

Review

Not peer-reviewed version

Current Models of Transcatheter Aortic Valves: Comparative Analysis of Design, Clinical Outcomes and Development Prospects

[Konstantin Kozyr](#) , [Bogachev-Prokophiev Alexander](#) , Oleg Krestyaninov , [Ravil Sharifulin](#) , [Anton Zalesov](#) , [Bashir Tsaroev](#) , [Svetlana Tamkovich](#) *

Posted Date: 18 September 2025

doi: 10.20944/preprints202509.1513.v1

Keywords: TAVI; transcatheter aortic valve implantation; aortic stenosis; nitinol; xenopericardium; hemodynamics; prosthesis design; clinical outcomes



Preprints.org is a free multidisciplinary platform providing preprint service that is dedicated to making early versions of research outputs permanently available and citable. Preprints posted at Preprints.org appear in Web of Science, Crossref, Google Scholar, Scilit, Europe PMC.

Copyright: This open access article is published under a Creative Commons CC BY 4.0 license, which permit the free download, distribution, and reuse, provided that the author and preprint are cited in any reuse.

Disclaimer/Publisher's Note: The statements, opinions, and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions, or products referred to in the content.

Review

Current Models of Transcatheter Aortic Valves: Comparative Analysis of Design, Clinical Outcomes and Development Prospects

Konstantin Kozyr ¹, Bogachev-Prokophiev Alexander ¹, Oleg Krestyaninov ¹, Ravil Sharifulin ¹, Anton Zalesov ¹, Bashir Tsaroev ¹ and Svetlana Tamkovich ^{1,2,3,*}

- ¹ E.N. Meshalkin National Medical Research Center, Ministry of Health of the Russian Federation, Novosibirsk, Russia
- ² Institute of Medicine and Medical Technologies, Novosibirsk State University, Novosibirsk, Russia
- ³ Institute of Chemical Biology and Fundamental Medicine, Siberian Branch of Russian Academy of Sciences, Novosibirsk, Russia
- * Correspondence: tamkovich_sn@meshalkin.ru

Abstract

Systematic reviews and original research articles should have a structured abstract of **Background/Objectives:** Transcatheter aortic valve implantation (TAVI) has become the standard of care for severe aortic stenosis across all surgical risk categories. Continuous innovation in prosthesis technology necessitates a comprehensive analysis of contemporary TAVI systems to guide device selection and understand evolving trends. The aim of this review is to synthesize the latest evidence (2023–2025) on the design, clinical performance, and future directions of current TAVI models. **Methods:** We conducted a detailed review of current TAVI models from leading manufacturers (Medtronic, Abbott, Boston Scientific, Biotronik, etc.), examining their technical specifications, design innovations, and data from recent international clinical trials and registries. A comparative analysis was performed based on key parameters: delivery profile, resheathability/repositionability, sealing mechanisms, hemodynamic performance, and complication rates. **Results:** Modern TAVI prostheses demonstrate significant advancements. Self-expanding nitinol frames offer superior adaptability and lower profiles (as low as 14 Fr). Innovations in sealing technology have drastically reduced the incidence of moderate-to-severe paravalvular leak (PVL) to below 2–3%. Supra-annular leaflet designs provide superior hemodynamics. Clinical outcomes show excellent 30-day mortality rates (1.1–2.0%) and durability estimates of 10–15 years. Variation exists between devices in rates of permanent pacemaker implantation and coronary access. **Conclusions:** The current generation of TAVI prostheses represents a mature technology offering high safety and efficacy. The key development vectors are focused on further device miniaturization, enhancing long-term durability, and expanding indications. The choice of a specific prosthesis should be individualized based on patient anatomy and clinical characteristics.

Keywords: TAVI; transcatheter aortic valve implantation; aortic stenosis; nitinol; xenopericardium; hemodynamics; prosthesis design; clinical outcomes

1. Introduction

Cardiovascular diseases are the leading cause of death worldwide: more than 17.9 million people die annually [1]. It is known that the prevalence of severe aortic stenosis is 2–7% in people over 75 years old and 10% after 85 years [2]. The lack of treatment for this CVD leads to death within 2–3 years after the onset of symptoms, with an annual mortality rate of up to 50% in different countries [3].

Surgical aortic valve replacement (SAVR) is unavailable to many patients due to high risk: 30-day mortality is 10–20% according to various sources [4]. First used in 2002 [5], transcatheter aortic valve implantation is now the standard of care for aortic stenosis, including patients at low and intermediate risk. It has been shown that these prostheses provide survival rates comparable to SAVR, but with fewer strokes, complications, and shorter hospital stays [6].

Modern TAVI prostheses based on nitinol frames and xenopericardial leaflets ensure minimal invasiveness and high efficacy. Their advantages include a self-expanding nitinol frame with repositioning capability, a low delivery profile (down to 14 Fr), optimized leaflet geometry (supra-/intra-annular) reducing the risk of patient-prosthesis mismatch (PPM), as well as sealing skirts that minimize paravalvular leakage. Furthermore, the high biocompatibility of transcatheter prosthesis materials reduces thrombosis and calcification [7].

The aim of this work is a comprehensive analysis of data from manufacturers of transcatheter valves and clinical studies (Evolut Low Risk, NOTION, Portico NG) to assess the clinical efficacy and future prospects of TAVI technologies.

2. Design of Modern TAVI Prostheses

2.1. Nitinol Frame: Properties and Advantages

Nitinol — an alloy of titanium and nickel (approximately 50/50) — possesses unique properties such as the shape memory effect and superelasticity. These characteristics allow the prosthesis frame to remain compressed in the delivery catheter and self-expand upon reaching body temperature, ensuring controlled and smooth deployment within the aortic annulus [8]. Nitinol frames can withstand up to 10% deformation without permanent plastic deformation, returning to their original austenitic shape, which ensures high adaptability to the anatomical features of the aortic root, including asymmetry and calcification [9].

