CFD Credibility for Hinge Washout in a Bileaflet Mechanical Valve: Three Models, Two Mechanisms, and Risk-Informed Scoring Under ASME V&V 40

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Abstract

Computational predictions of hinge washout in bileaflet mechanical heart valves are increasingly used to support pre-clinical decisions and to rationalize benchtop testing. We executed a risk-informed credibility assessment under ASME V&V 40 for three computational fluid dynamics models that target two flow-driven clearance mechanisms in the hinge recess: diastolic leakage-driven washout and systolic vortex-pumping washout. Model A is a large-eddy simulation (LES) of the aortic root with prescribed leaflet kinematics; Model B is a steady Reynolds-averaged Navier–Stokes (RANS) representation with porous-hinge surrogates; Model C is a lattice–Boltzmann microscale solver using voxel-resolved hinge geometry. The context of use is to demonstrate washout equivalence of a modified hinge to a reference design in vitro to support reduced dye-visualization testing under ISO 5840-like pulsatile loops. Model influence is high, decision consequence is medium, and overall model risk is high. We quantified the credibility of each model–mechanism pair across six factors on a 0–7 scale: governing-physics appropriateness, correctness of implementation, discretization and iteration uncertainty control, applicability of reported metrics, alignment of comparison tests to the decision setting, and representativeness of operating conditions. The LES and microscale lattice–Boltzmann models achieved high scores for diastolic washout (median 6), with mesh/time-step refinements yielding washout time-constant changes below 2.6% and validation against dye washout and micro-PIV within 8–10% for key quantities of interest. The steady RANS surrogate achieved moderate-to-low credibility for systolic vortex-pumping due to model-form limitations in capturing unsteady entrainment. Sensitivity analyses to waveform and viscosity indicated linear-to-weakly nonlinear scaling of washout metrics in the in-vitro range. We provide risk-informed credibility tables, one per model, to enable read-across to similar hinge geometries and to guide selective substitution of benchtop dye studies with computation when the mechanism of interest aligns with the model's strengths.

Keywords: ASME V&V 40, mechanical heart valve, CFD validation

1. Introduction

Bileaflet mechanical heart valves (BMHVs) have been implanted for decades, with hinge regions that enable leaflet rotation but also present confined recirculating spaces where blood elements may reside and experience elevated shear. The balance between rapid clearance of hinge fluid (washout) and excessive shear exposure relates to the risk of thrombus initiation and growth. Historically, evidence for adequate washout has relied on dye-injection visualizations and flow measurements in ISO 5840-like pulse duplicators. As computational fluid dynamics (CFD) has matured, device developers increasingly propose simulation-derived hinge washout metrics to supplement or partially replace benchtop studies when geometries are modified within established design envelopes.

The present work evaluates the credibility of three CFD models for predicting hinge washout under a defined decision context. We consider two flow-driven process mechanisms that contribute to washout: diastolic leakage jets produced by reverse pressure and systolic entrainment associated with vortical structures adjacent to the hinge. Our aim is not to rank models generically but to assess, in a risk-informed way, whether each model is fit to support a specific decision: to show equivalence of a modified hinge geometry to a reference design under in-vitro aortic conditions and thereby reduce the scope of dye-based benchtop testing.

We implement the framework prescribed by ASME V&V 40 for computational modeling of medical devices. The framework promotes alignment of the computational model's credibility activities to the model risk posed in the given context. We therefore first frame the question of interest and context of use, then characterize model risk, and finally assemble an evidence-based credibility argument for each model–mechanism pair. Our numerical evidence spans model equations and closures, implementation checks, mesh and time-step convergence, input parameter mapping and boundary conditions, and quantitative comparison to laboratory measurements designed to be directly informative to the decision. We summarize the final credibility assessment as three compact, model-specific tables with a 0–7 scoring scale along six factors.

We address three models: (A) a large-eddy simulation (LES) of the aortic root domain with prescribed leaflet kinematics derived from high-speed imaging; (B) a steady Reynolds-averaged Navier–Stokes (RANS) representation where hinge leakage is represented by porous-joint surrogates; and (C) a lattice–Boltzmann method (LBM) model of the hinge recess resolved from micro-CT imaging. We target two mechanisms: (1) diastolic leakage-driven washout and (2) systolic vortex-pumping washout. For each model and mechanism we identify the quantities of interest (QoIs) that will inform the decision: hinge through-flow, Lagrangian particle residence time and its distribution, washout time constants, near-wall shear proxies, and escape probabilities.

Our scope is confined to in-vitro ranges consistent with adult aortic testing per ISO 5840, using Newtonian surrogates of blood at 37 C. We do not predict clinical endpoints; rather, we assess whether the computational outputs are credible surrogates for bench-observed washout behavior under matched conditions. The credibility argument is specific to this decision and does not generalize to endocardial thrombosis risk in vivo. Within this focused scope, we provide detailed numerical evidence and transparent scoring to help practitioners judge when computation can carry evidentiary weight comparable to bench measurements for hinge washout equivalence.

Risk-informed scoping under ASME V&V 40 — gradation.

a.
Model described without explicit decision context; no linkage to risk.

b.
Decision context stated; qualitative statement of model influence and consequence.

c.
Quantified classification of influence and consequence; overall model risk assigned with rationale.

d.
Risk classification informs the choice and depth of credibility activities; evidence traceable to risk drivers.

2. Question of Interest

The decision-maker seeks to determine whether a proposed hinge geometry modification maintains hinge washout performance equivalent to a reference bileaflet valve design when operated under adult aortic in-vitro conditions. The term equivalent is defined operationally as no more than a 10% increase in hinge fluid residence time at the median and 90th percentile relative to the reference, and no more than a 10% decrease in hinge through-flow during diastole, as measured in a pulse duplicator using ISO 5840-consistent waveforms and Newtonian blood analog fluid. The sponsor proposes to use CFD predictions of the specified quantities of interest (QoIs) to demonstrate equivalence, thereby reducing the number of benchtop dye-visualization repeats required in the development program.

The key question of interest is thus whether computational predictions of hinge washout metrics can be trusted, for the two dominant physical mechanisms of washout, to support a regulatory and product-development decision to limit benchtop dye testing. The credibility assessment presented here addresses that question by assembling and evaluating model-specific evidence under ASME V&V 40.

Clarity of decision question — gradation.

a.
Vague question of interest; no quantitative decision rule.

b.
Qualitative decision rule; QoIs implied but not specified.

c.
Quantitative decision rule and QoIs defined; acceptance thresholds stated.

d.
Quantitative decision rule mapped to experimental protocols and computational outputs with explicit traceability.

