International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Scholarly Publisher
RS Global Sp. z O.O.
ISNI: 0000 0004 8495 2390

Dolna 17, Warsaw,
Poland 00-773
+48 226 0 227 03
editorial_office@rsglobal.pl

ARTICLE TITLE	BIOMATERIALS IN TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI): ENGINEERING INNOVATIONS AND THEIR IMPACT ON PATIENT QUALITY OF LIFE IN AN AGING SOCIETY
DOI	https://doi.org/10.31435/ijitss.4(48).2025.4522
RECEIVED	16 October 2025
ACCEPTED	11 December 2025
PUBLISHED	30 December 2025
LICENSE	The article is licensed under a **Creative Commons Attribution 4.0 International License.**

BIOMATERIALS IN TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI): ENGINEERING INNOVATIONS AND THEIR IMPACT ON PATIENT QUALITY OF LIFE IN AN AGING SOCIETY

Mikołaj Zalewski *(Corresponding Author, Email: mikolaj.zalewski01@gmail.com)*
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0002-7803-6145

Marianna Rudzińska
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0002-9622-7439

Konrad Zieliński
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0005-3652-592X

Jagoda Józefczyk
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0007-5235-2074

Łukasz Krzystek
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0001-1988-0402

Karolina Buć
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0000-8491-7200

Paweł Buć
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0001-1533-6610

Karolina Ganczar
F. Chopin University Teaching Hospital, Rzeszów, Poland
ORCID ID: 0009-0003-8152-8076

Stanisław Jurkowski
Pomeranian Medical University, Szczecin, Poland
ORCID ID: 0009-0005-9715-8385

Michał Mazurek
F. Chopin University Teaching Hospital, Rzeszów, Poland
ORCID ID: 0009-0005-7111-2397

ABSTRACT

Background: Severe aortic stenosis (AS) constitutes a significant epidemiological challenge in aging populations, frequently referenced in the context of the "Silver Tsunami." Transcatheter aortic valve implantation (TAVI) has transitioned remarkably from a high-risk or prohibitive-risk intervention to a standard treatment strategy, thereby facilitating accelerated recovery and improved social functioning for elderly patients. The widespread clinical success of this method is inextricably linked to continuous advancements in material science and device engineering.

Aim: This study conducts a comparative analysis of the leading material technologies utilized in transcatheter heart valve (THV) devices: specifically, Nitinol-based self-expanding valves (SEV) and cobalt-chromium (CoCr)-based balloon-expandable valves (BEV), alongside the performance of contemporary biological leaflet materials. The primary objective is to critically evaluate the influence of these material characteristics on long-term durability, valve hemodynamics, the incidence of prosthesis-patient mismatch (PPM), and the resulting impact on patient quality of life (QoL) and healthcare system resource utilization throughout the patient's lifetime management.

Methods: A systematic synthesis of available literature and clinical trial data spanning the years 2018–2025 was performed, drawing primarily on outcomes from pivotal randomized clinical trials, notably PARTNER 3 (BEV) and EVOLUT Low Risk (SEV), complemented by specialized engineering reports on material fatigue and biocompatibility. The investigation focused on quantifying the correlation between the physicochemical properties of the implant—including stent alloy composition, leaflet configuration, and deployment behavior (e.g., ellipticity)—and critical clinical endpoints defined by the Valve Academic Research Consortium 3 (VARC-3). Emphasis was placed on complications impacting the patient's socio-functional outcomes, such as structural valve deterioration (SVD), severe PPM, and the complexity of coronary re-access during prospective redo procedures.

Findings: Comparative data consistently indicate that SEV platforms, leveraging the properties of Nitinol, are associated with superior post-procedural hemodynamics, including lower mean gradients and larger effective orifice area (EOA), relative both to surgical valves and often to BEV, particularly within the challenging anatomical context of a small aortic annulus. Specifically, the utilization of SEV demonstrated a lower rate of severe PPM (9.0%) compared to BEV (24.0%) in patients with extra-small aortic annuli. Furthermore, long-term follow-up (up to 10 years) confirms that TAVI with early-generation SEV provides durable hemodynamic performance and low rates of SVD and bioprosthetic valve failure (BVF). These analytical results underscore the necessity of optimizing material selection, focusing on devices capable of delivering superior hemodynamic profiles to ensure prolonged prosthetic efficacy and minimize the resource-intensive burden associated with subsequent re-interventions in a population enjoying increasingly extended life expectancy.

Conclusions: The decision matrix concerning biomaterial selection within transcatheter aortic valve implantation (TAVI) transcends conventional technical specifications, yielding profound socio-economic and long-term strategic implications in the management of severe aortic stenosis (AS). As the indications for TAVI broaden to encompass younger, lower-surgical-risk cohorts, maintaining the functional independence of this aging demographic ("Active Aging" strategy) relies critically on ensuring prosthetic valve durability and facilitating future re-interventions.

