Cardiovascular Medical Devices: Heart Valves, Pacemakers and Defibrillators, Mechanical Circulatory Support, and Other Intracardiac Devices

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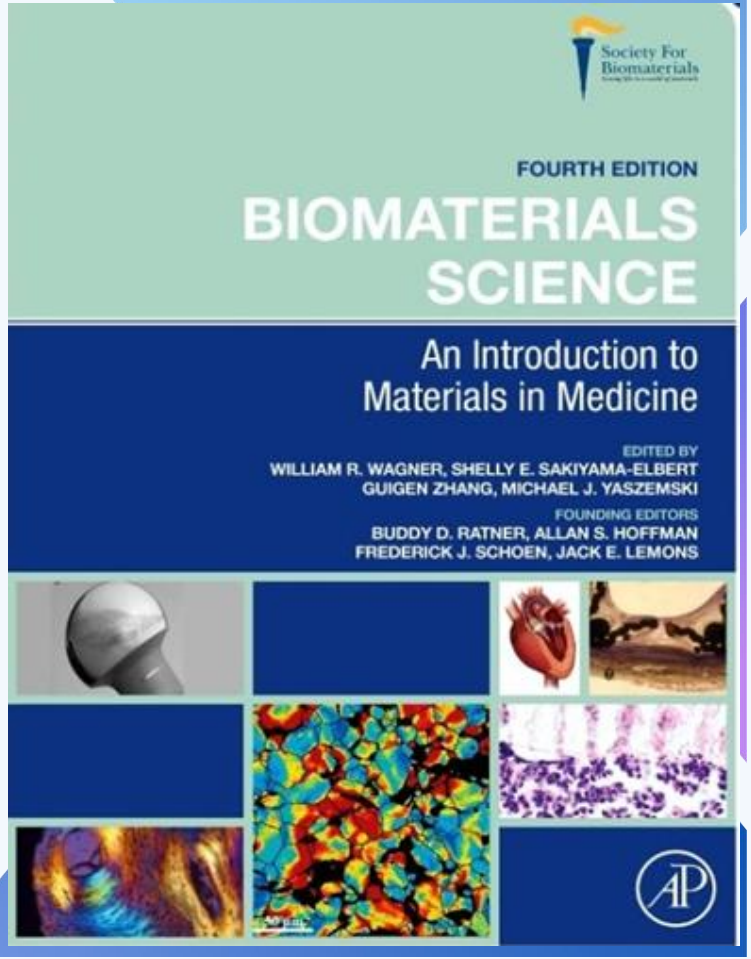
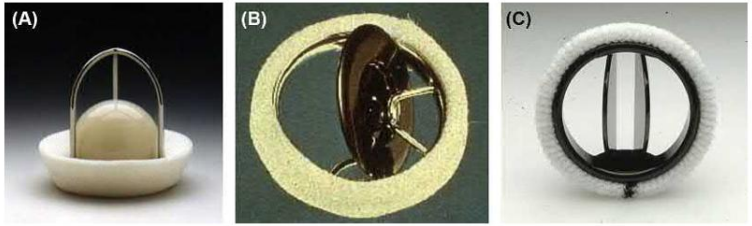
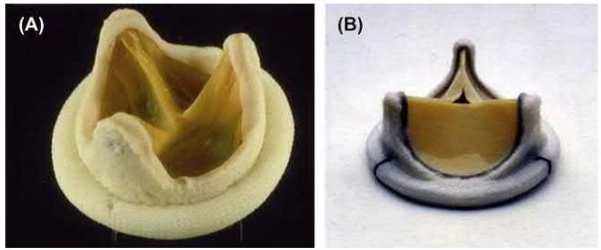


Introduction



• **Figure 2.5.2A.3** Mechanical prosthetic heart valves. (A) Starr-Edwards caged-ball valve. (B) Bjork-Shiley tilting disk valve. (C) St. Jude Medical bileaflet tilting disk heart valve. (Reproduced by permission from Schoen, F.J., 2001. Pathology of heart valve substitution with mechanical and tissue prostheses. In: Silver, M.D., Gotlieb, A.I., Schoen, F.J. (Eds.), Cardiovascular Pathology, third ed. Churchill Livingstone, New York.)



• **Figure 2.5.2A.4** Tissue heart valve replacement devices. (A) Hancock porcine valve. (B) Carpentier-Edwards bovine pericardial valve. (Reproduced by permission from Schoen, F.J., 2001. Pathology of heart valve substitution with mechanical and tissue prostheses. In: Silver, M.D., Gotlieb, A.I., Schoen, F.J. (Eds.), Cardiovascular Pathology, third ed. Churchill Livingstone, New York.)

Cardiovascular Disease: A Global Challenge

Leading cause of mortality and morbidity in the Western world.

Over 800,000 deaths annually in the United States (nearly one-third of all deaths).

Globally: over 17 million deaths per year, projected to exceed 23 million by 2030.

Major Causes of Mortality

Key Subtypes of Cardiovascular Disease

1. Coronary Heart Disease: Accounts for more than 1 in 7 deaths, killing over 360,000 people annually in the US.

2. Valvular Heart Disease: Over 25,000 deaths per year in the US. Aortic valve disease accounts for 17,000 of these deaths, expected to double by 2040 and triple by 2060.

Modern Medical Advancements

The Rise of Innovative Cardiovascular Procedures

Significant advancements in surgical and interventional diagnostic and therapeutic procedures over the past decades.

Approximately 8 million major cardiac and vascular operations performed annually in the United States.

Device Application in Cardiology

Widespread Use of Prostheses and Medical Devices

- 475,000 percutaneous coronary interventions (stents).
- 371,000 coronary artery bypass graft procedures.
- 156,000 cardiac valve procedures.
- 420,000 pacemakers, leads, and cardioverter-defibrillators.
- Extensive use of cardiac assist devices, vascular grafts, umbrellas, patches, and other devices.

These devices, often composed of highly advanced biomaterials, are integral to modern cardiovascular care.

Importance of Cardiovascular Devices

Critical Role of Cardiovascular Prostheses

Enable choices for surgical or catheter-based interventions.

Optimize short- and long-term patient management.

Continuous efforts to improve performance and safety through biomaterials and device research.

Resulted in significant improvements in patient care.

Presentation Overview

Focus of this Presentation

- Underlying pathology of conditions treated by devices.
- Relevant biomaterials information.
- Important complications to circumvent.
- Emphasis on biomaterials and engineering design for cardiac valve prostheses.
- Discussion of pacemakers, ICDs, implantable cardiac assist devices, artificial hearts, and intracardiac devices.

Heart Valve Basics

Heart Valve Function: Ensuring Unidirectional Blood Flow

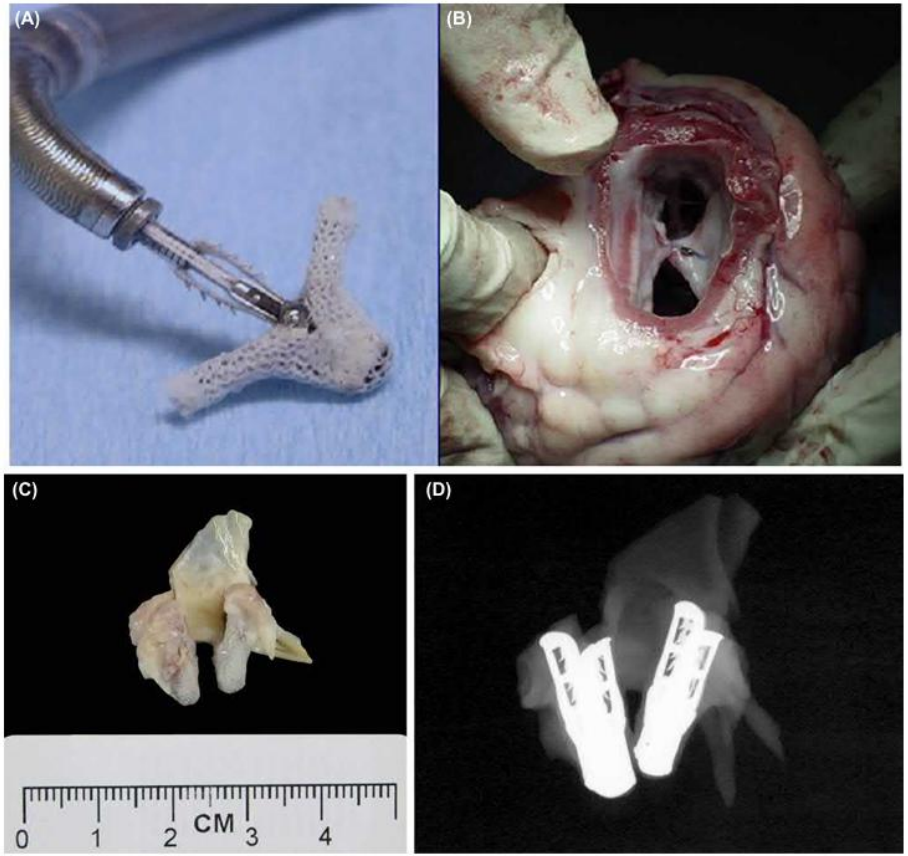
- Tricuspid valve: Right atrium to right ventricle.
- Pulmonary valve: Right ventricle to pulmonary artery.
- Mitral valve: Left atrium to left ventricle.
- Aortic valve: Left ventricle to aorta.

Heart Valve Mechanics

The Dynamic Nature of Heart Valves

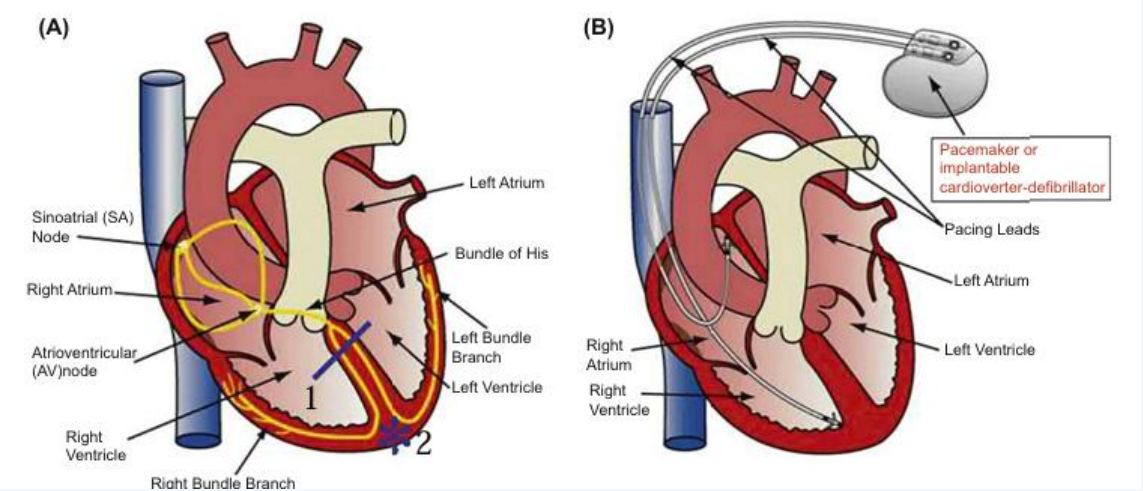
Heart valves open and close with each cardiac cycle.

