Case Study
ISSN: 3051-8814
Journal homepage: https://www.harrisonacademicpress.com/index.php/FBEMD
Frontiers in Biomedical Engineering and Medical Devices

Harrison Academic Press

Biomechanical Evaluation of a Novel Transcatheter Heart Valve Prototype in a Bench Model

Papadopoulos S[1*], Maes T[2] and Horvath E[3]

[1]*Department of Biomedical Engineering, National and Kapodistrian University of Athens, Athens, Greece*
[2]*Department of Cardiothoracic Surgery, Ghent University, Ghent, Belgium*
[3]*Department of Mechanical Engineering, University of Debrecen, Debrecen, Hungary*

ABSTRACT

Background: Bench-model biomechanical evaluation is the mandatory first evidentiary tier for any novel transcatheter heart valve (THV) prototype, but reported methods and findings are scattered across a heterogeneous literature. Objective: This narrative review synthesizes real, peer-reviewed literature on how THV prototypes are evaluated at the bench, using the framing of a hypothetical novel prototype only as an organizing device. Methods: We reviewed published studies employing pulse-duplicator hydrodynamic testing, ISO 5840-3 accelerated wear and fatigue testing, leaflet stress analysis, and paravalvular leak models, covering prototypes such as TRISKELE, TRISKELION, Poli-Valve, DurAVR, and polymeric leaflet designs. Findings: Bench methods reliably differentiate designs on hydrodynamic efficiency, regurgitant fraction, and fatigue resistance, but reported performance is highly sensitive to test-rig anatomy, loading protocol, and comparator choice, and accelerated durability testing to hundreds of millions of cycles remains an imperfect surrogate for decades of physiological loading. Conclusions: ISO 5840-3 compliance provides a necessary but not sufficient baseline for clinical durability; anatomically representative, standardized bench models integrated with subsequent preclinical follow-up remain essential as new THV materials and geometries progress toward clinical use.

Keywords: *transcatheter heart valve; bench testing; hydrodynamic performance; durability testing; paravalvular leak*

Citation: Papadopoulos S, Maes T, Horvath E (2025) Biomechanical Evaluation of a Novel Transcatheter Heart Valve Prototype in a Bench Model. Front Biomed Eng Med Devices, 3(1): 01-06.
DOI: 10.5281/zenodo.22547655

Corresponding Author: *Sofia Papadopoulos*

E-mail Address: *sofia.papadopoulos@uoa.edu*

Article History: *Received 8 January 2025 | Accepted 2 April 2025 | Published 20 June 2025*

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Introduction

Transcatheter aortic valve implantation (TAVI) has transformed management of severe aortic stenosis since Cribier and colleagues reported the first percutaneous implantation of a balloon-expandable valve in a human patient in 2002 [1]. What began as compassionate-use therapy in inoperable patients has expanded across surgical risk strata, and the commercial success of early platforms has driven active prototype development in which academic groups, start-ups, and established manufacturers pursue design changes intended to improve hydrodynamic efficiency, durability, and paravalvular sealing. Because no transcatheter heart valve (THV) prototype can ethically or practically proceed directly from concept to human implantation, bench-model biomechanical evaluation occupies a central, mandatory position in the translational pathway. Pulse-duplicator hydrodynamic testing, accelerated fatigue and durability testing, leaflet stress analysis, and dedicated paravalvular leak (PVL) models together constitute the evidentiary basis on which regulators and reviewers judge whether a new design merits progression toward preclinical and first-in-human trials.

This review synthesizes methods and reported findings of bench-model biomechanical evaluation for THV prototypes, drawing on real, peer-reviewed studies rather than presenting new experimental data. The "novel prototype" framing of the title is used deliberately as an organizing device: rather than describing a single unpublished device, we survey how the field evaluates novel THV concepts at the bench, illustrating each testing modality with specific, verifiable literature examples, including polymeric leaflet valves, biomimetic stent-leaflet geometries, and next-generation leaflet materials [2]. We first describe the principal bench-testing methods used across the field: pulse-duplicator hydrodynamics, accelerated wear/fatigue testing under ISO 5840, and leaflet stress analysis. We then review reported biomechanical performance from specific published prototype designs, and finally discuss durability standards and regulatory expectations that shape interpretation of bench data.

Bench-Model Testing Methods for Transcatheter Heart Valves

Principal bench-model methods used in transcatheter heart valve biomechanical evaluation.