3. Context of Use (ASME V&V 40)

The computational predictions will be used to demonstrate that a hinge geometry modification does not degrade hinge washout relative to a reference design in an adult-sized bileaflet mechanical valve mounted in the aortic position. The evidence is intended to support reduced benchtop dye-visualization testing within a development program. Predictions are limited to in-vitro operating ranges consistent with ISO 5840 test loops: heart rate 60–80 bpm (nominal 70 bpm), cardiac output 4.5–5.0 L/min (nominal 5.0 L/min), systolic/diastolic pressures of 120/80 mmHg, and Newtonian fluid at 37 C with dynamic viscosity 3.5 mPa·s and density 1.06 g/cm3. Valve size is 25 mm nominal with an orifice area of 2.6 cm2. Hinge geometry is typical of adult bileaflet valves, with a recess depth of 0.9 mm, a span of 3.2 mm, and sub-gap dimensions in the 50–100 μm range as measured by micro-CT.

Only the hinge washout equivalence under the specified bench conditions is in scope. No inference is made to in vivo patient-specific hemodynamics, thrombosis incidence, or optimization of anticoagulation. The models are not used to predict leaflet structural stresses or to assess cavitation. The computational results will be cross-compared to benchtop measurements from a pulse duplicator and transparent hinge replicates to determine whether the QoIs for the modified geometry fall within the pre-specified equivalence bounds relative to the reference design.

The decision is of medium consequence within product development because it alters the scope of benchtop testing but does not directly guide clinical use or labeling. However, the computational evidence will be the primary basis for the hinge washout equivalence claim, rendering model influence high. Per ASME V&V 40, we therefore treat overall model risk as high and align the depth and breadth of credibility activities accordingly.

Context specificity — gradation.

a.
General description with no constraints on use.

b.
Constraints on use defined qualitatively.

[redacted]

Figure 1: Schematic of the three computational models and the two target mechanisms. Model A: macro-scale LES domain encompassing the aortic root and ascending aorta with leaflet kinematics prescribed from high-speed videography; Model B: steady RANS domain with porous-hinge representations for sub-gap leakage; Model C: lattice–Boltzmann voxel-resolved hinge recess from micro-CT. Mechanism 1 emphasizes diastolic reverse-pressure leakage jets through the hinge; Mechanism 2 emphasizes systolic vortex-pumping entrainment adjacent to the hinge.

c.
Quantified operating envelope and device geometry specified.

d.
Quantified envelope mapped to model setup and validation design; off-label use explicitly excluded.

4. Model Risk Analysis (ASME V&V 40)

Model influence is high because the computational predictions are the primary evidence to demonstrate washout equivalence after a hinge geometry modification. If the computational evidence is judged credible, benchtop dye testing will be reduced, and design progression will rely on CFD outputs for the hinge washout claim. If the computational evidence is inconclusive or non-credible, additional benchtop dye studies will be required and the design gate may be delayed.

Decision consequence is medium. The outcome affects the extent and cost of benchtop testing and may influence internal design decisions, but it does not directly affect patient management or regulatory clearance pathways for a new valve model because the hinge modification is within an established platform. The risk to public health from an incorrect decision based on these computations is mitigated by the limited scope and by subsequent verification stages in the product lifecycle.

Combining high influence with medium consequence yields an overall high model risk classification. The rationale is that incorrect CFD conclusions could mischaracterize hinge washout equivalence and lead to insufficient bench testing within the development program. High-risk classification justifies extensive credibility activities focused on the mechanisms of interest: strong examination of the governing equations and closures relative to hinge physics, rigorous checks of numerical implementation, mesh and time-step independence for the QoIs, representative test conditions, validation using measurements performed under the same pulsatile waveforms and fluids as the intended application, and explicit accounting of sensitivity to test conditions within the ISO-like envelope.

Risk classification and linkage to activities — gradation.

a.
Model risk not classified; activities generic.

b.
Model risk classified without influence/consequence rationale.

c.
Influence and consequence analyzed; risk level justified.

d.
Risk level maps to targeted credibility activities with mechanism-specific emphasis.

5. Device and Hinge Geometry Overview

The device considered is an adult-size bileaflet mechanical heart valve seated in an aortic-root test fixture. The valve has an outer diameter of 25 mm and an orifice area of 2.6 cm2. The leaflets are made of pyrolytic carbon with pivoting hinges located at the annular ring. The hinge recess has a typical geometry for this valve class: pocket length 3.2 mm, width 1.1 mm, depth 0.9 mm, and leaflet pin and saddle features that create sub-gaps ranging from 50 to 100 µm at full closure. At opening, the leaflet rotation alters the local recess shape and increases effective communication to the main stream. The geometry is scanned after assembly using micro-CT at 3 µm isotropic voxel size, which resolves the recess surfaces, pivot components, and internal fillets with sufficient fidelity for the microscale model (Model C) and for informing the porous surrogates in Model B.

The test loop uses a rigid acrylic aortic root with physiological expansion of 5% under peak systolic pressure. The inlet and outlet tubing provide Womersley numbers of 15–17 at the operating heart rate. A Newtonian glycerol–saline mixture at 37 C with dynamic viscosity 3.5 mPa·s and density 1.06 g/cm3 is circulated. The target heart rate is 70 bpm with a stroke volume of 71.4 ml, yielding a cardiac output of 5.0 L/min. Pressure waveforms at the aortic root target 120/80 mmHg with peak pressure gradient across the valve of 60–70 mmHg during deceleration. Under these conditions, peak Reynolds number based on orifice diameter and bulk velocity is approximately 6000 during systole, and reverse leakage jets in diastole attain velocities of 1.8–2.3 m/s through the hinge sub-gaps.

Transparent replicas of the hinge region are fabricated by stereolithography at 10× scale for optical validation and at 1× scale for dye washout comparisons. The 1× hinge insert is mounted into a surrogate valve ring to produce realistic leakage paths. The 10× model enables time-resolved micro-PIV imaging of flow topology in the hinge recess during prescribed pressure waveforms scaled by Reynolds and Strouhal matching.

Geometry characterization for modeling — gradation.

a.
Nominal dimensions only; no imaging.

b.
Imaging data available but not used to build model geometry.

c.
Imaging-based geometry used directly for at least one model; tolerances reported.

d.
Imaging-based geometry used across models; sub-gaps resolved; manufacturing variability quantified and mapped to models.

6. Computational Models: A (FSI-informed LES), B (Steady RANS with porous-hinge surrogates), C (Lattice–Boltzmann microscale CFD)

Model A performs large-eddy simulation (LES) in an anatomic test-domain geometry that includes the aortic root, the ascending aorta up to 10 diameters downstream, and the inflow section upstream of the valve. The LES uses a finite-volume solver with a dynamic Smagorinsky subgrid-scale model on an unstructured mesh of 25 million control volumes. Local refinement to 15 µm minimum cell size is applied in the hinge vicinity via an overset mesh, and y+ values are less than 1 on relevant solid surfaces in the hinge pocket. Leaflet kinematics are prescribed based on high-speed imaging of the reference valve in the same test loop, mapped into the computational domain through a moving-boundary framework. Time stepping is second-order implicit at 10 µs per step during diastole and 5 µs during systolic acceleration to maintain CFL less than 1 in the hinge region. The model produces time-resolved velocity fields, instantaneous shear rates, Lagrangian particle trajectories seeded in the hinge pocket, particle residence time distributions, and exponential washout time constants τ derived from hinge tracer decay curves. Boundary conditions use the measured inflow waveform and downstream pressure to match the benchtop loop.

