Establishing credibility of FSI aortic valve leaflet models for coaptation and stress: a V&V 40-aligned, factor-by-factor assessment across mechanisms

Mira L. Gonsalves, PhD[a], Rafael E. Jimenez, PhD[1], Priya N. Venkataraman, MS[1], Lukas Hartmann, PhD[1], Ananya S. Iyer, PhD[1]

[a] *Center for Cardiovascular Modeling and Simulation, Department of Biomedical Engineering, Montrose Institute of Technology, Boston, MA, USA,*

Abstract

Computational models of trileaflet aortic valves must be justified against clinically meaningful outcomes if they are to contribute to design, risk management, and regulatory decision-making. We report a verification and validation program, aligned with ASME V&V 40, for three fluid–structure interaction (FSI) models of a polymeric aortic valve leaflet with edge reinforcement evaluated as a complete trileaflet assembly. The models span three commonly used strategies: (A) an arbitrary Lagrangian–Eulerian (ALE) anisotropic shell FSI with contact-induced coaptation, (B) an immersed boundary method (IBM) with a homogenized leaflet material, and (C) a partitioned FSI with an explicitly compliant aortic root and mortar-based leaflet contact. We assess credibility against three mechanisms central to valve performance: sustained diastolic sealing under physiologic transvalvular pressure, systolic opening at peak flow, and rapid closure under decelerating flow with water-hammer amplification. For each model–mechanism pair, we grade six credibility factors—numerical resolution, solver iteration and coupling, constitutive and physics representation, boundary and material inputs, mapping of laboratory hydrodynamics to physiology, and representativeness of test leaflets—on a 0–100 Credibility Index. Acceptance requires all factors to score 75 or greater and no single score below 60. Mesh and timestep studies showed that halving characteristic spacings changed peak principal stress by less than 3% for Mechanisms 1–2 and up to 3.8% during closure, while tightening coupling tolerances from 1e3 to 1e5 shifted quantities of interest by under 0.6% except during closure (up to 2.2% for one model). Diastolic coaptation area errors were 5–8% for models A and C (global line load errors 7–10%) and 11% for model B. Peak systolic stress magnitude differed from experimental surrogates by 9–15% depending on model. During closure, all models underpredicted water-hammer amplification (20–36%) and exhibited rebound timing offsets of 6–12 ms. Laboratory waveforms matched target physiology within 3–5% RMS, except for a deceleration overshoot of 9% that biases closure metrics. Two of six leaflet constructs showed 4–6% drift over preconditioning cycles and a variability in reinforcement width of ±0.18 mm contributed to spread in the backflow waveform. These data yield failing Credibility Index scores for several model–mechanism pairs, driven primarily by insufficient physics for the closure transient and unrepresentative test leaflets. On the stated acceptance criteria, the decision outcome is Not accepted.

Keywords: aortic valve, verification and validation, fluid–structure interaction

1. Introduction

Quantitative arguments for model credibility must be matched to how the model will be used and to the clinical risks of wrong answers. ASME V&V 40 establishes a structured pathway to do this, requiring that the question of interest and context of use be explicit, followed by a factor-by-factor collection of evidence that can be weighed against acceptance criteria appropriate to the model risk. For prosthetic aortic valves, three mechanisms dominate performance: sealed coaptation under diastolic load, stress during peak systolic opening, and the rapid, high-rate closure transient. The third of these is the least forgiving from a numerical and physical modeling perspective, as hydrodynamic amplification and contact dynamics combine to produce short-lived but large forces that can govern acute safety and fatigue life.

We report a structured verification and validation program for three computational fluid–structure interaction (FSI) models of a polymeric aortic valve leaflet with edge reinforcement, assembled into a trileaflet configuration and exercised under physiological waveforms. The models are deliberately diverse—an ALE shell-based formulation with contact-induced coaptation (Model A), an immersed boundary method with homogenized leaflet properties (Model B), and a partitioned FSI with an explicitly compliant aortic root and mortar contact (Model C)—to test how modeling choices propagate through the credibility factors for the mechanisms of interest. For each model–mechanism pair we assign a Credibility Index on a 0–100 scale for six factors, using common data and protocols to make the scores comparable. Scores of 75 or higher on all factors, with no single score below 60, are required for acceptance.

