

# Replacement of Cardiac Valves

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**Abstract:** Open heart replacement is widely used to treat various valvular pathologies. The development of transcatheter valve replacement technology may pave the way for less invasive treatment options. The study characterized the epidemiology of valvular repair and replacement procedures in the US. The nationwide inpatient sample (NIS) was used to identify closed and open heart valvotomy, heart valve replacement, annuloplasty and percutaneous valvotomy procedure between 1993 and 2007. NIS is an annual surgery of 1000 hospitals and contains 20% of the US inpatient hospitalizations. Heart valve replacement included 302, 932, 89, 249, 13, 828, and 4,680 aortic, mitral, pulmonary and tricuspid valve procedures with tissue graft, respectively and 479, 168, 253, 804, 3, 904, and 7,494 prosthetics, aortic, mitral, pulmonary and tricuspid valve procedures respectively.

The first clinical use of a mechanical prosthetic valve was by Charles Huse, who in 1952 partially corrected aortic incompetence by inserting an acrylic ball valve prosthesis into the descending aorta. A few of these prostheses functioned for up to 18 years, but it was only after Gibbon had introduced the heart-lung machine in 1953 that an open heart operation could be performed under direct vision.

**Keywords:** Cardiac Valves

## 1. Introduction

The heart has four valves: the mitral valve and tricuspid valve, which control blood flow from the atria to the ventricles. The aortic valve and pulmonary valve, which control blood flow out of the ventricles. The aortic valve and the mitral valve are the most commonly replaced valves. Pulmonary and tricuspid valve replacement are fairly uncommon in adults. Valves can be repaired or replaced with heart valve surgery or a minimally invasive heart valve surgery. Heart valve may also be repaired by other procedures such as percutaneous balloon valvuloplasty. Transcatheter aortic valve replacement (TAVR) is a newer surgical option. A heart valve normally allows blood to flow in only one direction through the heart. The four valves are commonly represented in a mammalian heart that determines the pathway of blood flow through the heart. A heart valve opens or closes in response to differential blood pressure on each side. Its beat is an amazing display of strength and flexibility. A normal healthy heart valve minimizes any obstruction and allows blood to flow smoothly and freely in one direction. It closes completely and quickly, not allowing any blood to flow back through the valve. Replacement is the surgical gold standard

for MR and AS. Mechanical valves are preferred in younger patients when 65 years of age. And is already on anti-coagulation therapy. The benefit of mechanical valves is their durability and long life. Mechanical valves also tend to be thrombogenic; therefore, they require lifelong adherence to anti-coagulation. Valve replacement is the most common surgical treatment for valvular disease. Patients with mitral and aortic stenosis, regurgitation or both are the primary candidates for surgery. A median sternotomy is the route of access to the heart. Common valve replacement includes mitral valve replacement and aortic valve replacement. Valve replacement is not recommended for preventing initial or recurrent stroke. Typically, surgery is recommended for patients with acute or refractory congestive heart failure. Mitral and aortic stenosis with regurgitation, or both, are the primary candidates for this surgery. Like CABG, a median sternotomy is the route of access to the heart. Common valve replacement includes mitral valve replacement and aortic valve replacement (AVR).

*The four valves in the mammalian heart are*

The two atrioventricular (AV) valves, the mitral valve [bicuspid valve], and the tricuspid valve, which are between the upper chamber (atria) and the lower chamber (ventricles). The two semilunar valves, the aortic valve and the pulmonary valve, which are in the arteries leaving the heart.

The mitral valve and the aortic valve are in the left heart; the tricuspid valve and the pulmonary valve are in the right heart.

*Aortic valve:*

Aortic valve replacement is the procedure where the failing aortic valve of a heart is replaced with an artificial heart valve.

*Pulmonary valve:*

When the pressure in the right ventricle falls rapidly, the pressure in the pulmonary artery will flow through the pulmonary valve. The closure of the pulmonary valve contributes to the P2 component of the second heart sound. The right heart is a low pressure system, so the P2 component of the second heart sound is usually softer than the A2 component of the second heart sound.