Comparative analyses between self-expanding valves (SEV), typically constructed with Nitinol frames, and balloon-expandable valves (BEV), often incorporating cobalt-chromium or rhenium alloys, underscore material-dependent clinical heterogeneity. Data demonstrate that the inherent properties of SEV contribute to a more favorable post-procedural hemodynamic profile. Specifically, SEV deployment is associated with a markedly lower incidence of severe prosthesis-patient mismatch (PPM) (9.0% for SEV versus 24.0% for BEV in patients with extra-small aortic annuli), a crucial factor mitigating long-term mortality risk. Furthermore, extended follow-up (up to 10 years) confirms that SEV platforms exhibit durable hemodynamic performance and lower rates of structural valve deterioration (SVD) compared to surgical aortic valve replacement (SAVR), although rates of bioprosthetic valve failure (BVF) are comparably low.

The future trajectory of material engineering in this domain is focused on reducing system profiles (e.g., Optimum TAV with the lowest SEV frame), mitigating long-term risks such as thrombogenicity, and simplifying subsequent "valve-in-valve" (TAV-in-TAV) procedures. The emergence of advanced polymeric heart valves (PHV), such as Foldax TRIA (utilizing LifePolymer), offers the prospect of durability exceeding 35 years in fatigue testing and elimination of the need for lifelong anticoagulation, which constitutes a fundamental change for patient quality of life (QoL) and reduction of the healthcare system burden (Health Technology Assessment). In the context of lifetime management planning, engineering tools such as computed tomography (CT) simulations become essential for personalizing device selection and predicting the feasibility of future TAV-in-TAV interventions, which is key for younger populations.

KEYWORDS

Biomaterials, TAVI, Nitinol, Cobalt-Chromium, Quality of Life, Aging Society, Health Technology Assessment

CITATION

Mikołaj Zalewski, Marianna Rudzińska, Konrad Zieliński, Jagoda Józefczyk, Łukasz Krzystek, Karolina Buć, Paweł Buć, Karolina Ganczar, Stanisław Jurkowski, Michał Mazurek. (2025) Biomaterials in Transcatheter Aortic Valve Implantation (TAVI): Engineering Innovations and Their Impact on Patient Quality of Life in an Aging Society. *International Journal of Innovative Technologies in Social Science*. 4(48). doi: 10.31435/ijitss.4(48).2025.4522

Introduction

Social and Demographic Context

Severe aortic stenosis (AS) constitutes an accelerating public health challenge globally, intrinsically linked to the demographic phenomenon of aging populations. The prevalence of valvular heart disease (VHD) escalates dramatically with age, rising from 0.7% in the 18–44 age group to 13.3% in individuals 75 years and older (Tsao et al., 2022; Rezvova et al., 2023). Untreated symptomatic severe AS severely compromises health status, leading to substantial disability, morbidity, and diminished quality of life (QoL) (Rezvova et al., 2023). The inherent physical limitations associated with symptoms such as dyspnea significantly impede functional independence and social participation among the elderly, underscoring the necessity for effective, definitive therapeutic intervention (Rezvova et al., 2023).

The evolution of treatment has fundamentally shifted the management paradigm for AS (Zornitzki & Ben-Shoshan, 2025). Historically, surgical aortic valve replacement (SAVR) was the standard, a procedure characterized by lengthy hospital stays and complex rehabilitation protocols (Mack et al., 2019; Popma et al., 2019). In contrast, transcatheter aortic valve implantation (TAVI) has transitioned from a salvage procedure for inoperable patients to the preferred method for many elderly individuals (Zornitzki & Ben-Shoshan, 2025; Mack et al., 2019). TAVI offers considerable logistical advantages over SAVR, resulting in less trauma, accelerated recovery, and significantly shorter index hospitalization times (e.g., 3 days for TAVI versus 7 days for SAVR in low-risk trials), thereby reducing the socio-economic burden associated with caregiver absence from work and protracted post-procedural dependency (Mack et al., 2019; Popma et al., 2019; Sun et al., 2018).

The Engineering Imperative and Material Science Gap

Despite its clinical success and expanding indications—now encompassing younger, lower-risk patients with longer life expectancies—TAVI represents an extreme engineering challenge (Sheikh et al., 2025; Zornitzki & Ben-Shoshan, 2025; Søndergaard et al., 2019). The implantable bioprosthesis must be compressed (crimped) to a minimal profile for transfemoral delivery and subsequently perform flawlessly under high cyclic stress within the dynamic aortic root for an anticipated 10 to 15 years (Mao et al., 2025). This equates to the valve enduring millions of opening and closing cycles annually (e.g., bench tests for advanced polymeric valves demonstrating durability exceeding 100 million cycles) (Rezvova et al., 2023; Mao et al., 2025).

The majority of contemporary transcatheter heart valves (THVs) rely on biological leaflets, typically bovine or porcine pericardium, whose durability is fundamentally limited by structural degeneration, including calcification and thrombosis (Mao et al., 2025; Rezvova et al., 2023). Furthermore, the fabrication process—specifically the unavoidable micro-damages incurred during crimping—raises critical concerns regarding long-term structural integrity and sustained function (Rezvova et al., 2023). Suboptimal deployment geometry, such as oval deployment or under-expansion caused by calcified annuli, can severely alter valve hemodynamics, increasing transvalvular pressure gradients and potentially predisposing the device to early failure or thrombosis (Sun et al., 2018). The utilization of novel materials and stent technologies, such as Nitinol and cobalt-chromium alloys, is paramount to mitigate these risks and optimize immediate and long-term performance (Zornitzki & Ben-Shoshan, 2025).

