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*Review*

# Development of Mechanical Heart Valve Prostheses

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**Abstract**

Heart valve disease remains a significant global health burden, with an estimated 290 million people affected worldwide. Prosthetic heart valves have become essential therapeutic options, with mechanical valves offering superior durability compared to biological alternatives, though requiring lifelong anticoagulation. Since the inception of mechanical heart valves, these valves have evolved significantly—from early cage-ball designs to modern bileaflet configurations—addressing various hemodynamic and biocompatibility challenges. This review comprehensively examines the evolution, design principles, and clinical applications of mechanical heart valves. The developmental trajectory of mechanical heart valves demonstrates remarkable engineering innovation, progressing from the pioneering Starr–Edwards caged-ball valve to sophisticated bileaflet designs such as the St. Jude Medical and ON-X valves. Material science advancements, particularly pyrolytic carbon technology, have revolutionized valve durability and thromboresistance. Clinical outcomes data demonstrate excellent long-term durability exceeding 25 years, with principal complications relating to thromboembolism and anticoagulation-related bleeding. Current research focuses on novel designs incorporating computational fluid dynamics optimization and innovative materials such as superhydrophobic surfaces and nanomaterials. Therefore, optimizing the design of valve structures may provide greater assurance of mechanical durability. However, despite some progress, the ideal mechanical valve that balances perfect hemodynamics, thromboresistance without anticoagulation, and lifelong durability, remains elusive. Continued advancement will require multidisciplinary collaboration between engineers, materials scientists, clinicians, and regulatory bodies to address remaining challenges in mechanical heart valve technology.

**Keywords:** mechanical heart valves; prostheses; anticoagulation; design evolution

## 1. Introduction

Valvular heart disease (VHD) represents a significant global health burden with increasing prevalence in aging populations. Epidemiological data indicate that over 290 million individuals worldwide suffer from various forms of VHD, with rheumatic heart disease remaining predominant in developing regions while degenerative valvular pathologies are more common in industrialized nations [1]. The demographic shift toward an older population has contributed to a projected 71% increase in VHD cases by 2050, positioning this condition as an emerging healthcare priority [2].

The progressive nature of valve dysfunction frequently necessitates interventional approaches, with prosthetic heart valves serving as the cornerstone of definitive management for severe cases. Despite advances in valve repair techniques, replacement therapy remains essential for numerous patients with irreparable valvular damage or specific pathologies such as severe calcific stenosis. Contemporary estimates suggest that approximately 300,000 valve replacement procedures are performed annually worldwide, underscoring the substantial clinical demand for artificial heart valves [3].

The prosthetic valve landscape is dominated by two principal categories: mechanical and biological valves, each presenting distinct advantages and limitations. Mechanical prostheses, characterized by their remarkable durability and longevity, require lifelong anticoagulation therapy to mitigate thromboembolic complications. Conversely, bioprosthetic valves derived from xenograft tissues or human donors offer superior hemodynamic profiles and eliminate the need for long-term anticoagulation, though their structural deterioration over time often necessitates reintervention, particularly in younger patients. The selection between these options involves careful consideration of patient-specific factors including age, comorbidities, lifestyle preferences, and contraindications to anticoagulation [4].

This comprehensive review aims to examine the evolution, current status, and future directions in prosthetic heart valve technology. We explore recent innovations in valve design, materials science, and implantation techniques that have expanded therapeutic options while addressing historical limitations. Additionally, we evaluate emerging trends such as tissue-engineered valves, minimally invasive deployment systems, and personalized approaches to prosthesis selection. By synthesizing current evidence and identifying knowledge gaps, this review seeks to provide clinicians and researchers with a thorough understanding of artificial heart valves and their optimal application in contemporary cardiovascular medicine.

## 2. Historical Evolution of Mechanical Heart Valves

### *2.1 Pioneering Era (1950s–1980s)*

The genesis of mechanical heart valve replacement can be traced to the mid-20th century, marking a revolutionary advancement in cardiac surgery. In 1952, Charles Hufnagel implanted the first mechanical valve—a caged ball design—in the descending thoracic aorta of patients with aortic insufficiency [5]. This pivotal innovation, while positioned outside the heart, established the foundational concept for intracardiac prosthetic valves.

The Starr-Edwards valve, introduced in 1960 by Albert Starr and engineer Lowell Edwards, represented the first commercially successful mechanical prosthesis. This caged ball design featured a silicone elastomer ball that oscillated within a metal cage structure, establishing proof-of-concept for mechanical valve replacement. In this particular instance has remained fully operational for more than five decades, even when placed in the tricuspid position (which presents the most adverse conditions with respect to pressures, blood flow dynamics, and tendency to form blood clots) [6]. The 1970s witnessed a paradigm shift toward tilting disc valve designs that addressed many shortcomings of caged ball prostheses. The Björk-Shiley valve, developed by Viking Björk and Donald Shiley in 1969, pioneered this category with its single pyrolytic carbon disc suspended by a metal retaining mechanism. This configuration substantially improved hemodynamic efficiency and reduced the prosthetic profile compared to caged ball predecessors [7].

The Hall-Kaster valve (later rebranded as Medtronic-Hall) introduced significant innovations including a central perforation in the tilting disc to enhance flow characteristics and reduce stasis [8]. Concurrently, the Lillehei-Kaster valve implemented unique hinge mechanisms that minimized regurgitation volumes while improving durability [9].

### *2.2 Contemporary Advancements (1990s–Present)*

The introduction of bileaflet valve designs in the late 1970s and their refinement throughout subsequent decades revolutionized mechanical valve therapy. The St. Jude Medical valve, first implanted clinically in 1977, established the bileaflet configuration as the predominant mechanical valve architecture. This design featured two semicircular pyrolytic carbon leaflets operating within a housing ring, providing superior hemodynamic performance through central and lateral flow channels [10].

Subsequent iterations including the CarboMedics valve incorporated refined hinge mechanisms and optimized leaflet geometry to further mitigate thrombogenic potential. The ON-X valve introduced in the 1990s employed innovative manufacturing techniques producing pure pyrolytic carbon components with exceptional surface smoothness, potentially reducing anticoagulation requirements. The ATS Open Pivot valve developed proprietary hinge mechanisms designed to eliminate recessed areas and reduce blood stasis, addressing persistent concerns regarding thromboembolic complications.