- Approximately once per second.
- Equates to ~40 million times per year.
- Approximately 3 billion times in a 75-year lifetime.



• **Figure 2.5.2A.8** The MitraClip device for mitral regurgitation. (A) MitraClip device on delivery apparatus. (B) Edge-to-edge approximation of the anterior and posterior leaflets of the mitral valve is achieved by deployment of the MitraClip device that is analogous to an Alfieri stitch, thereby creating a double orifice with improved leaflet coaptation. (C) Two MitraClip devices are seen attached to a portion of the mitral valve. The portion of valve and devices were removed surgically during a valve replacement necessitated by worsening mitral regurgitation. The cloth covering has facilitated tissue ingrowth into the device to help passivate the blood-contacting surface and minimize thrombosis. (D) A specimen radiograph shows the structure of the two cobalt-chromium metallic arms in the closed position. ((A) and (B) reproduced with permission from Schoen, F.J., Butany, J., 2016. Cardiac valve replacement and related interventions. In: Buja, L.M., Butany, J. (Eds.), Cardiovascular Pathology, fourth ed. Elsevier, 529–576.)

Understanding Valve Disorders



Valvular Heart Disease: Overview

Stenosis: Obstruction to blood flow through the valve.

Regurgitation (Insufficiency): Reverse flow across the valve.

Both can occur simultaneously in the same valve.

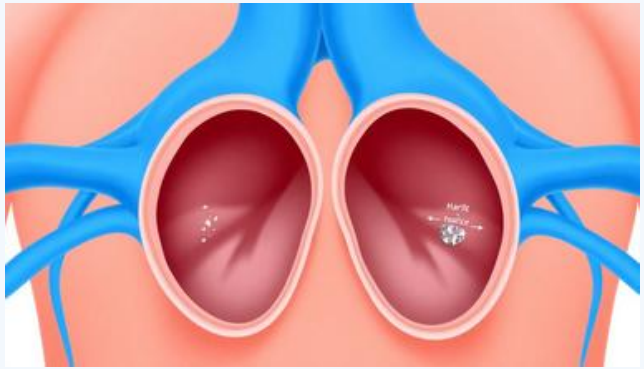
Disease Progression

Progression of Valvular Heart Disease

1. Rapid onset: Infective endocarditis can cause rapid valve destruction, leading to heart failure and death in days.
2. Slow progression: Calcific aortic stenosis can take decades to manifest clinically.

Recent progress in understanding the functional structure, biomechanical properties, and pathobiological behavior of cardiac valves.

Aortic Valve Diseases



Common Forms of Valvular Heart Disease

Most common types involve the aortic and/or mitral valves.

- Calcific Aortic Stenosis: Most frequent, age-related calcification of previously normal tricuspid aortic valve cusps. Leads to obstruction.
- Bicuspid Aortic Valve: Congenital condition (1-2% of individuals) with only two cusps instead of three. Dysfunction develops earlier.

Calcific Aortic Stenosis Mechanisms

Mechanisms of Calcific Aortic Stenosis

Precise mechanisms are complex, but insights gained from studying mechanical forces on valvular interstitial cells

Calcific nodules form in valve cusps, preventing full opening.

Results in pressure overload of the left ventricle, inducing hypertrophy (enlargement) of the chamber walls.

Typically produces symptoms in the seventh and eighth decades of life.

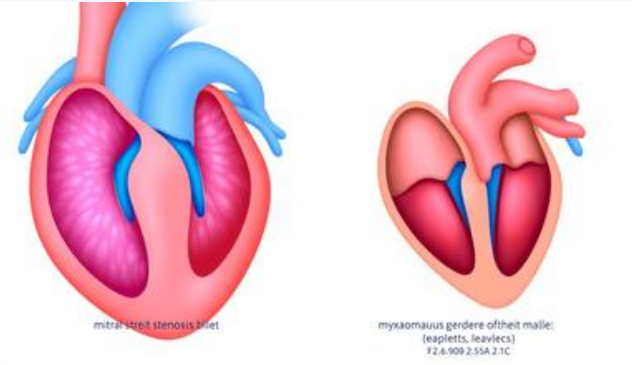
Aortic Regurgitation

Aortic Regurgitation (Insufficiency)

Less frequent but significant problem.

- Most often caused by dilation of the aortic root.
- Prevents complete closure of cusps, leading to backflow.
- Results in volume overload of the left ventricle.

Mitral Valve Diseases



Mitral Valve Diseases

- Mitral Stenosis: Predominant cause is chronic rheumatic heart disease, leading to scarring and stiffening of leaflets. Clinically manifests years or decades after acute rheumatic fever.
- Mitral Regurgitation: Results from various conditions, most frequent being myxomatous valve degeneration (floppy mitral valve), where tissue strength is deficient, causing leaflet deformation.

Mitral Regurgitation Causes

Other Causes of Mitral Regurgitation

1. Abnormally dilated and/or scarred left ventricle (valve not properly supported).
2. Infective endocarditis (infection of the valve).

Right Heart Valve Diseases

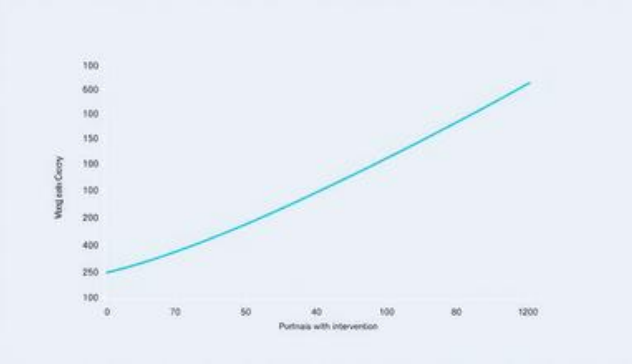
Right-Sided Valve Diseases

Diseases of the tricuspid and pulmonic valves are much less common than left-sided valves.

However, in children with congenital heart disease, there is a need for pulmonary valve replacements.

Valve replacements for congenital anomalies account for ~5% of all valve replacements.

Complications of Valvular Disease



Major Clinical Complication: Cardiac Failure

- Secondary to changes in the myocardium induced by pressure or volume overload.
- Occurs in chambers either upstream or downstream of the diseased valve.
- For example, mortality of nonsurgically treated critical aortic stenosis is ~50% at 2-3 years, more severe than many cancers.

Benefits of Valve Replacement

Valve Replacement: A Highly Beneficial Therapy

1. Survival rates after valve replacement are 50-70% at 10-15 years.
2. Serious complication-free survival is approximately 30-50% at 10-15 years.
3. Operative mortality: 3% for aortic valve replacement, 6% for mitral valve replacement.

Despite substantial improvement over natural disease history, patients with artificial valves can suffer device-related complications.

Surgical Options for Valve Disease

Surgical Treatments for Valvular Heart Disease

1. Replacement: Excision of part or all of the diseased valve and substitution with a prosthesis.
2. Repair: Restoration of existing abnormal valve tissue to make it functional.
3. In 2005, 36,678 aortic/mitral valve replacements and 8,669 valve repairs in the US.

Advantages of Valve Repair

Valve Repair vs. Replacement: Why Repair is Preferred

- Eliminates the risk of prosthesis-related complications.
- Avoids the need for chronic anticoagulation (mandatory for mechanical valves).
- Mitral valve operations for regurgitation increasingly use repair (69% currently).
- Often accompanied by stabilization of the annulus (with/without annuloplasty ring).
- Repair is usually not possible for most forms of aortic valve disease.

The 'Ideal' Valve

Characteristics of an Ideal Replacement Valve

- Nonthrombogenic: Does not promote blood clot formation.
- Nonhemolytic: Does not cause red blood cell destruction.
- Infection resistant.
- Chemically inert.
- Durable.
- Easily inserted.
- Opens fully and closes quickly and completely.

Evolution of Prosthetic Valves

Surgical Heart Valves: Early Developments

Early 20th century: Cardiac catheterization, innovative surgical techniques, cardiopulmonary bypass, heparin enabled progress.

Late 1950s: Collaboration between surgeons and biomedical engineers translated lab innovations to clinical practice.

First prosthetic valve: Hufnagel ball valve (descending thoracic aorta for aortic regurgitation). Partially relieved cardiac work, but did not improve coronary flow.

Starr-Edwards Valve

The Starr-Edwards Valve: A Landmark Achievement

- Fabricated by cardiac surgeon Dr. Albert Starr and mechanical engineer Lowell Edwards.
- Components:
- - Stainless-steel cage
- - Heat-cured Silastic ball
- - Teflon fabric sewing cuff (for orthotopic surgical implantation).

These three generic components (moving part, superstructure, sewing cuff) form the basis of all modern surgical heart valve prostheses.

Foundational Innovators

Pioneering Contributions: Starr and Carpentier

Cardiac valve prostheses: A significant achievement of biomaterials science and biomedical engineering.