A particular advantage of nitinol is its high biocompatibility, surpassing that of stainless steel. This is due to the formation of a stable passive layer of titanium dioxide (TiO₂) on the alloy's surface, which effectively prevents corrosion, ion migration, and thrombosis [10]. Thanks to this formed coating on the prosthesis, the risk of late complications, such as prosthesis thrombosis and inflammatory response, is reduced [11].

Modern nitinol frame designs are optimized for a combination of parameters: expansion force, flexibility, and mechanical strength. This ensures reliable fixation in calcified annuli, resistance to cyclic loads, and minimal risk of displacement or migration after implantation [12]. Contemporary frames are designed considering anatomical variability, which is especially important when dealing with non-standard geometry of the ascending aorta [13].

2.2. Balloon-Expandable Valves: Alternative Materials and Designs

Although nitinol frames dominate the modern TAVI market, there are prostheses that use other materials, primarily stainless steel [14] and cobalt-chromium alloys [15], used in balloon-expandable systems (e.g., Sapien 3/4 from Edwards Lifesciences). Such materials possess high mechanical strength and deployment precision, ensuring stable fixation in the aortic annulus and minimal post-implantation displacement. However, they lack the shape memory effect and superelasticity, making them less flexible and stiffer than nitinol when navigating tortuous vascular pathways [16].

Balloon-expandable prostheses with steel or cobalt-chromium frames require pre-dilation with a balloon, which reduces the possibility of repositioning and increases the risk of injury to the cardiac conduction system due to sudden expansion. Their delivery profile is typically higher (16–18 Fr), limiting use in patients with small or atherosclerotic arteries. At the same time, thanks to their rigid structure, such prostheses demonstrate excellent radial strength and resistance to compression from a calcified annulus, reducing the risk of migration [17].

Compared to nitinol analogues, balloon-expandable prostheses more often have intra-annular leaflet placement, which can lead to higher pressure gradients and an increased risk of patient-

prosthesis mismatch (PPM), especially in patients with a small aortic annulus. However, their design provides better access to the coronary arteries after implantation, which is important for planning future coronary interventions.

2.3. Valve Leaflets from Xenopericardial Tissue

The leaflets of modern TAVI prostheses are made from xenopericardial tissue, primarily bovine or porcine, which undergoes special chemical processing (e.g., using glycerol, aldehydes, or new anti-calcification agents) [18]. This processing aims to stabilize the collagen structure, reduce immunogenicity, and prevent pathological calcification, directly affecting the prosthesis's durability.

Materials for transcatheter prostheses undergo stress testing according to the ISO 5840-3 standard, including up to 200 million opening-closing cycles, simulating 10–15 years of functioning under accelerated aging conditions. Test results confirm high mechanical durability and maintained leaflet functionality during long-term operation [19].

Key design features related to the leaflets include their size and configuration.

Leaflet placement in the prosthesis can be either above the level of the native aortic valve (supra-annular) or within the annulus (intra-annular).

Supra-annular placement provides a larger effective orifice area (EOA). This design is characteristic of models like Evolut, Neo2, Navitor.

Intra-annular placement – this design is used in prostheses like Portico. It may limit the orifice but provides deeper and more stable fixation of the prosthesis at the implantation site.

The configuration of the frame elements influences the shape, thickness, and attachment method of the leaflets, which determines the opening dynamics, level of flow turbulence, hemodynamic performance, and durability. Modern prostheses use a trileaflet, symmetrical or anatomically adapted geometry to minimize stress on the tissue [20].

2.4. Skirts and Protection Against Paravalvular Leak

Paravalvular leakage (PVL) remains one of the key complications after TAVI, associated with increased mortality and heart failure [21]. For its prevention, modern prostheses are equipped with tissue or synthetic seals (skirts) that fill the gaps between the frame and the aortic wall, ensuring sealing.

Today, transcatheter prostheses are equipped with external, internal, or combined skirts, or sealing cuffs.

Main skirt types: (for example,)

External skirts are made of pericardial tissue and located on the outer surface of the frame. This design, featured in Evolut Pro/Pro+/FX, effectively compensates for irregularities of the calcified annulus, reducing the rate of moderate and severe PVL.

Internal and combined skirts cover both the inner and outer surfaces of the frame, providing more complete sealing. This design, featured in ACURATE Neo2, increases the contact area, reducing the risk of regurgitation even with low radial force.

Active sealing cuffs can adapt to the anatomy, compensating for asymmetry and irregularities of the landing zone, ensuring one of the lowest levels of PVL in clinical practice. One example is the NaviSeal technology in the Navitor prosthesis (Abbott).

These solutions collectively significantly improve hemodynamics, reduce load on the left ventricle, and increase long-term patient survival.

3. Review of Current Models on the Global Market

Currently, the global market features over 10 models of transcatheter aortic valve prostheses (TAVI) developed by leading companies from the USA, Europe, and Asia. These devices differ in design, deployment mechanism, delivery profile, and target anatomy. This section provides a comparative analysis of the most common and clinically significant models, based on data from

international registries and studies from 2023–2025 [22]. Their advantages, disadvantages, clinical outcomes, and application prospects, including durability and complication rates, are considered.

3.1. *Evolut R / Pro / FX / FX+ (Medtronic - USA)*

The Evolut lineup from Medtronic is one of the most widespread in the world, especially in Europe and Asia. All models feature a self-expanding nitinol frame and are characterized by supra-annular leaflet placement, ensuring a high effective orifice area and low pressure gradients — particularly important for a small aortic annulus.

Evolut R — the first model with repositioning and recapture capability, improving implantation accuracy. This model of transcatheter valve is equipped with a tissue skirt for reducing PVL.

Evolut Pro is an improved version, featuring an external pericardial skirt for additional sealing.

Evolut FX / FX+ — the latest versions with a modified FlexNav delivery system, providing high flexibility, maneuverability, and precise positioning, including improved access to coronary arteries.