Thesis Statement

Consequently, advancements in material science—from the engineering of stent platforms and leaflet biomaterials (e.g., innovative synthetic polymers designed for lifelong durability) to design optimizations minimizing mechanical stress (Sheikh et al., 2025)—are not merely technical enhancements, but represent critical factors that directly correlate with improved clinical outcomes, reduced long-term morbidity (such as prosthesis-patient mismatch), and ultimately, sustained functional independence and elevated patient quality of life (Zornitzki & Ben-Shoshan, 2025; Sheikh et al., 2025). The objective analysis of these material-based innovations is essential for advancing personalized lifetime management strategies for patients with AS.

Biomaterials in TAVI Stents

Nitinol (Nickel-Titanium) – The "Smart" Metal

Technical Description

Nitinol (nickel-titanium) is the core metallic alloy employed in the construction of self-expanding valves (SEV) utilized for transcatheter aortic valve implantation (TAVI) (Sheikh et al., 2025; Popma et al., 2019; Adams et al., 2014; Rezvova et al., 2023). This material possesses two defining characteristics: superelasticity and shape memory, phenomena that enable the device to be highly compressed (crimped) for delivery and subsequently self-expand within the patient's native anatomy (Rezvova et al., 2023).

The basis of this function is a stress- or temperature-induced phase transformation. Specifically, the valve is typically constrained in the flexible martensite phase during delivery, but at body temperature (37°C) it transitions to the rigid austenite phase, seeking to revert to its pre-programmed deployment shape (Rezvova et al., 2023). This mechanism results in sustained, active apposition against the native annular structures, known as chronic outward force (COF), which is essential for fixation and sealing (Sheikh et al., 2025).

Impact on Patient

The primary clinical advantage stemming from the Nitinol frame's COF is its effective self-sealing mechanism, which is particularly valuable in treating patients with extensive annular calcification (Tirado-Conte et al., 2023; Rezvova et al., 2023). This continuous radial force contributes to better hemodynamic outcomes by minimizing paravalvular leak (PVL) (Tirado-Conte et al., 2023; Zornitzki & Ben-Shoshan, 2025). Furthermore, SEV devices generally achieve superior hemodynamic profiles, especially in patients with a small aortic annulus (SAA), displaying lower mean gradients and lower rates of severe prosthesis-patient mismatch (PPM) (Tirado-Conte et al., 2023; Zornitzki & Ben-Shoshan, 2025). For instance, SEV devices have been shown to be associated with significantly lower severe PPM rates (9.0%) compared to balloon-expandable valves (BEV) (24.0%) in patients with extra-small aortic annuli (Tirado-Conte et al., 2023).

However, a significant mechanical risk is associated with the depth of the Nitinol frame's extension into the left ventricular outflow tract (LVOT). The constant pressure exerted on this area can compromise the cardiac conduction system (Husser et al., 2016).

Social Consequence: Permanent Pacemaker Implantation (PPM)

The mechanical stress placed on the conduction system often necessitates the implantation of a new permanent pacemaker (PPM) (Jorgensen et al., 2021). The PPM rate is demonstrably higher following SEV implantation compared to surgical aortic valve replacement (SAVR). For example, the NOTION trial reported a PPM rate of 42.5% for TAVI (using a self-expanding valve) versus 10.9% for SAVR (Thyregod et al., 2021). The need for a PPM represents a major long-term prognostic factor, increasing systemic healthcare costs related to follow-up, battery replacements, and device checks (Jorgensen et al., 2021). While the sources do not specifically address the psychological impact, the functional constraint and increased medical surveillance associated with a pacemaker constitute a critical component of lifetime management planning (Zornitzki & Ben-Shoshan, 2025).

Cobalt-Chromium (Co-Cr) – Strength and Precision

Technical Description

Cobalt-chromium (Co-Cr) and related high-strength alloys (such as rhenium superalloys used in the Siegel THV system) are the structural materials primarily used for balloon-expandable valve (BEV) frames (Sheikh et al., 2025). These alloys provide high density and tensile strength (Sheikh et al., 2025). This mechanical robustness allows manufacturers to engineer stents with thinner structural components (struts) while maintaining the necessary integrity and ensuring optimal visualization under fluoroscopy (radiopacity) (Sheikh et al., 2025).

The deployment mechanism relies on plastic deformation induced by balloon inflation, fundamentally distinguishing it from Nitinol's thermoelastic properties (Schuhbaeck et al., 2015). Once expanded, the Co-Cr frame retains the dimension and configuration imposed by the balloon, as it lacks the shape memory or continuous outward force characteristic of Nitinol (Schuhbaeck et al., 2015).

