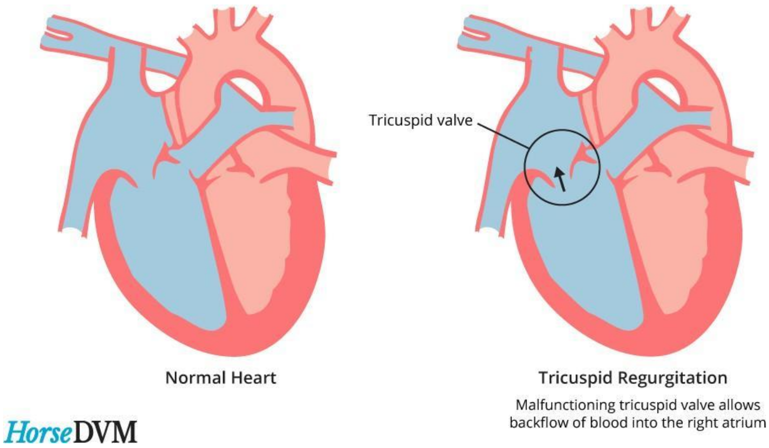


Fig (1.8): Tricuspid valve regurgitation

- **Tricuspid valve stenosis**: causes the tricuspid valve to become narrowed or obstructed, which makes it more difficult for blood to flow from the right atrium to the right ventricle. Tricuspid valve stenosis may also be accompanied by tricuspid regurgitation or backflow. Tricuspid valve stenosis may be caused by congenital heart disease, thickening of the valve's closure flaps (leaflets), carcinoid heart disease or as a result of rheumatic fever [12] [13] [14].
- **Tricuspid atresia:** is a type of congenital heart disease that occurs when a baby is born without a tricuspid valve or opening to allow blood to flow from the right atrium to the right ventricle. As a result, the right ventricle is not fully developed and surgery is often needed to increase blood flow to the lung [12]

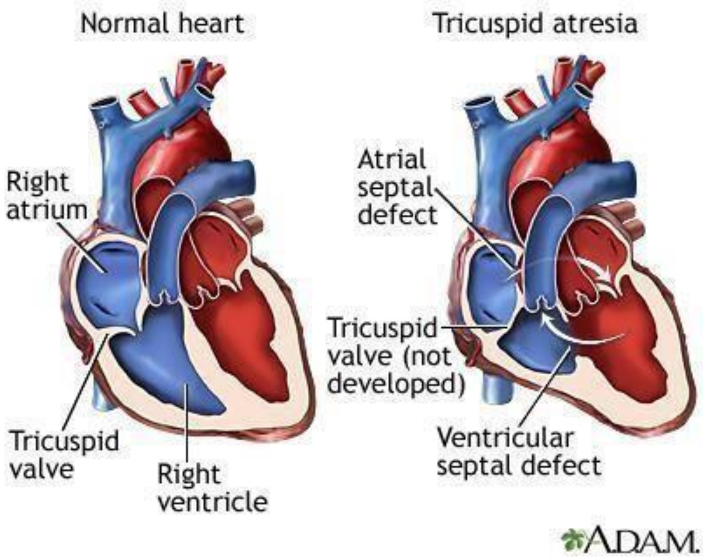


Fig (1.9): Tricuspid atresia

4. The Mitral Valve

Is located in the left side of the heart, between the left atrium and left ventricle. Oxygen-rich blood flows into the left atrium from the pulmonary veins. When the left atrium fills with blood, the mitral valve opens to allow blood to flow to the left ventricle.

It then closes to prevent blood from flowing back into the left atrium. All of this happens in a matter of seconds as the heartbeat.

The mitral valve has two leaflets. These are projections that open and close. One of the leaflets is called the anterior leaflet. This is a semicircular structure that attaches to two-fifths of the mitral valve’s area. The other is called the posterior leaflet. It attaches to the remaining three-fifths of the valve. Doctors usually divide the posterior leaflet into three scallops called P1, P2, and P3 [15]

Disease of the mitral valve:

- **Mitral valve regurgitation:** refers to extra blood flowing backward through the mitral valve and into the left atrium. This makes the heart work harder to move blood, causing an enlarged heart. Mitral valve prolapse can cause mitral valve regurgitation. A variety of other conditions, including a heart attack or rheumatic fever, can also cause it [16][17].

This condition can cause a range of symptoms, including:

- ✓ heart palpitations
- ✓ irregular heartbeat
- ✓ shortness of breath
- ✓ swelling in legs or feet & chronic cough

- **Mitral valve stenosis**: occurs when the mitral valve doesn't open efficiently. This results in less blood going through the valve. In response, the heart has to squeeze harder and faster to move enough blood through the heart.