The central novelty is not in proposing new physics or solvers, but in executing and documenting, end-to-end, the specific evidence that a decision-maker would need before trusting the model outputs for coaptation area, coaptation line load, regurgitation surrogates, and peak stress. We interpolate between numerical verification, laboratory-to-physiology mapping, and experimental comparisons of mechanism-specific quantities of interest (QoIs), then compress that evidence into a Credibility Index per factor for each combination of model and mechanism. Finally, we synthesize the weakest-link picture across mechanisms to deliver a binary decision, as stipulated by the acceptance criteria.

Overview of evidence maturity in V&V 40 terms — gradation.

a.
Ad hoc reporting of modeling and testing steps without stated acceptance criteria.

b.
Explicit question of interest and context of use, descriptive verification/validation but no graded levels.

c.
Quantitative mapping of evidence to risk-based levels with mechanism-specific QoIs and thresholds.

d.
Formal decision rule and factor-by-factor scoring traceable to data and protocols across mechanisms.

2. Question of interest and context of use

The question of interest is whether each of three FSI models can provide trustworthy estimates of (i) coaptation area and coaptation line load under physiologic diastolic transvalvular pressure; (ii) peak maximum principal stress in the open state at peak systolic flow and its spatial location; and (iii) transient load amplification and spatial stress trajectories during valve closure in the decelerating phase of the cardiac cycle. The context of use is preclinical design assessment of a polymeric trileaflet valve concept with edge reinforcement, where computational outputs are used to prioritize design alternatives and to screen for risk of regurgitation and material over-stress before in vitro testing.

The decision context is comparative and mechanism-specific: we seek to rule in or out the three models for design screening of the stated QoIs. The constraints are realistic: cycle-by-cycle kinematics and stresses are computed under physiologic waveforms in a hydrodynamic loop, and the laboratory system is explicitly mapped to an adult human aortic root pressure–flow environment. A single Credibility Index per factor supports a go/no-go decision, favoring a conservative acceptance rule. If any model–mechanism pair fails the criteria, the model is not accepted for that mechanism in the stated context.

Question of interest specificity — gradation.

a.
QoIs or physiology vaguely stated.

b.
QoIs identified but not tied to mechanisms.

c.
Mechanism-tied QoIs with measurement plans.

d.
Mechanism-tied QoIs with measurement plans and predefined error-to-credibility mapping.

3. Computational models: geometry, constitutive laws, coupling strategies, and computed quantities

All three models represent a trileaflet geometry derived from a CAD description of the device concept: a polymeric leaflet with 180 μm nominal thickness, locally thickened by 30–50 μm at the commissural edges by a reinforcement strip stitched into the leaflet free edge, assembled into a 25 mm internal diameter annulus. The compliant aortic root in Model C is a tubular structure with sinusoidal bulges, 2.0 mm mean wall thickness, and a circumferential compliance of 3.5% per 40 mmHg, derived from silicone surrogate measurements.

Model A (ALE-based anisotropic shell FSI) discretizes each leaflet by 4-node quadrilateral rotation-free shell elements with in-surface anisotropy aligned with the free edge. Leaflet material behavior follows a transversely isotropic Fung-type hyperelastic law with a Prony-series viscoelastic branch (two terms, $\tau 1$ = 0.012 s, $\tau 2$ = 0.19 s; relative moduli g1 = 0.12, g2 = 0.06). The blood analog is modeled as an incompressible Newtonian fluid, ρ = 1060 kg/m3, μ = 3.5 cP. FSI is monolithically coupled in an ALE frame with a low-distortion mesh motion algorithm, and leaflet–leaflet contact uses a surface-to-surface penalty with an augmented Lagrangian update. Computed quantities include time-resolved leaflet kinematics, contact pressure along coaptation, coaptation area, near-valvular velocity fields, and instantaneous principal stresses.

Model B (immersed boundary with homogenized leaflet material) represents the leaflet as a volumetric, uniformly hyperelastic solid embedded in a finite-volume fluid mesh using a distributed Lagrange multiplier formulation. The leaflet's fine-scale reinforcement is homogenized into an orthotropic stiffness with equal in-plane and transverse shear moduli, chosen to match biaxial test curves to within 8% RMSE in the physiological strain range. The FSI algorithm advances fluid and structure in a staggered manner with sub-iterations to satisfy interfacial force balance to a residual of 103 in nondimensional units. Outputs emphasize global orifice dynamics, a surrogate regurgitant fraction computed from the backflow waveform, and cycle-averaged stress as an effective measure of durability risk.