Impact on Patient

The inherent stability and precise final shape achieved via balloon expansion allow for the design of devices featuring open cell architecture and a typically lower frame height compared to many SEV platforms (Sheikh et al., 2025). This design feature is paramount for preserving easy access to the coronary arteries (Sheikh et al., 2025).

Maintaining future coronary access is vital, as patients often require subsequent procedures such as coronary angiography or percutaneous coronary intervention (Tarantini et al., 2021; Zornitzki & Ben-Shoshan, 2025). Low-profile BEV designs, like the Siegel THV, are specifically engineered to offer improved coronary re-access by reducing frame height (Sheikh et al., 2025).

Social Consequence: Lifetime Management

The expanding indication of TAVI to include younger and lower-risk patients necessitates a long-term lifetime management strategy (Jubran et al., 2024; Zornitzki & Ben-Shoshan, 2025; Sheikh et al., 2025). The durability of the initial implant and the feasibility of managing future complications, such as re-intervention (TAV-in-TAV), are paramount (Jubran et al., 2024; Sheikh et al., 2025). Since TAV-in-TAV procedures carry a risk of coronary obstruction, selecting a valve design that inherently simplifies future interventions—such as a low-profile BEV that ensures easier coronary cannulation—is considered an optimal strategic choice for long-term health planning (Medranda et al., 2022; Tarantini et al., 2021). Detailed pre-procedural assessment using computed tomography (CT) simulation is routinely employed to predict and mitigate the risk of coronary obstruction in potential future re-interventions (Medranda et al., 2022; Tarantini et al., 2021).

Biological Leaflets in Transcatheter Aortic Valve Implantation

The long-term durability of transcatheter heart valves (THVs) remains a central challenge, particularly as indications expand to include younger patients with longer life expectancies. The efficacy of these devices is inextricably linked to the performance of the biological leaflet materials and the advanced chemical engineering employed to ensure their biostability (Rezvova et al., 2023).

Material: Bovine vs. Porcine Pericardium

Contemporary bioprosthetic heart valves overwhelmingly utilize xenograft tissues—primarily bovine pericardium (BP) or porcine pericardium/aortic valves—mounted onto metallic frames (Tarantini et al., 2021). The primary rationale for the generalized shift toward biological tissue valves (THVs) over mechanical heart valves (MHVs) is the superior physiological outcome regarding thromboembolism; THV recipients generally do not require lifelong anticoagulation therapy, a considerable benefit for elderly patients (Rezvova et al., 2023). Avoiding chronic anticoagulation minimizes complications, improves patient quality of life (QoL), and is a crucial determinant in the therapeutic decision-making process (Nissen et al., 2019).

Bioprosthetic valves are broadly classified based on their tissue origin (porcine versus bovine pericardial) and frame characteristics (Tarantini et al., 2021). While the sources indicate that both tissue types are fundamental to TAVI technology—bovine pericardium is commonly used in TAV fabrication (Sun et al., 2017)—they differ in failure mechanisms: bovine pericardial valves tend to fail more commonly due to stenosis, whereas porcine valves are more prone to failure via regurgitation (Tarantini et al., 2021). Structural analysis also reveals architectural differences; for instance, porcine valves often yield a true internal diameter (ID) that is at least 2 mm less than the stent ID, whereas pericardial valves with leaflets sutured inside the stent frame yield an ID that is at least 1 mm less than the stent ID (Tarantini et al., 2021). These material-dependent architectural characteristics underscore the complex engineering required to optimize valve hemodynamics for patient anatomy (Tirado-Conte et al., 2023).

Chemical Engineering: Anti-calcification Strategies

The Threat of Structural Valve Deterioration (SVD)

The principal limitation of xenograft materials is the structural valve deterioration (SVD) of the leaflets, typically commencing within a decade of implantation, although increasing patient lifespan challenges this timeframe (Nissen et al., 2019; Rezvova et al., 2023). SVD encompasses acquired intrinsic changes, including leaflet tears, fibrosis, and, most frequently, calcification (Bagur et al., 2018; Tarantini et al., 2021). Calcification is a pathological process involving the formation of insoluble calcium salts, which restricts the mobility and elasticity of the leaflets (Rezvova et al., 2023).

The common fixation method for xenograft tissue is treatment with glutaraldehyde, which stabilizes the tissue but leaves chemical residues that serve as nucleation sites for calcification upon reaction with calcium in the bloodstream (Sun et al., 2017). This process contributes to the loss of tensile strength, surface cracking, and subsequent bioprosthetic failure (Rezvova et al., 2023).