Symptoms of mitral valve stenosis include:

- ✓ dizziness
- ✓ swollen feet
- ✓ shortness of breath
- ✓ coughing up blood
- ✓ chest pain [17] [18] [19] [20].

4. Reasons for Replacement

The valves of the heart are responsible for allowing nutrient-rich blood to flow through the chambers of your heart. Each valve is supposed to close completely after ushering in blood flow. Diseased heart valves aren't always able to perform the job as well as they should.

Stenosis, or a narrowing of the blood vessels, causes a less-than-normal amount of blood to flow to the heart. This causes the muscle to work harder. Leaky valves can also pose a problem. Instead of closing tightly, a valve may remain slightly open, letting blood flow backwards. This is called regurgitation. The signs of valvar heart disease can include:

- ✓ Fatigue
- ✓ Dizziness
- ✓ Lightheadedness
- ✓ Shortness of breath
- ✓ Cyanosis
- ✓ Chest pain
- ✓ Fluid retention, epically in the lower limbs

Heart valve repair is also a solution for valvar heart disease. In some people, the damage is too far advanced and a total replacement of the affected valve is the only option.

5. Types of Valve Replacement Surgery

1. Aortic Valve Replacement

The aortic valve is on the left side of the heart and serves as an outflow valve. Its job is to allow blood to leave the left ventricle, which is the heart's main pumping chamber. Its job is also to close so that blood doesn't leak back into the left ventricle. You may need surgery on your aortic valve if you have a congenital defect or disease that causes stenosis or regurgitation.

The most common type of congenital abnormality is a bicuspid valve. Normally, the aortic valve has three sections of tissue, known as leaflets. This is called a tricuspid valve. A defective valve has only two leaflets, so it's called a bicuspid valve. A recent study found that aortic valve replacement surgery has a 94 percent five-year survival rate. Survival rates depend on:

- ✓ age
- ✓ overall health
- ✓ other medical conditions you have
- ✓ heart function

2. Mitral Valve Replacement

The mitral valve is located on the left side of the heart. It serves as an inflow valve. Its job is to allow blood from the left atrium to flow into the left ventricle. Surgery may be required if the valve doesn't fully open or completely close. When the valve is too narrow, it can make it difficult for blood to enter. This can cause it to back up, causing pressure in the lungs. When the valve doesn't close properly, blood can leak back into the lungs. This can be due to a congenital defect, infection, or a degenerative disease [19].

The defective valve will be replaced with either a metal artificial valve or a biological valve. The metal valve will last a lifetime but requires you to take blood thinners. The biological valve lasts between 15 to 20 years, and you won't be required to take medication that thins your blood. The five-year survival rate is about 91 percent. The following also play a role in survival rate:

- ✓ age
- ✓ overall health
- ✓ other medical conditions you have
- ✓ heart function

3. Double Valve Replacement

A double valve replacement is a replacement of both the mitral and the aortic valve, or the entire left side of the heart. This type of surgery is not as common as the others and the mortality rate is slightly higher.

4. Pulmonary Valve Replacement

The pulmonary valve separates the pulmonary artery, which carries blood to the lungs for oxidation, and the right ventricle, which is one of the heart's chambers. Its job is to allow blood to flow from the heart to the lungs through the pulmonary artery. The need for pulmonary valve replacement is usually due to stenosis, which restricts blood flow. Stenosis may be caused by a congenital defect, infection, or carcinoid syndrome [14] [19] [20].

1. Overview

Serval specialists team and scientists across years trying to create something that acting or reparation the defect that occurs in the normal heart valves, in this chapter more details will be talked about.

A team at the University of Minnesota established the structure of heart valves taken from cattle and human cadavers. While the valves appear very delicate, the collagen in their structure makes them enormously strong.

Attempts were made to manufacture valves structured in much the same way using various polymers. Testing these valves in dogs, it was soon discovered that copying the natural design was not the answer. It was difficult to get the anchoring mechanism right, and the lack of strength was a major problem. Blood clotting around sutures was a problem with early designs. [21]

For durability, more robust materials and designs were clearly required. Woven materials such as knitted Teflon increased post-operative survival, with some dogs living for several weeks. This in turn led to the possibility of studying the problem of clotting, which is inevitably caused by foreign materials or damaged surfaces in the heart. It was established that the valve design should not have any nooks or crannies where blood could stagnate and tend to clot. Even when this problem is avoided, long-term anticoagulant drugs are necessary.