Model C (partitioned FSI with compliant aortic root and mortar contact) treats the root as a deformable solid using 8-node hexahedral elements and the leaflet as a 3D solid with reduced integration, coupled to the fluid via a Robin–Neumann partitioned approach with interface quasi-Newton acceleration. Leaflet contact uses a dual mortar method for accurate pressure transmission across the coaptation line. The root's material is a near-incompressible silicone model with a Mooney–Rivlin fit (C10 = 0.12 MPa, C01 = 0.03 MPa). Computed outputs include coupled leaflet–root motion, transient loads during closure, spatial stress trajectories across the cycle, and a coaptation contact map in time.

For all models, the fluid domain extends 5 diameters upstream and downstream of the annulus with a fully developed inflow profile and a three-element Windkessel condition downstream to match target aortic pressure. Cycle periodicity is achieved by running five cycles and reporting the fifth. Time integration is second-order accurate for both fluid and solid

Figure 1: Overview of the aortic valve leaflet geometry, load cases and the mechanisms assessed, shown across the full page width.

subsystems, with adaptive stepping subject to a maximum Courant number of 0.8 on the fluid side and a maximum structural timestep of 0.2 ms.

Throughout, we adhere to a common set of quantities of interest per mechanism: (Mechanism 1) coaptation area over the central 100 ms of diastole (mean and standard deviation) and mean coaptation line load; (Mechanism 2) peak maximum principal stress during peak systole (averaged over a 20 ms window centered at maximum flow) and the centroid of the top 5% stressed leaflet area; and (Mechanism 3) the peak transvalvular pressure increase at closure (water-hammer amplification over the pre-closure pressure), the time from zero flow to rebound onset, and the maximum principal stress overshoot relative to the systolic baseline.

Model characterization completeness — gradation.

a. Geometry or materials not fully specified.

b. Geometry and materials specified; coupling described qualitatively.

c. Geometry, materials, and coupling specified with parameter values and references.

d. Geometry, materials, coupling, and computed QoIs specified with protocols and cycle-to-cycle conditioning.

4. Mechanisms and quantities of interest: coaptation metrics and stress metrics

Mechanism 1 (diastolic coaptation under physiologic transvalvular pressure) is central to valve competence. In the hydrodynamic loop, we prescribe an aortic pressure waveform with mean 95 mmHg and diastolic nadir at 80 mmHg, while the ventricular side is driven to achieve a reverse gradient peaking at 110 mmHg. In this period, the acceptable performance envelope is sustained coaptation area and adequate coaptation line pressure along the free edges. Experiments measure coaptation area by high-speed imaging with segmentation of leaflet overlap, and line load by calibrated pressure-sensitive film integrated along the coaptation line. Models measure the same quantities directly from contact integrals.

Mechanism 2 (systolic opening at peak flow) is where long-term durability is governed by stress magnitudes and distributions in the open state. The target peak flow is 24 L/min at a heart rate of 70 bpm. Peak principal stress and its location on the leaflet surface are computed from the structural solver. Experimental surrogates for stress are obtained via stereo digital image correlation (DIC) on transparent leaflets with a stochastic speckle and via strain-to-stress conversion using material curves from planar biaxial tests synchronized to the flow peak.

Mechanism 3 (rapid closure transient) challenges both physics and numerics. As flow decelerates through zero, the onset of reverse gradient produces a water-hammer-like transient that loads the leaflet suddenly. The loop captures transvalvular pressure at 5 kHz, synchronized with backflow rate and leaflet kinematics. The QoIs in this phase are the peak amplification of pressure across the valve relative to its pre-closure value, the timing of the first rebound relative to zero crossing of flow, and the peak overshoot of principal stress compared to the systolic open state.

These QoIs are chosen to align with the failure modes we wish to guard against: inadequate sealing and regurgitation risk (Mechanism 1), material damage accumulation (Mechanism 2), and high-rate overloading or flutter onset (Mechanism 3).

Mechanism-to-QoI traceability — gradation.

a. QoIs only loosely related to mechanisms.

b. QoIs linked qualitatively to mechanisms with limited measurement fidelity.

c. Quantified QoIs mapped to mechanisms with synchronized experimental readouts.

d. QoIs mapped to mechanisms with synchronized, high-rate readouts and model–experiment parity of observables.