2007 Lasker Award for Clinical Medical Research:

- Dr. Albert Starr: Performed the first successful in-heart valve replacement (1960, caged-ball mechanical valve in mitral position)

- Dr. Alain Carpentier: Fabricated the first

Carpentier's Bioprosthesis

Bioprosthetic (Tissue) Valves

1. Carpentier developed the 'bioprosthesis' combining chemically treated biologic tissue with a mechanical structure.

2. These are tissue-based, non-living heart valve replacements.

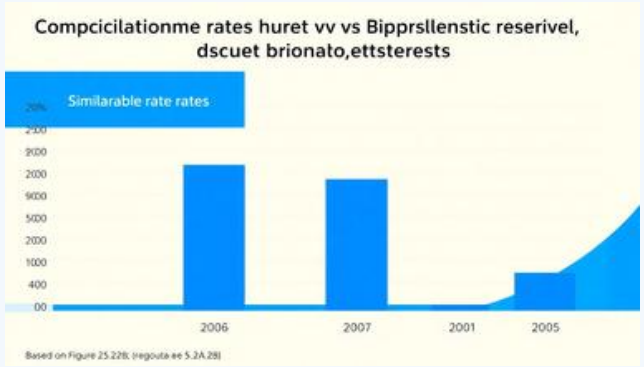
Outcome data and pathological descriptions of complications are well-known for many types of valve prostheses.

Modern Valve Replacement

Current Landscape of Heart Valve Replacement

1. Over 80,000 valves replaced annually in the United States.
2. More than 275,000 worldwide.
3. Rapid innovation in minimally invasive and percutaneous (catheter-based) valve replacement and repair.
4. Exciting progress towards creating living tissue-engineered heart valve replacements.

Mechanical vs. Tissue Valves



Types of Cardiac Valvular Substitutes

Two generic types are widely used today:

- Mechanical valves
- Biological tissue valves

The choice for a particular patient is complex, though overall complication rates are similar over time in both aortic and mitral positions.

Mechanical Valves

Mechanical Prosthetic Heart Valves

- Composed of non-physiologic biomaterials.
- Employ rigid, mobile occluders.
- Examples:
- - Caged-ball (Starr-Edwards)
- - Tilting disk (Bjork-Shiley, Hall-Medtronic, OmniScience)
- - Bileaflet tilting disk (St. Jude Medical, CarboMedics CPHV, Medical Carbon Research Institute, On-X).

Mechanical Valve Materials

Materials in Mechanical Valves

Superstructure: Metallic cage (cobalt-chrome or titanium alloy).

Occluders: All modern mechanical valve occluders are fabricated from pyrolytic carbon.

Pyrolytic carbon properties: High strength, fatigue and wear resistance, exceptional biocompatibility, relative thromboresistance.

Visually, mechanical valves do not resemble natural heart valves

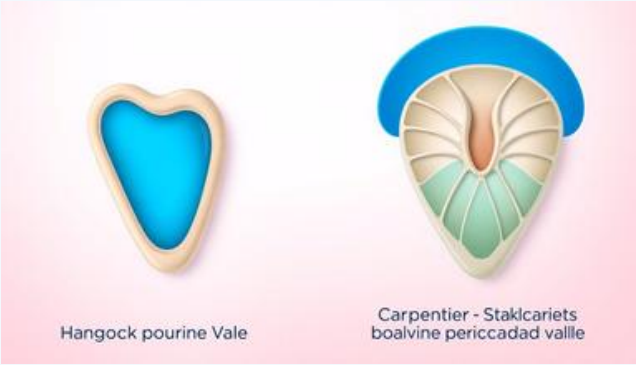
Mechanical Valve Care

Anticoagulation with Mechanical Valves

Patients receiving mechanical valves must be treated with lifelong anticoagulation.

- Typically warfarin derivatives.
- Reduces the risk of thrombosis and thromboembolic events.
- However, it introduces a risk of hemorrhage, which can be serious and sometimes fatal.

Bioprosthetic Valves



Biological Tissue Valves (Bioprostheses)

- Resemble natural valves with a trileaflet configuration and central orifice.
- Composed of three cusps of tissue derived from animals (xenografts).
- Most frequently: porcine (pig) aortic valve or bovine (cow) pericardium.
- Tissue is treated with glutaraldehyde for preservation, reduced immunological reactivity, and cell killing.

Bioprosthesis Considerations

Advantages and Limitations of Bioprostheses

Advantages: No immunosuppression required (xenografts) as cells are non-viable, less thrombogenic compared to mechanical

Limitations: Cusps cannot remodel or respond to injury as normal tissue does due to lack of viable cells.

Fabricated cusps are usually mounted on a metal or plastic stent with three posts to simulate native valve geometry.

Base ring covered by Dacron- or Teflon-covered sewing cuff for implantation and healing.

Allograft Valves

Allografts (Homografts): Human-Derived Valves

1. Derived from human cadaveric aortic or pulmonary valves (with/without associated vascular conduit).

2. Advantages: Good hemodynamic profiles, low thromboembolic incidence without chronic anticoagulation, low reinfection rate (especially for endocarditis).

3. Evolution of preservation: Early chemical/irradiation methods led to high calcification/rupture. Current practice uses cryopreservation with dimethyl-sulfoxide and liquid nitrogen (-196°C).

Allograft Challenges

Limitations of Allograft Valves

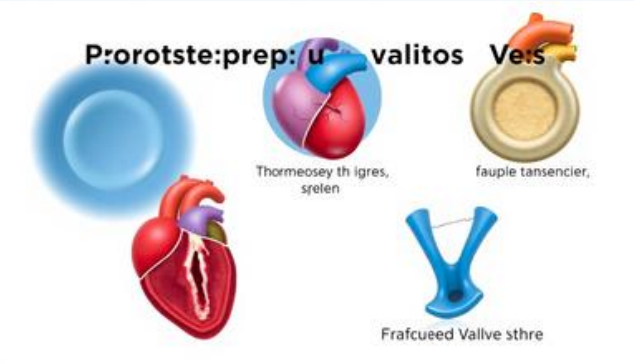
Limited by availability.

Difficulty in obtaining the proper size.

More complex surgical procedure for implantation.

Despite limitations, contemporary allografts offer similar or better freedom from degeneration and tissue failure compared to

Valve-Related Complications



Key Complications of Valve Prostheses

The reliability of a valve prosthesis and its interactions with the host significantly impact patient outcome.

- Thrombosis and Thromboembolism
- Infection
- Structural Dysfunction (failure or degeneration of biomaterials)
- Nonstructural Dysfunction (miscellaneous complications not fitting above)

Thromboembolism Risks

Thromboembolic Complications

1. Major cause of mortality and morbidity after cardiac valve replacement with mechanical valves.
2. No artificial surface is as thromboresistant as normal unperturbed endothelium.
3. Predicted by Virchow's triad: surface thrombogenicity, hypercoagulability, locally static blood flow.

Blood-Device Interactions

Effects of Blood Exposure to Artificial Surfaces

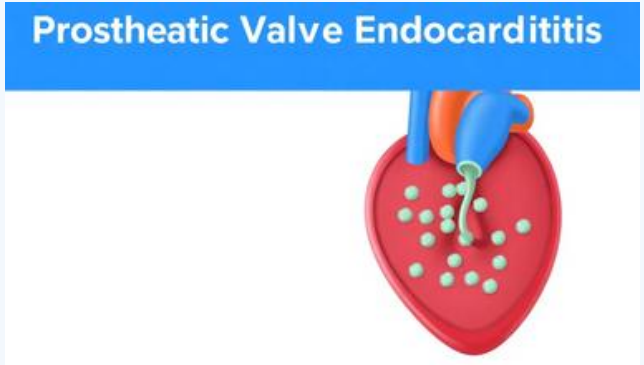
Can induce thrombosis, embolization, and consumption of platelets and plasma coagulation factors.

Can cause systemic effects of activated coagulation, complement products, and platelets.

Patients with mechanical valves require lifetime therapeutic anticoagulation (warfarin), carrying a risk of hemorrhage.

Thrombotic deposits can immobilize the occluder or shed emboli to downstream arterial beds.

Prosthetic Valve Infection



Prosthetic Valve Infection (Endocarditis)

- Occurs in 3-6% of substitute valve recipients; risk increases if original replacement was due to endocarditis.
- Rates are similar for bioprostheses and mechanical valves.
- Mechanical valves: infection localized to prosthesis/tissue junction at sewing ring; can cause tissue destruction.
- Bioprosthetic valves: infection can also be at junction, but biological tissue can support

Infection Etiology & Management

Common Microorganisms and Treatment

1 Frequent portals of entry: dental procedures, urologic infections, indwelling catheters.

2 Early post-op (<60 days): Dominated by Staphylococcus epidermidis and Staphylococcus aureus.

3 Late post-op (years): S. epidermidis, S. aureus, Streptococcus viridans, Enterococci.

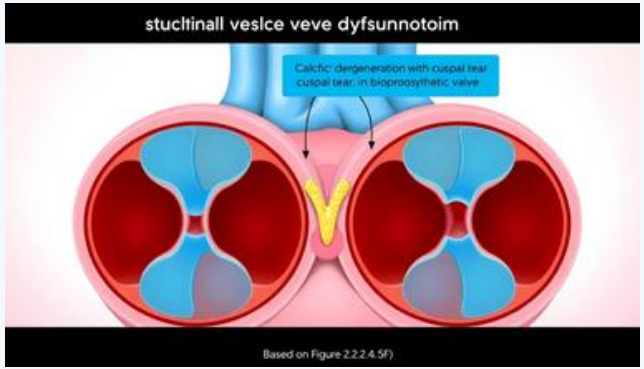
4 Treatment: Difficult to eradicate with antibiotics alone, usually requires surgical reintervention.

Mechanical Valve Structural Failures

Structural Dysfunction: Mechanical Valve Fractures

- Fractures of metallic or carbon components are usually catastrophic but rare.
- Noteworthy past design defects: Bjork-Shiley 60- and 70-degree convexoconcave tilting disk valves (fractures of welded metallic outlet strut leading to disk escape).
- Edwards (previously Hemex)-Duromedics bileaflet tilting disk valves (fractures of carbon components).

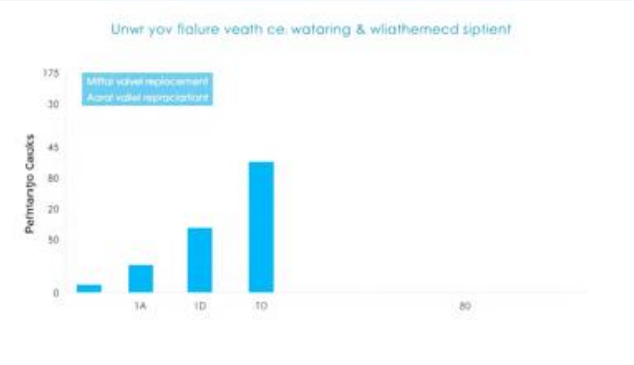
Bioprosthetic Valve Failures



Structural Dysfunction: Bioprosthetic Valve Failure

- Frequent and a major cause of failure for widely used bioprostheses.
- Usually results in progressive symptomatic deterioration requiring reoperation.
- Within 15 years, 30-50% of porcine aortic valves require replacement due to primary tissue failure.
- Major pathologic mechanism: Cuspal calcification.