Simpler, stronger designs:

Stronger designs were still needed if these valves were to be used in patients. In the late 1950s/early 1960s, Albert Starr developed a simple caged ball valve. Implanted in dogs, survival times of 10 days, then seven months and later 13 months were reported. These long survival times enabled examination of effectiveness of the valves, in the living heart, even one year after implantation [22].

Obtaining long term dog survivors without anticoagulant treatment encouraged Starr to try replacing mitral valves in patients. By October 1961, of the 12 patients who had received artificial mitral valves, two had died from unrelated causes, and three from infections. The remaining patients were well and two had returned to work [23].

The Starr-Edwards caged-ball valve is still in use. Its success encouraged development and testing, in calves and dogs, of further designs, such as the caged disc valve and the tilting disc valve. The Bjork-Shiley tilting disk valve5 was introduced in 1969, and bi-leaflet, pivot designs were introduced in the 1970s. These are now the most common type of mechanical valve [24].

Replacement valves from pigs

The possibility of using transplanted valves was also explored in dogs and the best methods of preparation and storage were established. Human valves from cadavers were transplanted into human patients, but it became clear that there were logistical problems in maintaining an adequate supply. By the mid-1960s it was realised that the answer lay in transplanted valves from other species.

Xenograft valves, from pigs, sheep, calves and goats were transplanted into dogs in the early 1970s.6 Blood clots were not a problem, but durability and rejection needed to be tackled. Following work in rabbits, guinea pigs and rats, a biologically inert, functional and durable valve was produced by washing, denaturing and tanning processes. Such 'bioprosthetic' valves, usually from pigs, have been used successfully in many human patients [25].

Valves engineered from tissue

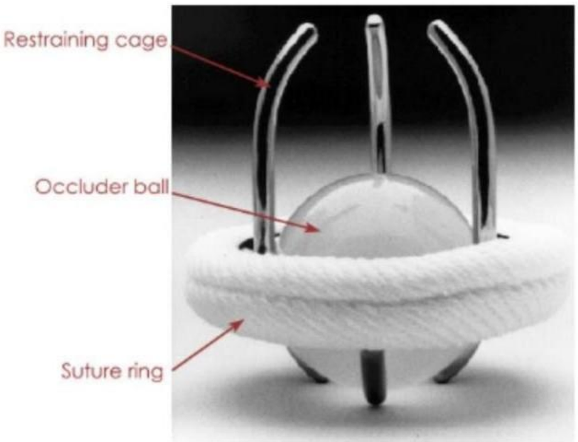
The future for replacement heart valves may lie in tissue engineering. The perfect replacement would obviously be formed from tissue from the patient, tailored to the right shape. Tissue from the artery of a lamb has been grown on a matrix of the correct shape in an artificial culture medium, and the resulting valves have been transplanted into sheep. [26] [27]

2. Classification of Artificial Heart Valves

Artificial heart valves can be classified into mechanical and biological. We have three types of mechanical heart valves: caged ball, tilting disc and leaflet.

1. Caged ball valve

The ball valve was the first mechanical heart valve used and designed by Charles Hufnagel. The Starr-Edwards ball valve was first used clinically as a mitral valve replacement in 1960. After the Starr-Edwards valve was established, several other design variations were created such as Magovern– Cromie, DeBakey–Surgitool, and Smeloff–Cutter ball valves. A variation of the ball valve utilizes a metal cage to contain the ball which allows a smaller ball to be used. A caged ball valve is shown in Figure (2.1). Ball valves operate on the simple principle that the ball will be forced to one side of the valve or the other depending on which way blood is flowing. They were modeled after ball valves used in industrial applications to allow the flow of fluids on only one direction. When the pressure exerted by the heart onto the blood (and the ball) exceeds the pressure in the aorta, the ball is pushed away from the heart. This is the open position of the valve and blood can flow out of the heart into the aorta. After the heart ejects blood, the pressure inside the heart is greatly reduced so blood will try to flow back inside the heart. The negative pressure backflow of blood. In a natural heart valve, blood flows directly through the center of the valve (central flow.) With a ball heart valve, the heart must work harder to push blood around the ball. There is no central flow with a ball valve and although it works in principle, it is not a good solution. Ball valves also are known to damage or kill blood cells due to colliding with the ball [28] [29] [32].