5. Model risk analysis and rationale

Risk to decision quality arises from the combination of model form limitations, numerical errors, and the representativeness of boundary conditions and samples. For Mechanism 1, the physics are quasi-static and contact-dominated; risk is primarily from constitutive mis-specification at low strain and contact law behavior. For Mechanism 2, stresses are sensitive to anisotropy, viscous damping, and fluid loading; model simplifications that homogenize reinforcement or use shells rather than solids change stress distributions. For Mechanism 3, closure dynamics are governed by high-rate fluid–structure coupling, wave propagation in the root, and the specific contact law at coaptation; this mechanism is most sensitive to missing physics such as compressibility, rate-dependent damping, and accurate wall compliance.

We therefore anticipated, a priori, that Model B would trade spatial stress fidelity for global flow fidelity (due to homogenization and volumetric immersion of the leaflet), that Model A would capture coaptation area and line loads robustly (due to explicit surface contact with anisotropy) and do reasonably for systolic stresses, and that Model C would be advantaged in closure transient predictions (due to an explicitly compliant root and mortar contact). These expectations guided the allocation of verification and validation effort, with an emphasis on high-rate measurements and solver checks around closure for all models.

Risk-informed allocation of V&V effort — gradation.

a.
Uniform effort with no linkage to mechanism risk.

b.
Effort broadly scaled by perceived difficulty.

c.
Effort targeted to mechanisms and physics with highest impact on decision.

d.
Effort quantitatively allocated based on sensitivity and prior error profiles.

6. Evidence plan and acceptance criteria on the 0–100 Credibility Index

We defined a six-factor evidence plan applied separately to each model–mechanism pair. The factors are: numerical resolution of discretized domains and timestepping; solver iteration and partition coupling accuracy; physics and constitutive choices including contact representation and fluid rheology; boundary and material parameterization including uncertainty characterization; correspondence between hydrodynamic loop conditions and physiologic waveforms; and the degree to which the tested leaflet constructs represent the design's intended population. Each factor is graded 0–100 using a private scale translated from V&V 40 level descriptors into a numerical index that allows aggregation across mechanisms without masking weak links.

Acceptance requires every factor at or above 75, and no single factor below 60, for every model–mechanism pair. This rule enforces both a high minimum bar and distributes confidence evenly across the chain of evidence: one fragile link disqualifies the model for that mechanism. We publish one table per model listing all factors for each mechanism with their gradation and a brief basis statement restating numbers presented in the Results and Synthesis sections.

The plan's measurement and computation cadence is as follows: all models are run to cycle periodicity (five cycles), with outputs recorded at 1 kHz equivalent. Mesh and timestep convergence studies are performed with at least two refinements (characteristic element length h and timestep Δt halved) and reported as percent changes in QoIs. Solver iteration and coupling accuracy are probed by tightening nonlinear and interface tolerances by two orders of magnitude and re-running a representative cycle. Physics and constitutive choices are justified against benchtop mechanics and hydrodynamics. Boundary and material uncertainties are propagated via one-at-a-time perturbations and, for selected parameters, a Latin hypercube design of 50 samples to measure output spread for the closure event. Hydrodynamic mapping fidelity is quantified by RMS and peak errors between loop waveforms and physiological targets. Representativeness of test constructs is evaluated by preconditioning drift, reinforcement geometry measurements, and mounting reproducibility.

Credibility index ladder for decision readiness — gradation.

a.
Qualitative traffic-light assessments without numeric thresholds.

b.
Numeric thresholds defined post hoc to match observed data.

c.
Predefined numeric thresholds with factor-by-factor scoring per mechanism.

d.
Predefined numeric thresholds with factor-by-factor scoring per mechanism and a pass/fail decision rule tied to model risk.

7. Software quality assurance (brief overview)

All three codes were maintained under version control with branch protection and continuous integration executing unit and regression tests on each commit. Run manifests, solver settings, and post-processing scripts were archived with persistent identifiers. We note that independent code review and formal tool qualification were not in scope and are mentioned here only for transparency.

Engineering controls for code and data handling — gradation.

a.
Manual file handling and informal change tracking.

b.
Version control with basic test suites.

c.
Continuous integration with regression tests and run manifests.

d.
Independent code audits, tool qualification, and traceable execution environments.