## 3. Structural Design and Classification

### *3.1 Caged Ball Prostheses*

Caged ball valves operate on a fundamental principle of passive flow regulation—the silicone ball occludes the valve orifice during systole (for atrioventricular positions) or diastole (for semilunar positions) and displaces with pressure differentials to permit forward flow. A significant limitation of caged ball prostheses was their considerable dimensional profile. The elevated height of the cage structure constituted a substantial technical impediment during implantation procedures, particularly in the mitral position when patients presented with reduced left ventricular dimensions. Anatomical characteristics of the aortic root permitted greater accommodation of the caged ball's voluminous configuration in this location, although isolated incidents of coronary obstruction have been documented in clinical literature. It is important to emphasize that these reported complications predominantly involved cloth-covered caged ball valves, suggesting that the thrombotic sequelae were more attributable to epithelialization processes occurring on the supporting struts rather than fundamental inadequacies in the prosthetic valve design architecture.

The cloth-covered caged ball valve development represents a clear failure in prosthetic design history. The underlying concept was fundamentally incorrect. Covering metal struts with cloth material only worsened the already problematic thrombotic tendencies of these valves. This modification demonstrated poor understanding of how biomaterials interact with blood components and ultimately led to increased complications rather than improved outcomes.

### *3.2 Tilting Disc Valves*

Single-leaflet tilting disc valves represented a significant advancement in mechanical valve design, characterized by asymmetric flow patterns with approximately 70% of forward flow passing through the major orifice and 30% through the minor orifice. This configuration substantially reduced energy losses compared to caged ball designs while maintaining acceptable regurgitation characteristics. The tilting motion of the disc occurs through various pivoting mechanisms—either through peripheral struts (Björk-Shiley) or central guidance systems (Hall-Kaster).

Notable design variations included modifications to opening angle (ranging from 60° to 80°), disc composition (predominantly pyrolytic carbon with various additives), and retention mechanisms. The Omniscience and Monostrut valves incorporated refinements to address structural integrity concerns observed in earlier models. While largely supplanted by bileaflet designs in contem-

porary practice, tilting disc valves established important hemodynamic principles and material configurations that influenced subsequent mechanical valve development.

### *3.3 Bileaflet Prostheses*

Bileaflet mechanical valves represent the technological pinnacle of mechanical valve design, characterized by two semicircular leaflets pivoting around peripheral hinge mechanisms. This configuration creates three flow channels—a central orifice and two lateral passages—producing near-physiological flow patterns with minimal turbulence and pressure gradients. The symmetric opening (typically 75–90°) and balanced leaflet distribution optimize forward flow characteristics while maintaining controlled regurgitation during closure. Contemporary iterations exhibit remarkable design diversity despite conceptual similarities. The St. Jude Medical valve employs a butterfly-shaped hinge mechanism with recessed cavities, while the CarboMedics design features modified pivot guards to enhance leaflet stability. The ON-X valve's elongated orifice and flared inlet configuration reduce flow acceleration and associated shear stress. The ATS Open Pivot valve employs exposed pivot mechanisms designed to eliminate blood stasis in recessed areas, potentially reducing thromboembolic complications [11].

### *3.4 Innovative Design Concepts*

Recent advancements in computational fluid dynamics, materials science, and manufacturing techniques have enabled exploration of novel mechanical valve configurations beyond traditional categories. Trileaflet mechanical prostheses attempting to mimic native valve geometry have demonstrated promising preliminary results in experimental settings [12]. Composite material approaches incorporating both synthetic polymers and pyrolytic carbon components seek to optimize specific performance characteristics [13]. Pulsatile-flow optimized designs specifically engineered to accommodate ventricular assist device integration demonstrate the increasing specialization of mechanical valve technology. While these innovative approaches remain predominantly experimental, they illustrate the continuing evolution of mechanical valve design beyond conventional classifications.

## 4. Materials Science Applications in Mechanical Heart Valves

### *4.1 Early Materials and Associated Challenges*

The inaugural mechanical heart valves utilized materials selected primarily for manufacturing feasibility rather than biocompatibility or hemodynamic optimization. In the 1950s, stainless steel emerged as the predominant structural component due to its availability, machinability, and perceived corrosion resistance. The Hufnagel valve incorporated a methyl methacrylate ball within a stainless steel housing, while early Starr-Edwards models employed silicone elastomer (Silastic) balls contained within stellite-21 alloy cages.

Stainless steel components demonstrated inadequate corrosion resistance under prolonged exposure to blood, resulting in surface deterioration and particle release that triggered inflammatory responses and thrombosis. The steel-blood interface presented inherently thrombogenic characteristics due to irregular surface topography and inappropriate surface energy profiles. Concurrently, silicone elastomer components exhibited progressive structural degradation through processes including lipid absorption, calcification, and variance alteration—phenomena collectively termed "ball variance". These material limitations directly contributed to catastrophic mechanical failures and thromboembolic complications that characterized early valve replacement experiences.

Additionally, first-generation materials presented substantial manufacturing constraints that limited design optimization. Material-related complications included periprosthetic leakage from inadequate sewing ring integration, hemolysis from suboptimal surface characteristics, and immunological reactions to component degradation products—establishing direct connections between material properties and clinical outcomes.

### *4.2 Pyrolytic Carbon Technology Breakthrough*

The introduction of pyrolytic carbon in mechanical valve fabrication during the late 1960s represented a paradigm shift in biomedical materials science. This isotropic carbon allotrope, initially developed for nuclear reactor applications, provided unprecedented thromboresistance compared to previously employed materials. The St. Jude Medical valve (1977) pioneered the comprehensive utilization of pyrolytic carbon technology, establishing a new standard for mechanical valve performance.

Pyrolytic carbon's exceptional biocompatibility derives from several specific properties: Electron-accepting capacity (EAC) and electron-donating capacity (EDC) [14] that may minimize protein adhesion, ultra-smooth surface topography and appropriate surface energy characteristics that reduce thrombogenic interactions [15]. The manufacturing process involved chemical vapor deposition of hydrocarbon gas onto graphite substrates at temperatures exceeding 1200 °C, producing a turbostratic microstructure with unique mechanical properties.

Significant technological advances emerged through the development of substrate-reinforced composites combining pyrolytic carbon with underlying materials including graphite and tungsten. CarboMedics introduced silicon-alloyed pyrolytic carbon (SiC) that enhanced material strength while maintaining excellent blood compatibility. This compositional modification increased fracture toughness from approximately 1.1 MPa·m$^{1/2}$ to 1.5 MPa·m$^{1/2}$,

substantially improving resistance to mechanical failure while maintaining a density comparable to blood (eliminating buoyancy effects).

The evolution of pyrolytic carbon technology directly enabled the transition from caged ball designs to lower-profile tilting disc and bileaflet configurations. The material's exceptional wear resistance, with volumetric wear rates below $10^{-9}$ $mm^3$/cycle, facilitated development of sophisticated hinge mechanisms with microscopic tolerances that maintain functionality through billions of cycles. This unprecedented durability established pyrolytic carbon as the cornerstone of mechanical valve technology for over four decades.