Test Method	Primary Parameters Measured	Representative Standard/Reference
Pulse-duplicator hydrodynamics	Mean pressure gradient, effective orifice area, regurgitant fraction	ISO 5840-3:2021; Buse et al. 2016
Accelerated wear/fatigue testing	Cycles to failure, structural integrity, wear debris	ISO 5840-3:2021; Rotman et al. 2020
Leaflet stress analysis	Peak/mean leaflet stress, stress concentration location	Stanová et al. 2024
Paravalvular leak testing	Regurgitant fraction vs. implant depth/eccentricity	Sedaghat et al. 2018
Accelerated environment fluid dynamics	Downstream flow field at high test frequency	Ponnaluri et al. 2022

The pulse duplicator is the workhorse instrument of prosthetic valve bench testing. It reproduces a physiological pressure-flow waveform across a valve mounted in a chamber mimicking the aortic (or mitral) annulus, typically using a glycerin-saline blood-mimicking fluid, and permits measurement of forward-flow pressure gradients, effective orifice area, and regurgitant fraction under standardized cardiac output and heart-rate conditions [3]. Ponnaluri and colleagues formalized an "accelerated" testing environment coupling pulse-duplicator hydrodynamics with the loading and kinematic profiles a THV experiences during rapid-rate durability testing, showing that fluid-dynamic behavior at accelerated rates can diverge from that measured physiologically, and arguing for hybrid protocols combining both regimes [4]. Because hydrodynamic function depends strongly on surrounding anatomy, Sadat et al. compared a self-expanding valve's function within rigid, native-tissue, and calcified-tissue compartments and found that full frame expansion and downstream hydrodynamics were markedly sensitive to compartment design, implying idealized rigid bench models may overstate performance relative to anatomically faithful, tissue-based rigs [5].

Durability assessment follows a complementary track. ISO 5840-3:2021 defines accelerated wear testing (AWT) requirements specific to transcatheter heart valve substitutes, specifying cyclic loading regimes run at high frequency, intended to simulate roughly ten years of in vivo loading (on the order of 400 million cycles) before failure or unacceptable deterioration is deemed to have occurred [6]. Rotman and colleagues applied this to a polymeric transcatheter valve, running accelerated wear testing to 400 million cycles without structural failure while tracking hydrodynamic parameters and calcification propensity [7]. Sathananthan and colleagues' widely cited synthesis of bench durability data across multiple THV platforms tested to the equivalent of 25 years of cyclic loading highlighted substantial heterogeneity in wear patterns, leaflet calcification, and frame fatigue behavior between designs and even between lots of the same design [8]; an accompanying editorial cautioned that extrapolating accelerated results to long-term clinical durability requires care given differences between in vitro and in vivo mechanical and biological environments [9].

Leaflet stress analysis complements hydrodynamic and durability testing by localizing the mechanical loading that drives fatigue failure and calcific degeneration. Stanová et al. quantified leaflet stress distributions across different THV designs and generations in vitro, demonstrating that geometric differences in commissural support and leaflet coaptation produce measurably different peak stress concentrations correlating with regions of clinically observed leaflet tearing and calcification [10]. Paravalvular leak evaluation typically uses standardized annular models with adjustable eccentricity and calcification mimics within the pulse duplicator, or patient-specific three-dimensional printed root replicas, to quantify regurgitant fraction as a function of implant depth, oversizing, and annular geometry mismatch [11].

Biomechanical Performance of Reported Prototype Designs

Several published prototype programs illustrate how these methods combine when a genuinely new THV concept is introduced. The TRISKELE valve, an asymmetric, low-profile design developed at University College London, was assessed hydrodynamically against commercially available self-expanding and balloon-expandable comparators; Rahmani and colleagues reported forward-flow gradients and effective orifice areas comparable to or better than controls, with a notable reduction in paravalvular regurgitation attributed to a conformable sealing skirt [12]. A related concept, TRISKELION, extended this philosophy using additive manufacturing: Tschorn and colleagues 3D-printed multiple polymeric valve iterations and used pulse-duplicator testing to iteratively refine leaflet geometry, achieving systolic gradients comparable to commercial bioprosthetic and mechanical valves, although residual regurgitation remained a limitation requiring further iteration [13].

Selected published transcatheter heart valve prototype bench studies and reported outcomes.

Prototype/Study	Leaflet Material	Key Bench Finding	Reference
TRISKELE	Bioprosthetic tissue	Reduced paravalvular regurgitation vs. commercial comparators	Rahmani et al. 2017
TRISKELION	3D-printed polymer	Systolic gradients comparable to commercial valves; residual regurgitation	Tschorn et al. 2022
Poli-Valve	Styrenic block copolymer	Met ISO hydrodynamic/durability benchmarks pre-in vivo study	Stasiak et al. 2020
Polymeric TAVI (Rotman et al.)	Polymer	No structural failure to 400 million accelerated cycles	Rotman et al. 2020
Foldax-type SiPUU valve	Siloxane poly(urethane-urea)	Favorable hemodynamics and biocompatibility over 90-day ovine implant	Stanfield et al. 2026