Model B solves the steady Reynolds-averaged Navier–Stokes equations with a k–ω SST turbulence closure in a domain similar to Model A but without moving leaflets. Instead, the leaflets are represented at nominal open and nominal closed positions, and the hinge is represented by porous-joint surrogates with direction-dependent permeability calibrated to benchtop reverse-head leakage tests. The unstructured mesh contains 8 million control volumes with minimum cell size of 40 µm near the hinge. Residuals are converged to 106. Outputs include mean hinge through-flow under steady reverse pressure gradients, a scalar washout index computed from the ratio of through-hinge volume flux to recirculating pocket volume, and near-wall shear proxies in the recess. For systolic conditions, a steady inflow at the peak bulk velocity is used to approximate vortex pumping effects.

Model C uses the lattice–Boltzmann method (LBM) with a D3Q19 lattice and two-relaxation-time (TRT) collision operator to simulate flow in the voxel-resolved hinge recess geometry derived from micro-CT at 3 µm resolution. The computational domain includes the recess, adjacent leaflet and ring surfaces, and small connecting gaps to the main stream. Inlet and outlet boundary conditions are driven by pressure waveforms measured in the loop; interface planes to the main flow are placed within the leaflet-ring gaps and near the pocket mouth. Time stepping is explicit with Δt = 0.5 µs during diastole and 0.25 µs during systole. The fluid is treated as Newtonian at the bench test viscosity. The model outputs full Lagrangian residence-time distributions for thousands of tracer particles seeded uniformly in the recess, escape probabilities over one or more beats, and shear exposure metrics integrated along trajectories. During systole, the model captures the unsteady interaction of shear layers and cavity vortices within the recess as influenced by the upstream-downstream pressure fluctuations.

All three models are implemented in-house with reproducibility workflows that log input files, solver settings, and post-processing scripts. Results are archived with version-controlled metadata and are re-runnable with identical inputs.

Mechanism-to-model mapping — gradation.

a.
Target mechanisms identified but not explicitly mapped to model capabilities.

b.
Mechanisms mapped qualitatively to modeled physics; limitations listed.

c.
Mechanisms mapped quantitatively to resolved scales and closures; evidence of capturing key signatures.

d.
Mechanism coverage demonstrated with diagnostic metrics and cross-model consistency checks.

7. Mechanistic Targets: Diastolic leakage-driven washout and Systolic vortex-pumping washout

Mechanism 1: Diastolic leakage-driven washout dominates during the valve closure and diastolic holding phases. A reverse-pressure gradient drives micro-jets through the sub-gaps around the leaflet pivots and hinge saddle. These jets impinge on recess surfaces, accelerate local recirculation, and actively eject fluid from the pocket into the main stream. The strength and directionality of leakage determine both the residence-time distribution and the shear exposure of elements originally in the recess. Signatures of this mechanism include measurable reverse leakage volume flow per beat, jet peak velocities of 1.8–2.3 m/s in our setup, and exponential-like decay of a passive scalar seeded in the hinge pocket. Computationally, diastolic washout requires resolving leakage pathways and near-wall jet impingement within the recess.

Mechanism 2: Systolic vortex-pumping washout occurs during forward flow when shear layers peel off leaflet edges and the ring, forming vortical structures in the sinuses and adjacent to hinge mouths. These structures entrain fluid from the recess and exchange it with the accelerating main stream. The entrainment rate depends on the local shear layer strength, vortex persistence and proximity to the pocket opening, and the details of recess geometry in contact with the main stream. Signatures include elevated shear adjacent to the pocket mouth (order 1000 s1), coherent vortex cores identified by Q-criterion in instantaneous snapshots, and net mass flux across the pocket interface during ejection. Computational capture requires unsteady resolution of shear-layer dynamics and pocket-mouth interactions.

The two mechanisms may act sequentially and jointly within a cardiac cycle: diastolic leakage clears a substantial fraction of the recess contents before ejection, while systolic entrainment further exchanges residual fluid. A credible model for hinge washout equivalence would represent both mechanisms adequately or, alternatively, would be used within a narrowed context that targets only the mechanism relevant to the decision. In our assessment, the decision-maker wishes to claim equivalence across both mechanisms under the ISO-like bench conditions, hence the need for two-pronged evaluation.

Mechanism articulation — gradation.

a. Mechanisms identified in name only.

b. Mechanisms described with qualitative flow features; no quantitative targets.

c. Mechanisms defined with quantitative signatures and diagnostic metrics.

d. Mechanisms tied to model diagnostics and validation observables with acceptance ranges.

8. Model Form Assessment by Model–Mechanism Pair

For diastolic leakage-driven washout (Mechanism 1), Model A's unsteady LES with prescribed leaflet kinematics directly resolves leakage jets as they traverse the sub-gaps and impinge on recess walls. The local cell sizes near the hinge pocket, together with low y+ and dynamic subgrid modeling, support capture of the rapid shear layers and jet-induced recirculation. The prescribed leaflet motion, taken from high-speed benchtop imaging, ensures that the timing of gap closure and the sub-gap opening fraction during the reverse-pressure phase replicate the experiment. The dominant physical ingredients of Mechanism 1—leakage jets, impingement, and pocket recirculation—are therefore represented with hierarchy-consistent fidelity in this model.

For systolic vortex-pumping (Mechanism 2), Model A's LES resolves the unsteady shear layers and vortex formation near the pocket mouth under forward flow. The large-scale unsteadiness that entrains recess fluid is an LES strength, provided the mesh and time step maintain adequate resolution in the hinge-adjacent region. The prescribed kinematics also align the mouth exposure to the main stream correctly. Thus, for Mechanism 2, the closure choice and large-eddy approach are appropriate, although one could argue that full fluid–structure interaction might further refine pocket exposure timing; in our context, the kinematic prescription is drawn from the very test loop used for validation, mitigating this concern.

Model B approximates the hinge leakage using porous-joint surrogates calibrated to steady reverse-head leakage. For Mechanism 1, this surrogate can represent net through-flow under reversed pressure and hence provides a plausible driver for pocket flushing in an average sense. However, it cannot replicate the detailed jet impingement within the recess nor the unsteady interaction of jets with pocket topology. Thus its ability to reproduce residence-time distributions rests on a scalar washout index tied to mean flux rather than to trajectory-level mixing. For Mechanism 2, Model B's steady RANS with a fixed leaflet position is expected to miss the transient shear-layer dynamics responsible for vortex pumping; entrainment would be underpredicted because the mechanism relies on unsteady vortical structures, not on mean flows.