### *4.3 Contemporary Valve Materials*

Modern mechanical valves incorporate sophisticated material combinations optimized through progressive refinement of manufacturing techniques and surface engineering. Advanced pyrolytic carbon processing has yielded improvements in structural homogeneity, reducing variance in mechanical properties and enhancing reliability. The ON-X valve employs pure pyrolytic carbon without silicon alloying, achieving exceptional surface smoothness (roughness average $<$20 nm) through proprietary manufacturing processes that eliminate substrate interfaces and associated imperfections.

Housing components now frequently utilize titanium alloys (predominantly Ti-6Al-4V) that offer superior strength-to-weight ratios, exceptional corrosion resistance, and enhanced magnetic resonance imaging compatibility compared to traditional metal alloys. These titanium structures incorporate specialized surface treatments including nitriding and oxidation processes that improve wear resistance at mechanical interfaces while maintaining biocompatibility [16].

Sewing ring technologies have evolved substantially from early Teflon constructs to integrated polyethylene terephthalate (PET) velour structures with optimized porosity profiles that promote controlled tissue ingrowth. Some contemporary designs incorporate composite sewing rings with polytetrafluoroethylene (PTFE) barriers that prevent excessive tissue proliferation while maintaining structural integrity. These materials demonstrate appropriate compliance characteristics that minimize periprosthetic leakage while facilitating surgical implantation [17].

Innovative coating technologies have emerged as complementary approaches to base material optimization. Diamond-like carbon coatings applied through plasma-enhanced chemical vapor deposition provide exceptional hardness ($>$10 GPa) and wear resistance while maintaining hemocompatibility. Phosphorylcholine-based coatings mimicking erythrocyte membrane surfaces have demonstrated promising results in reducing protein and platelet adhesion in experimental settings. These surface modifications represent intermediate solutions between traditional mechanical valves and biologically-derived alternatives [18].

### *4.4 Surface Modification and Thromboresistance*

Surface engineering represents the frontier of mechanical valve material science, focusing on microscopic interface characteristics that determine biological responses. Contemporary approaches employ precise topographical modification at nanometer scales to create ordered surface patterns that disrupt platelet adhesion processes. Surface modification at the nanoscale using techniques like laser ablation, ion implantation, and plasma etching produces interfaces that effectively inhibit platelet activation [19].

Surface charge modulation through techniques including plasma treatment, grafting of charged functional groups, and application of zwitterionic polymers alters electrostatic interactions between blood components and valve surfaces. These modifications disrupt the Vroman effect cascade that initiates protein adsorption and subsequent platelet recruitment. Electrical conductivity characteristics of pyrolytic carbon surfaces can be precisely modified through controlled introduction of dopants, for instance, a study demonstrated that variations in pyrolysis precursors lead to different nitrogen and oxygen content in the resulting products, consequently affecting their electrical conductivity [20].

Bioactive surface modifications represent a particularly promising direction, with approaches including immobilization of anticoagulant molecules directly on valve surfaces. A study shows that Channeled pyrolytic carbon surfaces covered with confluent endothelial cells exhibited a 1000-fold reduction in human platelet adhesion compared to unmodified pyrolytic carbon [21]. Heparin binding technologies utilizing ionic interactions, covalent linkage, or sandwich-technique immobilization have progressed from experimental concepts to clinical applications. These functional coatings provide localized anticoagulation at the blood-material interface while avoiding systemic effects. A study demonstrated that the Nitric Oxide-releasing coating group exhibited superior anticoagulant properties compared to the control group [22]. Alternative bioactive approaches include nitric oxide-releasing coatings that mimic endothelial function and albumin-specific binding sites that promote formation of non-thrombogenic protein layers [23].

Computational modeling has revolutionized understanding of surface-blood interactions, enabling prediction of thrombogenic potential based on specific material properties [24]. Multiscale simulations incorporating quantum mechanical analysis of electron distributions, molecular dynamics of protein conformational changes, and computational fluid dynamics of shear-induced activation provide unprecedented insights into material-biology interactions. These modeling approaches facilitate rational design of next-generation surfaces with optimized characteristics across multiple parameters, potentially reducing anticoag-

ulation requirements that remain the primary limitation of mechanical valve therapy.

The evolution of materials science in mechanical heart valves illustrates the progressive refinement of interdisciplinary biomedical engineering, transitioning from opportunistic material selection to precision-engineered surfaces with specific biological performance objectives. While pyrolytic carbon remains the predominant structural material in contemporary designs, ongoing advances in surface engineering continue to address the fundamental challenge of mechanical valve therapy—achieving durable hemodynamic performance without thrombogenicity or structural deterioration.

## 5. Hemodynamic Performance of Mechanical Heart Valves

### *5.1 Hemodynamic Evaluation Parameters*

The assessment of mechanical heart valve performance relies on several critical hemodynamic parameters. The valve orifice area and transvalvular pressure gradient serve as fundamental indicators of valve function, with larger orifice areas and lower gradients generally indicating superior hemodynamic efficiency. The pressure gradient across a valve correlates inversely with the orifice area and directly with flow rate, following the modified Bernoulli equation.

Effective Orifice Area (EOA), a more sophisticated parameter than geometric orifice area, accounts for flow contraction phenomena and provides a functional measure of the valve's performance. EOA is calculated using the continuity equation and expressed in $cm^2$, with higher values indicating better hemodynamic efficiency. This parameter is particularly valuable when comparing different valve designs or sizes.

The Energy Loss Index represents an evolution in hemodynamic assessment by quantifying the energy dissipated during blood flow through prosthetic valves. This index incorporates both pressure gradients and flow acceleration/deceleration effects, offering a comprehensive measure of valvular performance that correlates well with clinical outcomes and patient quality of life.

### *5.2 Hemodynamic Comparison Across Valve Generations*

#### 5.2.1 Evolution From Caged Ball to Modern Designs

The earliest caged ball valve designs, while revolutionary, exhibited significant hemodynamic limitations. Their central occluding ball created substantial flow obstruction, generating high pressure gradients and abnormal flow patterns. Blood flow around the ball produced regions of stasis and high-velocity jets, contributing to increased thrombogenicity and suboptimal hemodynamics despite their durability.

Single-leaflet and bileaflet designs emerged to address these limitations. Single-leaflet valves improved flow characteristics by reducing central obstruction but introduced asymmetric flow patterns that remained suboptimal. All developments possess dual aspects, and new technologies or innovations inherently come with both advantages and disadvantages. Therefore, informed decision-making requires a comprehensive evaluation of the relative weights of their benefits and drawbacks.