Primary Valve Failure Statistics



Primary Valve Failure Over Time

Cuspal mineralization is the major pathologic mechanism with regurgitation through tears as the most frequent failure mode in bioprostheses.

Nonstructural Complications

Nonstructural Dysfunction of Prosthetic Valves

Relates to healing at the implantation site (too little or too much).

Inadequate healing: Paravalvular leaks (reverse flow through small defect at prosthesis-host tissue junction). May cause hemolysis or heart failure.

Overexuberant healing: Tissue overgrowth (pannus). Can block occluder motion or lead to secondary thrombus.

Bioprosthetic Valve Advances

Improvements in Bioprosthetic Valves

1. Active investigation into methods to prevent calcification.
2. Early data suggests extended durable lifetime for bioprosthetic valves.
3. Dramatic resurgence in their use due to these improvements.
4. Industry data shows disproportionate growth in tissue valve market due to innovations and enhanced durability.

Shift Towards Tissue Valves

Trends in Valve Implantation

Increasing fraction of tissue valves implanted relative to mechanical valves.

Tissue valves now represent up to 80% of all substitute heart valves in some countries.

Especially high use in older recipients, who have diminished rates of calcific failure and where anticoagulation carries increased risk of hemorrhage.

Sutureless Valve Technology

Sutureless Aortic Valves

1. Allow quicker implantations using a more minimally invasive surgical approach.
2. Involves removing diseased aortic cusps and deploying the sutureless valve.
3. Designed to minimize aortic cross-clamp time and maximize effective valve area.

Specific Sutureless Valves

Examples of Sutureless Valves

1. 3f Enable valve (Medtronic): Equine pericardium on a self-expanding Nitinol frame with polyester flange.
2. Perceval S valve (LivaNova): Bovine pericardial cusps mounted within a Nitinol frame, designed for anchoring to aortic root.
3. Both have shown clinical promise for selected patients.

Performance and safety demonstrated for up to 5 years.

Next-Gen Valve Designs

Future Valve Approaches: Beyond Current Designs

Bioprosthetic valve stent design modifications: Reduce cuspal stresses.

Tissue treatment: Alternative to glutaraldehyde for enhanced durability and biocompatibility.

Minimally cross-linked autologous pericardial valves.

Polymeric materials: Near-anatomic, central flow trileaflet prostheses using flexible synthetic polymeric leaflets (e.g.,

Polymer Valve Hurdles

Challenges with Polymeric Valves

Although used in cardiac assist devices, durability limitations have been a major concern for orthotopic (in-heart) flexible polymeric valve replacement.

Preclinical failures often marked by thrombosis, tearing, and/or calcification of the cusps.

Living Valve Replacements

Tissue-Engineered Heart Valves (TEHVs)

Goal: Generate a living valve replacement that would obviate complications, adapt to environmental changes, and potentially grow with the patient.

- Long-term success depends on viable cellular components (valvular interstitial cells).
- Cells need to assume normal function, repair structural injury, remodel extracellular matrix, and grow.

TEHV Research Advances

Progress in TEHV Research

1. Valved conduits grown from autologous cells (vascular wall cells or bone marrow-derived mesenchymal stem cells) on biodegradable synthetic polymers.

2. Grown in vitro and functioned in pulmonary circulation of growing lambs for months.

3. Some grafts evolved in vivo to resemble native semilunar valves.

4. New biomaterials technologies like 3D bioprinting, multilayer biomaterials, and decellularized valves are enabling further progress.

Decellularized Scaffolds

Decellularized Scaffolds for TEHVs

Alternative to in vitro cell seeding and culture.

Uses decellularized naturally derived biomaterials (animal xenograft, human allograft, sheep intestinal submucosa) or

Implanted without prior seeding, relying on intrinsic circulating cells for repopulation and remodeling.

Challenges: Must possess desirable 3D architecture, mechanical properties, and cell adhesion/migrati on sites

Introduction to TAVI

Percutaneous Transcatheter Valves: A New Frontier

- Surgical implantation of bioprosthetic and mechanical valves has long-proven success.
- However, many patients (30-40% of aortic stenosis cases) are unsuitable for surgery due to age, frailty, comorbidities.
- Transcatheter Aortic Valve Implantation (TAVI): A minimally invasive alternative for these patients, extending effective mechanical correction.

TAVI Procedure Steps

The TAVI Procedure: Catheter-Based Approach

- Uses peripheral arterial access (e.g., femoral artery) via catheter.
- Catheter passed retrograde up the aorta to the aortic valve.
- Avoids opening the chest (in contrast to classical open surgery).
- Alternative: Transapical implantation via minimally invasive surgical approach exposing left ventricle apex.
- Device is collapsed into a sheath, expanded within the calcified aortic valve, pushing diseased cusps out of flow stream (diseased tissue not removed).

TAVI Clinical Outcomes

Clinical Experience and Efficacy of TAVI

1. Rapidly growing clinical experience: Over 300,000 TAVI procedures worldwide since 2002.

2. Clinical trials: TAVI is at least as effective as classical aortic valve replacement regarding morbidity and mortality in high-risk patients.

3. TAVI and surgical valve replacement are comparable hemodynamically.

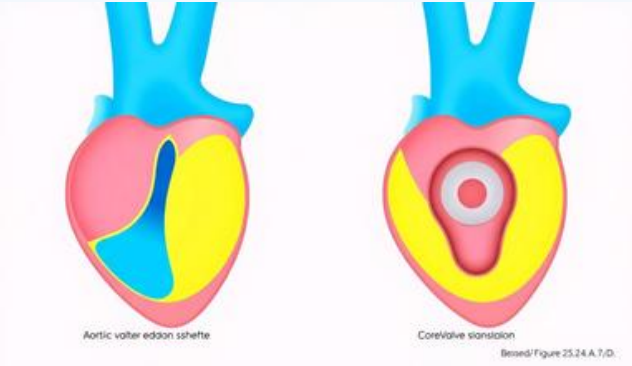
4. Recent data: TAVI is an excellent alternative for patients with intermediate or lower surgical risk.

Transcatheter Valve Design

Components of Transcatheter Valve Devices

1. Outer stent-like structure: Holds open the valve annulus, resists recoil, supports leaflets, provides seating.
2. Valve leaflets: Tissues include bovine, equine, or porcine pericardium; bovine jugular venous valves.
3. Stents: Made from self-expandable stainless steel, platinum-iridium, or shape-memory materials (e.g., Nitinol).

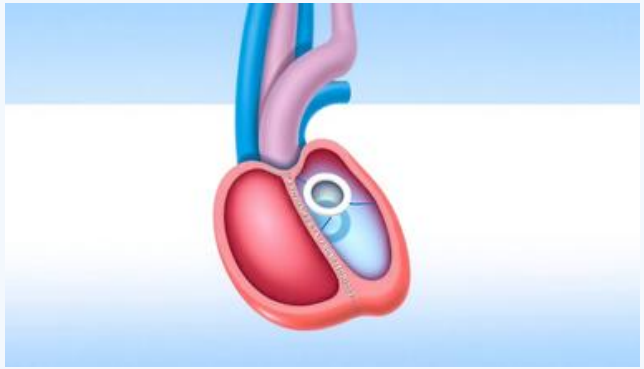
Main TAVI Devices



Key Transcatheter Aortic Valves

- Edwards-Sapien family of devices: Balloon-expandable stainless-steel stent with bovine pericardial trileaflet valve. Polymer skirt to reduce paravalvular leaks.
- CoreValve ReValving system (Medtronic): Self-expandable Nitinol stent with porcine pericardial trileaflet valve. Tapered midsection, flared aortic portion.

Melody Pulmonary Valve



Transcatheter Pulmonary Valve

- Medtronic Melody transcatheter pulmonary valve:
- - Used in children with failed right-ventricular to pulmonary artery devices (congenital heart defects).
- - Composed of a balloon-expandable platinum-iridium alloy stent.
- - Houses a segment of bovine jugular vein with its native venous valve.
- - Threaded from femoral vein to inferior vena

Valve-in-Valve Therapy

Valve-in-Valve Application

Catheter-based valves can treat failing surgically implanted bioprosthetic valves.

A new prosthesis is inserted directly into a prior one.

TAVI Challenges

Challenges with Transcatheter Valve Implantation

- Large device size: Difficult vascular access, potential damage along catheter path.
- Emboli risk: Dislodging debris during catheter passage.
- Risk of impeding coronary flow or interfering with anterior mitral leaflet mobility.
- Potential interference with conduction system or native diseased leaflets.
- Stent architecture may preclude future catheter access to coronaries.
- Ensuring secure seating within annulus/conduit and long-term durability.

TAVI Complications

Complications of Transcatheter Heart Valves

- Surgical complications: Paravalvular leak, vascular injury with hemorrhage, embolic stroke.
- Prosthesis-associated failure modes:
- - Prosthetic valve endocarditis (PVE).
- - Structural valve failure due to leaflet calcification.
- - Thrombosis.
- A critical unknown is the long-term durability of these prostheses.

TMVR Developments

Transcatheter Mitral Valve Replacement (TMVR)

First TMVR in a native valve performed in 2012.

Slower progress compared to TAVI due to complexities and variability of mitral valve anatomy and neighboring structures.

Can be applied to degenerated prosthetic valves and annuloplasty rings, or various native mitral valve diseases.

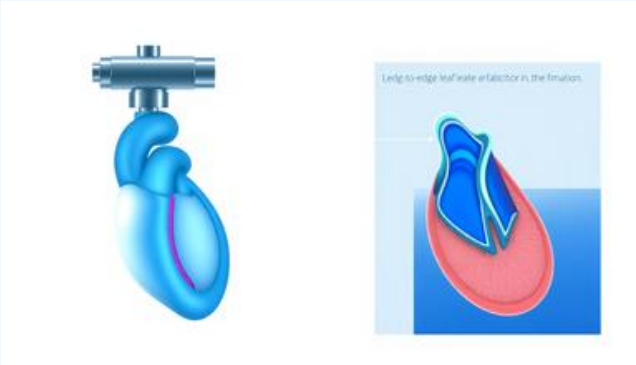
Aortic TMVR devices can be implanted for degenerated bioprosthetic valves or severe mitral annular calcification with high

Native Valve TMVR

TMVR for Native Mitral Valve Disease

1. Complexities have led to development of several TMVR systems with different anchoring mechanisms and geometry.
2. All are currently investigational and none are FDA approved for native valve disease.
3. Percutaneous mitral valve replacement has been investigated using devices similar to TAVI.