Model C voxel-resolves the recess and sub-gaps directly from micro-CT. For Mechanism 1, the LBM solver resolves leakage jets through the actual gaps and captures detailed impingement and recirculation paths, producing particle-level trajectories and residence-time distributions. For Mechanism 2, the recess-mouth interaction with the main stream is represented through pressure-driven interface conditions rather than an explicit upstream flow field. Even so, the local formation of cavity vortices within the recess during systolic pressurization is captured, and exchange across the opening is predicted with reasonable fidelity provided that the interface pressure signals are physically consistent with the macro flow. Taken together, the lattice–Boltzmann microscale model is well suited for Mechanism 1 and capable, with acknowledged boundary-condition limitations, for Mechanism 2.

Appropriateness of governing equations and closures — gradation.

a. Key physics for the mechanism are omitted or simplified beyond recognition.

b. Key physics included but with coarse surrogates that do not capture primary features.

c. Key physics represented with appropriate equations and closures; secondary effects approximated.

d. Key physics and secondary effects represented; closure choices justified by data and scale analyses.

9. Numerical Code Verification by Model

We checked the correctness of the numerical implementation for each solver using a combination of method-of-manufactured-solutions (MMS), canonical benchmarks, and internal cross-checks. For Model A, the finite-volume LES code's advection–diffusion subsystem was subjected to MMS with a trigonometric manufactured velocity and scalar field;

L2 norm of the error decreased by approximately a factor of four upon halving the grid spacing, indicating second-order spatial accuracy with an observed order of 1.98. Additionally, decaying homogeneous isotropic turbulence was simulated in a periodic cube and compared to a reference DNS dataset; the compensated energy spectrum matched the 5/3 inertial-range slope within ±5% over a decade of wavenumbers, and kinetic energy decay followed the expected tn law with exponent error below 3%. For moving boundaries, a sloshing tank verification reproduced analytical free-surface periods within 1.5%, increasing confidence in the moving-grid implementation used to prescribe leaflet motion.

For Model B, the steady RANS code underwent MMS with a vortical manufactured solution combining polynomial and trigonometric components under k–ω SST closure. The observed order of accuracy for the velocity field was 2.01 in L2 norm as the grid was uniformly refined from 2 to 32 million elements in a benchmark cube. In a laminar Poiseuille flow test, the pressure drop over a unit-length channel was recovered within 0.2% of the analytical value at moderate Reynolds number, confirming pressure–velocity coupling implementation quality. Turbulence-model source terms were verified in isolation to preserve second-order consistency via patch tests.

For Model C, the lattice–Boltzmann implementation was verified using MMS tailored to the D3Q19 TRT formulation, with a divergence-free manufactured velocity field and corresponding forcing term. The observed convergence rate was 1.95 in grid refinement from 8 µm to 2 µm voxel sizes in a periodic domain. Lid-driven cavity flows at Reynolds numbers 100 and 1000 reproduced benchmark centerline velocity profiles and vortex-center locations within 2% and 0.5 grid spacings, respectively. The pressure boundary implementation was tested in a one-dimensional acoustic propagation problem to ensure minimal spurious reflections; amplitude decay and phase speed matched analytical predictions within 1%.

Across all three codes, unit tests exist for boundary-condition modules, particle tracking (for Models A and C), and porous-joint flux calculations (Model B). Regression tests are run nightly on a representative suite to detect implementation regressions.

Numerical code verification — gradation.

a.
No verification; only informal checks.

b.
Some benchmark comparisons; no convergence evidence.

c.
MMS or equivalent performed; observed orders consistent with nominal.

d.
MMS and multiple canonical benchmarks completed; moving boundaries or special modules verified; automated regression tests in place.

10. Numerical Solver Error: Mesh/time-step independence and iterative residual control by Model–Mechanism Pair

We assessed discretization and iteration uncertainties for each QoI via systematic refinement and residual control. For Model A during diastole (Mechanism 1), we refined the unstructured mesh from 25 million to 35 million cells in the hinge-adjacent region and reduced the time step from 10 µs to 5 µs. The washout time constant τ for a passive scalar initially filling the recess changed by 2.4% with mesh refinement and by 1.1% with time-step reduction, while the median Lagrangian residence time adjusted by 2.0% and 0.9% respectively. Residuals of the pressure-based iteration scheme reduced below 105 each time step. A Roache GCI estimated from the two-grid sequence gave 2.6% for τ and 2.2% for median residence time. For Model A during systole (Mechanism 2), refinement altered the entrainment mass flux across the pocket mouth by 3.1% (mesh) and 1.8% (time step), with a GCI of 2.9% for the exchange fraction per beat.

For Model B under reverse-pressure steady conditions (Mechanism 1), we refined from 8 to 12 million cells near the hinge surrogates and tightened the residual tolerance to 107. The mean hinge through-flow changed by 2.7% upon refinement and by 0.6% upon tightening the residual tolerance; the scalar washout index varied by 3.4% under the same changes. For the systolic steady approximation (Mechanism 2), entrainment proxies based on near-mouth velocity and wall shear changed by 2.2% with refinement and 0.5% with residual tightening, indicating that numerical uncertainty is not the dominant source of error for this mechanism in Model B.

For Model C during diastole (Mechanism 1), voxel size was refined from 4 µm to 3 µm (limited by the micro-CT resolution) and the time step halved from 0.5 µs to 0.25 µs. The washout time constant changed by 1.5% with spatial refinement and 0.9% with temporal refinement. The 90th percentile of the residence-time distribution changed by 1.2% and 0.7% respectively. For the systolic phase (Mechanism 2), the exchange probability per beat changed by 2.1% with spatial refinement and 1.0% with temporal refinement. We confirmed negligible iteration error by comparing synchronous and asynchronous domain decompositions, which yielded QoIs within 0.3% of each other.

Discretization and iteration uncertainty control — gradation.

a.
Single grid and time step; residuals not monitored.

b.
Some refinement attempted; no QoI-based assessment.

c.
Mesh and time-step independence assessed for primary QoIs; residuals below stated thresholds.

d.
Systematic refinement with GCI or equivalent; QoI changes reported with bounds; iteration error negligible relative to discretization.

11. Input Parameter Mapping and Test Conditions

The input parameters for all models were drawn from benchtop measurements in the ISO-like pulse duplicator. Fluid properties were fixed across models: dynamic viscosity 3.5 mPa·s at 37 C and density 1.06 g/cm3. The inflow waveform for Model A was prescribed from a high-resolution ultrasonic flow probe trace acquired in the test loop, and the downstream pressure was matched to the measured aortic pressure waveform. For Model B, steady simulations used the mean reverse pressure gradient during diastole (60–70 mmHg) and the peak bulk velocity during systole (approximately 2.0 m/s through the orifice). The porous-hinge permeability tensor was estimated from dedicated reverse-head leakage tests in the loop that produced a mean leakage of 0.25 ml/beat for the reference hinge. For Model C, inlet and outlet pressure signals were sampled at 2 kHz from the test loop and used directly as driving conditions on planes placed at the recess interfaces with the main stream.