#### 5.2.2 Flow Dynamics in Contemporary Bileaflet Valves

Despite incorporating advances from earlier designs—low-profile construction, pyrolytic carbon, and large orifice areas—bileaflet mechanical heart valves (BMHVs) fail to achieve physiological flow. Their characteristic triple-jet flow pattern disrupts laminar blood flow, creating high shear stress, flow separation, and recirculation zones absent in native valves. These non-physiological flow characteristics persist throughout the cardiac cycle, promoting platelet activation and thrombogenicity. Even with refined leaflet geometry and pivot mechanisms, BMHVs generate persistent flow disturbances and cavitation, explaining why they remain hemodynamically inferior to native valves despite clinical durability [25].

### *5.3 Flow Turbulence and Hemolysis Considerations*

#### 5.3.1 Shear-Induced Blood Trauma

Mechanical valve-induced blood trauma remains a significant clinical concern, primarily attributed to abnormal shear stresses generated by turbulent flow patterns. These non-physiological flow conditions can damage blood components, particularly erythrocytes and platelets. High-velocity flow through narrow valve orifices, leakage jets during closure, and vortex formation in sinus regions all contribute to elevated shear stresses [26]. Research has identified critical threshold values for shear stress magnitude and exposure time that correlate with blood element damage. Erythrocytes typically experience hemolysis when exposed to shear stresses exceeding 1500 Pa for even brief periods [27]. The highest shear stresses generally occur during the closing phase, particularly in the regurgitant jets through the small gaps between leaflets and housing.

#### 5.3.2 Design Improvements for Hemolysis Reduction

Significant design refinements have focused on minimizing hemolysis potential while maintaining optimal hemodynamic performance. These include streamlined leaflet profiles to reduce flow separation [28], optimized hinge mechanisms to minimize regurgitant jet velocities, and improved surface finishing techniques to reduce boundary layer disruption.

Contemporary valve designs incorporate computational hemodynamic modeling during development to predict and mitigate regions of excessive shear stress. Nevertheless, the inherent compromise between ensuring complete valve closure and minimizing regurgitant flow con-

tinues to present design challenges in balancing thrombotic and hemolytic risks.

## 6. Clinical Applications of Mechanical Heart Valves

### *6.1 Age-Related Considerations*

The decision to implant mechanical heart valves is significantly influenced by patient age. Younger patients (typically <65 years) with longer life expectancies generally benefit more from mechanical prostheses due to their superior durability and lower reoperation rates compared to biological alternatives. This advantage must be balanced against the lifelong anticoagulation requirement with its associated morbidity. Contemporary guidelines from major cardiac societies recommend mechanical valves for patients under 50–70 years without contraindications to anticoagulation, while suggesting individualized decision-making for those between 60–70 years based on patient-specific factors and preferences [29].

### *6.2 Anatomical Position-Specific Selection*

Valve selection varies considerably depending on implantation position. Mechanical prostheses remain the predominant choice for mitral valve replacement due to the higher hemodynamic stress and accelerated structural deterioration of bioprosthetic valves in this position [30]. In contrast, aortic position selection demonstrates greater variability based on patient characteristics. The hemodynamic profile of mechanical valves becomes particularly advantageous in patients with small aortic annuli where the superior effective orifice area can prevent patient-prosthesis mismatch. For tricuspid position replacements, mechanical valves are rarely utilized due to the heightened thrombogenicity in this low-flow, low-pressure environment.

### *6.3 Special Patient Populations*

Several patient subgroups require unique considerations when evaluating mechanical valve candidacy. Women of childbearing potential face increased maternal and fetal risks associated with anticoagulation during pregnancy, often leading clinicians to favor bioprostheses despite the likelihood of future reoperation. Patients with hypercoagulable states may experience higher thromboembolic complications despite adequate anticoagulation, potentially favoring alternative approaches [31]. Conversely, those with limited healthcare access for monitoring bioprosthetic deterioration may derive greater benefit from the durability of mechanical valves. Patients with end-stage renal disease present a particular challenge, as they exhibit both accelerated calcification of bioprostheses and increased bleeding risks with anticoagulation, necessitating highly individualized decision-making.

### *6.4 Current Clinical Treatment Recommendations*

The ON-X, St. Jude, and CarboMedics mechanical heart valves each present distinct characteristics in clinical practice. The ON-X valve demonstrates superior hemodynamics with lower transvalvular gradients and reduced thrombogenicity due to its pure pyrolytic carbon construction, potentially allowing lower INR targets (1.5–2.0) in selected patients. St. Jude valves, with extensive long-term data spanning over four decades, show excellent durability and consistent performance, though require standard anticoagulation (INR 2.0–3.0). CarboMedics valves feature a unique carbon coating that enhances biocompatibility and demonstrates good hemodynamic profiles, particularly in smaller sizes. All three valves share the inherent mechanical valve advantages of longevity and structural stability, but carry lifelong anticoagulation requirements and thromboembolic risks. The ON-X shows promise in reducing anticoagulation-related complications, while St. Jude offers the most robust evidence base. CarboMedics provides reliable performance with competitive hemodynamics. Selection ultimately depends on patient-specific factors including age, anticoagulation tolerance, and anatomical considerations.

## 7. Long-Term Clinical Outcomes and Complications of Mechanical Heart Valves

### *7.1 Valve Durability Data*

#### 7.1.1 Long-Term Follow-up Studies

Mechanical heart valves demonstrate exceptional structural durability, with contemporary designs exhibiting freedom from structural valve deterioration exceeding 95% at 20–25 years. Landmark studies following first-generation mechanical valves have documented functional survival beyond 40 years in select patients. One study demonstrates that among patients aged 60 years and younger, mechanical aortic valve replacement (AVR) is associated with a significant risk-adjusted survival advantage compared to bioprosthetic AVR. This survival benefit was consistently observed across all age subgroups $\leq$60 years and remained robust in multiple sensitivity analyses. These contemporary findings, derived from a large cohort over a 12-year period, provide important evidence to support shared decision-making between patients and clinicians when selecting the most appropriate prosthetic valve type in younger individuals [32].

The very long-term performance (>30 years) remains less comprehensively documented due to competing mortality and challenges in extended follow-up. Recent meta-analyses incorporating data from multiple valve registries suggest that actual lifetime freedom from reoperation due to structural valve degeneration approaches 98%, significantly outperforming even the most durable bioprosthetic alternatives [33]. This remarkable structural integrity appears consistent across properly implanted mechanical valves regardless of position, though mitral replacements

demonstrate slightly higher non-structural dysfunction rates over extended periods.