Prototype/Study	Leaflet Material	Key Bench Finding	Reference
DurAVR	Biomimetic balloon-expandable	Design intended to preserve favorable hemodynamic profile across TAVI/valve-in-valve use	Meier et al. 2025

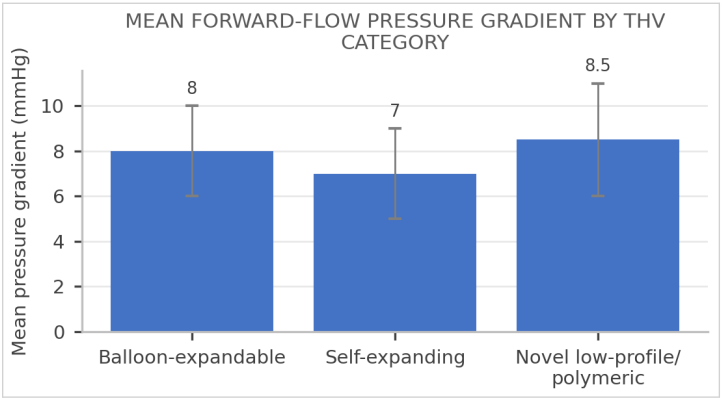
Polymeric leaflet materials have been a particularly active area of prototype development, promising more consistent manufacturing and potentially superior fatigue behavior than glutaraldehyde-fixed bioprosthetic tissue. Stasiak and colleagues developed the Poli-Valve, an injection-molded styrenic block copolymer THV, reporting that it met relevant ISO hydrodynamic and durability benchmarks prior to an in vivo feasibility study [14]. Rotman et al.'s polymer valve, evaluated to 400 million accelerated cycles, similarly demonstrated preserved hydrodynamic function and reduced calcification propensity relative to tissue-valve comparators [7]. Most recently, Stanfield and colleagues reported bench and chronic ovine preclinical data for a self-expanding THV incorporating siloxane poly(urethane-urea) leaflets and an electrospun skirt, showing favorable hydrodynamic performance and biocompatibility over a 90-day implant period [15]. Wang and colleagues' broader review of polymeric heart valve development, from basic materials research through early clinical trials, situates these prototype reports within a maturing field where manufacturing consistency and long-term biostability remain the principal translational barriers [2]. Zhang, Bianco, and Schoen's review of preclinical assessment approaches for tissue-engineered valves underscores that bench hydrodynamic and durability data, while necessary, are insufficient predictors of remodeling and structural degeneration that only large-animal implantation can reveal, a caution equally applicable to transcatheter platforms [16].

Not all prototype evaluation targets a wholly new valve; some studies examine how existing platforms behave under conditions relevant to next-generation applications such as valve-in-valve implantation. Sathananthan and colleagues' bench analysis of repeat TAVI demonstrated that a second transcatheter valve's hydrodynamic performance, and its interaction with a previously implanted device's frame, depends heavily on relative frame geometry and implantation depth [17]. The recently reported DurAVR valve, a biomimetic balloon-expandable design intended for native TAVI as well as valve-in-valve and redo-TAVI applications, was evaluated with explicit design rationale toward preserving a favorable hemodynamic profile, illustrating how design intent, bench data, and intended clinical niche are presented together in current prototype literature [18]. Sedaghat and colleagues' bench comparison of a novel self-expanding THV across multiple surgical bioprosthesis models demonstrated hydrodynamic performance that varied appreciably with the specific surgical valve into which the device was deployed, reinforcing that reported "prototype performance" figures are conditional on the specific bench model and comparator chosen [11].

Durability, Fatigue, and Regulatory Standards

ISO 5840-3:2021 remains the central regulatory reference standard for transcatheter heart valve substitutes, specifying hydrodynamic test conditions, structural and fatigue test durations, and acceptance criteria a prototype must satisfy before proceeding to preclinical and clinical evaluation [6]. Its accelerated wear testing requirement, generally interpreted as demonstrating durability equivalent to ten years of cyclic loading at accelerated frequencies, shapes prototype translational timelines, since a single durability run can occupy many months of continuous testing even at frequencies well above physiological heart rate [4]. Sathananthan and colleagues' synthesis of bench durability data across commercial platforms illustrates both the value and limits of this framework: valves that passed accelerated wear testing per the standard nonetheless displayed heterogeneous wear signatures, and post-market structural valve deterioration signals have not always been anticipated by pre-market bench data, prompting calls for more standardized reporting of bench methodology [8]. The accompanying editorial commentary emphasized that accelerated fatigue protocols necessarily compress and distort the loading environment relative to true in vivo conditions, so a favorable bench durability result should be read as necessary, but not sufficient, for long-term clinical durability [9].

Illustrative mean forward-flow pressure gradient ranges typically reported for balloon-expandable, self-expanding, and novel low-profile/polymeric transcatheter valve categories in pulse-duplicator hydrodynamic bench studies.