Leaflet kinematics for Model A were derived from high-speed imaging at 2000 frames per second, synchronized to the pressure waveform; the measured angle–time curve was smoothed and applied to the moving-boundary solver. Micro-CT imaging at 3 µm isotropic voxel size provided the hinge recess geometry for Model C and informed the porous representation in Model B by quantifying sub-gap areas at closure. The geometries for Models A and B used a CAD representation of the valve and root, aligned to the micro-CT to ensure hinge position consistency.

We note in passing that achieving strict alignment of all inputs across models is complex due to differences in domain scales, boundary condition abstractions, and data ingestion pathways; mapping choices were made to preserve the dominant flow drivers in each model.

$$\text{CI\_\{score\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{1}$$

$$\text{\textbackslash varepsilon\_\{rel\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{2}$$

$$\text{U\_\{val\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{3}$$

Representativeness of operating conditions — gradation.

a.
Model conditions loosely related to target tests; key parameters differ materially.

b.
Most parameters matched; some differences not justified.

c.
All major parameters (waveform, viscosity, density, temperature, geometry) matched; minor differences justified.

d.
Parameters matched and uncertainty ranges propagated; synchronization between measured and simulated transients documented.

12. Quantities of Interest and Their Relevance to Hinge Washout

We report three classes of QoIs that map to the decision: (1) through-flow and exchange metrics, (2) residence-time statistics, and (3) shear exposure proxies. Through-flow and exchange metrics include the mean reverse leakage volume per beat through the hinge (ml/beat) in diastole, the entrainment mass flux across the pocket mouth during systole (mg/s), and the exchange fraction per beat defined as the fraction of initial pocket fluid volume that exits to the main stream within one beat. Residence-time statistics include the median and 90th percentile of Lagrangian particle residence times computed from pathline tracking of massless tracers seeded in the pocket at end-systole. Shear exposure proxies include the time-averaged shear rate in the pocket near-wall zones during diastole and systole, and the proportion of trajectories exceeding a threshold cumulative shear metric relevant to platelet activation, though we do not map this to clinical risk.

These QoIs align with benchtop observables: the leakage volume per beat is measured in reverse-head tests; dye washout in the pocket produces exponential-like decay curves from which $\tau 63$ and $\tau 90$ can be estimated; entrainment across the pocket mouth can be inferred from time-resolved micro-PIV in a 10× transparent model and from dye thinning during ejection in the 1× loop. By tying the computational outputs to these benchtop observables, the predicted metrics directly support the equivalence decision rule (±10% tolerance relative to the reference design).

Model A computes velocity fields and pathlines across the macro-domain, enabling derivation of all QoIs, including the exchange fraction per beat. Model B computes steady through-flows and a scalar washout index defined as the ratio of through-hinge volume flux to the recirculating recess volume; we calibrate the relationship between this index and τ from bench data to support relevance. Model C yields full Lagrangian residence-time distributions and escape probabilities for the recess at microscale resolution, providing direct access to the τ statistics and exchange fraction per beat.

QoI traceability to decision metrics — gradation.

a.
QoIs reported are weakly related to decision metrics.

b.
QoIs qualitatively related to decision; partial mapping to tests.

c.
QoIs quantitatively related to test observables and decision thresholds.

d.
QoIs are the same metrics as used in tests; computational and experimental estimators aligned.

13. Validation Activities and Relevance to the COU

We performed two families of benchtop measurements designed to be directly informative to the context of use. First, dye washout tests were run in the 1× pulse duplicator under the operating conditions specified above. A small volume of neutrally buoyant dye was injected into the hinge pocket at end-systole, and the decay of pocket dye intensity was recorded by a high-speed camera at 1000 fps through an optical window. Exponential time constants $\tau 63$ and $\tau 90$ were estimated by fitting the decay curve over one to three beats. These tests provide direct comparators for computational washout time constants and residence-time quantiles. Second, time-resolved micro-PIV was performed in a 10× scaled transparent hinge replica under dynamically scaled conditions matching Reynolds and Strouhal numbers. PIV seeding density and image magnification allowed resolution of jet cores and recirculation patterns in the pocket; the data yielded peak jet velocities, shear rates near the pocket mouth, and entrainment flux proxies during forward flow.

Additionally, reverse-head leakage tests were performed by imposing a steady diastolic reverse pressure across the mounted valve and measuring the volumetric leakage through the hinge at 1 kHz with a thermal mass flow sensor. These tests provide calibration and validation data for Model B's porous-joint representation and a cross-check for Model A and Model C leakage-driven washout predictions. All tests were conducted using the same test loop, same valve models (reference and modified), and same fluids as those assumed by the computational models.

Comparisons were made for the reference geometry first to establish baseline model performance; then the modified hinge was scanned and its washout behavior predicted under the same conditions. For the reference geometry, dye washout $\tau 63$ measured in the pocket was 0.44 s on average over 10 cycles (SD 0.03 s), with $\tau 90$ of 1.20 s (SD 0.08 s). Peak diastolic leakage jet velocities measured by PIV in the 10× model scaled to 2.1 m/s (SD 0.1 m/s) at 1×. During systole, entrainment flux proxies indicated that 58% (SD 5%) of the pocket volume exchanged with the main stream within one beat after diastole. These observables anchor our validation comparisons.

Alignment of validation with intended use — gradation.

a.
Validation against unrelated data or conditions.

b.
Validation against partially related tests; key parameters differ.

c.
Validation against same device and conditions; QoIs comparable.

d.
Validation designed to mirror the intended use; synchronized waveforms; measurement uncertainty quantified.

14. Sensitivity of Washout Metrics to Test Conditions

We explored sensitivity of hinge washout metrics to variations in heart rate (60–80 bpm), cardiac output (4.5–5.0 L/min), and viscosity (3.0–4.0 mPa·s) within the ISO-like envelope. In Model A, increasing heart rate from 60 to 80 bpm (holding cardiac output constant) compressed the diastolic interval and reduced $\tau 63$ for the hinge pocket by 6% due to more frequent diastolic leakage events but a shorter per-beat clearance period; $\tau 90$ decreased by 5%. Increasing viscosity from 3.0 to 4.0 mPa·s increased $\tau 63$ by 7% due to reduced leakage jet Reynolds number and weaker impingement-driven recirculation. Entrainment exchange fraction during systole changed by ±4% across the envelope, primarily due to changes in shear-layer thickness.

In Model B, the scalar washout index scaled linearly with reverse-head pressure gradient and inversely with viscosity, as expected from porous-flow theory; however, for systolic approximations, the entrainment proxies showed weak sensitivity to peak bulk velocity due to the steady-state assumption, underpredicting observed changes in dye thinning at higher heart rates. In Model C, τ statistics and escape probabilities showed trends similar to Model A with respect to viscosity and heart rate, with sensitivity magnitudes within 10% of those predicted by Model A. These sensitivity findings support the robustness of equivalence conclusions to small deviations in loop settings; however, decisions were based on matched nominal conditions with documented tolerances.

Sensitivity characterization — gradation.

a.
No sensitivity analysis.

b.
One-factor-at-a-time sensitivity; qualitative.

c.
Quantified sensitivity to key test conditions; linearity assessed.

d.
Sensitivity across operating envelope; cross-model consistency explored; implications for decision margins stated.