MitraClip Therapy



MitraClip Device for Mitral Regurgitation

- Transcatheter-delivered device (Abbott Laboratories).
- Reduces mitral regurgitation by fastening anterior and posterior leaflets together (edge-to-edge).
- Approved by FDA in 2013.
- Composed of polyester-covered implant with two cobalt-chromium metallic arms.
- Creates a 'figure-of-eight' with two openings instead of one.

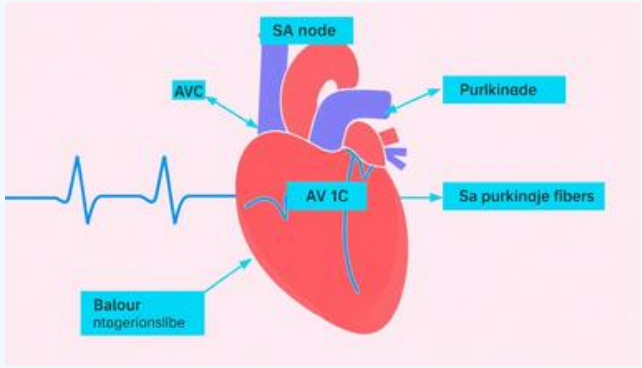
MitraClip Details

MitraClip: Mechanism and Outcomes

Polyester is macroporous, allowing tissue ingrowth for anchoring and minimizing thrombosis.

Clinical trials demonstrate safety and efficacy in patients with heart failure due to moderate-to-severe or severe mitral regurgitation.

Cardiac Electrical Conduction



Cardiac Arrhythmias: Normal Electrical Cycle

- Impulse initiated by Sinoatrial (SA) node (heart's natural pacemaker) in right atrium.
- Spreads through atrial walls, causing depolarization and atrial contraction.
- Arrives at Atrioventricular (AV) node (posterior right atrium).
- Short delay in AV node, then impulse passes to Bundle of His and into left/right bundle branches (intraventricular septum).
- Spreads through ventricular myocardium

Cardiac Arrhythmias

Disturbances in Cardiac Electrical Activity

- Arrhythmias reflect disturbances of impulse initiation or conduction.
- Ectopic foci: Impulse-generating cells outside SA node. Can cause tachyarrhythmias (fast rhythms), leading to suboptimal contractions or fatal ventricular fibrillation.
- SA node dysfunction: Can cause disturbances in impulse initiation.
- Conduction blocks: Failure of impulse propagation through specialized muscle (due to disease or drugs). Can be complete or incomplete, permanent or transient.
- Reentry: Cardiac impulse re-excites previously excited tissue without new SA node impulse.

Arrhythmia Treatment

Therapeutic Options for Arrhythmias

For patients whose arrhythmias cannot be controlled pharmacologically:

- Electrical Therapy: Direct current cardioversion, implantable devices (pacemakers, ICDs).
- Interventional/Surgical Therapy: Remove affected tissue or interrupt abnormal pathway (endocardial resection, cryoablation, radiofrequency ablation).

Introduction to Pacemakers

Cardiac Pacemakers: Overview

1. Medical devices that provide electrical impulses to initiate cardiac contraction.
2. First implanted in 1958.
3. Over 1 million patients in the US currently have pacemakers; over 250,000 new permanent pacemakers implanted annually.
4. Most recipients are over 60, but also used in children/infants.

Pacemaker Indications

Indications for Permanent Cardiac Pacing

Various types of conduction block:

- Bradycardia (abnormally low heart rate).

- Ventricular dyssynchrony (left/right bundles), leading to inefficient ventricular contraction despite normal heart rate

These conditions can result in decreased cardiac output and congestive heart failure symptoms, which are well-treated by

Pacemaker System

Components of a Modern Cardiac Pacing System

Pulse Generator: Contains power source and circuitry to initiate stimulus and sense cardiac activity.

Leads: One or more electrically insulated conductors from generator to heart, with bipolar electrode at distal end.

Tissue/Blood and Tissue Interface: Between electrode and adjacent myocardial cells.

The pacemaker delivers a small current (2-4 mA) to the myocardium via electrodes, causing depolarization and contraction.

Temporary Pacing

Temporary Cardiac Pacing

1

Most often used for acute myocardial infarction complicated by conduction system disturbances (risk of complete heart block).

2

Leads generally directed transvenously into right ventricle apex; pulse generator is external.

3

During cardiac surgery (epicardial exposure): Insulated wires with bare ends placed on atrial/ventricular epicardial surfaces, leads emerge transthoracically.

Temporary pacemakers are eventually replaced by permanent devices or

Permanent Pacing

Permanent Cardiac Pacing: Implantation and Materials

- Involves long-term implantation of both pulse generator and electrode leads.
- Generator: Usually titanium alloy, placed in tissue pocket beneath skin (left anterior chest).
- Leads: Advanced transvenously through left subclavian vein to endocardial surface of heart.
- Conducting elements: MP-35N alloy (nickel, cobalt, chromium, molybdenum) with high conductance materials (silver, stainless steel).
- Insulation: Silicone and/or urethane outer coating.
- Electrode tips: Placed in right atrium and/or right ventricle based on pacing modality.

Pacemaker Modalities

Types of Permanent Pacemakers

Single Chamber Pacemaker: Delivers stimulus based on programmed timing, senses intrinsic cardiac activity, can be inhibited (demand pacing) for intermittent problems.

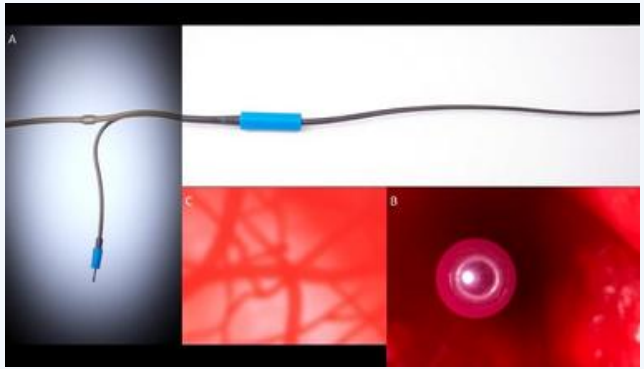
Dual-Chamber Pacemaker: Electrodes in atrium and ventricle, delivers sequential atrial and ventricular signals to approximate normal heartbeat timing. Senses and delivers stimuli for proper chamber synchrony.

Cardiac Resynchronization Therapy

Cardiac Resynchronization Therapy (CRT)

- For patients with ventricular conduction delays (e.g., left bundle branch block) causing heart failure due to ventricular dyssynchrony.
- Involves biventricular pacing.
- Pacing electrodes placed in: right atrium, right ventricle, and coronary sinus (stimulates lateral wall of left ventricle).
- Allows simultaneous excitation of ventricles and more uniform left ventricular contraction.
- Significantly improves cardiac function.

Pacemaker Longevity & Biointerface



Pacemaker Battery Life and Tissue Interface

- Powered by lithium-iodide batteries with 5-8 year lifespan, requiring replacement.
- Improved battery technology minimizes reimplantations and complications.
- Interface between electrode and myocardium is critical.
- Fibrous tissue forms around electrode tip, increasing stimulation threshold (undesirable).
- Strategies to reduce fibrosis: improved lead

Pacemaker Lead Innovation

Pacemaker Lead Design Considerations

- Ideal lead: Stable fixation immediately, minimal stimulation threshold, maximized sensing, reliable for years.
- Electrode fixation:
- - Active fixation: Electrode designed to grasp endocardial surface.
- - Passive fixation: Projecting 'tines' or 'fins' near tip.
- Porous metal surfaces: Foster tissue ingrowth for improved fixation.
- Special designs: J-shaped atrial lead for right atrial appendage placement (stable site).

Leadless Pacemakers

Leadless Pacemaker Therapy

- New technology in clinical practice.
- Devices: Nanostim Leadless Pacing System (St. Jude Medical) and Micra Transcatheter Pacing System (Medtronic).
- Consist of a single capsule-like module containing all traditional single-chamber pacemaker functions.
- Implanted entirely within the apical aspect of the right ventricle, attached via helical coil or tines.

Leadless Pacemaker Benefits

Advantages of Leadless Pacemakers

1

Aim to provide same pacing function without complications associated with large subcutaneous generator pocket and long leads (traversing cardiac chambers and valves).

2

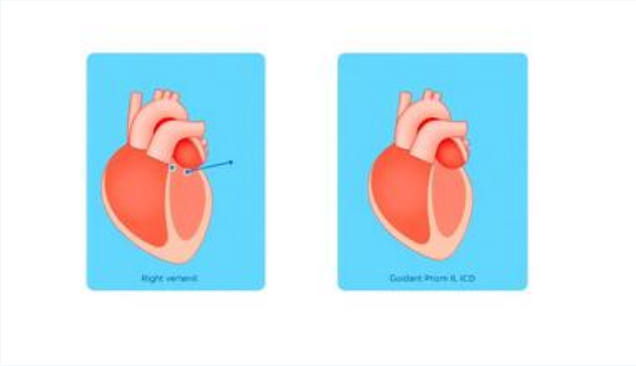
Design feature allows recapture for repositioning during implantation or later removal.

Introduction to ICDs

Implantable Cardioverter-Defibrillators (ICDs)

- First implanted in 1980; >100,000 implanted annually in the US.
- Goal: Prevent sudden death in patients with life-threatening arrhythmias.
- Resets heart's electrical activity, stimulating normal rhythm.
- Effective in reverting sustained ventricular tachycardia and ventricular fibrillation.
- Proven benefit in overall mortality.

Transvenous ICD System



Components of a Transvenous ICD

- Similar components to a pacemaker: pulse generator and leads.
- Pulse Generator: Self-powered, self-contained computer with lithium-silver vanadium oxide batteries and aluminum electrolytic storage capacitors. Service life: 3-5 years.
- Lead: Generally placed in the right ventricle through a transvenous approach.
- Leads: Coaxial conducting elements for

ICD Operations

ICD Function and Indications

- Monitors ventricular rate; delivers therapy if rate exceeds a set value.
- Initial therapy: Short burst of rapid ventricular pacing (terminates up to 96% of episodes without large shock).
- If pacing fails: Delivers a 10-30J shock between right ventricular electrode and pulse generator surface.
- Keeps record of arrhythmias and treatment results.
- Indications: High risk for ventricular arrhythmias (primary prevention) and prior aborted sudden cardiac death (secondary prevention).