8. Discretization error: mesh convergence protocols and element technology checks

We established resolution studies for each model and mechanism, measuring changes in QoIs upon halving characteristic element length and timestep. For Model A, leaflet shells used three meshes: coarse (h = 0.45 mm along free edge, 18k elements per leaflet), medium (h = 0.30 mm, 34k per leaflet), and fine (h = 0.20 mm, 72k per leaflet). The fluid mesh was refined accordingly from 2.1 million to 6.8 million cells, with near-leaflet layers preserving y+ < 1. Timesteps were 0.30, 0.20, and 0.10 ms in the structural solver; fluid maxima were set by a Courant cap. The same pattern was executed for Model B with immersed structures discretized on a 3D grid (0.35, 0.25, 0.17 mm), and for Model C with 3D structural elements (0.40, 0.28, 0.20 mm) and a matching fluid refinement.

We performed element technology checks appropriate to each model. For Model A, we verified shell locking behavior by comparing rotation-free elements to MITC4 on a cantilevered leaflet strip under bending; differences in midspan deflection were under 1.4% at strains comparable to diastolic coaptation. For Model B, we tested the immersed coupling's sensitivity to grid anisotropy by rotating the mesh 15 degrees relative to the commissural axis; changes in peak systolic flow rate were under 0.6%. For Model C, reduced-integration 3D solid elements were checked against fully integrated elements on a single-leaflet patch, with less than 1.0% difference in peak stress at equivalent resolution.

The convergence protocol computed relative changes in QoIs between medium and fine resolutions. These changes, reported later under Results for each mechanism and model, form the numerical basis for the resolution-related scores. We did not extrapolate to zero mesh size due to prohibitive costs in the closure transient, but the two-level study sufficed to map errors to the Credibility Index thresholds defined.

Spatial and temporal resolution rigour — gradation.

a.
Single mesh and timestep; no sensitivity checks.

b.
Two-level refinement without quantification of all QoIs.

c.
Two- or three-level refinement on all QoIs with element technology checks.

d.
Multi-level refinement with extrapolation to zero size and cross-element technology verification.

9. Numerical solver error: partitioning tolerance, coupling stability, and time-integration accuracy

All models were run with baseline solver tolerances, then repeated with tighter settings to assess algorithmic sensitivity. For Model A, the monolithic Newton residual was tightened from 104 to 106, contact augmentation was allowed up to 20 iterations per step (from 10), and the time integrator's nonlinear iterations were capped at 30 (from 15). For Model B, the fluid–structure sub-iterations per step increased from 5 to 20 and the interface residual target was reduced from 103 to 105; the pressure–velocity coupling in the fluid advanced from PISO to PIMPLE with two outer corrections. For Model C, the Robin–Neumann partitioning used interface quasi-Newton acceleration with secant recycling; the interface residual was tightened from 103 to 105 and the structural and fluid solvers' nonlinear tolerances from 104 to 106.

Coupling stability was monitored via residual histories and by tracking the energy balance over a cycle. For Model A, the monolithic approach exhibited robust quadratic convergence except during closure, where line search reduced step lengths to maintain stability. For Model B, mass conservation at the interface remained within 0.3% per timestep at baseline and 0.05% when tightened. For Model C, the quasi-Newton acceleration reduced interface iterations by 40% relative to Picard for Mechanisms 1–2, but closure still required up to 25 interface iterations per step when tolerances were tightened.

Time-integration accuracy was evaluated by halving the maximum timestep in the structural and fluid solvers while holding spatial resolution fixed at medium. Changes in QoIs are documented in the Results, providing numerical evidence for the solver-related Credibility Index scores.

Solver coupling and iteration control — gradation.

a.
Default tolerances; no sensitivity or stability checks.

b.
Sensitivity to tolerances measured on a subset of QoIs.

c.
Sensitivity to tolerances measured on all QoIs; energy balance and interface mass conservation tracked.

d.
Sensitivity mapped to mechanism-specific events with adaptive control demonstrated at closures.

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

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

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

10. Model form: constitutive representation, contact/coaptation formulation, and fluid rheology choices

Constitutive laws and contact formulations differ across models in ways expected to influence the QoIs. Model A's anisotropic shell formulation with a Prony-series viscoelastic branch captures time-dependent response under diastolic load and anisotropy induced by the reinforcement strip along the free edge. The augmented Lagrangian contact algorithm enforces coaptation with a penalty parameter calibrated against pressure-sensitive film under static pressurization, producing a coaptation line load within an 8% band in a static test.

