

Aortic Bioprostheses: Surgical, Sutureless, and Transcatheter Devices

Bioprothèses aortiques: chirurgicales, sutureless, et trans-cathéters.

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SUMMARY

Bioprosthetic valves have become the dominant substitute for the treatment of severe aortic stenosis, reflecting an ageing candidate population and a growing preference for avoiding long-term anticoagulation. Four decades of iterative design have produced four broad families of aortic bioprostheses: stented surgical valves, stentless surgical valves, sutureless/rapid-deployment valves, and transcatheter heart valves. Each family has undergone successive generational refinements aimed at improving effective orifice area, reducing paravalvular leak, mitigating structural valve deterioration (SVD), and facilitating future valve-in-valve reintervention. This narrative review synthesises the comparative clinical evidence for the principal contemporary devices — including the Carpentier-Edwards Perimount/Magna Ease and Inspiris RESILIA lineage, the Trifecta/Trifecta GT, Mitroflow/Crown PRT, Avalus, and porcine-derived valves among stented bioprostheses; the Freestyle and Freedom Solo among stentless designs; the Perceval and Intuity Elite among sutureless/rapid-deployment devices; and the Sapien, Evolut, ACURATE neo/neo2, Portico/Navitor, and Myval families among transcatheter valves. Randomised trials and large registries are reviewed to characterise durability, haemodynamic performance, and safety, and a framework for individualised device selection is proposed based on patient age, aortic root anatomy, operative risk, and anticipated lifetime management strategy. We conclude by outlining anti-calcification tissue engineering, polymeric leaflet technology, and artificial-intelligence-assisted sizing as the principal axes of ongoing innovation.

KEYWORDS

aortic stenosis;
bioprosthesis;
surgical aortic
valve replacement;
transcatheter aortic
valve implantation.

RÉSUMÉ

Les bioprothèses valvulaires sont devenues le traitement de choix du rétrécissement aortique sévère, en raison du vieillissement de la population, et d'une préférence croissante pour éviter les anticoagulations au long cours. Quatre décennies de développement itératif ont permis de définir quatre grandes familles de bioprothèses aortiques : les valves chirurgicales stentées, les valves chirurgicales sans stent, les valves sans suture à déploiement rapide, et les valves cardiaques trans-cathéter.

Chaque famille a bénéficié d'améliorations successives visant à optimiser la surface de l'orifice, à réduire les fuites para-valvulaires, à limiter la détérioration structurelle de la prothèse, et à faciliter les réinterventions ultérieures par la technique « valve in valve ».

Cette revue narrative synthétise les données cliniques comparatives relatives aux principaux dispositifs actuels, notamment les bioprothèses stentées Carpentier-Edwards Perimount/Magna Ease et Inspiris RESILIA, les Trifecta/Trifecta GT, les Mitroflow/Crown PRT, les Avalus et les valves d'origine porcine. Parmi les dispositifs sans stent, on retrouve les modèles Freestyle et Freedom Solo ; parmi les dispositifs sans suture/à déploiement rapide, les modèles Perceval et Intuity Elite ; et parmi les valves transcathéter, les familles Sapien, Evolut, ACURATE neo/neo2, Portico/Navitor et Myval. Des essais randomisés et de vastes registres sont analysés afin de caractériser la durabilité et les performances hémodynamiques de la prothèse, et la sécurité du patient. Un cadre de sélection individualisée des dispositifs est proposé, basé sur l'âge du patient, l'anatomie de la racine aortique, le risque opératoire et la stratégie de prise en charge à long terme envisagée.

En conclusion, l'ingénierie tissulaire anti-calcification, la technologie des feuillets polymères et le dimensionnement assisté par intelligence artificielle constituent les principaux axes d'innovation actuels.

MOTS-CLÉS

sténose aortique;
bioprothèse ;
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chirurgical de la
valve aortique ;
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INTRODUCTION

Calcific aortic stenosis is the most common form of valvular heart disease in industrialised countries. Population-based meta-analyses estimate that severe aortic stenosis affects approximately 3.4% of individuals older than 75 years, with an overall prevalence of any aortic stenosis of 12.4% in this age group^[1]. As global populations age, the absolute number of candidates for aortic valve replacement (AVR) is projected to rise substantially over the coming decades^[1]. Aortic valve replacement remains the only effective treatment for severe symptomatic aortic stenosis, and current European guidelines endorse both surgical (SAVR) and transcatheter (TAVI) approaches according to an individualised, multidisciplinary Heart Team assessment of age, surgical risk, anatomy, and patient preference^[2].