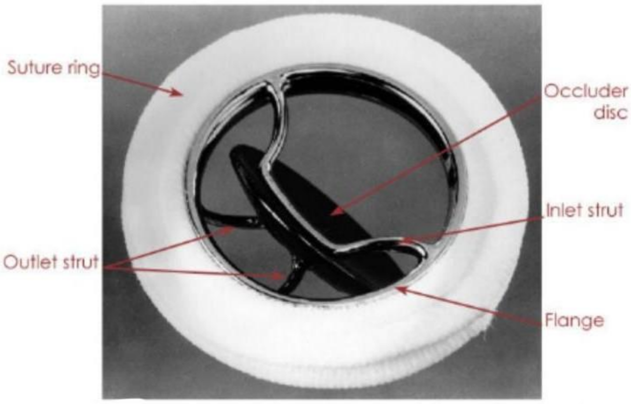


Caged-ball valve.

Fig (2.1): Caged ball valve

2. Tilting disc valve

In the mid-1970s, a new valve was introduced: the tilting disc valve. A more modern tilting disc valve and some earlier models are shown in Figure (2.2). The purpose in creating the titling-disc valve was to restore the central blood flow that was lost with the ball valve design. These valves consist of a single circular disc restrained by two metal struts and a metal ring. The struts are attached to the metal ring. The struts prevent the disc from escaping the device in either direction. The disc opens and closes based on the same principles used in the ball valve design, except a disc is used instead of a ball. Tilting disc valves can open at an angle of 60° and at a rate of 70 beats per minute. The angular opening of this valve reduces damage to blood cells. These are major improvements over the ball design but the struts of the tilting disc valves tend to fatigue and fracture over long periods of time [29] [30] [31].



Over view of the titling-disc valve

Fig (2.2): Titling disc valve

3. Bileaflet valve

The first bileaflet valves were introduced in 1978. Some bileaflet valves are shown in figure (2.3). The bileaflet design consists of two semicircular leaflets which pivot on hinges. Bileaflet valves have the best central flow – the leaflets open completely, allowing very little resistance to blood flow. These valves correct the problem of central flow and blood cell damage; however, they allow some backflow. This is a serious design flaw: many natural heart valves are replaced with mechanical valves because the valve became stiff and allowed backflow. Nevertheless, the majority of mechanical heart valves used today are bileaflet valves because they allow the least resistance to flow and the least blood damage. [29] [30]

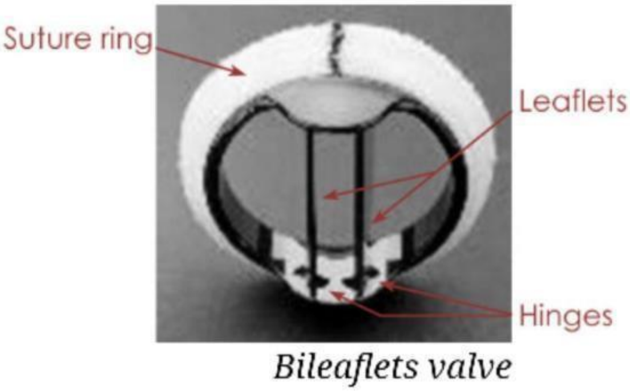


Fig (2.3): Bileaflets valve

1. ***Overview***

The mitral valve also known as the bicuspid valve or left atrioventricular valve, is a valve with two flaps in the heart, that lies between the left atrium and the left ventricle. The mitral valve and the tricuspid valve are known collectively as the atrioventricular valves because they lie between the atria and the ventricles of the heart.

In normal conditions, blood flows through an open mitral valve during diastole with contraction of the left atrium, and the mitral valve closes during systole with contraction of the left ventricle. The valve opens and closes because of pressure differences, opening when there is greater pressure in the left atrium than ventricle, and closing when there is greater pressure in the ventricle than atrium [34][35].

2. ***Mitral valve diseases***

1. **Mitral valve prolapse and regurgitation**

In this condition, the flaps (leaflets) of the mitral valve don't close tightly, causing blood to leak backward into the left atrium of your heart. If not treated, it can result in heart muscle damage.

This condition is commonly caused by mitral valve prolapse, in which the leaflets bulge back into the left atrium as your heart contracts [34].