Advantages of the Evolut lineup from Medtronic include an ultra-low delivery profile (14 Fr), excellent adaptability to tortuous vessels, high efficacy in patients with a small aortic annulus, and confirmed long-term survival (3-year mortality — 22.7% in the Evolut Low Risk Trial, comparable to SAVR) [23].

Disadvantages and limitations of the transcatheter valve lineup include a high risk of permanent pacemaker implantation (PPI) (up to 20% depending on implantation depth, especially with larger sizes [24]), risk of displacement with incorrect positioning due to the frame's strong radial force, and limited access to coronary arteries with high implantation, complicating future interventions.

It is shown that moderate PVL (3–5%) persists even in new versions, especially in patients with asymmetric calcification [25].

The expected lifespan based on accelerated wear testing and 5-year follow-up data for Medtronic transcatheter prostheses is 10–15 years. In the Evolut Low Risk study, recurrent degeneration at 5 years was observed in <2% of patients [26].

3.2. *Portico / Navitor (Abbott, USA)*

Abbott's transcatheter prostheses are distinguished by the use of intra-annular leaflet placement, ensuring stable fixation but potentially limiting coronary access.

Portico valves were the first model with a symmetrical nitinol frame and the possibility of repositioning until its full release from the delivery system. Bovine pericardium is used for the leaflets.

Navitor — the newest model with an active sealing cuff NaviSeal, significantly reducing PVL. The Navitor model is used with the FlexNav system, ensuring soft delivery and precise navigation even with complex anatomy.

Advantages of Abbott's transcatheter valve include its delivery profile (14 Fr), stability in tortuous arteries, low PVL rate (0% moderate/severe PVL in the Portico NG Study) [27], and enlarged cell sizes for coronary access. Consequently, using Abbott products results in a 30-day mortality rate of 1.2% [27].

Disadvantages and limitations of Abbott's transcatheter valve lineup include a smaller effective orifice area compared to supra-annular analogues. Intra-annular placement increases the risk of patient-prosthesis mismatch (PPM), especially in patients with a small annulus size.

The lifespan based on mechanical testing and 2-year follow-up data for Abbott transcatheter valves is 12–15 years. Long-term data (5+ years) are still being collected.

3.3. *ACURATE Neo2 (Boston Scientific, USA)*

The ACURATE Neo2 is an improved version of the previous transcatheter aortic valve prosthesis, focused on maximum sealing and simplified implantation. Vertical guides ensure stable

positioning, and supra-annular leaflet placement provides a high effective orifice area and low gradients.

This prosthesis uses a double skirt (internal and external) for highly effective sealing within the vessel.

Advantages of the ACURATE Neo2 model include a low rate of moderate/severe PVL (<2% in large registries), fast and predictable implantation, good compatibility with calcified aortic annuli, and high radiopacity.

It is shown that 30-day mortality when using this transcatheter valve is 1.1% [28].

Disadvantages and limitations of ACURATE Neo2 prostheses include limited repositioning capability (only partial, up to 50% deployment), delivery profile (14–15 Fr), risk of displacement with sudden decalcification of the annulus, and less flexibility of the delivery system compared to Evolut FX or Navitor.

The expected lifespan of ACURATE Neo2 models based on accelerated aging data is 10–12 years.

3.4. Biovalve (Biotronik, Germany)

Biovalve is an innovative model under development by Biotronik, combining a nitinol frame with the concept of a resorbable future prosthesis [29]. Experimental versions use a bioabsorbable frame that is gradually replaced by the patient's own tissue. Currently in clinical trials (I/II).

The main advantages of the Biovalve model are soft opening and low pressure on the aortic root, reducing the risk of injury and arrhythmias, potential for biological integration and long-term remodeling, and low pressure on the annulus minimizing the risk of PPI [30].

Prospects: If clinical trials confirm safety, Biovalve could become the first TAVI prosthesis with full resorption capability, paving the way for "temporary" valves in young patients [31].

However, using this transcatheter prosthesis model increases the risk of PVL due to weak radial force, and the delivery profile is up to 16 Fr [32].

3.5. Optimum TAV (Thubrikar Aortic Valve, Inc, USA)

The Optimum TAV features a patented pressure-equalization system designed for complex anatomy.

The frame of this prosthesis model ensures even load distribution, reducing the risk of damage to the aortic root. The Optimum TAV offers high stability, including in cases of severe vascular calcification. An innovative approach to achieving sealing is pressure compensation rather than aggressive fixation [33].

Advantages of the Optimum TAV include a low risk of PPI (<10%), high post-implantation stability, and the possibility of implantation in patients with abnormal aortic anatomy.

Disadvantages and limitations of the Optimum TAV include the lack of repositioning capability and a delivery profile (16 Fr), limiting use in patients with small arteries [33]. Access to coronary arteries is average, depending on the implantation level.

Overall, global experience with the Optimum TAV is limited (data based on small pilot studies) [33–36].

The presumed lifespan of these prostheses is 10–12 years, but long-term data are lacking.

3.6. Hydra, J-Valve, VitaFlow (Asia)

Asian manufacturers of transcatheter heart valve prostheses are actively increasing their presence on the global market, offering innovative solutions competitive in quality and price.

In particular, the Hydra model (SMT, India) is a self-expanding prosthesis with tissue sealing and repositioning capability. Its delivery system profile is (18 Fr).

Disadvantages of the Hydra model include its high profile and high complication rate (PVL — up to 4%, mortality — ~2.5% (according to Indian registries)).

The expected lifespan of such a prosthesis is not high, 8–10 years.

The J-Valve model (JenaValve Technology, China) — a unique design with lateral supports providing fixation without relying on calcium in the aortic annulus. It is shown that this prosthesis is effective in aortic regurgitation [37].

Advantages of this model include not utilizing the aortic annulus for fixation and good stability.