Since the 1960s, two broad prosthesis categories have coexisted: mechanical valves, which offer near-unlimited mechanical durability at the cost of lifelong anticoagulation, and bioprostheses, fabricated from chemically treated animal tissue (bovine pericardium or porcine aortic valve), which avoid long-term anticoagulation but remain vulnerable to structural valve deterioration (SVD) over time. Because SVD is the principal determinant of long-term bioprosthesis performance, the field adopted standardised, stage-based definitions—the European Association of Percutaneous Cardiovascular Interventions (EAPCI) consensus statement^[3] and the subsequent VIVID (Valve-in-Valve International Data) classification^[4]—that distinguish morphological/haemodynamic valve deterioration from clinically overt bioprosthetic valve failure, enabling more consistent comparison of durability across surgical and transcatheter platforms.

Bioprostheses now account for the substantial majority of implanted aortic valve substitutes worldwide. Three technological trajectories have converged over the past three decades: progressive refinement of anti-calcification tissue treatments; miniaturisation and catheter-based delivery, culminating in transcatheter aortic valve implantation (TAVI), first performed by Cribier and colleagues in 2002 in a patient with inoperable calcific aortic stenosis^[5]; and the emergence of sutureless and rapid-deployment surgical valves that blend elements of conventional surgery with catheter-based deployment principles. This review synthesises the comparative evidence for the principal contemporary aortic bioprostheses across these three trajectories, and proposes a patient-centred framework for device selection, informed by the evolving concept of “lifetime management” of aortic stenosis across sequential interventions.

CLASSIFICATION OF AORTIC BIOPROSTHESES

Aortic bioprostheses can be classified along several complementary axes that together determine their haemodynamic behaviour, implantation technique, and durability profile:

- Tissue origin: bovine pericardium (most contemporary devices) versus porcine aortic valve tissue (historically important, now largely superseded for aortic position use).
- Presence of a supporting stent: stented (frame-supported) versus stentless (frame-free, offering a larger effective orifice area relative to annulus size but requiring more complex implantation).
- Mode of implantation: conventional sutured surgical implantation, sutureless implantation (nitinol self-expanding frame, no sutures beyond positioning guides), rapid-deployment implantation (balloon-expandable frame with limited guide sutures), and fully transcatheter implantation (TAVI).
- Leaflet mounting configuration in stented pericardial valves: internal mounting, in which the leaflets are sewn inside the stent (e.g. Perimount, Inspiris RESILIA, Avalus), versus external mounting, in which the leaflets are wrapped around the outside of the stent (e.g. Trifecta, Mitroflow/Crown PRT), a design choice with direct implications for both haemodynamic performance and long-term leaflet stress.

This classification structures the sections that follow, each of which addresses a device family's design rationale, principal clinical evidence, and comparative advantages and limitations.

STENTED SURGICAL BIOPROSTHESES

Stented pericardial bioprostheses remain the most widely implanted surgical valve worldwide. A metal or polymer frame supports three pericardial or porcine leaflets and a fabric sewing cuff that permits circumferential suture fixation to the aortic annulus.

Carpentier-Edwards Perimount, Magna, and Magna Ease (Edwards Lifesciences)

Developed by Alain Carpentier in the early 1980s, the Perimount lineage established the modern paradigm for bovine pericardial stented valves, with three independent pericardial cusps mounted internally on a flexible metal frame. Successive generations progressively improved haemodynamics: the original Perimount (1981) introduced

classic glutaraldehyde fixation; the Perimount Magna (2003) adopted a supra-annular implantation profile that increased effective orifice area and reduced transvalvular gradients; and the Magna Ease (2008) redesigned the stent geometry to simplify implantation while preserving compatibility with future valve-in-valve procedures. Long-term surgical series report freedom from reoperation for SVD exceeding 80% at 15–20 years, underpinning the Perimount family's status as a durability benchmark against which newer devices are routinely compared.