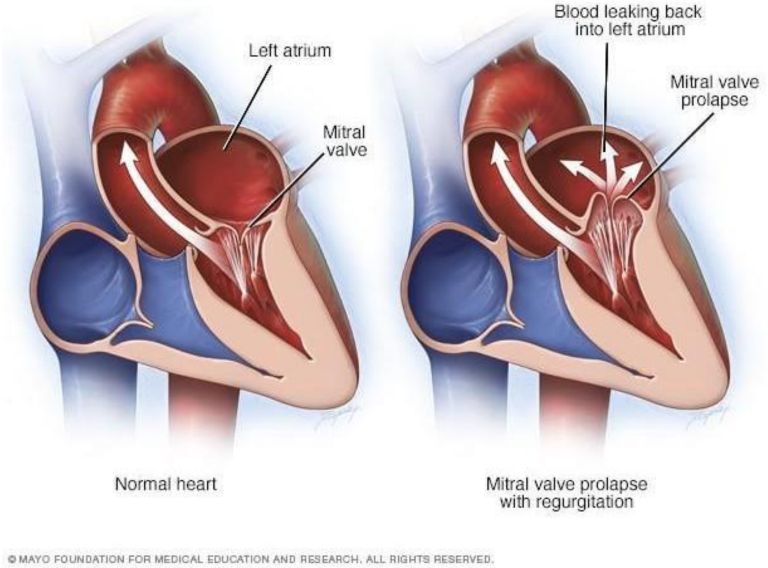


Fig (3.1): Mitral valve prolapse and regurgitation

2. Mitral valve stenosis

In this condition, the flaps of the mitral valve become thick or stiff, and they may fuse together. This results in a narrowed valve opening and reduced blood flow from the left atrium to the left ventricle [35].

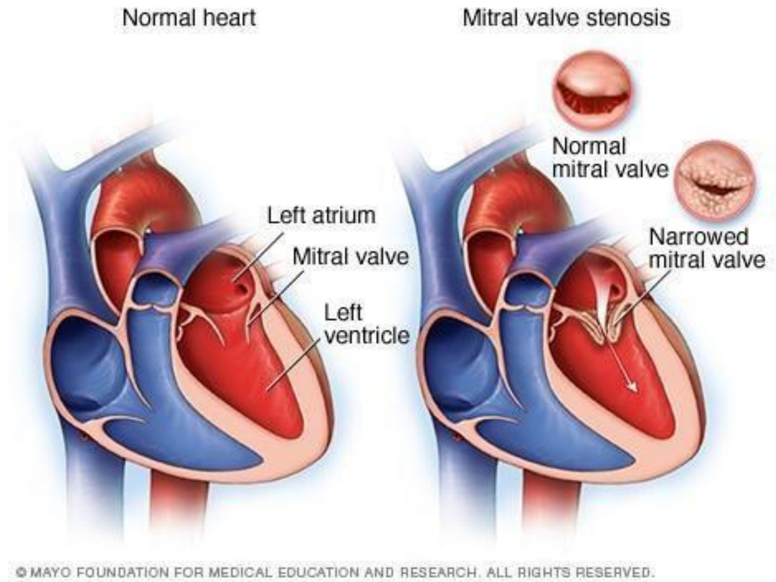


Fig (3.2): Normal heart and heart with mitral valve stenosis

3. Causes

Your heart has four valves that keep blood flowing in the correct direction. These valves include the mitral valve, tricuspid valve, pulmonary valve and aortic valve. Each valve has flaps (leaflets or cusps) that open and close once during each heartbeat. Sometimes, the valves don't open or close properly, disrupting the blood flow through your heart to your body.

In mitral valve disease, the mitral valve between the upper left heart chamber (left atrium) and the lower left heart chamber (left ventricle) doesn't work properly. It may not be closing properly, which causes blood to leak backward to the left atrium (regurgitation), or the valve may be narrowed (stenosis).

Mitral valve disease has many causes. Some forms of mitral valve disease can be present at birth (congenital heart defect).

Mitral valve regurgitation can be caused by problems with the mitral valve, also called primary mitral valve regurgitation. Mitral valve regurgitation is often caused by mitral valve prolapse, in which the mitral valve flaps (leaflets) bulge back into the left atrium. Diseases of the left ventricle can lead to secondary mitral valve regurgitation.

Mitral valve stenosis is often caused by rheumatic fever, which is a complication of a strep infection that can affect the heart [36][37][38].

4. Risk factors

Several factors can increase your risk of mitral valve disease, including:

- ✓ Older age
- ✓ History of certain infections that can affect the heart
- ✓ History of certain forms of heart disease or heart attack
- ✓ History of use of certain drugs
- ✓ Heart conditions present at birth (congenital heart disease)

5. Complications

Mitral valve disease can cause many complications, including:

- ✓ Irregular heart rhythms in the upper heart chambers (atrial fibrillation)
- ✓ High blood pressure that affects the blood vessels in the lungs (pulmonary hypertension)
- ✓ Blood clots
- ✓ Heart failure
- ✓ Stroke [40][41].

3. Treatment

1. Medication

Medication can treat symptoms, although medication can't treat mitral valve regurgitation.