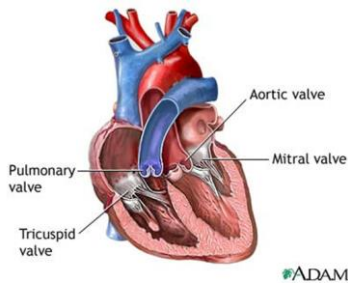
*Tricuspid valve:*

The tricuspid valve is a right atrioventricular valve located on the right dorsal side of the mammalian heart, at the superior portion of the right ventricle. The function of the valve is to prevent

back flow of blood from the right ventricle into the right atrium during right ventricular contraction piston.

*Mitral valve:*

Mitral valve of a heart is replaced by either a mechanical or tissue valve. The mitral valve is sited between the atrium and left ventricle.



**2. Types of heart valves**

The heart has four valves - one for each chamber of the heart. The valves keep blood moving through the heart in the right direction.

The mitral valve and tricuspid valve are located between the between the atria (upper heart chambers) and the ventricles (lower heart chambers).

The aortic valve and pulmonic valve are located between the ventricles and the major blood vessels leaving the heart.

- *Mitral Valve*

The valves are made of strong, thin flaps of tissue called leaflets or cusps.

The leaflets open to let blood move forward through the heart during half of the heartbeat. They close to keep blood from flowing backward during the other half of the heartbeat.

The mitral and tricuspid valves have two leaflets; the aortic and pulmonic valves have three. The leaflets are attached to and supported by a ring of tough, fibrous tissue called the annulus. The annulus helps to maintain the proper shape of the valve.

The leaflets of the mitral and tricuspid valves are also supported by:

- *Chordae tendineae:* tough, fibrous strings. These are similar to the strings supporting a parachute.
- *Papillary muscles:* part of the inside walls of the ventricles.

The chordae tendineae and papillary muscles keep the leaflets stable to prevent blood from flowing backward.

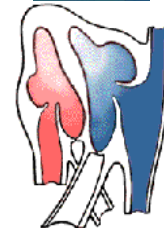
*Mitral Valve*

- *How Valves Work*

The four valves open and close to let blood flow through the heart. The steps below shows how the blood flows through the heart and describes how each valve works to keep blood moving.

*1. Open tricuspid and mitral valves*

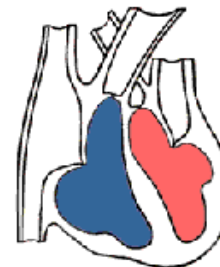
Blood flows from the right atrium into the right ventricle through the open tricuspid valve, and from the left atrium into the left ventricle through the open mitral valve.



*2. Closed tricuspid and mitral valves*

When the right ventricle is full, the tricuspid valve closes and keeps blood from flowing backward into the right atrium when the ventricle contracts (squeezes).

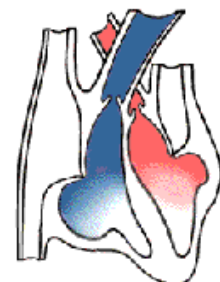
When the left ventricle is full, the mitral valve closes and keeps blood from flowing backward into the left atrium when the ventricle contracts.



*3. Open pulmonic and aortic valve*

As the right ventricle begin to contract, the pulmonic valve is forced open. Blood is pumped out of the right ventricle through the pulmonic valve into the pulmonary artery to the lungs.

As the left ventricle begins to contract, the aortic valve is forced open. Blood is pumped out of the left ventricle through the aortic valve into the aorta. The aorta branches into many arteries and provides blood to the body.



*4. Closed pulmonic and aortic valves*

When the right ventricle finishes contracting and starts to relax, the pulmonic valve snaps shut. This keeps blood from flowing back into the right ventricle.

When the left ventricle finishes contracting and begins to relax, the aortic valve snaps shut. This keeps blood from flowing back into the left ventricle.

This pattern is repeated, causing blood to flow continuously to the heart, lungs and body. The four normally working heart valves make sure blood always flows freely in one direction and that there is no backward leakage.