Subcutaneous ICD

Subcutaneous ICD (S-ICD)

- Developed for detection and termination of malignant arrhythmias.
- Uses an extravascular lead implanted in subcutaneous tissue (parallel to sternum, left of midline).
- Lead connected to generator in midaxillary line on left side of thorax.
- Senses 'far field' signal (like surface ECG).
- Shock delivered by generator in subcutaneous tissue over heart (similar to external defibrillator).

S-ICD Benefits

Advantages of S-ICD

1. Not in direct contact with the heart and blood.
2. More stable mechanical environment.
3. Aims to reduce complications associated with transvenous leads.

Device Complications Overview

Complications of Pacemakers and ICDs

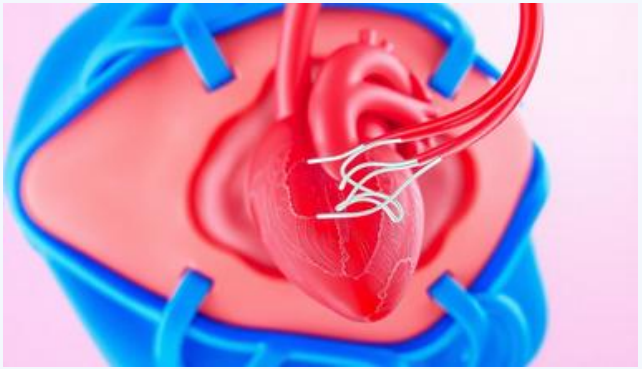
Many shared complications; often require device removal and replacement.

Life-sustaining technologies: Device failure can be fatal.

Normal end-of-service (depleted battery) requires replacement, can be premature due to increased fibrosis at lead-tissue interface

Most common malfunctions: Failures of hardware (battery/capacitor, charge circuit, connectors, leads).

Hardware Failures



Mechanical Failures of Devices

- Electrode dislodgment.
- Lead fractures.
- Electrode corrosion.
- Insulation failure.
- Lead improvements: Helical coil and multifilament designs for decreased electrical resistance and enhanced flexibility/durability.
- Recent generations: Improved resistance to electromagnetic interference (EMI) from

Host Interaction Complications

Device-Host Interaction Complications

- Infection: Dreaded complication, can originate in subcutaneous pocket, track along lead, or occur via bacterial implantation on traumatized endocardium.
- Thrombosis and Thromboembolism.
- Myocardial penetration or perforation.
- Pressure necrosis of skin overlying pulse generator.
- Migration or rotation of the pulse generator.

Device-Related Infection

Infection in Pacemakers and ICDs

1. Most common organisms: Coagulase-negative Staphylococcus species (e.g., S. epidermidis).
2. Can lead to septicemia and septic pulmonary emboli.
3. Fundamental therapeutic principle: Antibiotic treatment followed by removal of lead, and if pocket involved, entire pacing system.

ICD Unique Complications

ICD-Specific Complications

- More extensive hardware in ICDs contributes to higher complication frequency.
- Consequences of repeated defibrillations:
- - Direct effect on myocardium and vascular structures.
- - Possible thrombogenic potential of indwelling intravascular electrodes.
- Inappropriate shock: Startling and painful, can lead to post-traumatic stress disorder symptoms.

Removing Leads

Challenges of Lead Removal

Leads are designed to optimize interaction with myocardium, but this can make removal problematic.

Some leads removed by prolonged gentle traction.

Many require additional tools/techniques to free them from venous wall and myocardium (often tenaciously adherent)

May require cardiotomy with cardiopulmonary bypass if lead is densely incarcerated in fibrous tissue.

Understanding CHF

Congestive Heart Failure (CHF): A Major Health Burden

Defined as deficiency in the pumping function of the heart.

Extremely common: Affects ~6.2 million Americans.

Annually in the US: Principal cause of death in 60,000 individuals, contributing factor in >280,000 deaths, primary

Cardiac transplantation is a potential solution, but limited by donor heart availability (2,500/year vs. >100,000 needing it).

CHF Etiology and Pathology

Causes and Manifestations of CHF

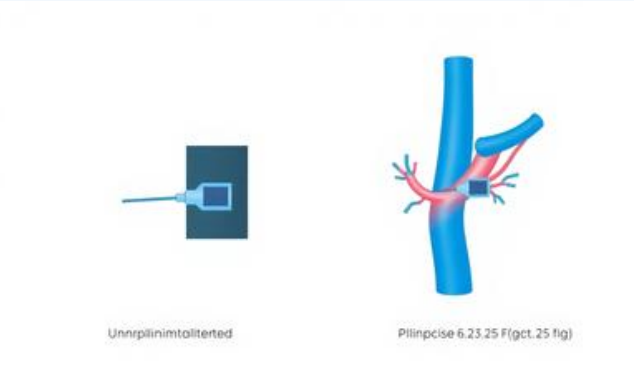
1. Final common pathway of many conditions: valvular heart disease, coronary artery atherosclerosis (ischemic heart disease), cardiomyopathies.

2. Onset: Can be precipitous (myocardial infarction, viral myocarditis) or slow and progressive (deterioration of heart muscle over months/years).

3. Postoperative manifestation: Can occur after cardiac or noncardiac surgery.

4. Left ventricular failure: Blood backs up into pulmonary circulation, increasing pulmonary vascular resistance and arterial pressure.

CardioMEMS System



Monitoring CHF with CardioMEMS HF System

- Provides hemodynamic information for monitoring and management of heart failure.
- Device: Wireless sensor implanted in distal pulmonary artery via catheter.
- Sensor components: Three-dimensional coil, pressure-sensitive capacitor (fused silica, encased in silicone).
- Electromagnetic coupling: Measures resonant frequency without implanted battery.

CardioMEMS Benefits

CardioMEMS: Data Transmission and Benefits

1. Resonant frequency converted to pressure measurement.
2. Pressure waveform (systolic, diastolic, mean arterial pressures) and heart rate transmitted to receiver (hospital or patient's home).
3. Treating physician accesses data remotely and in real time.
4. Beneficial for evaluating patients and adjusting medical regimens.

CHF Prognosis & Support

Natural History of Heart Failure and Mechanical Support

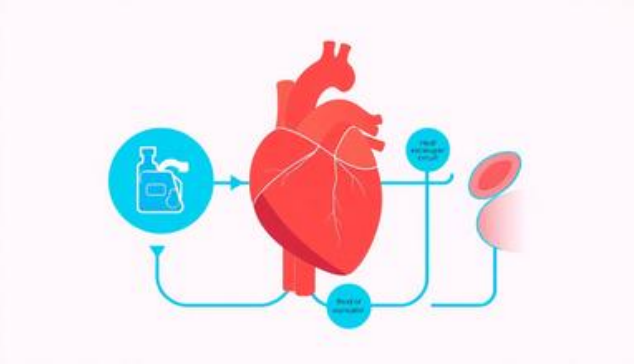
Depends on cause and progression of underlying disease.

Postcardiotomy shock: Often recover function after short mechanical support.

Dilated cardiomyopathy: Often need long-term mechanical support; ~50% mortality in 3-5 years without it.

Mechanical support systems must be designed considering different patient needs.

Introduction to CPB



Cardiopulmonary Bypass (CPB)

- First used in 1953 by Dr. John H. Gibbon.
- Pumps blood external to the body.
- Permits complex cardiac surgical procedures safely and effectively.
- Used in extracorporeal membrane oxygenation (ECMO) to assist oxygen/CO2 transport (e.g., for pulmonary diseases like respiratory distress syndrome).

CPB Mechanics

Operating Principles of Heart-Lung Machines

- Deoxygenated blood from right atrium withdrawn by gravity siphon into cardiotomy reservoir.
- Pumped into an oxygenator (most common: membrane oxygenator).
- Oxygen passes through tube side, blood through shell side; O2/CO2 exchanged via diffusion through synthetic membranes (polypropylene/silicone).
- Oxygenated blood passed through heat exchanger (adjusts temperature).
- Returned to systemic circulation via aorta.

CPB Management

Anticoagulation and Temperature Control in CPB

1. Patient anticoagulated with heparin at procedure start (reduces thrombosis risk).
2. Anticoagulation reversed with protamine when weaning from bypass.
3. Heat exchanger lowers core body temperature (decreases metabolic requirements, protects organs against ischemic damage).
4. Blood warmed to normal physiologic temperature at end of operation.

Perfusionist and CPB Advantages

Role of the Perfusionist and Benefits of CPB

Specially trained perfusionist controls heart-lung machine operation.

Allows surgeon/anesthesiologist to focus on their tasks.

Provides heart function (systemic blood flow/pressure) and lung function (oxygenating blood, removing CO2).

Enables stopping the heart for delicate surgical procedures.

CPB Modernization

Improvements in CPB Design

Early problem: Trauma to blood cells (hemolysis, platelet damage leading to bleeding).

Overcome with: Advanced pump designs (roller pumps, centrifugal pumps cause less hemolysis/shear), use of membrane oxygenators (less damaging than bubble oxygenators)

Newer devices: Allow processing and return of escaped blood, reducing need for transfusions.

CPB Complications & MECC

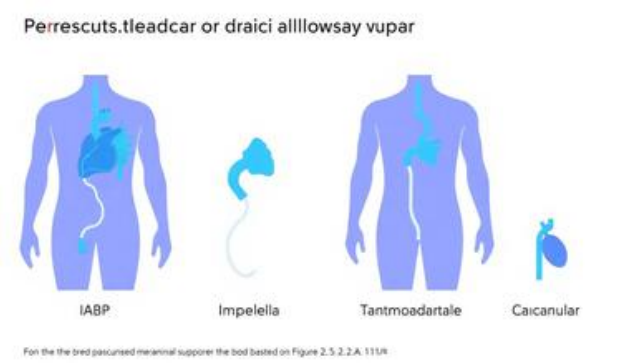
Physiological Changes and Complications of CPB

1. Can result in pathophysiologic changes: Complement activation, platelet/neutrophil activation, systemic vascular resistance changes, proinflammatory mediators.