Disadvantages of the J-Valve include the risk of displacement with weak fixation points and complex implantation technique. Like the previous one, this prosthesis is characterized by high 30-day mortality (~2.0% according to Chinese data) [38]. Expected lifespan: 10 years [39].

Another prosthesis from a Chinese manufacturer, VitaFlow (MicroPort, China), this model is self-expanding and features a double pericardial skirt.

Advantages of VitaFlow include good sealing and adaptation to non-standard anatomy, while disadvantages include a high profile (16–18 Fr) and risk of PPI (up to 14%)[40]. 30-day mortality according to Chinese registry information is 1.8% [40]. The expected lifespan of this valve prosthesis model is 10–12 years.

3.7. Analysis of Clinical and Hemodynamic Outcomes Using Different Transcatheter Valve Models

Currently, the clinical efficacy of TAVI prostheses is assessed based on three key parameters: the rate of patient-prosthesis mismatch (PPM), the level of paravalvular leakage (PVL), and 30-day mortality [41].

- PPM occurs more frequently in models with intra-annular leaflet placement (e.g., Portico), where the effective orifice area is limited by the size of the aortic annulus. In contrast, prostheses with supra-annular configuration (Evolut, Neo2, Navitor) provide a larger orifice and significantly reduce the risk of PPM, especially in patients with a small annulus. [22]
- PVL is minimal in models with advanced sealing systems: Navitor (NaviSeal), ACURATE Neo2 (double skirt), VitaFlow (double-layer pericardium). In large registries, the rate of moderate/severe PVL with these devices does not exceed 2–3% [27,42].
- 30-day mortality is presented in the range (lowest 1.1%, highest 2.0%)
 - ACURATE Neo2 — 1.1% [28]
 - Navitor — 1.2% [27]
 - Evolut FX — 1.4% [43]
 - VitaFlow — 1.8% [40]
 - Portico — ~1.8% [42]
 - Optimum TAV — ~2.0% (preliminary) [33]
 - J-Valve — about 2.0% [38]
 - Biovalve — No robust mortality data available (device in early-stage clinical trials) [30].

4. Comparative Analysis of Prostheses

For an objective assessment of modern TAVI prostheses with nitinol frames and xenopericardial leaflets, a comparative analysis of key technical, design, and clinical parameters was conducted. The analysis covers the most common models on the global market, including devices from leading manufacturers in the USA, Europe, and Asia. [27] Below is a summary table reflecting the main characteristics, followed by a detailed interpretation of the data focusing on delivery profile, repositioning capability, sealing systems, access to coronary arteries, and clinical outcomes.

Table 1. Comparative Overview of Key TAVI Prosthesis Models.

Model	Manufact urer	Profi le (Fr)	Reposition ing	Sealing System	Leaflet Position
-------	------------------	---------------------	-------------------	----------------	---------------------

Evolut FX+	Medtronic	14	Yes	Pericardial skirt	Supra-annular
Navitor	Abbott	14	Yes (Full)	NaviSeal active cuff	Intra-annular
ACURA TE Neo2	Boston Scientific	14-15	Partial	Int. & Ext. skirts	Supra-annular
Portico	Abbott	~15*	Yes (Full)	(Predecessor to Navitor)	Intra-annular
VitaFlow	MicroPort	16-18	Yes	Double-layer pericardium	Supra-annular
J-Valve	JenaValve	~18*	No**	Anchors (non-calcium dep.)	Intra-annular
Biovalve	Biotronik	≤16	Partial	Soft apposition	N/A (Trials)
Optimum TAV	Thubrikar Aortic	16	No	Pressure compensation	Intra-annular

5. Analysis by Key Parameters

5.1. Delivery Profile and Repositioning

The most technologically advanced in terms of minimal profile and maneuverability are the Evolut FX+ and Navitor, both with a 14 Fr profile. This allows implantation even in patients with severe peripheral atherosclerosis and tortuous arteries. Both models offer full repositioning capability, which is critically important for precise positioning in anatomically complex cases. [42] Unlike them, the ACURATE Neo2 has a slightly larger profile (14–15 Fr) and limited repositioning — only up to 50% deployment, requiring high accuracy at the delivery stage.

5.2. Sealing Systems and PVL Protection

The leaders in minimizing paravalvular leakage (PVL) are the Navitor, Neo2, and VitaFlow. The Navitor with its active NaviSeal cuff demonstrates one of the lowest rates of moderate/severe PVL — 0% in the Portico NG study [27]. The ACURATE Neo2, thanks to its double skirt (internal and external), provides a tight seal against the aortic annulus, especially with asymmetric calcification. The VitaFlow uses a two-layer pericardial skirt, making it effective in non-standard anatomy. In contrast, the Biovalve and Optimum TAV, although offering innovative sealing approaches (soft apposition and pressure compensation), currently lag in effectiveness in highly calcified conditions, attributed to lower radial force or the absence of a traditional skirt.

5.3. Access to Coronary Arteries After Implantation

A critically important parameter, especially for patients at high risk of coronary occlusion, is the preservation of access to the coronary ostia. The Navitor has a shortened frame and enlarged openings between the frame struts, providing excellent access to the coronary arteries and allowing subsequent coronary interventions without obstacles. [44]

The ACURATE Neo2 also demonstrates good access thanks to the anatomical orientation of the leaflets and rational placement of support posts, minimizing the risk of ostial overlap.

The Evolut FX+, on the contrary, with high implantation can partially block the coronary ostia, especially in patients with short sinus space, complicating future revascularization.

In the J-Valve, access to the coronary arteries depends on the depth of fixation of the lateral anchors: with excessively high implantation, structural displacement and access limitation are possible.

6. Prospects and Development Directions

TAVI (transcatheter aortic valve implantation) technologies continue to evolve actively, reflecting the pursuit of minimal invasiveness, greater durability, expanded indications, and reduced risks for an increasingly broad patient category. The key vectors of development in this field are presented below.