Innovations in Anti-Calcification Treatment

To combat calcification, modern bioprosthetic engineering focuses heavily on sophisticated chemical modification and tissue handling:

1. Proprietary Tissue Treatment: Surgical bioprosthetic valves incorporate proprietary anticalcification treatments (Tarantini et al., 2021). A leading example is the ADAPT tissue technology applied to bovine pericardial tissue used in systems like the DurAVR™ THV (Sheikh et al., 2025). This technology involves specific biochemical processes designed to significantly reduce leaflet calcification (Sheikh et al., 2025; Tirado-Conte et al., 2023). The utilization of advanced tissue preparations, such as the bovine pericardial tissue used in the SAPIEN 3 Ultra Resilia (S3UR) valve, is specifically aimed at mitigating the risk of leaflet calcification and SVD (Matsuhiro et al., 2025).
2. Leaflet Modification: Novel approaches focus on eliminating xenogenic tissue altogether. Third-generation polymer heart valves utilize synthetic polymer materials (e.g., Foldax TRIA™ with LifePolymer) engineered specifically to resist calcification and thrombus formation, offering the potential for lifelong durability without the chemical limitations of biological tissue (Sheikh et al., 2025). The durability of these advanced polymers can potentially reach an equivalent life of more than 35 years in accelerated fatigue tests (Rezvova et al., 2023).

Scholarly Conclusion on Material Engineering

The rigorous chemical engineering applied to both xenograft and synthetic leaflet materials is critical for the implementation of successful TAVI programs (Sheikh et al., 2025). Improvements in anti-calcification treatments directly translate into enhanced prosthetic valve durability, measured by freedom from SVD and bioprosthetic valve failure (BVF) (Matsuhiro et al., 2025). Maximizing valve lifespan is an essential pillar of the "Lifetime Management" strategy, particularly for younger patients with longer projected lifespans (Jubran et al., 2024; Sheikh et al., 2025). Long-term valve survival minimizes the inevitable, high-risk, repeat interventions, such as complex valve-in-valve (TAV-in-TAV) procedures, which are associated with increased procedural complications, risk of coronary obstruction, and heightened mortality (Medranda et al., 2022; Zaid et al., 2023). Therefore, continued innovation in biomaterials ensures sustained functional independence for the aging population and effectively reduces the complex burden and socioeconomic cost associated with recurrent high-risk cardiac interventions (Jubran et al., 2024).

Clinical and Social Implications

Low Profile Delivery Systems and Gender Equity

The continuous evolution in the engineering of stent alloys and delivery systems has achieved a remarkable miniaturization of TAVI technology. This is evidenced by the shift toward low-profile transfemoral access systems, now the preferred route in the vast majority of TAVI procedures (Elbasha et al., 2024; Popma et al., 2019). The ability to significantly compress the bioprosthesis, facilitated by the superelastic properties of materials like Nitinol (Rezvova et al., 2023), has enabled the reduction of catheter profiles from large-bore systems (e.g., 24 Fr historical systems) to contemporary profiles generally ranging from 14 Fr to 18 Fr (Sheikh et al., 2025; Popma et al., 2019).

This technological achievement holds significant implications for anatomical inclusion and gender equity. Small aortic annuli (SAA) are frequently encountered, with prevalence ranging from 22% to 34% in Western populations, exhibiting a strong statistical preponderance in female patients (Tirado-Conte et al., 2023). Furthermore, female patients often present with smaller iliofemoral access vessels, posing a historical constraint on the feasibility of the transfemoral approach (Tirado-Conte et al., 2023). The development of durable, low-profile delivery catheters has mitigated the issue of inadequate vascular access, thereby eliminating an anatomical form of exclusion that disproportionately affected women (Sheikh et al., 2025). This innovation ensures that TAVI remains a viable and preferred minimal-access treatment option across both sexes, particularly in the older, predominantly female cohort with SAA (Tirado-Conte et al., 2023).

Paravalvular Leak (PVL) and Re-hospitalization

Paravalvular leak (PVL) constitutes a significant mechanism of non-structural valve deterioration (NSVD) that is associated with adverse clinical outcomes, including increased mortality (Thyregod et al., 2021). Modern material engineering has addressed this risk through mechanical modifications, specifically the incorporation of external sealing elements, often termed "skirts" or "cuffs."

These sealing mechanisms, fabricated from biocompatible polymers (e.g., in the Foldax TRIA Valve) or biological tissue (pericardium) (Sheikh et al., 2025), are integral to newer-generation devices (e.g., SAPIEN

3, Evolut PRO/PRO+) (Ramlawi & Bedeir, 2020). The function of the sealing skirt is to bridge anatomical gaps caused by heavy or asymmetric calcification of the native annulus, which are often the genesis of PVL (Ramlawi & Bedeir, 2020). A valve that achieves an effective seal prevents significant regurgitation, thereby reducing the consequential strain on the left ventricle (Thyregod et al., 2021).

The successful mitigation of PVL yields critical implications for socio-economic burden. The reduction in post-procedural heart failure symptoms translates directly into a decreased rate of unplanned re-hospitalization (readmission) (Popma et al., 2019). TAVI already offers significantly shorter index hospitalizations (e.g., 3 days for TAVI versus 7 days for SAVR in low-risk trials) (Mack et al., 2019). Minimizing subsequent readmissions is not solely a measure of clinical success but an index of lowered burden on informal caregivers (family and friends), whose labor and time contribution often carries substantial, though often unmeasured, economic value. Thus, successful sealing technology supports the overall goal of accelerated functional recovery and sustained independence for the elderly population, aligning with broader public health strategies focused on "Active Aging" (Zornitzki & Ben-Shoshan, 2025, implicit in lifetime management).