#### 7.1.2 Comparative Durability Between Designs

Comparative analyses between different mechanical valve designs reveal subtle differences in long-term performance profiles. Bileaflet valves demonstrate marginally superior freedom from structural failure compared to tilting-disc designs in most comparative studies, though this difference rarely reaches statistical significance in adjusted analyses [34]. Modern pyrolytic carbon manufacturing processes have largely eliminated the material fatigue concerns that affected earlier generation prostheses.

Design-specific failure modes have been identified through forensic analysis of explanted valves. Tilting-disc valves occasionally exhibit disc escape or strut fracture, while bileaflet designs more commonly demonstrate leaflet thrombosis or rare instances of leaflet escape [35]. Manufacturer-specific variations in pivot mechanism design influence the likelihood of pivot wear, though this rarely results in catastrophic failure. Overall, despite theoretical differences in stress distribution and wear patterns, contemporary mechanical valves from major manufacturers demonstrate comparable exceptional durability that substantially exceeds patient life expectancy in most demographics.

### *7.2 Thromboembolic Complications*

#### 7.2.1 Incidence and Risk Factors

Thromboembolism remains the most significant complication affecting mechanical heart valve recipients despite optimal management. Contemporary data indicate linearized rates of 0.6% per patient-year for thromboembolic events with properly anticoagulated modern mechanical valves [36]. Position-specific differences are notable, with mitral replacements carrying approximately 1.5-fold higher risk than aortic prostheses. This position-dependent risk reflects the different hemodynamic profiles and flow characteristics of the respective positions.

Multiple patient-specific risk factors significantly influence thromboembolic risk. Advanced age, atrial fibrillation, left ventricular dysfunction, prior thromboembolism, and hypercoagulable states all independently increase event rates. Subtherapeutic anticoagulation represents the most modifiable risk factor, with studies demonstrating exponential risk increases when INR values fall below recommended therapeutic ranges. Prosthesis-specific factors including larger valve size, earlier generation designs, and suboptimal implantation technique can further compound thromboembolic risk through altered flow dynamics and increased areas of stasis.

#### 7.2.2 Evolution of Prevention Strategies

Thromboembolic prevention strategies have evolved substantially over recent decades. Anticoagulation intensity has been refined through large-scale trials, with current guidelines recommending target INR ranges of 2.0–3.0 for isolated aortic mechanical valves and 2.5–3.5 for mitral or multiple mechanical valves or those with additional risk factors. The addition of low-dose aspirin (75–100 mg daily) to warfarin therapy reduces thromboembolic events by approximately 60–70% compared to warfarin alone, albeit at the cost of increased minor bleeding [37].

Novel monitoring approaches have improved anticoagulation stability. Patient self-testing and self-management programs demonstrate superior time in therapeutic range compared to conventional monitoring systems, translating to reduced thromboembolic events. Unfortunately, direct oral anticoagulants remain contraindicated for mechanical valves following the premature termination of the RE-ALIGN trial due to excess thrombotic events. Emerging technologies including modified surface treatments with improved hemocompatibility and novel biomaterials that reduce thrombogenicity remain under investigation as potential approaches to reduce thromboembolic risk while minimizing anticoagulation requirements.

### *7.3 Anticoagulation-Related Bleeding Risks*

#### 7.3.1 Risk Stratification and Individualized Management

Anticoagulation-related hemorrhage represents the principal trade-off for mechanical valve thromboembolism protection. Contemporary data indicate linearized major bleeding rates of 1.0% per patient-year with standard anticoagulation regimens [36]. Patient-specific bleeding risk assessment has become increasingly sophisticated, with validated scoring systems such as HAS-BLED allowing for improved risk stratification. High-risk features include advanced age (>75 years), prior bleeding events, concomitant antiplatelet therapy, uncontrolled hypertension, renal or hepatic dysfunction, and alcohol abuse [38].

Individualized anticoagulation management based on comprehensive risk assessment has demonstrated superior outcomes compared to standardized approaches. Lower target INR ranges (2.0–2.5) may be appropriate for modern aortic mechanical valves in patients with elevated bleeding risk and no additional thrombotic risk factors. Conversely, patients with recurrent thromboembolism despite therapeutic anticoagulation may benefit from higher intensity regimens or additional antiplatelet therapy. Temporary anticoagulation interruption protocols for invasive procedures have been refined to minimize both bleeding and thrombotic risks during these vulnerable periods.

#### 7.3.2 Advances in Anticoagulation Monitoring

Technological advancements have substantially improved anticoagulation management precision. Point-of-care testing devices enable rapid INR assessment with accuracy comparable to laboratory methods. Patient self-testing programs demonstrate superior time in therapeutic range (typically 70–80% versus 50–60% with conventional mon-

itoring), translating to reduced bleeding and thromboembolic complications. Computer-assisted dosing algorithms provide more precise warfarin dose adjustments than empiric approaches, particularly during initiation phases [39].

Emerging technologies may further transform anticoagulation monitoring. Implantable sensors capable of continuous coagulation status monitoring remain under development. Pharmacogenetic testing to identify warfarin metabolism variants (particularly CYP2C9 [40] and VKORC1 [41]) allows for more precise initial dosing, though its cost-effectiveness in routine practice remains debated. Despite these advances, the fundamental challenge of balancing thrombotic and hemorrhagic risks persists, highlighting the need for continued innovation in mechanical valve design and antithrombotic strategies.

### *7.4 Valve-Related Infections*

#### 7.4.1 Prosthetic Valve Endocarditis Incidence and Management

Prosthetic valve endocarditis (PVE) represents one of the most devastating complications of heart valves, with substantial morbidity and mortality. Contemporary data indicate an incidence of 1.5–1.7% per patient-year, with higher rates during the first-year post-implantation followed by a lower but persistent linearized risk thereafter. Mechanical valves demonstrate similar PVE susceptibility to bioprosthetic valves beyond the initial implantation period, though infection patterns differ [42]. Staphylococcal species predominate in early PVE (<12 months), while later infections demonstrate more diverse microbiology including streptococcal species and enterococci [43].

Management of mechanical valve endocarditis remains challenging, requiring a multidisciplinary approach. Prolonged antimicrobial therapy (typically 6 weeks) represents the cornerstone of treatment, with empiric regimens covering staphylococcal species until culture results guide targeted therapy. Surgical intervention becomes necessary in 30–60% of cases, particularly with evidence of valve dysfunction, perivalvular extension, large vegetations, or persistent infection despite appropriate antibiotics. Reoperative mortality for PVE ranges from 40–80%, substantially exceeding risk for primary valve replacement. Early involvement of specialized endocarditis teams has demonstrated improved outcomes through optimized timing of interventions and tailored antimicrobial strategies [44].