15. Results

Model A predictions for the reference hinge under diastolic conditions yielded a washout time constant $\tau 63$ of 0.43 s and $\tau 90$ of 1.16 s, within 2% and 3% of the benchtop means, respectively. The median Lagrangian residence time was 0.42 s, and the 90th percentile was 1.12 s. Peak reverse leakage jet velocities at subgaps were 2.0 ± 0.1 m/s, consistent with the micro-PIV-derived 2.1 ± 0.1 m/s in the 10× model after scaling. During systole, Model A predicted an exchange fraction per beat of 0.60, close to the 0.58 measured by dye thinning, and identified coherent vortical structures near the pocket mouth with instantaneous shear rates up to 1200 s1. The hinge through-flow integral per beat during diastole was 0.23 ml/beat, in the vicinity of the reverse-head measurement of 0.25 ml/beat. Mesh and time-step refinements impacted τ and exchange fraction by less than 3.1% as detailed earlier.

Model B matched reverse-head leakage volume within 12% (0.22 ml/beat predicted vs 0.25 ml/beat measured) and yielded a scalar washout index that correlated to $\tau 63$ obtained from dye washout with R2 = 0.71 across six reverse-pressure settings. The predicted $\tau 63$ conversion for nominal conditions was 0.47 s, 7% above the measured mean, and $\tau 90$ was not directly computed but inferred to be 1.26 s assuming a mono-exponential decay, which matched within 5% of measured. For systolic vortex-pumping, the steady approximation produced an entrainment flux equal to 35% of that computed by Model A and implied an exchange fraction of 0.41 vs 0.58 from dye thinning, revealing model-form limitations for this mechanism.

Model C provided a full Lagrangian residence-time distribution for the hinge recess based on 10,000 tracer particles seeded at end-systole. For diastolic leakage-driven washout, the median and 90th percentile were 0.44 s and 1.10 s, respectively; the exponential time constant $\tau63$ estimated from scalar decay was 0.45 s. Peak leakage jet velocities in the voxel-resolved sub-gaps reached 2.2 m/s, aligning with scaled micro-PIV results. Escape probability per beat exceeded 0.70 for diastolic-only clearance and 0.85 when combined with systolic entrainment. During systole, exchange probability per beat was 0.62 at nominal conditions, compared to 0.58 estimated from dye thinning; however, the smaller number of synchronized systolic validation datasets (two repeated beats) resulted in wider confidence intervals for this comparison.

When applied to the modified hinge geometry, the three models predicted washout metrics within the ±10% equivalence bounds relative to the reference for Mechanism 1 (all three models) and Mechanism 2 (Models A and C). Specifically, Model A predicted $\tau63$ increases of 4% and exchange fraction decreases of 3% for the modified geometry; Model C predicted $\tau63$ increases of 6% and exchange fraction decreases of 5%. Model B, for systolic entrainment, predicted a 12% decrease in the proxy exchange fraction, which could not be directly validated and was not used for equivalence decisions for that mechanism.

With respect to the appropriateness of the governing equations and closures, the choices made in Models A and C reflect the physics that drive washout across the two mechanisms, and the outcomes reproduce the signatures of diastolic leakage jets and systolic entrainment under the bench conditions. For Models A, B, and C, numerical code verification was completed using manufactured solutions or canonical benchmarks, with observed orders of accuracy within 3% of nominal and benchmark errors under 2% for key tests, supporting the correctness of implementation. Discretization and iteration uncertainties were bounded: mesh and time-step refinements changed washout time constants by at most 2.6% and exchange fractions by at most 3.1% across the models and mechanisms, with residual controls maintaining iteration errors well below discretization effects. The reported metrics—hinge through-flow, Lagrangian residence time statistics, washout time constants, and exchange probability—map directly to dye washout endpoints and leakage tests in the ISO 5840 loop, enabling decisions without surrogate translation. Bench comparisons were executed under the same pulsatile waveforms, fluid properties, and valve mountings as the intended application, yielding differences within 8–12% for the primary QoIs and thus directly informing the decision. All simulations and experiments were executed within adult aortic ranges (4.5–5.0 L/min, 70 bpm, 120/80 mmHg), using 37 C glycerol–saline with 3.5 mPa·s viscosity and 1.06 g/cm3 density, and hinge geometries derived from micro-CT and CAD consistent with the test articles.

Result interpretability for decision-making — gradation.

a.
Results reported without context to decision rule.

b.
Results compared qualitatively to tests; uncertainty not discussed.

c.
Results compared quantitatively; uncertainty bounds provided for QoIs.

d.
Results synthesized into an explicit equivalence statement with margins relative to decision thresholds.

16. Credibility Factor Scoring (0–7) – Model A

We summarize credibility scores for Model A (FSI-informed LES) for both mechanisms on a 0–7 scale. Scores reflect the evidence discussed throughout, with the basis restating numerical findings that are detailed in the body of the paper. Factors scored are governing-physics appropriateness, correctness of implementation, discretization and iteration uncertainty control, applicability of reported metrics to hinge washout, alignment of comparison tests to the decision setting, and representativeness of operating conditions. Scores are not averaged across mechanisms and are presented as separate rows to preserve mechanism specificity.

Scoring scale interpretation (0–7) — gradation.

a.
0–1: absent or anecdotal evidence; 2–3: preliminary or partial evidence.

b.
4–5: moderate evidence with gaps or limitations tied to mechanism.

c.
6: strong evidence with small, acknowledged limitations.

d.
7: comprehensive evidence directly matching the intended use.

17. Credibility Factor Scoring (0–7) – Model B

We summarize credibility scores for Model B (steady RANS with porous-hinge surrogates) for both mechanisms. The diastolic mechanism benefits from direct calibration to reverse-head leakage and from steady through-flow comparators. The systolic mechanism emphasizes unsteady vortex pumping, which steady RANS is not designed to capture; scores reflect this model–mechanism mismatch.

Mechanism-specific scoring discipline — gradation.

a.
Single global score irrespective of mechanism.

b.
Mechanisms mentioned but scores not separated.

c.
Scores separated by mechanism; basis relates to mechanism evidence.

d.
Scores separated with mechanism-targeted evidence and limitations stated explicitly.

18. Credibility Factor Scoring (0–7) – Model C

We summarize credibility scores for Model C (lattice–Boltzmann microscale hinge CFD). The voxel-resolved approach aligns particularly well with diastolic leakage-driven washout, while systolic exchange is subject to interface boundary-condition uncertainties. Scores reflect direct measurement alignments and the solver's verification and discretization evidence.

Microscale modeling credibility — gradation.

a.
Geometry idealized; sub-gaps unresolved; limited validation.

b.
Imaging-based geometry used; limited mechanism-specific validation.

c.
Voxel-resolved geometry; mechanism signatures matched to measurements.

d.
Voxel-resolved geometry with synchronized waveform driving; trajectory-level validation and uncertainty quantified.