Model B homogenizes the reinforcement and uses a volumetric, orthotropic solid immersed in the fluid. The homogenization preserves global stiffness in biaxial tests, but it does not recreate the local reinforcement-induced stress concentration near the commissures observed in DIC, and the regularized delta used in the immersed constraint smears interface tractions over two to three grid cells. As a result, we expected accurate global flow and backflow waveforms but less fidelity in local coaptation and stress hotspots.

Model C uses 3D solids for the leaflet and an explicitly deformable root, with mortar contact enabling accurate traction transmission. The flexible root allows wave propagation effects during closure and better reproduces the spatial distribution of contact. However, due to the use of a Newtonian fluid and an incompressible structural model, this approach still omits compressibility effects that can matter in the first milliseconds of the closure transient.

For all models, we used a Newtonian fluid rheology as shear rates were in the range where non-Newtonian effects are modest. We verified that switching to a Carreau–Yasuda model changed peak systolic leaflet stress by less than 1.2% in Model A at medium resolution, consistent with the flow regime.

The mapping from model form to expected errors is further documented in the Results, where quantitative differences between predictions and measurements are presented per mechanism.

Physics representation adequacy — gradation.

a.
Key mechanisms omitted or simplified without justification.

b.
Simplifications justified qualitatively with partial tests.

c.
Simplifications justified quantitatively against mechanism-relevant data.

d.
Model form tailored to mechanisms with quantitative residual errors bounded against acceptance thresholds.

11. Model inputs: boundary conditions, material parameters, and uncertainties

Boundary conditions were constructed from the hydrodynamic loop's measured upstream and downstream impedances. The downstream three-element Windkessel parameters (R1, C, R2) were tuned to reproduce a target aortic pressure waveform with mean 95 mmHg and pulse pressure 45 mmHg at 70 bpm: R1 = 110 dyn·s·cm5, C = 1.5 mL/mmHg, R2 = 1400 dyn·s·cm5. The inflow waveform was prescribed to reach 24 L/min peak. Material parameters for the leaflet in Models A and C were obtained from planar biaxial tests on the polymer film with reinforcement strips: circumferential and radial moduli were identified via least-squares fits to Cauchy stress versus stretch data, with 95% confidence intervals of ±6% in the quasi-linear portion. For Model B, homogenized orthotropic parameters were chosen to match biaxial curves to 8% RMSE over 0.8–1.2 stretch.

Uncertainties were propagated by perturbing key inputs. We varied the leaflet loss factor by ±20% around its nominal value in the viscoelastic models (A, C) and adjusted the effective damping in Model B by varying the immersed drag coefficient accordingly. We also perturbed reinforcement width by ±0.20 mm around its nominal 0.80 mm and the Windkessel capacitance by ±10%. For closure, we sampled 50 realizations via Latin hypercube sampling over these ranges for each model and measured the spread in water-hammer amplification and rebound time. Quantitative outcomes appear in the Results, forming the basis for input-related scores.

Input characterization and uncertainty treatment — gradation.

a.
Nominal inputs only; no uncertainty quantification.

b.
Parametric sweeps on single inputs; limited ranges.

c.
Multi-parameter uncertainty analysis with sensitivity mapping.

d.
Mechanism-focused uncertainty quantification with probabilistic sampling and output spread-to-threshold comparison.

12. Test conditions: hydrodynamic loop settings and physiologic waveform mapping

The hydrodynamic loop used a programmable pulsatile pump upstream and a tunable compliance and resistance network downstream. Pressure and flow were measured by high-frequency transducers (5 kHz sampling for closure events, 200 Hz otherwise) and electromagnetic flowmeters. We matched an adult aortic waveform (70 bpm, 120/75 mmHg) by calibrating R1, C, and R2 ahead of experiments on leaflets using a rigid orifice; then we substituted the valve assembly and adjusted inflow to maintain target peak and mean flow rates.

The mapping fidelity to physiology was quantified as RMS error between the target and measured pressure waveforms over one cycle and as peak error during deceleration. Across all runs used for validation, the cycle-averaged RMS error in aortic pressure was 3.2–4.6%, and the deceleration segment exhibited an overshoot of 9% relative to the target, attributed to the compliance of the tubing upstream of the valve. Flow waveforms matched target peak to within 0.5 L/min and mean to within 0.3 L/min. These mappings, and their limits at deceleration, are reflected in mechanism-specific comparisons and in the scores for correspondence of laboratory conditions to physiology.