2. Severe changes can lead to 'postperfusion syndrome': Confusion, renal insufficiency, pulmonary dysfunction, hepatic dysfunction, increased infection susceptibility.

3. Mini Extracorporeal Circuit (MECC) CPB systems: Reduced tubing length, smaller priming volumes, reduced blood-air interface, fewer components. Show reduction in inflammatory

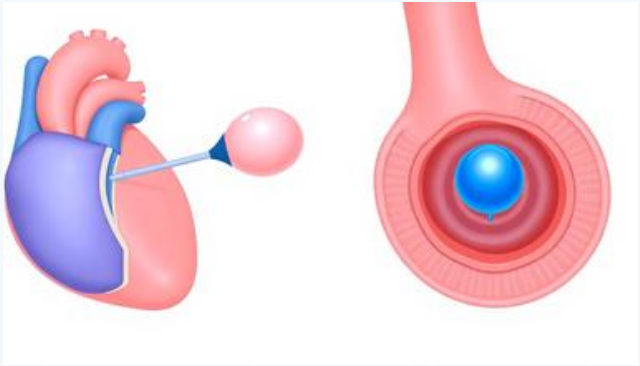
Percutaneous MCS Devices



Percutaneous Mechanical Circulatory Support Devices

- Primarily for potentially reversible acute heart failure or cardiogenic shock.
- Used when cardiac function likely to recover (e.g., postcardiotomy shock), or to stabilize for further therapies.
- Typical patient: Critically ill with acute cardiogenic shock, mechanical complications of MI, intractable arrhythmias, or advanced heart failure.

Intraaortic Balloon Pump (IABP)



Intraaortic Balloon Pump (IABP)

- First used in 1968.
- Catheter-based polyethylene or polyurethane balloons (25-50mL volume). Smaller for pediatric.
- Inflating gas: Helium (low viscosity, rapid inflation/deflation, rapidly dissolved if rupture).
- Positioned in descending thoracic aorta via femoral artery (fluoroscopic guidance).
- Timed to inflate during diastole and deflate

IABP Mechanisms & Benefits

Benefits of IABP Therapy

- Increases coronary blood flow (most occurs in diastole), delivering more oxygenated blood to myocardium.
- Decreases left ventricular afterload, reducing workload and myocardial oxygen requirement.
- Improves balance between myocardial oxygen supply and demand.
- Directly improves systemic circulation modestly (~10%).
- Permits heart to rest and recover function, typically removed after a few days.

IABP Risks

IABP Contraindications and Complications

1

Contraindications: Severe peripheral vascular disease (aneurysms), aortic valve regurgitation, aortic dissection.

2

Complications (~7% of patients): Limb ischemia (insertion site), bleeding, thrombosis with embolization, aortic dissection, balloon rupture, sepsis.

TandemHeart Device

TandemHeart Percutaneous VAD

- Supports systemic circulation.
- Withdraws blood from left atrium, reinjects into abdominal aorta or iliac artery.
- Commercially available since 2004.
- Pump: Extracorporeal, continuous flow centrifugal pump (up to 4-5 L/min blood flow).
- Inflow cannula (21-Fr): Femoral vein, advanced to right atrium, then across interatrial septum into left atrium (transseptal

TandemHeart Details

TandemHeart: Outflow, Applications, and Complications

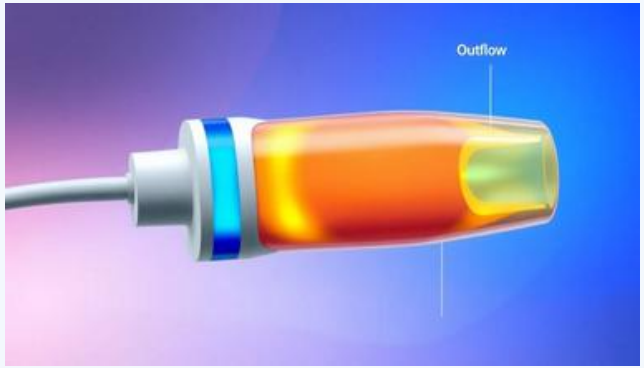
Outflow cannula (15-17-Fr): Femoral artery, advanced to iliac artery or abdominal aorta.

Clinical scenarios: High-risk percutaneous coronary interventions, bridge-to-recovery, bridge-to-decision

Right VAD use: Dual lumen cannula with inflow in right atrium, outflow in pulmonary artery.

Complications: Inflow cannula migration into right atrium (right-to-left shunt), decreased pulmonary arterial flow

Impella Device



Impella Device

- Continuous, nonpulsatile axial flow pump.
- Employs Archimedes-screw impeller: Draws blood from left ventricular cavity, expels into ascending aorta distal to aortic valve.
- Versions for left-sided support: Impella 2.5 (2.5 L/min), Impella CP (3.7 L/min), Impella 5.0 (5.0 L/min).
- Insertion: Typically femoral or axillary artery, retrograde across aortic valve; inlet in LV, outlet distal to aortic valve.

Impella Use & Risks

Impella: Benefits and Complications

- Benefits: Unloads left ventricular pressure and volume (advantageous for reducing LV oxygen consumption/demand).
- Used for: High-risk percutaneous coronary interventions, cardiogenic shock secondary to acute MI, bridge-to-decision, bridge-to-transplant.
- Contraindications: Mechanical aortic valves, left ventricular thrombi.
- Complications: Device migration, thrombosis/thromboembolism, bleeding, hemolysis, damage to LV cardiac structures (aortic/mitral valves).
- Impella RP: Similar device for right heart failure (inflow in right heart, outflow in pulmonary artery).

ECMO Therapy

Extracorporeal Membrane Oxygenation (ECMO)

1. Provides functions of both heart (blood pressure/flow) and lungs (gas exchange).
2. Increasingly used for acute cardiovascular and pulmonary diseases.
3. Circuit analogous to cardiopulmonary bypass, but usable at bedside.
4. Typical configuration: Venoarterial (VA-ECMO) for full biventricular support and gas exchange.

ECMO Implementation

ECMO Cannulation and Management

Cannulation: Peripherally and percutaneously (femoral vein/artery) or surgically (right atrium/aorta).

Requires experienced multidisciplinary team for adequate device functioning and patient monitoring.

Durable VADs Introduction

Durable Ventricular Assist Devices (VADs)

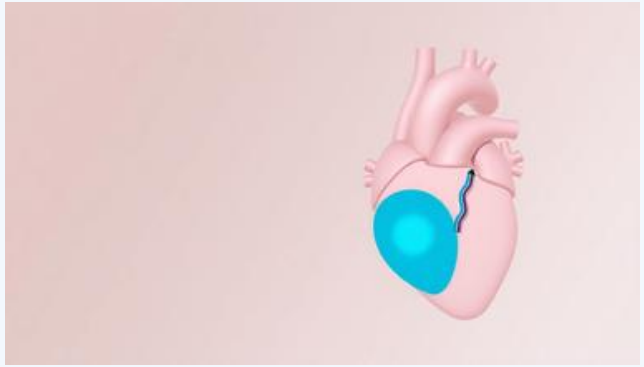
- First successfully used by DeBakey in 1963.
- Replace ventricular function for extended periods (unlike short-term CPB, IABP, percutaneous VADs).
- Primary uses:
- - 'Bridge-to-transplantation' for end-stage cardiac failure.
- - 'Destination therapy' for long-term support (not transplant candidates).
- - 'Bridge-to-recovery' for chronic CHF where

First-Gen VADs

First Generation Durable VADs (Pulsatile Systems)

- Large, pulsatile systems.
- Inflow cannula: Generally connected to left ventricular apex.
- Outflow cannula: Connected to ascending aorta.
- Pump: Either implanted in peritoneal cavity (driveline for power/controller) or extracorporeal.
- Components: Flexible polymer pumping bladder/diaphragm, pusher plate for filling/emptying, inflow/outflow valves.
- Examples: Thoratec HeartMate XVE, Novacor Ventricular Assist System, Thoratec PVAD (paracorporeal).

Second-Gen VADs



Second Generation Durable VADs (Continuous Axial Flow)

- Implantable continuous axial flow devices.
- Impeller's long axis parallel to blood flow.
- Examples: Thoratec HeartMate II, BerlinHeart INCOR, Jarvik 2000 FlowMaker.
- Smaller than first-gen, easier implantation, more durable.
- Continuous flow: Do not impart pulsatility to blood (reduced pulse pressure), but no significant clinical effects

Third-Gen VADs

Third Generation Durable VADs (Continuous Centrifugal Flow)

1. Implantable continuous centrifugal flow devices.
2. Impeller creates centrifugal force to add kinetic energy to blood.
3. Examples: HeartWare HVAD, Thoratec HeartMate 3, Evaheart LVAS.
4. Accelerating use, with decline in second-gen VAD use.

HeartWare HVAD

HeartWare HVAD

- First implantable third-gen centrifugal flow device in US.
- Pump is smaller, resides directly on epicardial surface of left ventricle, inflow cannula in LV cavity.
- Rotor produces continuous, centrifugal flow with magnetically levitated impeller (no inflow/outflow bearings).
- Smaller pump size, driveline, intrathoracic positioning, and flow characteristics aim to

HVAD Evolution

HVAD Design Challenges and Revisions

Original HVAD inflow cannula: Smooth, polished titanium surface raised concerns about cerebrovascular accidents due to thromboemboli.

Revised design: Sintered titanium microspheres for nonthrombotic passivating tissue overgrowth.

However, this created a discontinuity at the smooth-sintered interface, serving as a nidus for thrombus formation.