Mitral valve of a heart is replaced by either a mechanical or tissue valve. The mitral valve is sited between the atrium and left ventricle. 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. In abnormal conditions, blood may flow backwards through the valve (mitral regurgitation) or the mitral valve may be narrowed (mitral stenosis). Rheumatic heart disease often affects the mitral valve; the valve may also prolapse with age, and be affected by infective endocarditis. The mitral valve is named after the mitre of a bishop, which resembles its flaps. The mitral valve is typically 4 to 6 square centimetres (0.62 to 0.93 sq in) in area and sits in the left heart between the left atrium and the left ventricle. It has two leaflets (or'cusps'), an anteromedial leaflet, and a posterolateral leaflet. The opening of the mitral valve is surrounded by a fibrous ring known as the mitral annulus. The anterior cusp covers approximately two-thirds of the valve (imagine a crescent moon within the circle, where the crescent represents the posterior cusp). Although the anterior leaflet takes up a larger part of the ring and rises higher, the posterior leaflet has a larger surface area. The valve leaflets are prevented from prolapsing into the left atrium by the action of chordae tendineae. The chordae tendineae are inelastic tendons attached at one end to papillary muscles in the left ventricle, and at the other to the valve cusps. Papillary muscles are finger-like projections from the wall of the left ventricle. When the left ventricle contracts, the pressure in the ventricle forces the valve to close, while the tendons keep the leaflets coapting together and prevent the valve from opening in the wrong direction (thus preventing blood flowing back to the left atrium).

Each chord has a different thickness. The thinnest ones are attached to the free leaflet margin, whereas thickest ones (strut chords) are attached further from the free margin. This disposition has important effects on systolic stress distribution

physiology. The mitral annulus is a fibrous ring that is attached to the mitral valve leaflets. Unlike prosthetic valves, it is not continuous.



The mitral annulus is saddle shaped and changes in shape throughout the cycle. The annulus contracts and reduces its surface area during systole to help provide complete closure of the leaflets. Expansion of the annulus can result in leaflets that do not join soundly together, leading to functional mitral regurgitation.

*Tricuspid valve:*

The tricuspid valve, or right atrioventricular valve, is on the right dorsal side of the mammalian heart, at the superior portion of the right ventricle. The function of the valve is to prevent back flow (regurgitation) of blood from the right ventricle into the right atrium during right ventricular contraction: systole.

The tricuspid valve usually has three leaflets, named the anterior, posterior, and septal leaflets. Each leaflet is connected via chordae tendineae to the anterior,

posterior, and septal papillary muscles of the right ventricle, respectively. Tricuspid valves may also occur with two or four leaflets; the number may change over a lifetime.

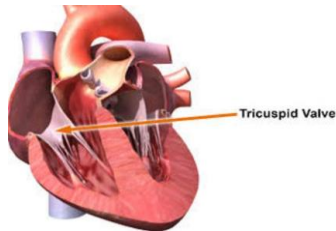
*Function:*

The tricuspid valve functions as a one-way valve that closes during ventricular systole to prevent regurgitation of blood from the right ventricle back into the right atrium. It opens during ventricular diastole, allowing blood to flow from the right atrium into the right ventricle. The back flow of blood is also known as regression or tricuspid regurgitation. Tricuspid regurgitation can result in increased ventricular preload because the blood refluxed back into the atrium is added to the volume of blood that must be pumped back into the ventricle during the next cycle of ventricular diastole. Increased right ventricular preload over a prolonged period of time may lead to right ventricular enlargement (dilatation), which can progress to right heart failure if left uncorrected.

*Disorders:*

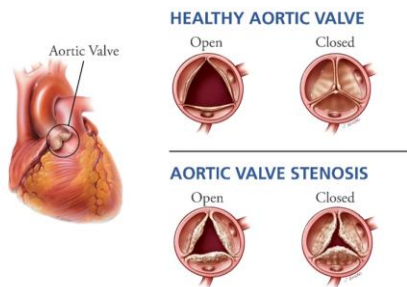
Tricuspid regurgitation is not uncommon. Infected valves can result in endocarditis in intravenous drug users. Patients who inject narcotics or other drugs intravenously may introduce infection, which can travel to the right side of the heart, most often caused by the bacteria *S. aureus*. In patients without a history of intravenous exposure, endocarditis is more frequently left-sided. The tricuspid valve can be affected by rheumatic

fever, which can cause tricuspid stenosis or tricuspid regurgitation. Some individuals are born with congenital abnormalities of the tricuspid valve. Congenital apical displacement of the tricuspid valve is called Ebstein's anomaly and typically causes significant tricuspid regurgitation. Certain carcinoid syndromes can affect the tricuspid valve by producing fibrosis due to serotonin production by those tumors. The first endovascular tricuspid valve implant was performed by surgeons at the Cleveland Clinic.