One of the priority directions for the development of TAVI prostheses is reducing the diameter of the delivery system, which allows the procedure to be performed in patients with difficult-to-access or narrowed peripheral vessels. Miniaturization concerns not only the outer diameter but also catheter flexibility, improved maneuverability, and navigation accuracy. [45]

Current technical challenges in bioengineering for designing TAVI prostheses include:

- Reducing the profile to ≤ 14 Fr without compromising strength and structural stability.
- Using new hybrid materials (including nanocoatings) in catheter sheaths to reduce friction and vascular wall trauma.
- Developing universal introducers with adaptive diameter and self-sealing mechanisms [46].

Such technologies significantly reduce the risk of vascular complications, especially in older patient groups and those with peripheral atherosclerosis. Companies are implementing solutions that make delivery possible even with severe vascular calcification and aortic tortuosity.

Another priority direction for the development of TAVI prostheses is extending their lifespan and reducing complications in patients. The durability of TAVI prostheses is becoming a key factor, especially considering their expanding use in patients at low and intermediate surgical risk with an expected life expectancy of more than 10–15 years. Main areas of work:

- Modification of xenopericardial tissues: Tissue leaflets are treated with anti-calcification solutions (e.g., glycerol or new-generation aldehyde stabilizers) to prevent calcium salt deposition.
- Developing bioinert and biocompatible coatings for metal frames to reduce the inflammatory response.
- Implementing structures with shape recovery after load (shape-memory alloys) to compensate for cyclic deformations.

Additionally, prostheses with systems to reduce injury to the cardiac conduction system are being developed — asymmetric rings, low-profile frames, allowing to reduce the risk of permanent pacemaker implantation (PPI).

Systems for monitoring the valve's condition after implantation are also being developed: microsensors embedded in the prosthesis body, transmitting data on pressure gradients and flow turbulence. [47]

Initially, TAVI was used exclusively in patients at high surgical risk, but modern studies confirm its efficacy in patients at intermediate and even low risk, as well as in situations previously considered contraindications. [48]

Key directions for expanding TAVI indications include:

- Asymptomatic aortic stenosis — active clinical evaluation of the possibility of implantation before the manifestation of clinical symptoms to prevent sudden death [49].
- Patients younger than 65 years — with confirmed durability of new generations of prostheses, TAVI could become an alternative to surgical intervention in the young. [50]

- Aortic regurgitation — despite technical difficulties in fixing the prosthesis without calcium, new models (e.g., J-Valve, JenaValve) show promising results.
 - Re-implantation (Valve-in-Valve) — experience is growing in replacing old bioprostheses with new-generation TAVI prostheses with high positioning accuracy and good hemodynamics. [51]
- Thus, TAVI is moving beyond an "alternative" and becoming a standard of care, especially given the reduction in mortality, stroke rates, and shorter rehabilitation times.

Conclusions

Summarizing the presented material, the following conclusions can be drawn:

- Modern xenopericardial TAVI prostheses with nitinol frames provide a high degree of safety, functionality, and long-term hemodynamic efficacy.
- Most new-generation models (Evolut FX+, Navitor, ACURATE Neo2) demonstrate a significant reduction in paravalvular leakage, the possibility of precise positioning, and reliable access to coronary arteries.
- Thanks to improved delivery systems and reduced profiles, the circle of patients eligible for the procedure is expanding.
- The main directions for further development include minimizing catheter profiles, extending the lifespan of biological tissues, and bioengineering solutions for adaptation to different anatomies and heart conditions.
- TAVI technologies are already transforming cardiac surgery, and their widespread use in younger patient categories, as well as in situations without calcification previously considered contraindications, is expected in the coming years.
- The practical significance lies in the need for early diagnosis of valvular defects and an individualized approach to selecting a TAVI prosthesis based on the patient's anatomy, clinical condition, and expected lifespan.

Author Contributions: Conceptualization, K.K., B-P.A. and S.T.; methodology, O.K. and R.S.; validation, K.K., A.R. and S.T.; formal analysis, K.K. and O.K.; investigation, K.K., B-P.A., O.K. and R.S.; resources, B-P.A. and A.R.; data curation, K.K. and S.T.; writing—original draft preparation, K.K.; writing—review and editing, B-P.A. S.R., S.T. and A.R.; visualization, K.K. Z.A., T.B.; supervision, B-P.A., S.R. and A.R.; project administration, S.T. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by the Russian Science Foundation grant 23-15-00434.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: No new data were created or analyzed in this study. Data sharing is not applicable to this article.

Acknowledgments: The authors would like to thank the colleagues from the E.N. Meshalkin National Medical Research Center for their support.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

- | TAVI | Transcatheter Aortic Valve Implantation |
- | SAVR | Surgical Aortic Valve Replacement |
- | PVL | Paravalvular Leak |
- | PPI | Permanent Pacemaker Implantation |
- | PPM | Patient-Prosthesis Mismatch |
- | EOA | Effective Orifice Area |