Medications may include:

- ➢ **Diuretics:** These medications can relieve fluid accumulation in your lungs or legs, which can accompany mitral valve regurgitation.
- ➢ **Blood thinners:** These medications can help prevent blood clots and may be used if you have atrial fibrillation.
- ➢ **High blood pressure medications:** High blood pressure makes mitral valve regurgitation worse, so if you have high blood pressure, your doctor may prescribe medication to help lower it [42].

2. Surgery

Your mitral valve may need to be repaired or replaced. Doctors may suggest mitral valve repair or replacement even if you aren't experiencing symptoms, as this may prevent complications and improve outcomes. If you need surgery for another heart condition, your doctor may repair or replace the diseased mitral valve at the same time.

Mitral valve surgery is usually performed through a cut (incision) in the chest. In some cases, doctors may conduct minimally invasive heart surgery, which involves the use of smaller incisions than those used in open-heart surgery.

Doctors at some medical centers may perform robot-assisted heart surgery, a type of minimally invasive heart surgery. In this type of surgery, surgeons view the heart in a magnified high-definition 3-D view on a video monitor and use robotic arms to duplicate specific maneuvers used in open-heart surgeries [43].

1. Bileaflets valve

(See section 2.2.3),

The specialist in (Ibn Al-Bitar Hospital) said:

The suitable and the most recommended also suitable for most cases and life styles is the bileaflets valve.

The bileaflets valve provide the best central flow that leading no damage for blood cells or adhere (see details in section 4.2)

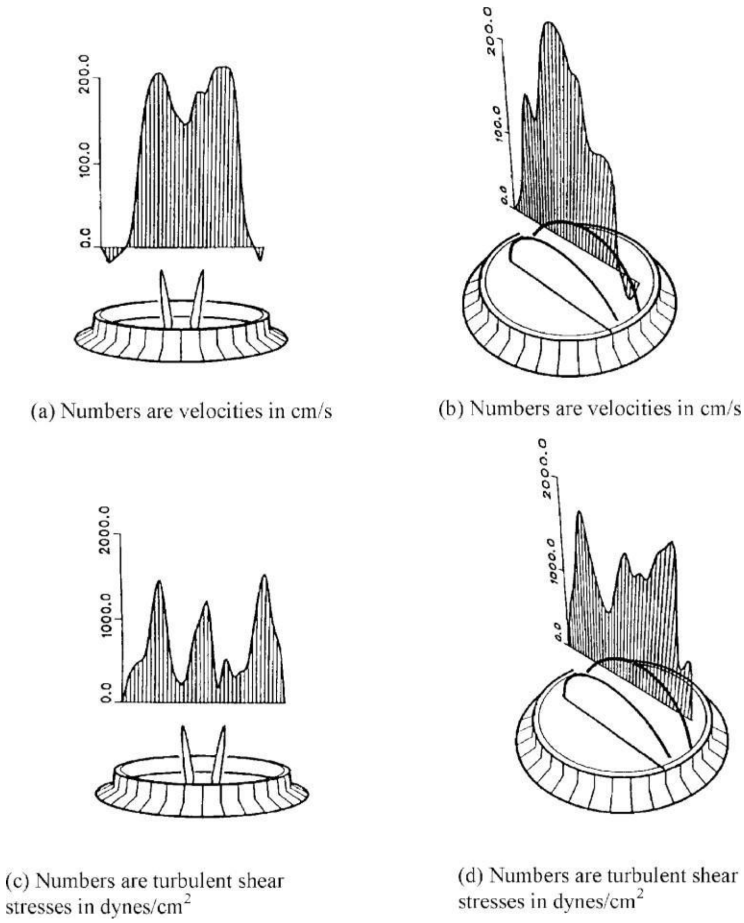


Fig (4.1): Blood flow through bileaflets valve

We choose the bileaflets because, this valve provides the best central blood flow that leads no or less damage for blood cells also the material properties.