19. Discussion

Risk-informed credibility assessment clarifies which models can carry evidentiary weight for a particular hinge washout decision. In our case, the highest-confidence predictions for diastolic leakage-driven washout come from Models A and C. Both resolve jets and recess recirculation sufficiently to recover dye washout time constants and residence-time statistics within single-digit percentages, and both operate under waveforms and geometries aligned to the test loop. Model B also provides informative diastolic insight through mean leakage and an empirically linked washout index, albeit with recognized limitations for trajectory-level fidelity in the pocket and a bias that reflects its surrogate representation of the hinge. For systolic vortex-pumping washout, the LES and LBM models again provide the most relevant outputs, with Model A directly resolving shear-layer dynamics at the pocket mouth and Model C capturing cavity vortices and exchange under pressure-driven conditions. The steady RANS approximation in Model B underestimates entrainment because unsteadiness is intrinsic to the mechanism.

The scoring highlights how the same computational method may be strong for one mechanism and weak for another. For instance, Model B achieves a composite of 5, 6, and 6 on implementation correctness and numerical uncertainty control yet earns a 2 for mechanism-appropriate physics in systolic entrainment. Conversely, Model C's code verification score is a notch below Model A's due to the relative maturity of LBM MMS tooling in our environment, yet its mechanism-appropriate physics score reaches 7 for diastolic leakage thanks to voxel-resolved geometry and direct pressure-driven dynamics. These distinctions matter because the decision hinges on mechanism-specific QoIs.

A central practical issue is alignment of validation activities with the context of use. Our dye washout and micro-PIV measurements were designed to mirror the intended application: same fluid, same waveforms, same geometries, synchronized imaging, and quantitative comparators that match computational QoIs. This approach reduces reliance on surrogate inferences and improves the interpretability of model-to-bench differences. For systole, our validation depth was constrained by the challenges of imaging near the pocket mouth at 1× scale and synchronizing pressure measurements with dye thinning; nonetheless, the exchange fraction comparisons provide meaningful confidence bounds for Models A and C.

Sensitivity analysis indicates that within the ISO-like envelope, hinge washout metrics vary modestly with heart rate, cardiac output, and viscosity. This suggests that small deviations in loop settings or unavoidable day-to-day variations are unlikely to flip an equivalence decision when margins of several percent are observed relative to the 10% threshold. However, mechanism balance can shift if diastole shortens disproportionately relative to systole at higher heart rates, a factor to consider when generalizing to different pulsatile regimes.

Limitations of the present work include the use of prescribed leaflet kinematics rather than full fluid–structure interaction in Model A, which could alter pocket-mouth timing slightly under pathological waveforms or device variants with different inertial properties. In Model C, the interface boundary conditions rely on measured pressures and placement at planes near the pocket mouth; pressure–velocity inconsistencies could in principle bias exchange predictions if the macro flow exhibits strong local dynamic pressure variations. Model B's steady approximation underserves systolic vortex-pumping and should not be used for that mechanism's equivalence demonstration; however, it remains a low-cost tool to bound diastolic leakage impacts during early design iterations.

For device developers and reviewers, the per-model tables provided here present a practical guide for selecting models aligned to the mechanism of interest and for interpreting model outputs alongside benchtop data. If the decision centers on diastolic leakage-driven washout under ISO-like loops, both Model A and Model C can credibly replace a portion of dye-visualization repeats, provided that the specific hinge geometry is imaged and boundary conditions are acquired under the same loop configuration. Where systolic vortex-pumping dominates, Model A is the preferred macro-scale approach, and Model C can supplement with recess-focused exchange probabilities; Model B should be reserved for scoping studies or for informing diastolic leakage calibration.

Finally, the approach taken—two-mechanism targeting, mechanism-to-model mapping, and risk-informed scoring—can be transferred to other small-cavity washout problems in cardiovascular devices, including pivot recesses in tilting-disc valves or spring recesses in percutaneous valve frames. The key is to articulate mechanisms, select or design validation observables that reflect them, and then gather numerical and experimental evidence that speaks directly to those observables under the intended conditions.

Limitations and transferability — gradation.

a.
No discussion of limitations.

b.
Limitations listed; no impact assessment.

c.
Limitations analyzed with respect to mechanisms and decisions.

d.
Limitations tied to future work; transferability delineated by mechanism and test envelope.

20. Conclusions

We executed a high-risk, mechanism-oriented credibility assessment under ASME V&V 40 for three computational approaches to hinge washout in a bileaflet mechanical valve under aortic in-vitro conditions. The assessment targeted two mechanisms—diastolic leakage-driven washout and systolic vortex-pumping washout—and scored six credibility factors on a 0–7 scale for each model–mechanism pair. Model A (FSI-informed LES) and Model C (lattice–Boltzmann microscale CFD) achieved strong scores and close agreement with dye washout and micro-PIV for diastolic washout, and they provided credible predictions of systolic exchange when validated against dye thinning and PIV proxies. Model B (steady RANS with porous-hinge surrogates) provided useful diastolic leakage estimates and a scalar washout index but was not credible for systolic vortex-pumping where unsteady entrainment governs exchange.

Key numerical evidence included: observed orders of accuracy within 3% of nominal in code verification tests; mesh and time-step independence with changes below 3.1% for primary QoIs; QoIs that directly match benchtop observables; validation comparisons made under the same waveforms, geometries, and fluids as the intended application; and operation within adult aortic ISO-like ranges. Sensitivity analyses confirmed modest dependence of washout metrics on heart rate, cardiac output, and viscosity within the test envelope.

For the context of use—demonstrating hinge washout equivalence of a modified geometry to a reference design to reduce benchtop dye-visualization testing—the LES and microscale lattice–Boltzmann models can credibly carry evidentiary weight for both mechanisms, with strongest support for diastolic leakage-driven washout. The steady RANS surrogate can support preliminary diastolic assessments but should not be relied upon for systolic entrainment equivalence. The structured per-model, per-mechanism tables provided herein are intended to be read alongside the body evidence to inform mechanism-aligned use of computation in device development.

Decision-focused conclusion — gradation.

a.
Conclusions restate results without decision context.

b.
Conclusions linked to mechanisms but no clear guidance.

c.
Conclusions address fitness for use per mechanism with rationale.

d.
Conclusions provide explicit guidance for computational substitution of tests, bounded by mechanism and conditions.

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Table 1: Credibility assessment summary for Model A (FSI-informed LES) under the two mechanisms of hinge washout.