**Aortic valve:**

The aortic valve is a valve in the human heart between the left ventricle and the aorta. It is one of the two semilunar valves of the heart, the other being the pulmonary valve. The heart has four valves and the other two are the mitral and the tricuspid valves. The aortic valve normally has three cusps or leaflets, although in 1–2% of the population it is found to congenitally have two leaflets. The aortic valve is the last structure in the heart the blood travels through before flowing through the systemic circulation.



**Structure:** The aortic valve normally has three cusps however there is some discrepancy in their Naming. They may be called the left coronary, right coronary and non-coronary cusp. Some sources also advocate they be named as a left, right and posterior cusp. Anatomists have traditionally named them the left posterior (origin of left coronary), anterior (origin of the right coronary) and right posterior.

The three cusps, when the valve is closed, contain a sinus called an aortic sinus or sinus of Valsalva. In two of these cusps, the origin of the coronary arteries are found. The width of the sinuses in cross-section is wider than the left ventricular outflow tract as well as wider than the ascending aorta. The junction of the sinuses with the aorta is called the sinotubular junction. The aortic valve is located posterior to the pulmonary valve and the commissure where the anterior two cusps join

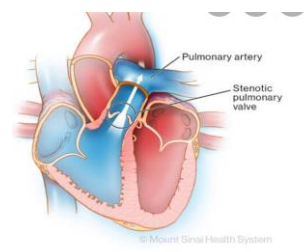
together points toward the pulmonary valve. It is these two sinuses that contain the origin of the coronary arteries. The congenital disease, transposition of the great arteries, these two valves are reversed (the anterior valve is the aortic valve) and the origin of the coronaries still follows this "rule" that the origins are in the sinuses facing the pulmonary valve.

**Function:**

When the left ventricle contracts (systole), pressure rises in the left ventricle. When the pressure in the left ventricle rises above the pressure in the aorta, the aortic valve opens, allowing blood to exit the left ventricle into the aorta. When ventricular systole ends, pressure in the left ventricle rapidly drops. When the pressure in the left ventricle decreases, the momentum of the vortex at the outlet of the valve forces the aortic valve to close. The closure of the aortic valve contributes the A2 component of the second heart sound (S2).

**Pulmonary valve:**

The pulmonary valve (sometimes referred to as the pulmonic valve) is the semilunar valve of the heart that lies between the right ventricle and the pulmonary artery and has three cusps. Similar to the aortic valve, the pulmonary valve opens in ventricular systole, when the pressure in the right ventricle rises above the pressure in the pulmonary artery. At the end of ventricular systole, when the pressure in the right ventricle falls rapidly, the pressure in the pulmonary artery will close the pulmonary valve. The closure of the pulmonary valve contributes the P2 component of the second heart sound (S2). The right heart is a low-pressure system, so the P2 component of the second heart sound is usually softer than the A2 component of the second heart sound. However, it is physiologically normal in some young people to hear both components separated during surgery.



**Causes:**

Valve repair or replacement surgery is done to correct the problems caused by one or more diseased heart valves. If your heart valve(s) becomes damaged or diseased, you may have the following symptoms: Dizziness Chest pain.

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. Heart valve disease may be present at birth (congenital).

It can also occur in adults due to many causes and conditions,

such as infections and other heart conditions Heart valve problems may include:

#### *Regurgitation*

In this condition, the valve flaps don't close properly, causing blood to leak backward in your heart. This commonly occurs due to valve flap bulging back, a condition called prolapse.

#### *Stenosis*

In valve stenosis, the valve flaps become thick or stiff, and they may fuse together. This results in a narrowed valve opening and reduced blood flow through the valve.

#### *Atresia*

In this condition, the valve isn't formed, and a solid sheet of tissue blocks the blood flow between the heart chambers.

#### *Diagnosis:*

Your doctor may evaluate your signs and symptoms and conduct a physical examination. In a physical examination, your doctor will likely listen for a heart murmur, as this can be a sign of a heart valve condition. Your doctor may order several tests to diagnose your condition.

### **3. Echochordigraphy**

In this test, sound waves directed at your heart from a wand like device (transducer) held on your chest produce video images of your heart in motion. This test assesses the structure of your heart, the heart valves and the blood flow through your heart an echocardiogram helps your doctor get a close look at the heart valves and how well they're working. Doctors may also use a 3D echocardiogram.

Doctors may conduct another type of echocardiogram called a trans esophageal echocardiogram. In this test, a small transducer attached to the end of a tube is inserted down the tube leading from your mouth to your stomach (oesophagus). This test allows doctors to have a closer look at the heart valves than is possible with a regular echocardiogram.