Cost-Effectiveness (Health Technology Assessment)

The utilization of advanced biomaterials (e.g., Nitinol, rhenium alloys, specialized anti-calcification tissue treatment like ADAPT) often results in a higher initial device cost compared to traditional surgical valves or first-generation TAVI devices (Sheikh et al., 2025). However, a comprehensive health technology assessment (HTA) dictates that the long-term total societal cost must be considered (Sheikh et al., 2025).

The economic rationale for employing premium biomaterials rests on the following premises:

1. Reduced Immediate Costs: TAVI procedures consistently demonstrate significantly shorter hospital stays than SAVR (3 days versus 7 days in low-risk patients), contributing to an overall lower cost profile for the index hospitalization (Mack et al., 2019).
2. Increased Functional Independence: TAVI enables a significantly faster recovery and a lower rate of poor treatment outcome (death or low quality of life score) at 30 days compared to SAVR (3.9% vs. 30.6%) (Mack et al., 2019). This rapid restoration of functional capacity reduces reliance on resource-intensive rehabilitation and continuous caregiver support (Sheikh et al., 2025).
3. Extended Durability and Prevention of Re-Intervention: The primary threat to TAVI's cost-effectiveness in younger, low-risk patients is the requirement for high-risk, expensive re-interventions (TAV-in-TAV) due to structural valve deterioration (SVD) (Zaid et al., 2023; Matsuhiro et al., 2025). Biomaterial innovations aimed at resistance to calcification (Rezvova et al., 2023), minimizing SVD (Matsuhiro et al., 2025), and reducing the risk of prosthesis-patient mismatch (PPM) (Tirado-Conte et al., 2023) extend the functional lifespan of the valve. Notably, the preservation of optimal indexed effective orifice area (iEOA) often superior with SEV devices (0.93 cm2/m2 for SEV vs. 0.73 cm2/m2 for BEV in extra-SAA), is key to mitigating long-term mortality risk associated with PPM (Tirado-Conte et al., 2023).

Thus, the increased front-end investment in superior biomaterials for TAVI is economically justified by the resultant reduction in downstream, long-term healthcare utilization, promoting both cost-effectiveness and sustained patient well-being (Sheikh et al., 2025).

Conclusions

The successful integration of transcatheter aortic valve implantation (TAVI) into standard clinical practice represents a quintessential example of how advanced medical technology effectively addresses the major demographic challenges of the 21st century, particularly the increasing burden of severe aortic stenosis (AS) within aging societies (Zornitzki & Ben-Shoshan, 2025; Tsao et al., 2022). The demonstrated efficacy of TAVI in achieving rapid recovery, facilitating short hospital stays, and supporting functional independence underscores its contribution to the strategy of "Active Aging" (Mack et al., 2019; Popma et al., 2019).

Critically, the clinical success of TAVI is not merely a procedural triumph but a direct reflection of continuous and sophisticated material engineering. Every modification to the stent framework alloy, leaflet composition, or fixation technique carries profound clinical and socio-economic consequences that directly impact the patient's quality of life (QoL) and the efficiency of the healthcare system. The inherent material properties define core outcomes:

1. Nitinol (Self-Expanding Valves, SEV): The utilization of superelastic Nitinol frames contributes to superior hemodynamic performance and demonstrably lower rates of severe prosthesis-patient mismatch (PPM), especially in challenging anatomies such as the small aortic annulus (SAA) (Tirado-Conte et al., 2023).

Avoiding PPM is crucial for mitigating long-term mortality risk (Levesque et al., 2024; Zornitzki & Ben-Shoshan, 2025). Furthermore, early-generation SEV platforms have shown durable hemodynamic performance and low rates of bioprosthetic valve failure (BVF) and structural valve deterioration (SVD) up to 10 years (Elbasha et al., 2024; Thyregod et al., 2024).

2. Cobalt-Chromium/Rhenium (Balloon-Expandable Valves, BEV): These high-strength materials enable low-profile, open-architecture designs that are fundamental for ensuring coronary re-access in the event of future TAV-in-TAV procedures (Sheikh et al., 2025; Medranda et al., 2022). For younger patients with longer life expectancies, material selection directly influences the feasibility of multi-stage "Lifetime Management" planning (Jubran et al., 2024; Zornitzki & Ben-Shoshan, 2025).

Therefore, subsequent research and development must be strategically directed toward technologies that eliminate the inherent limitations of biological components and further optimize device delivery.

Recommendations: Future innovation should urgently prioritize the development of polymeric heart valves (PHVs) utilizing advanced synthetic materials, such as LifePolymer (SiPUU) and its nanocomposite derivatives (Rezvova et al., 2023; Sheikh et al., 2025). These polymers hold the promise of achieving superior durability (bench testing showing an equivalent life of >35 years) and eliminating the critical issues associated with xenograft tissues, specifically calcification, SVD, and the necessity for long-term anticoagulation (Rezvova et al., 2023; Mao et al., 2025). Concurrently, technological efforts must continue to focus on miniaturization of the catheter delivery systems (reducing profiles from historical 24 Fr to contemporary 14 Fr), which is critical for ensuring minimal invasiveness, reducing vascular complications, and enhancing procedural equity, particularly for female patients who historically presented with smaller iliofemoral access vessels (Sheikh et al., 2025; Tirado-Conte et al., 2023). These advancements are essential to sustain the clinical and socio-economic gains afforded by TAVI.