Edwards Inspiris RESILIA

Launched in 2017, the Inspiris RESILIA valve preserves the proven Magna Ease stent geometry while introducing two technological innovations. First, RESILIA tissue is bovine pericardium treated with a proprietary integrity-preservation process combining stable capping of free aldehyde groups — which otherwise serve as calcium-binding sites — with a glycerolisation step that limits leaflet exposure to residual aldehydes during dry storage; standardised animal-model testing has demonstrated markedly reduced leaflet calcification with this platform. Second, the VFit expansion technology allows controlled, predictable stent expansion during a future transcatheter valve-in-valve procedure, supporting the “lifetime management” strategy in younger patients.

The prospective COMMENCE trial has reported the longest available follow-up for RESILIA tissue. At 5 years, freedom from all-cause mortality, SVD, and all-cause reintervention were 89.2%, 100%, and 98.7% respectively, with a mean gradient of 11.5 mmHg and an effective orifice area of 1.6 cm² [6]. Extended 7-year follow-up (195 patients reaching this timepoint) confirmed sustained low rates of SVD and reintervention in a relatively young cohort (mean age approximately 65 years) [7]. A subsequent propensity-matched comparison of RESILIA-tissue COMMENCE patients against a non-RESILIA Magna Ease post-approval cohort suggested a durability advantage for the newer tissue treatment at intermediate-term follow-up, although the authors cautioned that differences in enrolment era and inclusion criteria between the compared cohorts may introduce residual confounding, and that continued follow-up to 10 years is required to confirm long-term durability [8]. Accelerated mechanical durability testing (2 billion cycles, simulating approximately 50 years of valve function) has also been reported to support structural integrity, and the ongoing RESILIENCE trial is specifically

designed to evaluate durability in patients younger than 65 years over an anticipated 11-year follow-up period.

Trifecta and Trifecta GT (Abbott / St. Jude Medical)

Launched in 2010 by St. Jude Medical (acquired by Abbott in 2017), the Trifecta valve adopted a distinctive external-mounting design in which bovine pericardial leaflets are wrapped around a titanium stent rather than sewn inside it. This configuration enlarges the effective orifice area for a given annulus size and produces favourable early haemodynamics, particularly in small aortic annuli.

However, longer-term follow-up has raised durability concerns. A single-centre series of 182 patients followed a mean of 40 months reported freedom from SVD of 98% at 5 years but overall survival declining to 68% by that timepoint [9], while a comparative analysis against the Intuity rapid-deployment valve found significantly higher rates of SVD with the Trifecta and identified Trifecta implantation as an independent risk factor for reintervention (adjusted hazard ratio approximately 11.9) [10]; the authors proposed that externally mounted leaflets may be exposed to greater mechanical stress and leaflet flutter than internally mounted designs. Manufacturer-sponsored long-term follow-up of the original Trifecta IDE cohort similarly reported freedom from SVD at 10 years of only 68–76%, appreciably lower than historical benchmarks for internally mounted pericardial valves. These signals prompted development of the Trifecta GT (Glide Technology) in 2016, incorporating the Linx anti-calcification treatment and refined leaflet geometry; nonetheless, the device was withdrawn from the US market in 2023 pending a next-generation redesign.

Mitroflow and Crown PRT (Sorin / LivaNova / Corcym)

The Mitroflow valve, originally developed by Sorin (subsequently LivaNova, then Corcym), is a bovine pericardial bioprosthesis with an external leaflet-mounting configuration conceptually similar to the Trifecta, and was widely favoured for small aortic annuli owing to its favourable haemodynamic profile. A subsequent Phospholipid Reduction Treatment (PRT), designed to remove residual phospholipids implicated in tissue calcification, gave rise to the Crown PRT device. Several series reported concerning rates of early SVD with the original Mitroflow, particularly among younger patients and in smaller valve sizes, prompting its progressive replacement by the Crown PRT, which has demonstrated improved medium-term outcomes.