#### *Electrocardiogram (ECG):*

In this test, wires (electrodes) attached to pads on your skin measure electrical impulses from your heart. An ECG can detect enlarged chambers of your heart, heart disease and abnormal heart rhythms.

#### *Chest X-ray:*

A chest X-ray can help your doctor to determine whether the heart is enlarged, which can indicate certain types of heart valve disease. A chest X ray can also help doctors determine the condition of your lungs.

#### *Cardiac MRIMRI:*

A cardiac MRI uses magnetic fields and radio waves to create detailed images of your heart. This test may be used to determine the severity of your condition and assess the size and function of your lower heart chambers (ventricles).

#### *Exercise test or stress tests:*

Different exercise tests help measure your activity tolerance and monitor your heart's response to physical exertion. If you are unable to exercise, medications to mimic the effect of exercise on your heart may be used.

#### *Cardiac catheterization:*

This test isn't often used to diagnose heart valve disease, but it may be used if other tests aren't able to diagnose the condition or to determine its severity.

In this procedure, a doctor threads a thin tube (catheter) through a blood vessel in your arm or groin to an artery in your to determine its severity.

In this procedure, a doctor threads a thin tube (catheter) through a blood vessel in your arm or groin to an artery in your heart and inject dye through the

catheter to make the artery visible on an X-ray. This provides your doctor with a detailed picture of your heart arteries and how your heart functions. It can also measure the pressure inside the heart chambers.

#### *Heart Valve Disease*

##### *Valvular stenosis:*

This occurs when a heart valve doesn't fully open due to stiff or fused leaflets. The narrowed opening may make the heart work very hard to pump blood through it. This can lead to heart failure and other symptoms (see below). All four valves can develop stenosis; the conditions are called tricuspid stenosis, pulmonic stenosis, mitral stenosis, or aortic stenosis.

##### *Valvular insufficiency:*

Also called regurgitation, incompetence, or "leaky valve," this occurs when a valve does not close tightly.

##### *Symptoms*

Some people with heart valve disease might not experience symptoms for many years Signs and symptoms of heart valve disease Frequently, a leaky heart valve causes no disease symptoms. Many healthy people have onngestive heart failure, may include:

- Shortness of breath, especially with exertion or when lying flat.
- Leg swelling or fluid retention elsewhere in the body.
- Abnormal sound (heart murmur) when a doctor is listening to the heart beating stethoscope with a stethoscope.
- Fatigue.
- Shortness of breath, particularly when you have been very active or when you lie down.
- Swelling of your ankles and feet.
- Dizziness.
- Fainting.
- Irregular heartbeat.
- Shortness of breath, especially with exertion or when lying flat.
- Leg swelling or fluid retention elsewhere in the body.

Other symptoms of a leaky heart valve may include:

- Light-headedness.
- Rapid heartbeat.
- Heart fluttering or palpitations.

Treatment:

Heart valve disease treatment depends on how severe your

condition is, if you're experiencing signs and symptoms, and if your condition is worse.

may also recommend making healthy lifestyle changes and taking medications to treat symptoms.

You may eventually need heart valve surgery to repair or replace the diseased heart valve. Doctors may suggest heart valve surgery 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 valve at the same time.

Heart valve surgery is usually performed through a cut (incision) in the chest. Doctors may sometimes conduct minimally invasive heart surgery, which involves the use of smaller incisions than those used in open heart surgery.

. These procedures can involve the use of clips, plugs or other devices. In some cases, valves can be replaced during a catheter procedure. Doctors continue to study catheter procedures to repair or replace heart valves.

Medication Class	Purpose for a valve disease patient
ACE inhibitors	Vasodilator: Which means it opens blood vessels more fully and can help reduce high blood pressure and slow heart failure.
Antiarrhythmic medications	Helps restore a normal pumping rhythm to the heart.
Antibiotics	Can help to prevent the onset of infections.
Anticoagulants (*blood thinners)	Reduces the risk of developing blood clots from poorly circulating blood around faulty heart valves. Blood clots are dangerous because they can lead to stroke.
Beta-blockers	Can reduce the heart's workload by helping the heart beat slower. Some patients find them helpful for reducing palpitations.
Diuretics ("water pills")	Reduces amount of fluid in the tissues and bloodstream which can lessen the workload on the heart.