HeartMate 3

HeartMate 3 (Third-Gen Centrifugal Flow Pump)

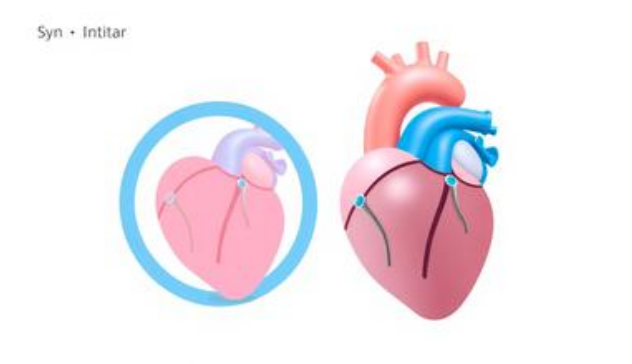
- Latest third-generation pump with fully magnetically levitated motor and active magnetic mounting.
- First implanted in humans in 2014.
- Motor incorporates contactless bearing technology (rotor, stator, sensors, microcontroller).
- Approx. one-third size of HeartMate I, implanted in pericardial space.
- Inflow cannula: Fully sintered, resides in LV

HeartMate 3 Benefits

HeartMate 3: Performance and Outcomes

1. Can deliver up to 10 L/min of flow.
2. Generates an 'artificial pulse' by periodically increasing/decreasing pump speed (mimics 30 bpm).
3. MOMENTUM 3 clinical trial: Compared HeartMate 3 (centrifugal) to HeartMate II (axial).
4. Results: HeartMate 3 showed lower rates of pump thrombosis, stroke, and reoperation at 2-year follow-up.

Total Artificial Hearts



Total Artificial Hearts (TAH)

- Composed of two pumping chambers that replace the entire heart.
- Provide both right and left ventricular function (analogous to heart transplantation).
- SynCardia Total Artificial Heart: Implanted in >1000 patients worldwide with biventricular heart disease.
- FDA approved in 2004, effective and reliable for bridge-to-transplant.

SynCardia TAH

SynCardia TAH: Indications and Complications

- Clinical indications: Biventricular failure, LV failure with prior mechanical heart valves, LV failure with severe anatomical damage, intractable malignant arrhythmias, massive ventricular thrombus, cardiac allograft failure, hypertrophic/restrictive cardiomyopathy, complex congenital heart disease.
- Device: Implantable, pneumatically driven pulsatile pair of polyurethane ventricles.
- Inflows anastomosed to left/right atria; outflows to ascending aorta/pulmonary artery after native ventricle/valve removal.
- Medtronic-Hall mechanical valves ensure unidirectional flow.
- Most common complications: Systemic infection, thromboembolic or hemorrhagic

VAD Complications

Major Complications of Cardiac Assist Devices

- Hemorrhage
- Thrombosis/Thromboembolism
- Infection
- Interactions with host tissue
- Device component failure (pump, electrical systems)

VAD Hemorrhage Risk

Hemorrhage in VAD Recipients

- Continues to be a problem, though risk decreasing with device/therapy/surgical improvements.
- Predisposing factors:
- - Anticoagulation therapy and its management.
- - Coagulopathy from liver dysfunction/poor nutrition.
- - Blood contact with device (intrinsic platelet dysfunction, acquired von Willebrand disease).
- - Extensive nature of required surgery.

VAD Thrombosis

Thrombosis and Thromboembolism in VADs

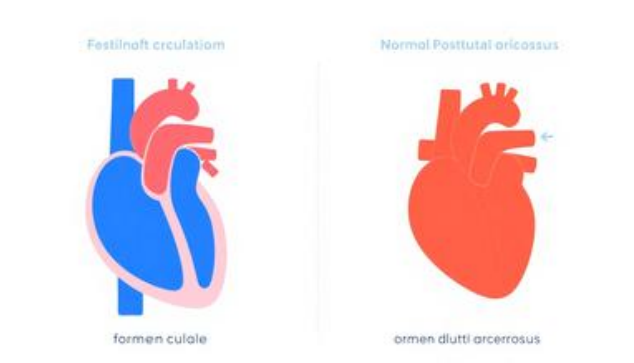
- Nonthrombogenic blood-contacting surfaces are essential.
- Occurred in most long-term Jarvik-7 artificial heart implants; major design consideration for current devices.
- Despite minimally thrombogenic surfaces and good blood flow, thrombi can form in disturbed flow areas (e.g., connections).
- Current continuous flow LVADs carefully designed to minimize thrombosis, but oral anticoagulation still required.
- Thrombi can detach and lead to catastrophic embolic events (e.g., ischemic stroke).

VAD Infection

Infection in Cardiac Assist Devices

- Significant morbidity and mortality after prolonged use.
- Can occur within device or associated with percutaneous drivelines.
- Susceptibility potentiated by: Usual prosthesis-associated factors, multi-system organ damage, postoperative hemorrhage, prolonged hospitalization (nosocomial infections).
- Often antibiotic-resistant; generally not an absolute contraindication to subsequent cardiac transplantation.
- Novel device designs (alternative driveline sites, transcutaneous energy transmission) aim to decrease infection.

Fetal Cardiac Shunts



Atrial Septal Defects and Other Intracardiac Defects

- Prenatal circulation differs: Fetal lungs not used for gas exchange, oxygenation via placenta.
- Requires two shunts:
- - Foramen ovale: Hole in fetal intraatrial septum, allows oxygenated blood from right to left atrium.
- - Ductus arteriosus: Between pulmonary artery and aorta, bypasses lungs.

Congenital Heart Defects

Failure of Shunt Closure and Septal Defects

Failure to close leads to: Patent foramen ovale (PFO) or patent ductus arteriosus (PDA), allowing inappropriate blood shunting.

Atrial septal defects (ASDs) or ventricular septal defects (VSDs): Result from abnormal formation of atrial/ventricular septum.

Closure options: Open surgical procedure (sutures, fabric patches for PFO/ASD/VSD, ligation for PDA) or minimally invasive

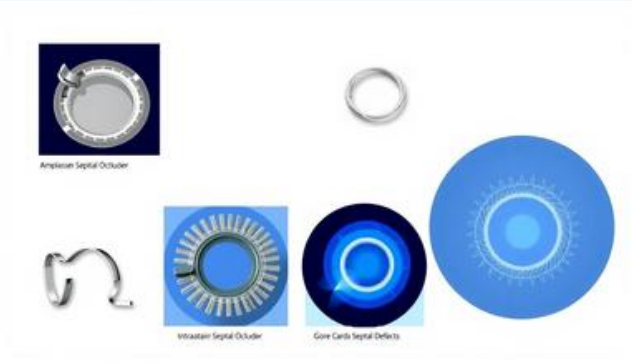
Decision to close and technique chosen depends on shunt size, patient symptoms, and defect anatomy.

Patent Ductus Arteriosus Closure

Transcatheter Closure Devices: PDA

- First catheter-based PDA closure in 1967 (Porstmann, Ivalon plug).
- Most PDA closure devices are metal-based, promote thrombosis, subsequent organization and fibrosis.
- Examples:
- - Gianturco coil (stainless-steel coil with polyester fibers).
- - Amplatzer Duct Occluder (ADO, conical device of Nitinol wires and polyester fiber).
- - Next-generation ADO II.

ASD/PFO Closure Devices



Transcatheter Closure Devices: ASD and PFO

- First transcatheter ASD closure in 1976 (Mills and King, double umbrella device).
- Early devices: Skeleton of ePTFE-coated wire supporting Dacron fabric occluder.
- Improvements: Better fixation, smaller introducers.
- Amplatzer device (St. Jude Medical): Self-centering, double Nitinol disks with polyester patches, connected by waist.

Benefits of Transcatheter Closure

Advantages of Nonsurgical Closure

1. Shorter hospital stay.
2. More rapid recovery.
3. No residual thoracotomy scar.
4. Interventional technology extended to some VSD closures, particularly for poor operative risk patients.

Closure Device Risks

Complications of Closure Devices

- Failure to fully close defect (residual shunting).
- Erosion of device through interatrial septum (perforation, device embolization) due to anatomy or device stiffness.
- Inadequate fixation or device-defect size mismatch (device embolization).
- Thromboemboli (if thrombosis extends beyond device).
- Fractures of device components, air embolism during deployment, infection, new arrhythmias.

Trends: Defect-specific design, minimization of foreign material, biodegradable components.

Understanding Atrial Fibrillation

Atrial Fibrillation (AF): The Most Common Arrhythmia

- Affects >3 million individuals in the US.
- Rapid, disorganized electrical activity in atria causes them to quiver/fibrillate (instead of orderly contraction).
- Results in poor contractile function and irregular flow within the chamber.
- Atrial appendage thrombi: Important source of thromboemboli due to flow abnormalities.
- Patients with AF are at 5x greater risk for

AF Anticoagulation

Anticoagulation for AF and its Drawbacks

- Anticoagulation (e.g., warfarin) is effective in reducing risk of atrial thrombosis and stroke.
- Drawbacks:
- - Narrow therapeutic window.
- - Variability in metabolism.
- - Interactions with other drugs/metabolites.
- - Need for frequent blood monitoring.
- - Poor patient compliance.
- - Risk of life-threatening bleeding.
- Newer non-vitamin K antagonist oral anticoagulants (NOACs) reduce some side

LAA Occlusion Strategy

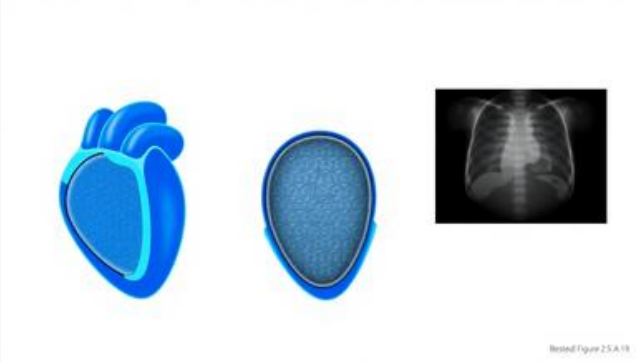
Left Atrial Appendage Occlusion: An Alternative

Approach to reduce risk of thromboembolic stroke in AF patients.

Involves removing or ligating the left atrial appendage (first proposed in 1930s).

Typically used when patient is undergoing concomitant cardiac surgical procedure (e.g., valve replacement, bypass surgery).

LAA Occlusion Devices



Percutaneous Left Atrial Appendage Occlusion Devices

- Nonsurgical device-based approaches developed to close the left atrial appendage.
- Deployed percutaneously to occlude opening, isolating it from blood in left atrium.
- Watchman device (Boston Scientific): FDA-approved, parachute-shaped Nitinol cage with PET membrane and fixation barbs.
- Watchman demonstrated noninferiority to warfarin for stroke prevention, superior for

LAA Occlusion Device Examples

Other LAA Occlusion Devices

1. Amplatzer Amulet (St. Jude Medical): Another percutaneously deployed LAA occlusion device, currently in clinical trials.

2. Arriclip Device System (Arricure): Applied on epicardial surface at base of LAA to close entrance by external compression. Consists of two parallel rigid titanium tubes with elastic Nitinol springs.