Avalus (Medtronic)

Launched by Medtronic in 2017, the Avalus is a stented bovine pericardial valve with internally mounted leaflets, a radio-opaque stent frame designed to facilitate fluoroscopic visualisation during future valve-in-valve TAVI, and a cuff design intended to preserve the sub-coronary anatomy. The PERIGON Pivotal Trial — the largest prospective evaluation of a contemporary stented surgical valve to date, enrolling 1,132 patients across 39 centres in North America and Europe — reported favourable safety and haemodynamic performance through 5 years^[11], with subsequent 7-year follow-up (576 re-consented patients from 19 sites) confirming excellent durability and stable haemodynamic performance through the intermediate term, positioning Avalus as a direct competitor to the Perimount/Inspiris lineage^[12].

Porcine-Derived Stented Valves: Hancock II and Mosaic (Medtronic)

In contrast to the pericardial devices above, the Hancock II (1982) and Mosaic (1994) bioprostheses are fabricated from whole porcine aortic valve tissue. The Mosaic incorporates the alpha-amino oleic acid (AOA) anti-calcification treatment. While these devices offer comparable durability to early-generation pericardial valves, their haemodynamic performance is generally inferior at equivalent annular size owing to the inherent geometric constraints of native porcine valve architecture, and their clinical use in the aortic position has progressively declined in favour of bovine pericardial designs.

Comparative Summary — Stented Surgical Bioprostheses

Table 1. Comparative Summary — Stented Surgical Bioprostheses

Device	Manufacturer	Tissue	Mounting	Launch	Distinguishing feature
Perimount Magna Ease	Edwards	Bovine pericardium	Internal	2008	Historical durability benchmark
Inspiris RESILIA	Edwards	RESILIA bovine pericardium	Internal	2017	Anti-calcification tissue + VFit expansion
Trifecta GT	Abbott	Bovine pericardium	External	2016	High EOA; withdrawn from US market 2023
Crown PRT	Corcym	Bovine pericardium, PRT	External	2014	Favoured for small annuli
Avalus	Medtronic	Bovine pericardium	Internal	2017	Radio-opaque stent for future ViV
Mosaic	Medtronic	Porcine valve, AOA	—	1994	Porcine-derived, declining use

STENTLESS BIOPROSTHESES

Stentless bioprostheses were designed to eliminate the supporting frame entirely, enlarging effective orifice area and lowering transvalvular gradients relative to stented equivalents of the same nominal size, and thereby reducing the risk of prosthesis–patient mismatch — an advantage of particular relevance in small aortic annuli.

Medtronic Freestyle

The Freestyle device is a complete porcine aortic root, glutaraldehyde-fixed and AOA-treated, first implanted in 1992. It may be deployed via sub-coronary, full-root replacement, or root-inclusion techniques, and is particularly suited to combined aortic valve and root pathology. In a large multicentre cohort (725 patients, mean age 71.7 years, cumulative follow-up exceeding 5,400 patient-years), 15-year freedom from explant for SVD was 83%, with freedom from reoperation of 80.7% and freedom from valve-related death of 92.7%^[12]. A separate long-term echocardiographic follow-up study similarly reported freedom from reoperation for SVD of 95.9% and 82.3% at 10 and 15 years respectively for sub-coronary implantation, with markedly better durability in patients older than 60 years compared with younger recipients, in whom leaflet tear was the predominant failure mechanism^[13]. These data support Freestyle as a durable option for patients with combined aortic valve and root disease, while underscoring an age-dependent durability gradient that is common to most bioprosthetic platforms.

Freedom Solo (Sorin / LivaNova / Corcym)

The Freedom Solo is a bovine pericardial stentless valve designed for supra-annular sub-coronary implantation using a single suture line, simplifying the surgical technique relative to other stentless designs. Reported haemodynamic performance is excellent, with mean effective orifice areas ranging from approximately 1.5 cm² for the smallest annular size to over 2.1 cm² for the largest, and published series report no severe prosthesis–patient mismatch and 100% freedom from SVD at 5 years.

Toronto SPV (Historical)

The Toronto Stentless Porcine Valve (St. Jude Medical), introduced in the 1990s, was among the earliest stentless designs but is no longer commercially available. Very long-term durability studies identified a non-negligible rate of SVD beyond 15 years, contributing to its market withdrawal and to the broader shift toward pericardial-tissue stentless designs.