**Risk factors**

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

- Older age.
- History of certain infections that can affect the heart.
- History of certain forms of heart disease or heart attack.
- High blood pressure, high cholesterol, diabetes and other heart disease risk factors.
- Heart conditions present at birth (congenital heart disease).

**Complications**

Heart valve disease can cause many complications, including:

- Heart failure
- Stroke.
- Blood clots.
- Heart rhythm abnormalities.
- Death.

**Heart valve replacement(or) surgery:**

In some cases, the valve can't be repaired, and surgeons may perform heart valve replacement. In heart valve replacement, your surgeon removes the damaged valve and replaces it with a mechanical valve or a valve made from cow, pig replacement or human heart tissue (biological tissue valve)

Biological tissue valves degenerate over time, and often eventually need to be replaced. People with mechanical valves will need to take blood-thinning medications for life to prevent blood clots. Your doctor will discuss with you the benefits and risks of each type of valve and discuss which valve may be appropriate for you.

Heart valve repair or replacement surgery requires a stay in a hospital. Procedures may vary depending on your condition and your healthcare providers practice.

Generally, open-heart valve repair or replacement follows this process:

1. You will be asked to remove any jewellery or other objects that may interfere with the procedure.
2. You will change into a hospital gown and empty your bladder.
3. A healthcare professional will start an intravenous (IV) line in your arm or hand for injection of medicine and to give IV fluids. More catheters will be put in blood vessels in your neck and wrist to monitor the status of your heart and blood pressure, and to take blood samples.
4. The anaesthesiologist will continuously monitor your heart rate, blood pressure, breathing, and blood oxygen level during the surgery

**History:**

The average heart beats 2.5 billion times in a human lifetime, during which its four valves must maintain unidirectional blood flow to maximize the heart's efficiency and provide oxygenated blood to the entire body. Although heart valves were documented by Leonardo da Vinci in some of his early sketches over 500 years ago, they have been available for implantation only since the 1950s.

Valvular disease-usually associated with advanced age, but also caused by congenital defects-can interrupt, slow, or prevent the efficient function of the valves, which lose functionality if they cannot maintain a proper seal or open completely.

The structure of the aortic and (similar) pulmonary valve is simpler than that of the other valves-they have greater symmetry and lack the sub valvular components characteristic of the mitral and tricuspid valves-making them an attractive target for early research. The aortic and pulmonary valves consist of three leaflets of similar size and shape that are attached to the tubular vessel; in contrast, the mitral and tricuspid valves have leaflets that vary in number and size. Whereas past efforts focused on the aortic valve, current technologies are being developed to create devices for the

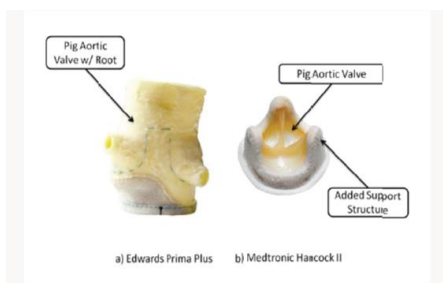
more Complex valves of the heart.

#### 4. Past technologies

Valve replacement devices can be classified into two Categories: whole valve and prosthetic valves. Whole valves Consist of allografts and xenografts; prosthetic valves are composed of pericardial (tissue) and mechanical valves. The valve Designs vary in numerous aspects and have evolved over time, But the goal has remained the same: an easily implantable and Durable solution that increases blood flow while decreasing the Risk of associated complications such as thrombosis. Each type of valve has advantages and disadvantages, which are taken into Consideration when deciding which device is appropriate for Individual patient.

##### Whole Valves

Allografts are valves transplanted from another human, and xenografts are from another species. Cow and pig valves are usually selected for transplant as they best mimic the size and structure of human valves.



Attempts have been made to transplant mitral valves (Gulbins et. al. 2000, Kumar et al. 2000), but the most successful and frequently used valves are pulmonary and aortic valves, which are often used interchangeably due to their similar geometry. Developments in transplanted valves have focused improving structural support, which is necessary when the valve is removed from its native surroundings (Figure 2). Vast strides have been made in tissue cryopreservation, which maintains high cell viability when thawed (O'Brien et al. 1987).