Laboratory-to-physiology mapping fidelity — gradation.

a.
Qualitative correspondence of lab and physiology; no metrics.

b.
Global metrics (means, peaks) matched; transients ignored.

c.
Global metrics and transients matched with quantified RMS and peak errors.

d.
Global and transient metrics matched; residual discrepancies characterized in phase segments relevant to mechanisms.

13. Test samples: leaflet constructs, mounting, and sample representativeness

Six leaflet sets were manufactured from the target polymer film with stitched reinforcement strips. The reinforcement strip width, measured by optical microscopy, had a mean of 0.82 mm with a standard deviation of 0.18 mm across all commissures and leaflets. The reinforcement stitch density was 5.8 ± 0.7 stitches/mm. Each leaflet set underwent ten preconditioning cycles at 70 bpm and the coaptation area drift across cycles was quantified to assess stabilization before measurement.

Mounting was performed in a rigid holder with a suture pattern standard across runs; alignment was verified by imaging commissural heights, which were within ±0.3 mm of nominal. Two of the six leaflet sets exhibited 4–6% drift in coaptation area over the ten preconditioning cycles and showed a gradual shift in backflow waveform during closure between cycles 1 and 10. The remaining four sets stabilized within 2% after the third cycle. Sample-to-sample variability, preconditioning drift, and reinforcement variability contribute to the eventual Credibility Index scores concerning representativeness.
Sample representativeness and mounting control — gradation.

a.
Single construct; no characterization.

b.
Multiple constructs with basic geometric checks.

c.
Multiple constructs with geometry and preconditioning characterized; mounting reproducibility quantified.

d.
Multiple constructs covering design variability; preconditioning stabilization criteria enforced and linked to QoI spread.

14. Results: per-factor 0–100 scores for every model × mechanism pair, with coaptation and stress comparisons

We summarize quantitative outcomes that underlie the Credibility Index tables printed in the following sections, organized by model and mechanism. For all models, results reported here correspond to the fifth cycle after periodicity, at medium resolution unless otherwise noted, with sensitivity studies as described below.

Model A, Mechanism 1 (diastolic coaptation). Coaptation area predicted by Model A averaged 152 mm2 over the central 100 ms of diastole (SD 7 mm2), compared with 160 mm2 measured by imaging (SD 9 mm2), an error of 5.0%. Mean coaptation line load integrated over the free edges was 17.2 N/m compared with 18.8 N/m by pressure-sensitive film, a 8.5% difference. Mesh and timestep refinement changed coaptation area by 1.8% (medium-to-fine) and mean line load by 1.2%. Tightening monolithic Newton and contact tolerances shifted area by 0.3%. Perturbing the leaflet loss factor by ±20% changed line load by ±3.1%, and reinforcement width by ±0.20 mm changed coaptation area by ±2.7%. The laboratory waveform matched physiology with 3.6% RMS error for aortic pressure over the cycle.

Model A, Mechanism 2 (systolic opening). Peak maximum principal stress reached 1.42 MPa (averaged over a 20 ms window around peak systole), with the centroid of the top 5% stress region located within 2.3 mm of the commissure in the belly region; stereo DIC plus stress conversion estimated 1.30 MPa with centroid offset 2.0 mm, yielding a 9.2% magnitude difference and good location agreement. Mesh and timestep refinement changed peak stress by 1.1% and centroid position by 0.4 mm. Solver tightening altered peak stress by 0.4%. Inputs sensitivity indicated that ±20% loss factor changed peak stress by ±2.0%. The hydrodynamic mapping error during systole was 3.2% RMS in aortic pressure.

Model A, Mechanism 3 (rapid closure transient). The water-hammer amplification over the pre-closure pressure was 18.5 mmHg in the experiment and 13.0 mmHg predicted, an underprediction of 29.7%; rebound onset occurred 9 ms after zero flow in the experiment and 15 ms in the model, a 6 ms delay. Peak principal stress overshoot was 0.38 MPa above the systolic baseline experimentally and 0.29 MPa in the model (24%). Resolution changes altered peak amplification by 3.6% and stress overshoot by 2.8%. Tightening solver tolerances shifted amplification by 1.9%. Input variations (±20% loss factor, ±0.20 mm reinforcement width, ±10% Windkessel C) led to a 10.4% spread (95% width) in predicted amplification and 7 ms spread in rebound time. The laboratory deceleration segment overshot the target by 9%.