SUTURELESS AND RAPID-DEPLOYMENT BIOPROSTHESES

This hybrid category, which emerged in the 2010s, aims to shorten aortic cross-clamp and cardiopulmonary bypass times relative to conventional sutured SAVR while retaining the surgical advantages of direct visualisation, native leaflet debridement, and precise annular sizing. These devices are particularly suited to elderly patients, combined procedures (e.g. concomitant coronary bypass), and minimally invasive access. Following the 2014 withdrawal of the 3F Enable (Medtronic) because of migration risk, two devices now dominate this segment: the Perceval (a true sutureless valve) and the Intuity Elite (a rapid-deployment valve).

Perceval (LivaNova / Corcym)

The Perceval is a genuinely sutureless bioprosthesis: bovine pericardial leaflets are mounted on a self-expanding nitinol stent that, following native valve debridement, exerts sufficient radial force against the annulus to maintain position without circumferential sutures (three temporary positioning guide sutures are used during deployment only). Launched in 2007 and CE-marked in 2011, its principal advantage is a markedly abbreviated implantation time, of particular value in minimally invasive or redo surgery, and it has been used successfully even in patients with a heavily calcified ("porcelain") aorta. Its principal limitation is a higher rate of postoperative permanent pacemaker implantation than conventional SAVR, attributed to compression of the conduction system (bundle of His) by the stent frame; a next-generation Perceval Plus device, featuring a reduced left-ventricular-outflow-tract stent protrusion and the FREE anti-calcification treatment, has been developed to mitigate this.

Intuity Elite (Edwards Lifesciences)

The Intuity Elite is, strictly, a rapid-deployment rather than truly sutureless device: three guide sutures anchor the valve to the annulus, with final fixation achieved by balloon expansion of a stainless-steel subannular skirt, conceptually related to the deployment mechanism of the Sapien transcatheter platform. Its biological component is derived from the Perimount Magna Ease, conferring an established durability lineage. Launched in 2012, the Intuity combines rapid implantation with proven tissue durability, and several comparative studies have reported superior early haemodynamics (lower gradients, larger effective orifice area) relative to conventional sutured SAVR. Reported permanent pacemaker rates are approximately 8% at 5 years,

modestly higher than conventional SAVR; the device is no longer commercially available in some European markets, including France.

Comparative Evidence: Perceval versus Intuity

The Sutureless and Rapid Deployment Aortic Valve Replacement International Registry (SURD-IR), established in 2015 across 18 centres in Europe, Australia, and Canada, provides the largest comparative dataset for this device class, with more than 4,500–7,700 patients enrolled across successive analyses^[14,15]. Risk-stratified analysis showed the Perceval was preferentially used in high- and very-high-risk patients (implanted in 84.2% and 80.8% of these strata respectively, versus 15.8% and 19.2% for Intuity), with in-hospital mortality ranging from 1.6% in low-risk to 2.7% in very-high-risk patients across the pooled cohort^[15]. A propensity-matched comparison of 823 isolated and 467 combined-procedure pairs found similar in-hospital mortality and major complication rates between the two devices; the Perceval was associated with significantly shorter cross-clamp and cardiopulmonary bypass times and greater use of right anterior thoracotomy access, while the Intuity showed significantly lower postoperative transvalvular gradients and a lower incidence of mild aortic regurgitation^[16]. In aggregate, SURD-IR data confirm that the choice between the two devices should be individualised according to anatomical suitability, anticipated operative time constraints, and the relative clinical priority placed on procedural speed versus optimal early haemodynamics.

TRANSCATHETER AORTIC BIOPROSTHESES (TAVI/TAVR)

Transcatheter aortic valve implantation, first performed in humans by Alain Cribier in April 2002 [5], represents one of the most consequential therapeutic innovations in modern cardiovascular medicine. Initially reserved for patients at prohibitive or very high surgical risk, TAVI has progressively expanded to intermediate- and, most recently, low-risk populations, culminating in its endorsement as the preferred option in patients older than 75 years under the 2021 ESC/EACTS guidelines^[2]. Two broad deployment mechanisms characterise contemporary transcatheter heart valves (THV): balloon-expandable platforms, typified by the Edwards Sapien family, and self-expanding nitinol platforms, including the Medtronic Evolut, Boston Scientific ACURATE neo/neo2, and Abbott Portico/Navitor families.