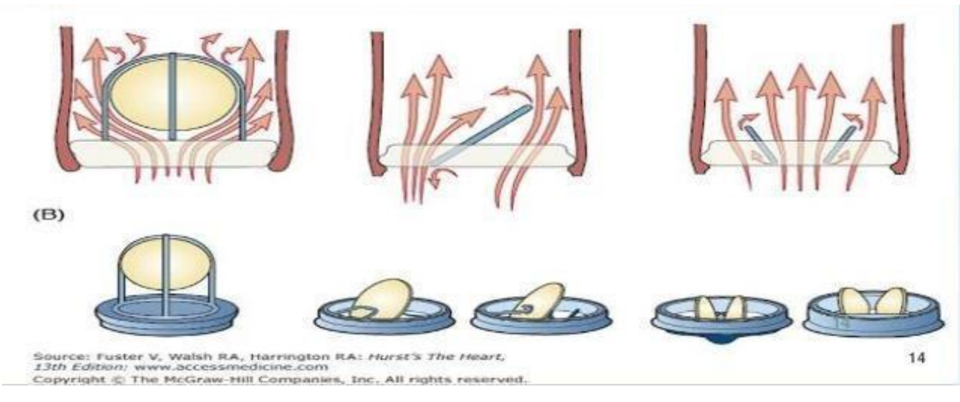


Fig (4.2): Blood flow in different types

2. Material

Another factor, other than the design which plays an important role in the reduction of the risk of blood clotting for patients with a mechanical valve, is the material used.

The material must be strong, durable, fatigue resistant and of course biocompatible. In the 1960s mechanical valves were suffering due to wear or thrombosis. However, a material was discovered, used at the time to coat nuclear fuel particles, which had the right characteristics for heart valves. This material was pyrolytic carbon, which is the principal material still used for mechanical heart valves today.

Other materials are used in the creation of artificial heart valves. Metal alloys consisting titanium is often used to give mechanical strength and for their corrosion resistance properties. The struts on some leaflet valves and the cage on caged-ball models are commonly made of metal alloys due to their strength and durability requirements.

1. Pyrolytic carbon:

- **Structure:** Pyrolytic Carbon or PyC is resistant to wear, strong, durable, is highly resistant to blood clotting and causes little damage to blood cells. It owes its unusual mechanical properties and its biocompatibility to a unique microstructure. The structure resembles that of graphite but is subtly different. In graphite, planar hexagonal arrays of covalently bonded carbon atoms are stacked so that the atoms in every other layer are coincident. Each layer is bonded by weak Van-der-Waals forces. In pyrolytic carbon, on the other hand, the layers are stacked in a disorderly manor causing wrinkles and distortions to occur within each layer. These distortions are responsible for the increased ductility and durability of PyC.
- **Fatigue Resistance:** Every time the heart beats a valve must open and close, therefore for a material to be successful in an artificial valve it must be highly fatigue resistant. Tests have shown that the strength of pyrolytic carbon is not affected by cyclic loading and further is not prone to cyclic stress-induced degradation. This means that it will not degrade over time, due to its own mechanical movement, making it an extremely suitable choice for heart valves. Like a ceramic, PyC is brittle and therefore cracks, once generated, can propagate through the material causing failure of the heart valve, resulting generally in the death of the patient. Although it must be noted that unlike a pure ceramic, pyrolytic carbon is ductile making it more difficult for a crack to occur in the first place.
- **Biocompatibility:** When a foreign material is placed into the human body, the immune system responds by coating it with layers of blood, however some materials such as PyC are not recognized as foreign and are thus called 'blood compatible' or biocompatible. A key indicator of how biocompatible a material is the amount of blood cells (platelets) that will adhere to it. If platelet adhesion is high, there is a high risk of blood clotting occurring. Tests have shown that Pyrolytic carbon, produces substantially less platelet aggregation than other materials tested (including titanium alloy, diamond like carbon, polycrystalline diamond) and thus as stated previously is highly biocompatible. The search for new materials and surface coatings with the required properties of high fatigue resistance and biocompatibility superior to those of pyrolytic carbon continues but in the meantime, PyC is adequate resulting in only very few failures (approximately 50 failures in every million valves in service).

2. Titanium:

Titanium has been widely used in surgeries since the mid-20th century, and this is mainly because of its very high biocompatibility (the compatibility to coexist with living tissues). It is often recognized as the most biocompatible of all metals. This compatibility is due to titanium's resistance to attack from bodily fluids, the ability to stay strong and flexible during use and the ability to remain inert in the patient's body. One reason why titanium has these characteristics when used in surgeries is because of an oxide film which occurs naturally on the surface of the titanium when in the presence of oxygen. The oxide film is highly adherent, insoluble and chemically non transportable, which prevents the titanium from reacting within the human body.

The general engineering properties Titanium shows a relatively low modulus of elasticity and tensile strength.

Properties of titanium

- **Biocompatibility:** Titanium is one of the most biocompatible material due to its excellent corrosion resistance. The corrosion resistance is due to formation of biologically inert oxide layer
- **Oxide layer:** Titanium spontaneously forms tenacious surface oxide on exposure to the air or physiologic saline. Three different oxides are

- TiO Anastase
- TiO2 Rutile
- Ti2 O3 Brookite

TiO2 is the most stable and mostly formed on titanium surface. This oxide layers are self-healing i.e. if surface is scratched or abraded during implant placement it passivates instantaneously.