Disclosure

Authors ’contributions:

Conceptualization: Michał Mazurek, Mikołaj Zalewski
Methodology: Marianna Rudzińska, Karolina Ganczar
Software: Łukasz Krzystek, Karolina Buć
Check: Łukasz Krzystek, Jagoda Józefczyk
Formal Analysis: Jagoda Józefczyk, Paweł Buć
Investigation: Konrad Zieliński, Stanisław Jurkowski
Resources: Łukasz Krzystek, Paweł Buć, Stanisław Jurkowski
Data curation: Karolina Buć, Konrad Zieliński
Writing - Original draft: Mikołaj Zalewski, Marianna Rudzińska
Writing - Review & editing: Karolina Ganczar, Mikołaj Zalewski
Visualization: Łukasz Krzystek, Jagoda Józefczyk
Supervision: Karolina Buć, Michał Mazurek
Project administration: Michał Mazurek, Karolina Ganczar

All authors have read and agreed with the published version of the manuscript.

Funding Statement: Not applicable.
Institutional Review Board Statement: Not applicable.
Informed Consent Statement: Not applicable.
Data Availability Statement: Not applicable.
Acknowledgments: Not applicable.
Conflict of Interest Statement: The authors have declared no conflicts of interest.
Declaration of the use of generative AI and AI-assisted technologies in the writing process: In preparing this work, the authors used ChatGPT for the purpose of improving language and readability. After using this tool, the authors have reviewed and edited the content as needed.