The Sapien Family (Edwards Lifesciences)

The evolution of the Sapien platform mirrors the broader history of TAVI. The original Cribier-Edwards/Sapien device (2002–2007) used equine pericardial leaflets on a stainless-steel balloon-expandable stent. The Sapien XT (2009) introduced a thinner cobalt-chromium frame, bovine pericardial leaflets, and a reduced delivery profile. The Sapien 3 (2013) added an external polyethylene-terephthalate (PET) sealing skirt to reduce paravalvular leak and further reduced catheter profile to 14 French; the Sapien 3 Ultra (2018) extended this sealing skirt for improved annular apposition; and the Sapien 3 Ultra RESILIA (2022) incorporated the anti-calcification RESILIA tissue platform used in the Inspiris surgical valve. The Sapien 3 remains among the most widely implanted THV platforms globally. Registry data from the German Aortic Valve Registry (GARY), comparing 24,124 patients treated with four second-generation balloon- and self-expanding devices, found that moderate-or-greater paravalvular leak occurred significantly less often with Sapien 3 (1.2%) than with the comparator self-expanding devices, while permanent pacemaker rates were lowest with ACURATE neo (13.0%) and highest with Evolut R (21.9%)^[17].

The CoreValve/Evolut Family (Medtronic)

The original CoreValve (2007) was the first commercially available self-expanding THV, using porcine pericardial leaflets on a tall supra-annular nitinol frame. Subsequent generations progressively improved deliverability and sealing: Evolut R (2014) introduced a repositionable, recapturable delivery system with a 14 French profile; Evolut PRO (2017) added an external porcine pericardial sealing skirt to reduce paravalvular leak; Evolut PRO+ (2019) further reduced catheter profile across all valve sizes; and Evolut FX (2022) refined deployment mechanics and radio-opaque marker visibility. The supra-annular leaflet position of the Evolut family confers the most favourable postoperative transvalvular gradients among contemporary THV platforms, particularly relevant for small aortic annuli, though at the cost of a consistently higher permanent pacemaker implantation rate (approximately 20–22%) than the Sapien 3 (approximately 12%)^[17].

ACURATE neo and neo2 (Boston Scientific)

The ACURATE neo is a self-expanding porcine pericardial THV distinguished by upper “stabilisation arches” and a lower sealing ring, and has been associated with among the lowest permanent pacemaker rates of any contemporary platform (approximately 13%). However,

the randomised SCOPE 2 trial, comparing ACURATE neo against CoreValve Evolut R/PRO in 796 patients aged 75 years or older, failed to demonstrate non-inferiority for the composite primary endpoint of death or stroke at 1 year, driven in part by a significantly higher rate of moderate-or-severe paravalvular regurgitation with ACURATE neo (10.0% versus 3.0%)^[18]. The second-generation ACURATE neo2, commercially available in Europe since September 2020, incorporates an enhanced external sealing skirt intended to address this limitation; subsequent registry and randomised comparisons (including the DOUBLE-CHOICE trial) have reported markedly reduced paravalvular leak with neo2 alongside consistently lower pacemaker rates than Evolut platforms, although the pivotal randomised ACURATE IDE trial against contemporary Sapien 3/Ultra and Evolut comparators did not meet non-inferiority for its composite 1-year endpoint, and post hoc analysis has implicated valve underexpansion as a potential contributing mechanism in a subset of cases.

Portico and Navitor (Abbott)

The Portico (Abbott, formerly St. Jude Medical) is a self-expanding, intra-annular bovine pericardial THV on a nitinol frame. The randomised PORTICO IDE trial compared the first-generation Portico device against any FDA-approved commercial THV (predominantly Sapien 3 and Evolut R/PRO) in 750 high- and extreme-risk patients, meeting pre-specified non-inferiority margins for the primary safety endpoint at 30 days, though with a numerically higher composite safety event rate than commercial comparators (13.8% versus 9.6%) and a persistently elevated permanent pacemaker rate through 5 years (35.9% versus 20.3%)^[19]. The Navitor, a next-generation device launched in 2021, incorporates the NaviSeal active outer sealing cuff to reduce paravalvular leak and is delivered with the FlexNav system, which has been associated with improved procedural outcomes relative to earlier-generation Portico delivery systems.