Also, Ti oxide layer inhibits low level of charge transfer, lowest among all metals. This is the main reason for its excellent biocompatibility.

- ✓ Good yield strength, tensile strength, fatigue strength.
- ✓ Modulus of elasticity (110 GPa) is half of other alloys and 5 times greater than bone. This helps in uniform stress distribution.
- ✓ Good strength, but less than Ti alloys.
- ✓ Ductile enough to be shaped into implant by machining
- ✓ Low density 4.5g/cm3, light weight
- ✓ Chemical resistant
- ✓ Rust resistant
- ✓ High strength to weight
- ✓ Recyclable
- ✓ Non toxic

Titanium is highly resistant to chemical attack and has the highest strength to weight ratio of any metal. These unique properties make Titanium suitable for a wide range of applications. It's stiffness to weight ratio as steel is similar to steel meaning it can be used as a substitute where weight is an important consideration.

Titanium has some disadvantage, for example it's high cost, difficult and dangerous to cast so that we use Titanium alloys Ti6Al4V in pump unit and other parts of total artificial heart.

Titanium alloys Ti6Al4V:

Consists of - Titanium –6% Aluminium – alpha stabilizer –4% Vanadium – beta stabilizer

Some of properties:

- ✓ Excellent corrosion resistance
- ✓ Oxide layer formed is resistant to charge transfer thus contributing to biocompatibility
- ✓ Modulus of elasticity is 5.6 times that of the bone ,more uniform distribution of stress
- ✓ Strength of titanium alloy is greater than pure titanium – 6 times that of bone hence thinner sections can be made
- ✓ Ductility is sufficient and exhibits osteointegration

3. Cad Model

Fig (4.3): Front view of bileaflet valve

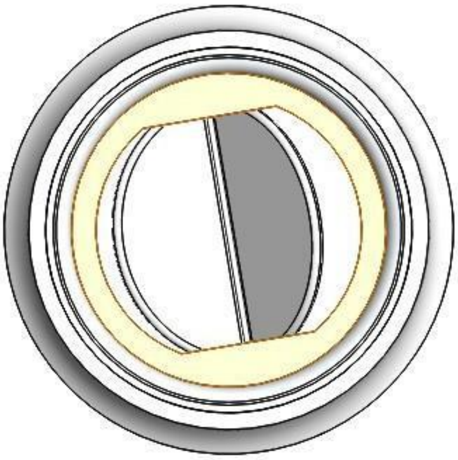


Fig (4.4): Top view of bileaflet valve

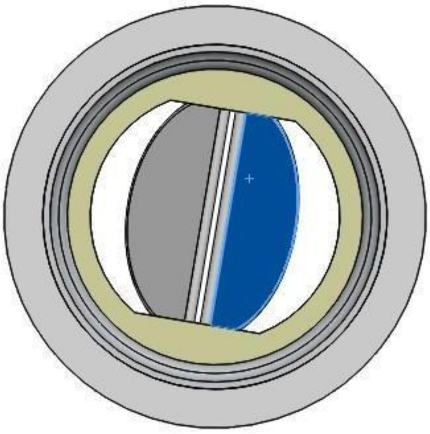


Fig (4.5): Bottom view of bileaflet valve

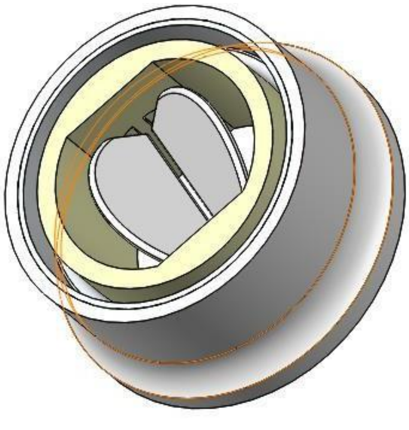


Fig (4.6): Isometric view

Conclusion

In this research we can obviously see that there are several different type of the artificial heart valve each one of them has a unique features.

The biological heart valve used to heart replacement with a damage in surrounding tissue of patient's heart, but we have a risky problem it is the antigens and FBR

The mechanical heart valve (bileaflets valve, caged ball, tilting disc valve) we see that the caged ball will damage the blood cells also the tilting disc because the angle of disc 60° and also may occur blood cloting

The best one is the bileaflets valve with its great properties like the material biocompatibility and the hydrophobic property for blood also has the best central flow that leads to a regular flow and no or less damage for blood components.

In Iraq most common cases of heart damage occur in mitral valve and the best valve for replacement was the bileaflets valve according to the experts here.

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