REFERENCES

1. Adnan, M., Akhtar, M., Usman, M., Hamza, M., Bakhtiari, M. I., Zaheer, W., Saleem, A., Naveed, H., & Alam, M. (2024). TCT-158 Comparative Efficacy and Safety of Self-Expanding Versus Balloon-Expandable TAVR in Patients With Aortic Stenosis: A Systematic Review and Meta-Analysis. *Journal of the American College of Cardiology*, *84*(18), B394–B395. https://doi.org/10.1016/j.jacc.2024.09.1218
2. Bagur, R., & Webb, J. (2018). Standardising definitions for bioprosthetic structural valve deterioration and failure: The European avant-garde. *EuroIntervention*, *13*(15), e1744–e1747. https://doi.org/10.4244/EIJV13I15A283
3. Elbasha, K., Kaur, J., Abdelghani, M., Landt, M., Alotaibi, S., Abdelaziz, A., Abdel-Wahab, M., Toelg, R., Geist, V., Richardt, G., & Allali, A. (2024). Ten-year Durability, Hemodynamic Performance, and Clinical Outcomes after Transcatheter Aortic Valve Implantation Using a Self-expanding Device. *Cardiology and Therapy*, *13*(3), 529–540. https://doi.org/10.1007/s40119-024-00369-2
4. Jørgensen, T. H., Thyregod, H. G. H., Ihlemann, N., Nissen, H., Petursson, P., Kjeldsen, B. J., Steinbrüchel, D. A., Olsen, P. S., & Søndergaard, L. (2021). Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. Surgical aortic valve replacement. *European Heart Journal*, *42*(30), 2912–2919. https://doi.org/10.1093/eurheartj/ehab375
5. Mack, M. J., Leon, M. B., Thourani, V. H., Makkar, R., Kodali, S. K., Russo, M., Kapadia, S. R., Malaisrie, S. C., Cohen, D. J., Pibarot, P., Leipsic, J., Hahn, R. T., Blanke, P., Williams, M. R., McCabe, J. M., Brown, D. L., Babaliaros, V., Goldman, S., Szeto, W. Y., … Smith, C. R. (2019). Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *New England Journal of Medicine*, *380*(18), 1695–1705. https://doi.org/10.1056/NEJMoa1814052
6. Makkar, R. R., Blanke, P., Leipsic, J., Thourani, V., Chakravarty, T., Brown, D., Trento, A., Guyton, R., Babaliaros, V., Williams, M., Jilaihawi, H., Kodali, S., George, I., Lu, M., McCabe, J. M., Friedman, J., Smalling, R., Wong, S. C., Yazdani, S., … Leon, M. B. (2020). Subclinical Leaflet Thrombosis in Transcatheter and Surgical Bioprosthetic Valves. *Journal of the American College of Cardiology*, *75*(24), 3003–3015. https://doi.org/10.1016/j.jacc.2020.04.043
7. Mao, Y., Liu, F., Chen, X., Liu, Y., Tang, J., & Yang, J. (2025). Innovation and Development in Polymer Heart Valves: A New Era of Transcatheter Aortic Valve Replacement. *European Cardiology Review*, *20*, e29. https://doi.org/10.15420/ecr.2024.40
8. Matsuhiro, Y., Mizote, I., Nakamura, D., Dohi, T., Maeda, K., Shimamura, K., Kawamura, A., Yamashita, K., Kosugi, S., Okuno, S., Sugae, H., Takeda, Y., & Sakata, Y. (2025). Long-Term Bioprosthetic Valve Durability After Transcatheter Aortic Valve Replacement With Supra-Annular Self-Expanding Versus Intra-Annular Balloon-Expandable Valves in Patients With a Small Aortic Annulus. *Catheterization and Cardiovascular Interventions*, *105*(5), 990–997. https://doi.org/10.1002/ccd.31415
9. Medranda, G. M., Soria Jimenez, C. E., Torguson, R., Case, B. C., Forrestal, B. F., Ali, S. A., Shea, C., Zhang, C., Wang, J. W., Gordon, P., Ehsan, A., Wilson, S. W., Levitt, R., Parikh, P., Bilfinger, T., Hanna, N., Buchbinder, M., Asch, F. A., Weissman, G., … Rogers, T. (2022). Lifetime management of patients with symptomatic severe aortic stenosis: A computed tomography simulation study. *EuroIntervention*, *18*(5), e407–e416. https://doi.org/10.4244/EIJ-D-21-01091
10. Popma, J. J., Deeb, G. M., Yakubov, S. J., Mumtaz, M., Gada, H., O'Hair, D., Bajwa, T., Heiser, J. C., Merhi, W., Kleiman, N. S., Askew, J., Sorajja, P., Rovin, J., Chetcuti, S. J., Adams, D. H., Teirstein, P. S., Zorn, G. L., Forrest, J. K., Tchétché, D., … Reardon, M. J. (2019). Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *New England Journal of Medicine*, *380*(18), 1706–1715. https://doi.org/10.1056/NEJMoa1816885
11. Ramlawi, B., & Bedeir, K. (2020). Overcoming the transcatheter aortic valve replacement Achilles heel: Paravalvular leak. *Annals of Cardiothoracic Surgery*, *9*(6), 499–501. https://doi.org/10.21037/acs-2020-av-19
12. Rezvova, M. A., Klyshnikov, K. Y., Gritskevich, A. A., & Ovcharenko, E. A. (2023). Polymeric Heart Valves Will Displace Mechanical and Tissue Heart Valves: A New Era for the Medical Devices. *International Journal of Molecular Sciences*, *24*(4), 3963. https://doi.org/10.3390/ijms24043963
13. Rodés-Cabau, J., Ellenbogen, K. A., Krahn, A. D., Latib, A., Mack, M., Mittal, S., Muntané-Carol, G., Nazif, T. M., Sondergaard, L., Urena, M., Windecker, S., & Philippon, F. (2019). Management of Conduction Disturbances Associated With Transcatheter Aortic Valve Replacement. *Journal of the American College of Cardiology*, *74*(8), 1086–1106. https://doi.org/10.1016/j.jacc.2019.07.014
14. Sheikh, O., Moras, E., Mascarenhas, L., Samimi, S., Kayani, W. T., & Zaid, S. (2025). Innovations in TAVR: The Latest in Device Technology. *Journal of Clinical Medicine*, *14*(14), 4906. https://doi.org/10.3390/jcm14144906
15. Sirois, E., Mao, W., Li, K., Calderan, J., & Sun, W. (2018). Simulated Transcatheter Aortic Valve Flow: Implications of Elliptical Deployment and Under-Expansion at the Aortic Annulus. *Artificial Organs*, *42*(7). https://doi.org/10.1111/aor.13107

16. Søndergaard, L., Ihlemann, N., Capodanno, D., Jørgensen, T. H., Nissen, H., Kjeldsen, B. J., Chang, Y., Steinbrüchel, D. A., Olsen, P. S., Petronio, A. S., & Thyregod, H. G. H. (2019). Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk. *Journal of the American College of Cardiology*, *73*(5), 546–553. https://doi.org/10.1016/j.jacc.2018.10.083
17. Tarantini, G., Dvir, D., & Tang, G. H. L. (2021). Transcatheter aortic valve implantation in degenerated surgical aortic valves. *EuroIntervention*, *17*(9), 709–719. https://doi.org/10.4244/EIJ-D-21-00157
18. Tirado-Conte, G., Rodés-Cabau, J., Oteo, J. F., Pan, M., Muñoz, E., Witberg, G., Cheema, A. N., Alpieri, A., Lopez, D., Amat-Santos, I. J., Akodad, M., Ojeda, S., Serra, V., Garcia-Blas, S., Alfonso, F., De Backer, O., Asmarats, L., Muñoz, A., Hamdan, A., … Nombela-Franco, L. (2023). Transcatheter aortic valve implantation in patients with extra-small aortic annuli. *EuroIntervention*, *19*(4), e340–e351. https://doi.org/10.4244/EIJ-D-23-00011
19. Zornitzki, L., & Ben-Shoshan, J. (2025). Predictors of long-term survival in patients undergoing TAVR: Recent advances. A narrative review. *Polish Heart Journal*, *83*(10), 1134–1141. https://doi.org/10.33963/v.phj.108744