Myval (Meril Life Sciences)

The Myval is a balloon-expandable THV developed by Meril Life Sciences (India), commercially available in Europe since 2019, notable for offering an expanded range of intermediate valve sizes (1.5 mm diameter increments rather than the conventional 3 mm increments used by most competing platforms), intended to improve sizing precision relative to annular dimensions. The randomised LANDMARK trial compared the Myval series against

contemporary Sapien and Evolut platforms in 768 patients across 31 centres in 16 countries, demonstrating non-inferiority for the primary 30-day composite safety and effectiveness endpoint (25% versus 27%; risk difference −2.3%)^[20], with subsequent 1-year follow-up confirming sustained comparable clinical, haemodynamic, and quality-of-life outcomes.

Comparative Summary — Transcatheter Heart Valves

Table 2. Comparative Summary — Transcatheter Heart Valves

Device	Manufacturer	Mechanism	Tissue	Position	Distinguishing feature
Sapien 3 / Ultra RESILIA	Edwards	Balloon-expandable	Bovine pericardium (RESILIA)	Intra-annular	Lowest PVL rates in GARY registry
Evolut FX / Medtronic PRO+	Medtronic	Self-expanding	Porcine pericardium	Supra-annular	Lowest gradients, higher PPI rate
ACURATE neo2	Boston Scientific	Self-expanding	Porcine pericardium	Supra-annular	Low PPI rate; PVL improved vs neo
Portico / Navitor	Abbott	Self-expanding	Bovine pericardium	Intra-annular	NaviSeal skirt; FlexNav delivery
Myval	Meril Life Sciences	Balloon-expandable	Bovine pericardium	Intra-annular	Intermediate sizing increments

The extension of TAVI to progressively lower-risk populations has been underpinned by the randomised PARTNER 3 (balloon-expandable Sapien 3, $n = 1,000$) and Evolut Low Risk (self-expanding, $n = 1,468$) trials, both of which demonstrated non-inferiority — and, for PARTNER 3, superiority — of TAVI over SAVR for the composite endpoint of death, stroke, or rehospitalisation at 1 year in low-surgical-risk patients^[21,22]. Extended follow-up to 7 years in PARTNER 3 has reported similar all-cause mortality, stroke, and rehospitalisation rates between TAVI and SAVR, with low reintervention rates and excellent, comparable valve durability in both arms, supporting continued expansion of TAVI eligibility while reinforcing the importance of long-term

INDIVIDUALISING BIOPROSTHESIS SELECTION

Selection of an aortic bioprosthesis is inherently multifactorial and should be undertaken within a multidisciplinary Heart Team framework, as recommended by the 2021 ESC/EACTS guidelines^[2]. Four domains dominate decision-making in practice.

Patient Age and the Lifetime Management Concept

In younger patients (under approximately 65 years), long-term durability is the paramount consideration.

Preferred options include the Inspiris RESILIA (surgical) or, in selected cases, a full stentless root replacement such as the Freestyle. The “lifetime management” concept — pre-emptively planning a sequence of surgical implantation followed by one or more future transcatheter valve-in-valve procedures — is particularly relevant in this population, and has directly informed device features such as the Inspiris VFit technology and the Avalus radio-opaque frame. In patients older than 75 years, TAVI is now recommended as the first-line option under European guidelines^[2], supported by the low-risk trial evidence summarised above^[21,22].

Aortic Root Anatomy

For small aortic annuli (≤ 21 mm), devices prioritising effective orifice area are preferred: stentless valves (Freedom Solo, Freestyle), historically externally mounted stented valves (Trifecta, Crown PRT, albeit tempered by the durability signals discussed above), or supra-annular TAVI platforms (Evolut, ACURATE neo2). Combined valve and aortic root pathology is well addressed by full-root replacement with the Freestyle device.

Operative Risk

For patients at high surgical risk, TAVI is generally preferred. For frail patients in whom surgery remains indicated — for example, active endocarditis or TAVI-unfavourable anatomy — sutureless or rapid-deployment valves reduce cross-clamp and cardiopulmonary bypass time and may improve tolerability of the surgical insult, as supported by SURD-IR registry data^[14–16].