Regulatory expectations have also evolved to address the sensitivity of bench results to test-rig design. Sadat and colleagues showed that the choice between rigid plexiglass, native-tissue, and calcified-tissue annular compartments materially changes measured valve expansion and function for the same device, pushing laboratories and regulatory reviewers toward more anatomically representative bench models alongside traditional idealized rigid-orifice testing [5]. Paravalvular leak assessment has followed a similar trajectory, with patient-specific three-dimensional-printed root models increasingly used to interrogate how eccentric or heavily calcified anatomies predispose to residual regurgitation, complementing standardized circular-orifice pulse-duplicator PVL testing [11]. For polymeric and other emerging leaflet materials, durability evaluation increasingly incorporates dedicated calcification and biostability assays alongside mechanical fatigue testing, since Rotman and colleagues' accelerated wear data showed reduced calcification propensity, not hydrodynamic performance per se, was among the most clinically relevant differentiators from tissue-valve durability behavior [7]. Zhang, Bianco, and Schoen further argue that regulatory frameworks built around fixed bioprosthetic tissue durability paradigms may need continued adaptation as tissue-engineered and polymeric substitutes, which can exhibit failure modes such as creep, oxidative degradation, or delamination rather than classical calcific stiffening, enter the pipeline [16]. Taken together, the literature converges on the view

that ISO 5840-3 compliance defines a necessary baseline rather than a guarantee of clinical durability, and that bench-model design matched to a prototype's specific novelty remains an active area of methodological development.

Conclusion

Bench-model biomechanical evaluation, encompassing pulse-duplicator hydrodynamics, ISO 5840-3-compliant accelerated fatigue testing, leaflet stress analysis, and paravalvular leak models, constitutes the indispensable first evidentiary tier for any novel transcatheter heart valve prototype. The peer-reviewed literature surveyed here, spanning asymmetric low-profile designs such as TRISKELE and TRISKELION, polymeric leaflet platforms such as Poli-Valve and a recently reported siloxane poly(urethane-urea) design, and biomimetic balloon-expandable concepts such as DurAVR, demonstrates that these bench methods can meaningfully differentiate design approaches on hydrodynamic efficiency, regurgitant fraction, and fatigue resistance well before any patient is exposed to the device. At the same time, the field's methodological literature is notably self-critical: reported bench performance is sensitive to test-rig anatomy, loading protocol, and comparator context, and accelerated durability data remain an imperfect surrogate for decades of true physiological loading and biological remodeling. Continued refinement of anatomically representative bench models, standardized reporting of testing methodology, and closer integration between bench data and subsequent large-animal and clinical follow-up will be essential as an increasingly diverse set of transcatheter heart valve prototypes progresses through the translational pipeline toward clinical use.

Acknowledgements

The authors thank colleagues at the National and Kapodistrian University of Athens, Ghent University, and the University of Debrecen for helpful discussions during preparation of this review.

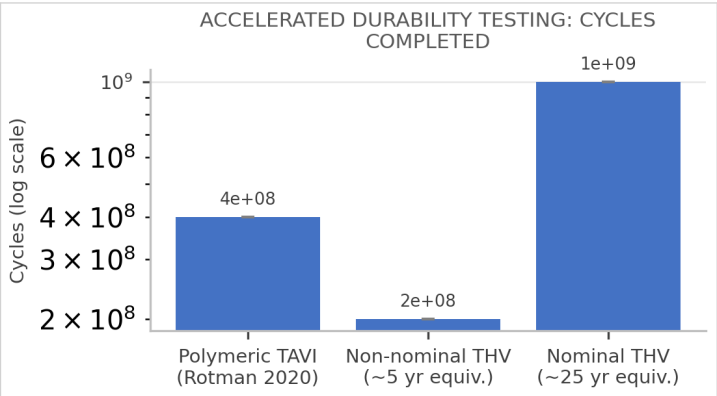
Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of Interest

The authors declare no conflict of interest.

Accelerated wear testing cycle counts reported in the transcatheter heart valve bench-durability literature, shown on a logarithmic scale: a polymeric prototype tested to 400 million cycles without structural failure, and nominal versus non-nominal transcatheter platforms assessed to the equivalent of roughly 25 and 5 years of simulated loading, respectively.



Author Contributions

Papadopoulos S conceived the review and drafted the manuscript. Maes T and Horvath E contributed to literature screening, critically revised the manuscript for important intellectual content, and approved the final version for submission.

Ethics Statement

Not applicable. This narrative review synthesizes previously published bench-testing literature and did not involve human participants, animal subjects, or new experimental data.

Data Availability

No new data were generated or analyzed for this review. All bench-testing data discussed are drawn from the cited published sources.

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