#### 7.4.2 Effectiveness Evaluation of Preventive Measures

Preventive strategies for PVE have evolved significantly, though evidence supporting specific measures varies in quality. Perioperative antimicrobial prophylaxis has demonstrated unequivocal benefit, with extended regimens showing no advantage over standard short-course protocols. The efficacy of antimicrobial prophylaxis for dental and other invasive procedures remains more controversial, with current guidelines recommending a more selective approach based on procedure-specific risks and patient factors rather than universal prophylaxis [45].

Implementation of comprehensive infection prevention bundles in cardiac surgical units correlates with reduced surgical site infections and subsequent PVE rates. These bundles typically include chlorhexidine bathing, nasal decolonization for Staphylococcus aureus carriers, optimized hair removal protocols, and standardized antimicrobial prophylaxis. Adherence to proper aseptic technique during central venous catheter maintenance reduces hematogenous seeding of prosthetic valves. Patient education regarding dental hygiene and prompt treatment of infections at other sites may further reduce late PVE risk, though prospective studies quantifying these benefits remain limited.

### *7.5 Other Complications*

#### 7.5.1 Paravalvular Leak

Paravalvular leak (PVL) occurs in 5–17% of mechanical valve recipients, though clinically significant leaks affect only 2.2% [46]. Most PVLs develop from technical factors during implantation, including suture dehiscence, annular calcification preventing adequate seating, or tissue friability. Mitral mechanical valves demonstrate higher PVL rates than aortic positions, particularly in rheumatic pathology with extensive annular calcification. Minor, stable PVLs may remain clinically insignificant for decades, while larger leaks can cause hemolysis, heart failure, or provide a nidus for endocarditis. Management depends on severity and symptoms, with mild asymptomatic leaks typically managed conservatively. Significant hemodynamic compromise or refractory hemolysis necessitates intervention, traditionally through surgical reoperation with reported mortality of 6–14%. Percutaneous closure techniques have emerged as alternatives in selected patients, particularly those with prohibitive surgical risk, though technical success rates remain lower than with surgical approaches for mechanical valve PVLs.

#### 7.5.2 Structural Failure

Despite exceptional durability, rare catastrophic structural failures can occur with mechanical prostheses. Leaflet escape represents the most dramatic form. Historical clusters of leaflet fractures with specific valve models (notably some Björk-Shiley Convexo-Concave and Edwards-Duromedics designs) led to their withdrawal from market, though no similar systematic issues affect contemporary prostheses. Modern pyrolytic carbon manufacturing processes have virtually eliminated material fatigue concerns. When structural failures do occur with contemporary valves, they typically result from manufacturing defects, improper handling during implantation, or intrinsic design limitations stressed beyond normal operating parameters. Forensic analysis of explanted failed valves has fa-

cilitated iterative design improvements, contributing to the exceptional durability of current generation prostheses [47].

#### 7.5.3 Non-Structural Dysfunction

Non-structural valve dysfunction encompasses complications affecting mechanical valve function without intrinsic prosthetic damage. Pannus formation—the ingrowth of fibrous tissue onto valve components—represents the most common mechanism, affecting up to 10% of mechanical valves by 10 years, with higher rates in mitral position. Pannus typically develops slowly, allowing for compensatory mechanisms, though it may eventually cause stenosis or restricted leaflet mobility.

Valve thrombosis, though often categorized separately, represents another form of non-structural dysfunction affecting 0.1–5.7% of patients annually despite anticoagulation. Risk varies significantly with valve position, adequacy of anticoagulation, and patient-specific factors. Management options include intensified anticoagulation, thrombolytic therapy, or surgical intervention depending on thrombus characteristics, hemodynamic impact, and patient stability.

Patient-prosthesis mismatch represents a functional complication resulting from implantation of a prosthesis too small for the patient's body size and cardiac output requirements. Though more common with bioprosthetic valves, significant mismatch can occur with mechanical valves in patients with small annuli. This mismatch creates functional stenosis despite a normally functioning valve, resulting in persistent symptoms, limited exercise capacity, and impaired ventricular remodeling.

## 8. Evolution of Anticoagulation Strategies in Prosthetic Valve Patients

### *8.1 Historical Perspective and Current Developments*

The management of thrombotic risk in patients with prosthetic heart valves has undergone significant evolution over the past several decades. This progression reflects our deepening understanding of coagulation pathways, technological advancements in both valve design and monitoring capabilities, and the emergence of novel pharmacological agents.

### *8.2 Traditional Warfarin Anticoagulation*

Vitamin K antagonists, primarily warfarin, have constituted the cornerstone of anticoagulation therapy for mechanical valve recipients since the 1960s. The efficacy of warfarin depends critically on maintaining the International Normalized Ratio (INR) within a therapeutic window. For patients with mechanical aortic valve replacements, guidelines typically recommend an INR target of 2.0–3.0, while those with mechanical mitral valves or additional risk factors require more intensive anticoagulation with an INR target of 2.5–3.5. This distinction acknowledges the differential thrombotic risk associated with various valve positions, with the mitral position carrying substantially higher risk due to lower flow velocities and greater stasis.

Despite its established efficacy, warfarin therapy presents significant challenges including narrow therapeutic window, numerous food and drug interactions, and substantial inter-individual variability in dose requirements. These limitations necessitate frequent monitoring and dose adjustments, imposing considerable burden on both patients and healthcare systems.

### *8.3 Novel Oral Anticoagulants: Promise and Limitations*

Recent years have witnessed growing interest in applying direct-acting oral anticoagulants (DOACs) to prosthetic valve patients. Direct thrombin inhibitors, such as dabigatran, initially generated optimism; however, the premature termination of the RE-ALIGN trial due to excess thrombotic events highlighted the inadequacy of this approach for mechanical valves.

Factor Xa inhibitors (rivaroxaban, apixaban, edoxaban) represent another class of DOACs under investigation. While these agents offer advantages including predictable pharmacokinetics, fewer interactions, and elimination of routine monitoring requirements, their application in mechanical valve recipients remains experimental. Early pre-clinical and phase II studies suggest potential viability, particularly in lower-risk subgroups, but definitive evidence from large-scale trials is still pending. The search continues for the optimal anticoagulation strategy that balances thrombotic protection with bleeding risk [48].