Credibility factor	Level	Basis
Model form - Model A - Diastolic leakage-driven washout	6	LES with 15 µm minimum cells and y+ < 1 resolves sub-gap jets; peak diastolic jet 2.0 ± 0.1 m/s vs micro-PIV 2.1 ± 0.1 m/s.
Model form - Model A - Systolic vortex-pumping washout	6	Unsteady shear layers and vortices near pocket mouth captured; exchange fraction 0.60 vs dye-based 0.58 at matched waveforms.
Numerical code verification - Model A - Diastolic leakage-driven washout	6	MMS L2 errors show order 1.98; isotropic turbulence spectrum within ±5% of 5/3 slope; moving boundaries verified within 1.5% period error.
Numerical code verification - Model A - Systolic vortex-pumping washout	6	Same implementation checks apply; benchmark energy decay exponent within 3% of reference; regression tests pass.
Numerical solver error - Model A - Diastolic leakage-driven washout	6	Mesh 25M35M changes τ by 2.4% and median residence by 2.0%; Δt 105 µs changes τ by 1.1%; residuals < 1e5; GCI 2.6% for τ.
Numerical solver error - Model A - Systolic vortex-pumping washout	5	Entrainment flux changes 3.1% (mesh) and 1.8% (Δt); exchange fraction GCI 2.9% across refinement.
Relevance of the quantities of interest - Model A - Diastolic leakage-driven washout	7	QoIs (τ63, median/90th residence, leakage ml/beat) directly match dye washout and reverse-leakage tests; τ63 0.43 s vs 0.44 s bench.
Relevance of the quantities of interest - Model A - Systolic vortex-pumping washout	6	Exchange fraction per beat (0.60 vs 0.58 bench) and near-mouth shear are reported and comparable to dye thinning and PIV proxies.
Relevance of the validation activities to the COU - Model A - Diastolic leakage-driven washout	6	Comparisons under same loop, waveform, and fluid; τ63 within 2% and leakage 0.23 vs 0.25 ml/beat (8% difference).
Relevance of the validation activities to the COU - Model A - Systolic vortex-pumping washout	5	Systolic validation limited to dye thinning and PIV proxies; exchange fraction within 3% but fewer synchronized datasets.
Test conditions - Model A - Diastolic leakage-driven washout	7	70 bpm, 5.0 L/min, 120/80 mmHg, 37 C, viscosity 3.5 mPa·s, density 1.06 g/cm3; geometry from micro-CT/CAD matches test articles.
Test conditions - Model A - Systolic vortex-pumping washout	7	Same matched operating envelope and kinematics from the test loop; pocket exposure timing mirrored from high-speed imaging.

Table 2: Credibility assessment summary for Model B (steady RANS with porous-hinge surrogates) under the two mechanisms of hinge washout.

Credibility factor	Level	Basis
Model form - Model B - Diastolic leakage-driven washout	4	Porous-joint surrogates calibrated to reverse-head leakage reproduce mean through-flow (12% bias: 0.22 vs 0.25 ml/beat); internal jet details absent.
Model form - Model B - Systolic vortex-pumping washout	2	Steady RANS at peak velocity cannot represent unsteady vortex pumping; entrainment 35% of LES prediction.
Numerical code verification - Model B - Diastolic leakage-driven washout	6	MMS with vortical solution yields order 2.01; Poiseuille pressure drop error 0.2%; turbulence source terms patch-tested.
Numerical code verification - Model B - Systolic vortex-pumping washout	6	Same verified implementation used; steady solver correctness established on canonical benchmarks.
Numerical solver error - Model B - Diastolic leakage-driven washout	6	Refinement 8M12M changes mean hinge flow 2.7%; residuals to 1e6; washout index varies 3.4% with refinement.
Numerical solver error - Model B - Systolic vortex-pumping washout	6	Entrainment proxies vary 2.2% with refinement; iteration error negligible (residuals 1e6).
Relevance of the quantities of interest - Model B - Diastolic leakage-driven washout	5	Scalar washout index correlates to τ63 with R2 = 0.71 across six settings; mean leakage matches bench within 12%.
Relevance of the quantities of interest - Model B - Systolic vortex-pumping washout	3	Proxy metrics (wall shear, mean velocity) only indirectly relate to dye thinning; poor correlation (R2 = 0.38).
Relevance of the validation activities to the COU - Model B - Diastolic leakage-driven washout	4	Validated to steady reverse-head leakage (9% bias at nominal); no trajectory-level validation in recess.
Relevance of the validation activities to the COU - Model B - Systolic vortex-pumping washout	3	Compared to time-averaged dye loss; bias 25%; validation lacks unsteady entrainment observables.
Test conditions - Model B - Diastolic leakage-driven washout	6	Reverse pressure 60–70 mmHg and fluid properties match tests; geometry aligned; steady approximation acceptable for this mechanism.
Test conditions - Model B - Systolic vortex-pumping washout	6	Peak Reynolds number and fluid properties match; steady inflow used to approximate forward flow.

Table 3: Credibility assessment summary for Model C (lattice–Boltzmann microscale CFD) under the two mechanisms of hinge washout.

Credibility factor	Level	Basis
Model form - Model C - Diastolic leakage-driven washout	7	Voxel-resolved recess at 3 μm resolves sub-gap jets and impingement; τ63 0.45 s; peak jet 2.2 m/s vs PIV 2.1 m/s.
Model form - Model C - Systolic vortex-pumping washout	6	Recess vortices resolved; exchange across pocket mouth driven by measured pressure; exchange probability 0.62 vs 0.58 bench.
Numerical code verification - Model C - Diastolic leakage-driven washout	5	LBM MMS shows order 1.95; lid-driven cavity benchmarks within 2% velocity error; pressure BC verified with 1% amplitude/phase error.
Numerical code verification - Model C - Systolic vortex-pumping washout	5	Same verified modules; interface handling validated on acoustic test; no additional systolic-specific MMS.
Numerical solver error - Model C - Diastolic leakage-driven washout	6	Voxel 43 μm changes τ by 1.5%; Δt 0.50.25 μs changes τ by 0.9%; 90th percentile residence changes 1.2%.
Numerical solver error - Model C - Systolic vortex-pumping washout	6	Exchange probability changes 2.1% (voxel) and 1.0% (Δt); iteration error $<$ 0.3% from sync vs async runs.
Relevance of the quantities of interest - Model C - Diastolic leakage-driven washout	7	Full Lagrangian residence-time distribution and τ63/τ90 computed; median 0.44 s and 90th 1.10 s align with dye (0.44 s, 1.20 s).
Relevance of the quantities of interest - Model C - Systolic vortex-pumping washout	6	Exchange probability per beat (0.62) and near-wall shear reported; compared to dye thinning and PIV proxies.
Relevance of the validation activities to the COU - Model C - Diastolic leakage-driven washout	6	Trajectory-level comparison via dye decay and PIV jet metrics under same waveforms and fluid; median within 0% and 90th within 8%.
Relevance of the validation activities to the COU - Model C - Systolic vortex-pumping washout	5	Limited synchronized systolic datasets (two beats); exchange probability within 7% at nominal; interface BCs from measured pressures.
Test conditions - Model C - Diastolic leakage-driven washout	6	Pressure waveforms at 2 kHz, 37 C, viscosity 3.5 mPa·s, density 1.06 g/cm3; Womersley α ~16; geometry from micro-CT.
Test conditions - Model C - Systolic vortex-pumping washout	6	Same matched conditions; interface planes placed near pocket mouth; boundary placement uncertainty controlled.