Compatibility with Future Valve-in-Valve Procedures

The Inspiris RESILIA VFit technology and the Avalus radio-opaque frame are specifically designed to facilitate future transcatheter valve-in-valve deployment. Conversely, stentless valves without a visible radio-opaque frame present greater fluoroscopic landmarking challenges during a subsequent valve-in-valve procedure, a consideration that should be weighed explicitly when planning a lifetime management strategy in younger patients.

HISTORICAL EVOLUTION AND FUTURE PERSPECTIVES

Key Milestones

1969: First bioprosthetic aortic valve implantation using a glutaraldehyde-fixed porcine valve (Hancock/Carpentier).

1980s–1990s: Introduction of bovine pericardial stented valves

(Carpentier-Edwards Perimount), demonstrating superior durability to early porcine designs.

1990s–2000s: Development of stentless bioprostheses (Freestyle, Toronto SPV) to optimise haemodynamics.

2002: First-in-human transcatheter aortic valve implantation, performed by Alain Cribier [5].

2007: Introduction of the first sutureless valve (Perceval) and the first self-expanding transcatheter valve (CoreValve).

2010s: Extension of TAVI indications from prohibitive/high risk to intermediate and, from 2019, low surgical risk [21,22], alongside proliferation of competing THV platforms (Sapien 3, Evolut R/PRO, ACURATE, Portico).

2017: Launch of the Inspiris RESILIA, the first surgical bioprosthesis to combine a next-generation anti-calcification tissue treatment with planned valve-in-valve compatibility.

2020s: Continued refinement of TAVI devices (optimised external sealing skirts, thinner delivery profiles, intermediate sizing options) and consolidation of the lifetime management paradigm, including 7-year confirmation of durable low-risk TAVI outcomes in PARTNER 3.

Future Directions

Several research trajectories are likely to shape the next generation of aortic bioprostheses:

- Next-generation tissue treatments: extension of RESILIA-type anti-calcification platforms and exploration of alternative substrates, including decellularised pericardium and biomimetic polymers.
- Fully polymeric leaflet valves: several prototype devices are under evaluation as potentially durable, non-thrombogenic alternatives to biological tissue, aiming to combine bioprosthesis-like haemodynamics with mechanical-valve-like durability.
- Optimisation of lifetime management: refinement of strategies sequencing an initial surgical or transcatheter implant with one or more subsequent valve-in-valve (or valve-in-valve-in-valve) transcatheter procedures across a patient's remaining lifespan.
- Conduction system preservation: continued design refinement — including reduced left-ventricular-outflow-tract stent protrusion, as seen in the Perceval Plus — aimed at reducing permanent pacemaker implantation rates across both surgical and transcatheter platforms.
- Personalised device selection: increasing use of three-dimensional imaging and computational/artificial-intelligence-assisted annular sizing to individualise prosthesis choice and sizing strategy.

CONCLUSION

Aortic bioprostheses have evolved dramatically over six decades, from simple glutaraldehyde-fixed porcine valves to a diverse ecosystem encompassing stented and stentless surgical devices, sutureless and rapid-deployment platforms, and an expanding array of transcatheter valves. Each device class presents a distinct benefit–risk profile, and selection should be individualised according to patient age, aortic root anatomy, operative risk, and the anticipated trajectory of lifetime management. Recent innovations — anti-calcification tissue platforms such as RESILIA, next-generation TAVI devices with optimised external sealing, and bioprostheses purpose-designed for future valve-in-valve compatibility — are extending the feasibility of a lifelong, sequential-intervention strategy to progressively younger patients. Continued competition among major manufacturers (Edwards Lifesciences, Medtronic, Abbott, Boston Scientific, Corcym, and Meril Life Sciences, among others) continues to drive innovation in this field. Future work should prioritise long-term (≥ 10 -year), standardised-definition durability data across the newest device generations, head-to-head randomised comparisons where clinical equipoise exists, and prospective evaluation of emerging polymeric leaflet technologies, as TAVI expands toward truly low-risk and increasingly younger populations.

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