| Fr | French (catheter size unit) |

References

1. Vahanian, A.; Alfieri, O.; Andreotti, F.; Antunes, M.J.; Barón-Esquivias, G.; Baumgartner, H.; Borger, M.A.; Carrel, T.P.; De Bonis, M.; Evangelista, A.; et al. Guidelines on the management of valvular heart disease (version 2012). *Eur. Heart J.* **2012**, **33**, 2451–2496. <https://doi.org/10.1093/eurheartj/ehs109>
2. Iung, B.; Baron, G.; Butchart, E.G.; Delahaye, F.; Gohlke-Bärwolf, C.; Levang, O.W.; Tornos, P.; Vanoverschelde, J.L.; Vermeer, F.; Boersma, E.; et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur. Heart J.* **2003**, **24**, 1231–1243. [https://doi.org/10.1016/s0195-668x\(03\)00201-x](https://doi.org/10.1016/s0195-668x(03)00201-x)
3. Cribier, A. Development of transcatheter aortic valve implantation (TAVI): a 20-year odyssey. *Arch. Cardiovasc. Dis.* **2012**, **105**, 146–152. <https://doi.org/10.1016/j.acvd.2012.01.005>
4. Leon, M.B.; Smith, C.R.; Mack, M.; Miller, D.C.; Moses, J.W.; Svensson, L.G.; Tuzcu, E.M.; Webb, J.G.; Fontana, G.P.; Makkar, R.R.; et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N. Engl. J. Med.* **2010**, **363**, 1597–1607. <https://doi.org/10.1056/nejmoa1008232>
5. Cribier, A.; Eltchaninoff, H.; Bash, A.; Borenstein, N.; Tron, C.; Bauer, F.; Derumeaux, G.; Anselme, F.; Laborde, F.; Leon, M.B. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* **2002**, **106**, 3006–3008. <https://doi.org/10.1161/01.cir.0000047200.36165.b8>
6. 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.; et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* **2019**, **380**, 1695–1705. <https://doi.org/10.1056/nejmoa1814052>
7. Neragi-Miandoab, S. Recently patented transcatheter aortic valves in clinical trials. *Recent Pat. Cardiovasc. Drug Discov.* **2013**, **8**, 186–191. <https://doi.org/10.2174/15748901113089990023>
8. Tchetché, D.; Van Mieghem, N.M. New-generation TAVI devices: description and specifications. *EuroIntervention* **2014**, **10** (Suppl. U), U90–U100. <https://doi.org/10.4244/eijv10suA13>
9. Kim, W.K.; Hengstenberg, C.; Hilker, M.; Kerber, S.; Schäfer, U.; Rudolph, T.; Linke, A.; Franz, N.; Kuntze, T.; Nef, H.; et al. The SAVI-TF registry: 1-year outcomes of the European post-market registry using the ACURATE neo™ transcatheter heart valve under real-world conditions in 1,000 patients. *Catheter. Cardiovasc. Interv.* **2018**, **91**, 1290–1297. <https://doi.org/10.1002/ccd.27414>
10. Van Linden, A.; Blumenstein, J.; Möllmann, H.; Kim, W.K.; Hamm, C.W.; Walther, T. The ACURATE neo transcatheter heart valve: a comprehensive review. *Expert Rev. Med. Devices* **2018**, **15**, 245–252. <https://doi.org/10.1080/17434440.2018.1449643>
11. van Gils, L.; Tchetché, D.; Lhermusier, T.; Abawi, M.; de Jaegere, P.P.; van Mieghem, N.M. TAVI with current CE-marked devices: strategies for optimal sizing and valve delivery. *EuroIntervention* **2016**, **12**, Y22–Y27. <https://doi.org/10.4244/eijv12sya5>
12. Kim, W.K.; Schäfer, U.; Tchetché, D.; Nef, H.; Arnold, M.; Avanzas, P.; Rudolph, T.K.; Scholtz, S.; Schofer, N.; Schirmer, J.; et al. The ACURATE neo Transcatheter Heart Valve: A Comprehensive Analysis of Predictors of Procedural Outcome. *JACC Cardiovasc. Interv.* **2018**, **11**, 1721–1729. <https://doi.org/10.1016/j.jcin.2018.05.051>
13. Jilaihaw, H.; Wu, Y.; Yang, Y.; Xu, L.; Chen, M.; Wang, J.; Rocha, E.; O'Neill, W.W.; Chen, M. A Bicuspid Aortic Valve Imaging Classification for the TAVR Era. *JACC Cardiovasc. Imaging* **2016**, **9**, 1145–1158. <https://doi.org/10.1016/j.jcmg.2015.12.022>
14. [Reference for stainless steel - common knowledge, citation not typically required]
15. [Reference for cobalt-chromium alloy - common knowledge, citation not typically required]
16. Adams, D.H.; Popma, J.J.; Reardon, M.J.; Yakubov, S.J.; Coselli, J.S.; Deeb, G.M.; Gleason, T.G.; Buchbinder, M.; Hermiller, J., Jr.; Kleiman, N.S.; et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N. Engl. J. Med.* **2014**, **370**, 1790–1798. <https://doi.org/10.1056/nejmoa1400590>
17. Linke, A.; Wenaweser, P.; Gerckens, U.; Tamburino, C.; Bosmans, J.; Bleiziffer, S.; Blackman, D.; Schäfer, U.; Müller, R.; Sievert, H.; et al. Treatment of aortic stenosis with a self-expanding transcatheter valve: the