But the appeal of allograft and xenograft valves suffers from the limited availability of size ranges and technically challenging procedure, in the case of stemless designs, which require the physician to remove the entire valve along with a portion the aortic root to attach the replacement valve.

##### Prosthetic Valves

Transplanted whole valves remain a viable option, but prosthetic valves, including both mechanical and pericardial tissue valves, hold the largest share of the market.

#### 5. Current technologies

Over the past 10 years, non-invasive implantation of heart valves has revolutionized the field. Implants traditionally required the chest to be splayed open to allow access to the heart but recent advances make it possible to access the valve through

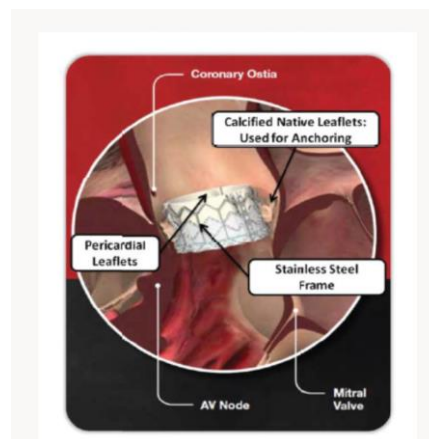
the femoral vein via an incision as small as an inch. This non-invasive approach, called Transcatheter valve replacement, suitable for patients who are not candidates for open-heart surgery and offers a faster recovery.

The first Transcatheter delivery of a valve was attempted the 1960s, but it has only recently become accepted as a viable procedure, aided by advances in stent design and non-invasive imaging techniques. The development of Transcatheter. heart valves showcase the power of a multidisciplinary approach: merge technologies for numerous devices (eg. coronary stents and balloon angioplasty) and disciplines (e.g., interventional cardiology and cardiac surgery) to create a paradigm shifting advance.

There are many advantages to a transcatheter approach, but added complexity arises because the valve must work with the patient's diseased anatomy. In the past the diseased valve was typically removed; now, the designs and their ability to succeed rely heavily on the patient's anatomy. For example, a transcatheter aortic valve is secured in place by applying an outward force on the calcium deposits on the native leaflet.

An additional obstacle that transcatheter technologies have had to overcome is the loss of direct visualization afforded open-heart surgery. This is especially important when deciding where to place the valve to ensure that it is secured while avoiding the coronary ostia, which is crucial to supplying blood to the heart (Figure 4). Advances in non-invasive imaging allow for real-time imaging using multiple modalities, such as echocardiography to visualize the native anatomy and fluoroscopy visualize the device.

#### 6. Future technologies



The valve replacement industry is beginning to focus on the other valves in the heart and developing devices that will work in concert with the native anatomy to repair instead of replace native valve function. The number of repair procedures is on the rise as compared to replacement procedures, which have remained steady from year to year. Recent trends favour repairing the native valve as opposed to replacing it, with approximately 32,000 mitral repairs as compared to 21,000 replacement procedures conducted in the United States in 2013

(Millennium Research Group 2013).

The introduction of transcatheter heart valves has brought new excitement to this area. Placed inside a defective tissue valve, transcatheter valves provide a way around the challenge of tissue valve durability: a tissue valve may be implanted in younger patient with the idea that an additional valve can be placed if needed the surgery.

### 7. Designing for the future

Next generation heart valves have brought excitement to the field, but it is also important to understand how we as engineers go from a concept to a lifesaving device. We must first survey the patient population and identify a need, then develop a concept to address that need. Bench studies and animal studies are used in conjunction to test the functionality and durability of a design. Then the materials are tested in animal models to ensure that no adverse effects arise as a result of interactions with the body. When heart valves were first implanted, regulatory requirements to review the process for implantation were minimal or non-existent. Now extensive testing is required to ensure short and long-term success prior to implantation. The test data are submitted to a regulatory body and reviewed before implantation can be cleared.

### 8. Conclusions

Now is an exciting time for heart valve development as companies are pushing the limits, expanding into new areas, and helping more patients than ever before. Advances continue to move heart valve development forward. As designs are optimized, engineers are turning their attention to other disease states with next generation designs and approaches. With increased confidence in current device durability for both mechanical and tissue valves, the focus is changing from surgical to transcatheter implants and from replacement to repair devices implanted with transcatheter methods. Each advance requires greater understanding of the disease state of the valve. The greatest successes will involve technologies and techniques that work in concert with the human body.

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