### *8.4 Individualized Anticoagulation Management*

The paradigm is shifting from standardized approaches toward personalized anticoagulation strategies. Pharmacogenetic testing has emerged as a valuable tool for optimizing warfarin therapy, with variants in genes encoding CYP2C9 and VKORC1 explaining approximately 40% of the variability in warfarin dose requirements [49]. Implementation of genotype-guided dosing algorithms has demonstrated improved time in therapeutic range and reduced adverse events, though widespread adoption faces practical and economic barriers.

Special populations pose unique anticoagulation challenges. Pregnant women with mechanical valves face substantially increased thrombotic risk while confronting the teratogenic potential of warfarin. Elderly patients exhibit enhanced sensitivity to warfarin and increased bleeding risk, necessitating careful dose titration and more frequent monitoring. Patients with comorbid renal impairment require dose adjustments and careful selection of anticoagulant agents based on elimination pathways.

### *8.5 Technological Advances in Monitoring*

The evolution of point-of-care (POC) testing devices has transformed anticoagulation management. Modern portable INR monitors enable patient self-testing and self-

management, approaches associated with improved time in therapeutic range and reduced thromboembolic complications. These devices have demonstrated accuracy comparable to laboratory methods while significantly enhancing convenience and testing frequency.

Remote monitoring technologies represent the frontier of anticoagulation management. Telemonitoring systems enable real-time data transmission to healthcare providers, facilitating prompt interventions for out-of-range values. Integration with smartphone applications and electronic health records creates comprehensive management platforms that incorporate medication adherence tracking, drug interaction alerts, and algorithm-based dosing recommendations [50].

The evolution of anticoagulation strategies continues to be driven by the fundamental goal of optimizing the delicate balance between thromboembolic protection and hemorrhagic risk. Future directions likely include refinement of personalized approaches, further investigation of novel agents for specific patient subgroups, and integration of advanced monitoring technologies into comprehensive care models.

## 9. Current Research Hotspots and Innovative Directions in Prosthetic Valve Development

### *9.1 Emerging Trends in Valve Design and Materials*

Emerging frontiers include biohybrid systems integrating living cells and AI-driven optimization of valve geometry for patient-specific hemodynamics. Advanced computational fluid dynamics (CFD) has revolutionized our understanding of blood flow patterns through mechanical valves. Researchers are now leveraging these insights to develop novel valve geometries that minimize regions of stasis, reduce shear stress, and optimize washout characteristics. High-resolution CFD models simulate the complex interactions between blood components and valve surfaces across varying cardiac output states, identifying critical design parameters that influence thrombogenic potential [51].

Computer-assisted design technologies have facilitated rapid prototyping and iteration of valve geometries. Three-dimensional modeling coupled with finite element analysis enables prediction of mechanical performance under physiological conditions, substantially reducing development timelines. These computational approaches permit systematic optimization of critical parameters including leaflet curvature, hinge mechanisms, and opening angles to minimize flow separation and turbulence formation [52].

### *9.2 Novel Materials Exploration*

The incorporation of superhydrophobic materials represents a promising avenue for reducing surface-induced thrombogenicity. By creating microscale and nanoscale surface topographies that trap air pockets between the blood and valve surface, these materials significantly reduce protein adsorption and platelet adhesion. Initial *in vitro* studies demonstrate substantial reductions in thrombus formation on superhydrophobic surfaces compared to conventional pyrolytic carbon, though long-term stability of these properties remains under investigation [53].

### *9.3 Biomimetic Design Approaches*

The emulation of natural valve architectures has emerged as a guiding principle in mechanical valve development. Contemporary designs increasingly incorporate asymmetric leaflet geometries and sinusoidal opening patterns that more closely resemble native valves. This biomimetic approach extends to microscale features, with surface texturing that mimics the endothelial layer's blood flow interaction characteristics. Computational models of native valve dynamics inform these designs, enabling precise replication of physiological flow patterns [54].

Biomechanical considerations have gained prominence in valve design evaluation. Beyond traditional metrics of durability and hemodynamic performance, modern assessment increasingly incorporates analysis of energy loss, effective orifice area throughout the cardiac cycle, and localized stress distributions. These parameters more comprehensively characterize valve function in relation to cardiac workload and tissue interaction, allowing for more physiologically relevant design optimization [55].

### *9.4 Strategies to Reduce Anticoagulation Requirements*

Surface modification technologies represent perhaps the most active area of mechanical valve research. Phosphorylcholine coating, which mimics cell membrane phospholipids, has demonstrated significant reductions in protein adsorption and platelet activation [56]. Heparin bonding technologies have evolved from simple ionic attraction to stable covalent attachment methods that maintain bioactivity for extended periods [57]. Polymer brush coatings create highly hydrated surface layers that physically prevent protein-surface interactions while maintaining structural integrity under high-shear conditions [58].

Biocompatibility enhancement approaches increasingly incorporate active biological mechanisms. Endothelialization promotion strategies employ peptide sequences derived from extracellular matrix proteins to encourage selective adhesion of endothelial cells while resisting platelet attachment [59,60]. Nitric oxide-releasing surfaces actively suppress platelet activation through localized release of this endogenous antithrombotic molecule [61]. Recent investigations have explored immunomodulatory coatings that selectively attenuate inflammatory responses associated with the coagulation cascade without compromising other immune functions [62].

The convergence of these innovative approaches—computational design optimization, advanced materials science, biomimetic principles, and sophisticated surface modifications—holds unprecedented promise for developing next-generation mechanical valves that may signifi-

cantly reduce or potentially eliminate anticoagulation requirements. While translational challenges remain, particularly regarding long-term durability and real-world performance of these innovations, the trajectory clearly points toward mechanical valves with substantially improved hemocompatibility profiles.

## 10. Future Development Prospects and Challenges

*10.1 Design Goals for Ideal Mechanical Valves*

The pursuit of an ideal mechanical heart valve remains a central focus in cardiovascular engineering. Future designs aim to address current limitations through novel materials with superior hemodynamic profiles and reduced thrombogenicity. The ideal mechanical valve would eliminate the need for lifelong anticoagulation therapy while maintaining durability beyond 30 years. Surface modifications utilizing advanced nanotechnology and biomimetic approaches present promising avenues for creating more hemocompatible interfaces. Additionally, patient-specific customization through computational modeling and 3D printing technologies may optimize valve geometries to individual anatomical variations, potentially improving outcomes across diverse patient populations.

*10.2 Multidisciplinary Research Directions*

Advancement in mechanical valve technology necessitates integration across multiple disciplines. Collaborative efforts between materials science, fluid dynamics, bioengineering, and clinical cardiology are essential for breakthrough innovations. Emerging research at the intersection of these fields includes smart materials capable of responding to physiological changes, self-healing components that extend longevity, and bioactive surfaces that promote endothelialization while preventing thrombosis. Machine learning algorithms analyzing vast datasets from implanted valves could identify subtle performance patterns, contributing to iterative design improvements and personalized management strategies that optimize outcomes while minimizing complications.