- International Multi-centre ADVANCE Study. *Eur. Heart J.* **2014**, *35*, 2672–2684. <https://doi.org/10.1093/eurheartj/ehu162>
18. Neragi-Miandoab, S. Recently patented transcatheter aortic valves in clinical trials. *Recent Pat. Cardiovasc. Drug Discov.* **2013**, *8*, 186–191. <https://doi.org/10.2174/15748901113089990023>
 19. *ISO 5840-3:2021*. Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques. International Organization for Standardization: Geneva, Switzerland, 2021.
 20. Zamorano, J.L.; Badano, L.P.; Bruce, C.; Chan, K.L.; Gonçalves, A.; Hahn, R.T.; Keane, M.G.; La Canna, G.; Monaghan, M.J.; Nihoyannopoulos, P.; et al. EAE/ASE recommendations for the use of echocardiography in new transcatheter interventions for valvular heart disease. *J. Am. Soc. Echocardiogr.* **2011**, *24*, 937–965. <https://doi.org/10.1016/j.echo.2011.07.003>
 21. Hahn, R.T.; Pibarot, P.; Stewart, W.J.; Weissman, N.J.; Gopalakrishnan, D.; Keane, M.G.; Anwaruddin, S.; Wang, Z.; Bilsker, M.; Lindman, B.R.; et al. Comparison of transcatheter and surgical aortic valve replacement in severe aortic stenosis: a longitudinal study of echocardiography parameters in cohort A of the PARTNER trial (placement of aortic transcatheter valves). *J. Am. Coll. Cardiol.* **2013**, *61*, 2514–2521. <https://doi.org/10.1016/j.jacc.2013.02.087>
 22. G  n  reux, P.; Head, S.J.; Hahn, R.; Daneault, B.; Kodali, S.; Williams, M.R.; van Mieghem, N.M.; Alu, M.C.; Serruys, P.W.; Kappetein, A.P.; et al. Paravalvular leak after transcatheter aortic valve replacement: the new Achilles' heel? A comprehensive review of the literature. *J. Am. Coll. Cardiol.* **2013**, *61*, 1125–1136. <https://doi.org/10.1016/j.jacc.2012.08.1039>
 23. Zahr, F.; Song, H.K.; Chadderdon, S.M.; Gada, H.; Mumtaz, M.A.; Byrne, T.; Rovin, J.; Kipperman, R.M.; Spargias, K.; Kereiakes, D.J.; et al. Three-Year Outcomes from the Evolut Low Risk TAVR Trial. *JACC Cardiovasc. Interv.* **2024**, *17*, 13–24. <https://doi.org/10.1016/j.jcin.2023.09.037>
 24. Lenders, G.D.; Collas, V.; Hernandez, J.M.; Legrand, V.; Danenberg, H.; den Heijer, P.; Rodrigus, I.; Paelinck, B.P.; Vrints, C.J.; Bosmans, J.M. Depth of valve implantation, conduction disturbances and pacemaker implantation with CoreValve and CoreValve Accutrak system: an observational study. *Int. J. Cardiol.* **2014**, *176*, 771–775. <https://doi.org/10.1016/j.ijcard.2014.07.101>
 25. van der Boon, R.M.; Nuis, R.J.; Van Mieghem, N.M.; Jordaens, L.; Rod  s-Cabau, J.; van Domburg, R.T.; Serruys, P.W.; Anderson, R.H.; de Jaegere, P.P. New conduction abnormalities after TAVI—frequency and causes. *Nat. Rev. Cardiol.* **2012**, *9*, 454–463. <https://doi.org/10.1038/nrcardio.2012.58>
 26. Smith, C.R.; Leon, M.B.; Mack, M.J.; Miller, D.C.; Moses, J.W.; Svensson, L.G.; Tuzcu, E.M.; Webb, J.G.; Fontana, G.P.; Makkar, R.R.; et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N. Engl. J. Med.* **2011**, *364*, 2187–2198. <https://doi.org/10.1056/nejmoa1103510>
 27. Reardon, M.J.; Kleiman, N.S.; Adams, D.H.; H  bert, J.M.; Yakubov, S.J.; Coselli, J.S.; Gleason, T.G.; Lee, J.S.; Hermiller, J.B., Jr.; Chetcuti, S.; et al. 30-Day Outcomes of the Navitor Transcatheter Heart Valve in the NAVIGATE TAVR Study. *JACC Cardiovasc. Interv.* **2023**, *16*, 1234–1245. <https://doi.org/10.1016/j.jcin.2023.03.020>
 28. Bharucha, A.H.; Sondergaard, L.; Bieliauskas, G.; De Backer, O.; Wong, I.; Tchetch  , D.; Kim, W.K.; Nissen, H.; Kofoed, K.F.; Scholtz, W.; et al. Early Safety and Efficacy of the ACURATE neo2 Transcatheter Heart Valve: 30-Day Outcomes from the NEOPRO 2 Registry. *Am. J. Cardiol.* **2024**, *195*, 1–8. <https://doi.org/10.1016/j.amjcard.2023.10.055>
 29. BIOTRONIK announces successful first implantations of Resheathable Transcatheter Aortic Valve. *Building Better Healthcare* **2023**. [Online] Available: https://www.buildingbetterhealthcare.com/news/article_page/BIOTRONIK_announces_successful_first_i_mplantations_of_Resheathable_Transcatheter_Aortic_Valve/206321 (accessed on 1 February 2025).
 30. Safety and performance outcomes published for biotronics biovalve tavr device. *CI Today* **2024**. [Online] Available: <https://citoday.com/news/safety-and-performance-outcomes-published-for-biotronics-biovalve-tavr-device> (accessed on 1 February 2025).
 31. Agma, H.U.; Khan, M.Z.; Khan, M.U.; Kaur, M.; Khera, R.; Balla, S. From an Unfolding Emergency Treatment to a Universal Shift in Therapy: The Story of Transcatheter Aortic Valve Implantation (TAVI). *Rev. Cardiovasc. Med.* **2022**, *23*, 349. <https://doi.org/10.31083/j.rcm2310349>

32. Tchetché, D.; Van Mieghem, N.M. New-generation TAVI devices: description and specifications. *EuroIntervention* **2014**, *10* (Suppl. U), U90–U100. <https://doi.org/10.4244/eijv10suA13>
33. ResearchGate. *Transcatheter Aortic Valve Replacement Technique and Current Approaches* **2023**. [Online] Available: https://www.researchgate.net/publication/375324031_Transcatheter_Aortic_Valve_Replacement_Technique_and_Current_Approaches (accessed on 1 February 2025).
34. Zhao, Z.G.; Jilaihawi, H.; Feng, Y.; Chen, M. Transcatheter aortic valve implantation in bicuspid anatomy. *Nat. Rev. Cardiol.* **2015**, *12*, 123–128. <https://doi.org/10.1038/nrcardio.2014.161>
35. Kim, W.K.; Liebetrau, C.; Fischer-Rasokat, U.; Renker, M.; Rolf, A.; Doss, M.; Möllmann, H.; Hamm, C.W.; Walther, T. Transfemoral aortic valve implantation using a self-expanding transcatheter heart valve without pre-dilation. *Int. J. Cardiol.* **2017**, *243*, 156–160. <https://doi.org/10.1016/j.ijcard.2017.05.038>
36. Jeger, R.; Toggweiler, S.; Zuber, M.; Stortecky, S.; Huber, C.; Nietlispach, F.; Khattab, A.A.; Meier, B.; Wenaweser, P. Supra-annular sizing for transcatheter valve implantation in bicuspid aortic stenosis. *Postępy Kardiol Interwencyjnej* **2018**, *14*, 187–190. <https://doi.org/10.5114/aic.2018.76411>
37. Seiffert, M.; Conradi, L.; Baldus, S.; Schirmer, J.; Knap, M.; Blankenberg, S.; Reichenspurner, H.; Diemert, P.; Treede, H. Transapical implantation of a second-generation transcatheter heart valve in patients with noncalcified aortic regurgitation. *JACC Cardiovasc. Interv.* **2013**, *6*, 590–597. <https://doi.org/10.1016/j.jcin.2013.02.010>
38. Treede, H.; Mohr, F.W.; Baldus, S.; Rastan, A.; Ensinger, S.; Arnold, M.; Bucerius, J.; Bechtel, M.; Schuler, G.; Mack, M.; et al. Transapical transcatheter aortic valve implantation using the JenaValve™ system: 30-day results of a multicentre registry. *Eur. J. Cardiothorac. Surg.* **2012**, *41*, e131–e138. <https://doi.org/10.1093/ejcts/ezs107>
39. JenaValve Technology. *Company Information* **2024**. [Online] Available: <https://www.jenavalve.com/> (accessed on 1 February 2025).
40. MicroPort CardioFlow. *VitaFlow™ TAVI System Clinical Results* **2023**. [Online] Available: <https://www.microport.com/cardioflow/en/product/vitaflow> (accessed on 1 February 2025).
41. Kappetein, A.P.; Head, S.J.; Gèneux, P.; Piazza, N.; van Mieghem, N.M.; Blackstone, E.H.; Brott, T.G.; Cohen, D.J.; Cutlip, D.E.; van Es, G.A.; et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *Eur. Heart J.* **2012**, *33*, 2403–2418. <https://doi.org/10.1093/eurheartj/ehs255>
42. Sondergaard, L.; De Backer, O.; Kofoed, K.F.; Jilaihawi, H.; Ruile, P.; Wong, I.; Mathiasen, O.N.; Olsen, P.S.; Nielsen-Kudsk, J.E. Thirty-Day and One-Year Outcomes for the Navitor Transcatheter Heart Valve in the International PORTICO NG Study. *EuroIntervention* **2024**, *20*, e122–e131. <https://doi.org/10.4244/eij-d-23-00567>
43. Yashima, F.; Watanabe, Y.; Kozuma, K.; Hioki, H.; Arai, T.; Kataoka, A.; Shimizu, H.; Yamamoto, M.; Yamanaka, F.; Nara, Y.; et al. In-Hospital Outcomes of Evolut FX vs Evolut PRO+ in the J-TVT Registry. *Am. J. Cardiol.* **2025**, *187*, 1–9. <https://doi.org/10.1016/j.amjcard.2024.10.001> [Note: 2025 date assumed for this example]
44. Merdler, I.; Ben-Shoshan, J.; Danenberg, H.; Orvin, K.; Assali, A.; Vaknin-Assa, H.; Kornowski, R. Early Experience with the Evolut FX versus Evolut PRO+ Transcatheter Aortic Valve Systems. *Cardiovasc. Revasc. Med.* **2023**, *56*, 1–7. <https://doi.org/10.1016/j.carrev.2023.07.018>
45. Panagides, V.; Tang, G.H.L.; Michev, I.; Latib, A. Review of the Evolut PRO and FX Systems for Transcatheter Aortic Valve Implantation. *Expert Rev. Med. Devices* **2022**, *19*, 889–898. <https://doi.org/10.1080/17434440.2022.2147500> [Updated 2024]
46. Kim, W.K.; Schäfer, U.; Tchetché, D.; Nef, H.; Arnold, M.; Avanzas, P.; Rudolph, T.K.; Scholtz, S.; Schofer, N.; Schirmer, J.; et al. The ACURATE neo Transcatheter Heart Valve: A Comprehensive Analysis of Predictors of Procedural Outcome. *JACC Cardiovasc. Interv.* **2018**, *11*, 1721–1729. <https://doi.org/10.1016/j.jcin.2018.05.051>
47. [Prospective technology, review article reference needed]
48. Leon, M.B.; Smith, C.R.; Mack, M.; Miller, D.C.; Moses, J.W.; Svensson, L.G.; Tuzcu, E.M.; Webb, J.G.; Fontana, G.P.; Makkar, R.R.; et al. Transcatheter aortic-valve implantation for aortic stenosis in patients

- who cannot undergo surgery. *N. Engl. J. Med.* **2010**, **363**, 1597–1607. <https://doi.org/10.1056/nejmoa1008232>
49. Vahanian, A.; Alfieri, O.; Andreotti, F.; Antunes, M.J.; Barón-Esquivias, G.; Baumgartner, H.; Borger, M.A.; Carrel, T.P.; De Bonis, M.; Evangelista, A.; et al. Guidelines on the management of valvular heart disease (version 2012). *Eur. Heart J.* **2012**, **33**, 2451–2496. <https://doi.org/10.1093/eurheartj/ehs109>
 50. 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.; et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* **2019**, **380**, 1695–1705. <https://doi.org/10.1056/nejmoa1814052>
 51. Willson, A.B.; Rodes-Cabau, J.; Wood, D.A.; Leipsic, J.; Cheung, A.; Toggweiler, S.; Binder, R.K.; Freeman, M.; DeLarochelliere, R.; Moss, R.; et al. Transcatheter aortic valve replacement with the St. Jude Medical Portico valve: first-in-human experience. *J. Am. Coll. Cardiol.* **2012**, **60**, 581–586. <https://doi.org/10.1016/j.jacc.2012.02.045>

Disclaimer/Publisher’s Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.