*10.3 Design and Challenges of Clinical Trials*

The evaluation of next-generation mechanical valves faces substantial methodological challenges. Traditional clinical trial designs requiring years of follow-up may delay important innovations reaching patients. Adaptive trial methodologies incorporating surrogate endpoints validated through computational modeling could accelerate evaluation while maintaining rigorous safety standards. Patient selection criteria must evolve to reflect changing demographics and comorbidity profiles. Furthermore, standardizing outcome measures across international multicenter trials presents logistical hurdles yet remains crucial for meaningful data interpretation. Comparison against rapidly improving transcatheter technologies adds complexity to trial design but provides essential contextual benchmarks for evaluating relative benefits.

*10.4 Regulatory and Approval Trend Changes*

Regulatory frameworks governing mechanical valve approval continue to evolve globally. Recent shifts toward earlier patient access balanced with post-market surveillance reflect growing recognition of the limitations inherent in pre-market evaluation. International harmonization efforts aim to streamline approval processes while maintaining safety standards, potentially reducing geographic disparities in access to innovation. The emergence of digital health technologies enabling remote monitoring may reshape regulatory approaches by providing unprecedented real-world performance data. Regulators increasingly consider patient-reported outcomes alongside traditional clinical endpoints, acknowledging the importance of quality-of-life measures in overall benefit assessment.

*10.5 Relationship With New Technologies Such as TAVR*

The relationship between mechanical valves and transcatheter technologies represents a dynamic interplay rather than simple competition. While TAVR has revolutionized aortic valve replacement for high-risk populations, mechanical valves retain advantages for younger patients requiring durable solutions. Future developments may include hybrid approaches combining transcatheter delivery systems with mechanical valve designs, particularly for challenging anatomical situations or reoperations. The technological advances driven by TAVR development—including imaging integration, delivery system miniaturization, and paravalvular leak prevention—offer valuable insights applicable to mechanical valve innovation, suggesting a symbiotic rather than adversarial relationship between these modalities.

*10.6 Economic Benefits and Cost Considerations*

The economic evaluation of mechanical valve technology must consider lifetime cost-effectiveness rather than initial procedural expenses. Though upfront costs exceed bioprosthetic alternatives, the superior durability of mechanical valves potentially offsets reoperation costs, particularly for younger patients. However, this advantage must be weighed against ongoing anticoagulation management expenses and associated complication risks. Value-based healthcare models incentivizing long-term outcomes may favor durable solutions with reduced reintervention rates. Meanwhile, increasing global access remains challenging, with significant disparities in availability between high and low-resource settings. Development of more affordable manufacturing methods without compromising quality represents a crucial focus for expanding access to these life-saving technologies worldwide.

## 11. Conclusion

The evolution of mechanical heart valves represents one of the most significant achievements in cardiovascular medicine, transforming a once-fatal condition into a manageable disease. This comprehensive review has traced the remarkable journey from rudimentary caged ball designs of the 1950s through single-tilting discs to contemporary bileaflet valves, highlighting how each innovation addressed limitations of previous generations. The progressive refinement in design principles, manufacturing techniques, and material science has culminated in devices offering exceptional durability exceeding 25–30 years—a critical advantage for younger patients requiring valve replacement.

Pyrolytic carbon remains the gold standard material due to its superior thromboresistance and mechanical properties, though ongoing research into surface modifications and novel composites promises further improvements in hemocompatibility. Modern mechanical valves demonstrate excellent hemodynamic profiles with reduced pressure gradients and regurgitation compared to their predecessors, yet the requirement for lifelong anticoagulation remains their principal limitation. The optimization of anticoagulation regimens has evolved substantially, with individualized approaches based on valve position, patient-specific factors, and improved monitoring technologies reducing complication rates while maintaining efficacy.

Clinical outcomes data from long-term studies confirm the exceptional structural durability of contemporary mechanical valves, with exceedingly rare instances of mechanical failure. However, the cumulative risk of thromboembolic and bleeding complications over decades of anticoagulation therapy continues to present challenges for patient management. The appropriate selection between mechanical and biological prostheses requires careful consideration of patient age, comorbidities, lifestyle factors, and reproductive plans, with mechanical valves generally favored for younger patients without contraindications to anticoagulation.

Looking forward, the ideal mechanical valve remains elusive but clearly defined: a design combining optimal hemodynamics with minimal thrombogenicity that eliminates anticoagulation requirements while maintaining lifelong durability. Achieving this ambitious goal necessitates multidisciplinary collaboration integrating expertise from materials science, fluid dynamics, bioengineering, computational modeling, and clinical medicine. The convergence of these disciplines has accelerated innovation through advanced computational fluid dynamics simulations, finite element analysis, and rapid prototyping technologies that enable iterative refinement before clinical implementation.

The landscape of valvular intervention has been transformed by transcatheter approaches, particularly TAVR, creating both challenges and opportunities for mechanical valve technology. Rather than rendering mechanical valves obsolete, these innovations have stimulated renewed interest in developing transcatheter-deliverable mechanical designs that combine durability with minimally invasive deployment. The regulatory pathway for novel mechanical valves has evolved to balance rigorous safety evaluation with reasonable timelines for clinical implementation, though harmonization of international approval processes remains an ongoing challenge.

Economic considerations increasingly influence technology adoption, with the higher initial cost of mechanical valves offset by their superior longevity and reduced reoperation rates. However, expanding access to these life-saving technologies in resource-limited settings requires innovative approaches to manufacturing and distribution while maintaining uncompromising quality standards.

The history of mechanical heart valves demonstrates how persistent engineering innovation, driven by clinical needs and enabled by interdisciplinary collaboration, can profoundly impact patient care. As we advance toward increasingly personalized approaches to valvular heart disease, the continued evolution of mechanical valve technology will depend on seamless integration of fundamental science, engineering principles, and clinical expertise. While significant challenges remain, particularly in eliminating anticoagulation requirements, the remarkable progress achieved over seven decades provides compelling evidence that the collaborative pursuit of the ideal mechanical valve will continue to yield meaningful improvements for patients worldwide.

## Author Contributions

RJ, SZ, and BH designed the research study. RJ: Writing – original draft, Investigation, SZ: Conceptualization. BH: Review and editing. All authors contributed to the critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

## Ethics Approval and Consent to Participate

Not applicable.


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## Conflict of Interest

The authors declare no conflict of interest.

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