Model B, Mechanism 1 (diastolic coaptation). The immersed boundary model predicted a smaller coaptation area at 142 mm2 (SD 8 mm2) against 160 mm2 measured, a 11.3% error. Mean coaptation line load is not directly computed as a sharp traction but was estimated from distributed interfacial forces integrated over the contact region as 17.0 N/m against 18.8 N/m (9.6%). Resolution studies (grid size and Δt halved) altered coaptation area by 2.3%. Tightening interface residual from 103 to 105 changed area by 0.4%. Input sensitivity to effective damping produced a ±3.6% change in area. RMS mapping error in aortic pressure was 4.1%.

Model B, Mechanism 2 (systolic opening). Cycle-averaged peak equivalent stress in the open state was 1.10 MPa, 15.4% below the DIC-derived estimate of 1.30 MPa. The centroid of the top 5% stress area was 3.6 mm from the commissure, more diffuse than observed. Resolution decreased the error by 1.7% in magnitude; solver tightening changed the QoI by 0.6%. Input perturbations shifted peak stress by ±2.5%. Hydrodynamic mapping RMS error during systole was 4.6%.

Model B, Mechanism 3 (rapid closure transient). The model estimated 11.8 mmHg amplification vs. 18.5 mmHg measured (36.2%), with rebound onset 12 ms late. Peak stress overshoot was 0.24 MPa vs. 0.38 MPa measured (37%). Resolution altered amplification by 3.8%; solver tightening changed it by 2.2%. The 50-sample uncertainty study produced a 12.1% spread in amplification and 10 ms spread in rebound time.

Model C, Mechanism 1 (diastolic coaptation). Coaptation area was 151 mm2 (5.6%) with mean line load 17.6 N/m (6.4%). Mesh and timestep refinement changed area by 1.7% and line load by 1.0%. Solver tightening shifted area by 0.5%. Input perturbations produced ±2.8% change in area. RMS mapping error in aortic pressure was 3.4%.

Model C, Mechanism 2 (systolic opening). Peak maximum principal stress was 1.36 MPa (10.8% against 1.30 MPa reference if we consider experimental uncertainty bands) with centroid offset by 2.1 mm. Resolution and timestep halving changed peak stress by 0.9% and centroid position by 0.3 mm; solver tightening shifted stress by 0.5%. Inputs varied stress by ±2.2%. RMS mapping error was 3.3%.

Model C, Mechanism 3 (rapid closure transient). With a compliant root and mortar contact, amplification was 14.8 mmHg (20.0%) and rebound onset 6 ms late. Stress overshoot was 0.31 MPa (18%). Resolution changed amplification by 3.2% and overshoot by 2.1%; solver tightening altered amplification by 1.6%. The 50-sample uncertainty run showed an 8.3% spread in amplification and 6 ms spread in rebound time. The deceleration overshoot in the loop remained at 9%.

These quantitative results support the factor-by-factor gradations per model and mechanism. In brief, resolution and solver sensitivities were small for Mechanisms 1–2 and modest for Mechanism 3; form-related discrepancies were acceptably small for Mechanisms 1–2 in Models A and C but larger for Model B; closure transients were underpredicted in all models; and the laboratory deceleration overshoot and sample-to-sample variability limited overall confidence.

Results traceability to credibility factors — gradation.

a.
Results qualitative; not mapped to factors.

b.
Quantitative results presented; factor mapping implicit.

c.
Quantitative results presented with explicit per-factor linkage.

d.
Quantitative results presented with explicit per-factor linkage and mechanism segmentation.

15. Credibility assessment table for Model A: ALE-based anisotropic shell FSI

The following table lists the Credibility Index gradations for Model A across all three mechanisms and six factors, with a one-line basis that restates numerical evidence reported in the Results and Synthesis sections.

16. Credibility assessment table for Model B: Immersed boundary FSI with homogenized leaflet material

The following table lists the Credibility Index gradations for Model B across all three mechanisms and six factors, with basis statements aligned to the quantitative data reported under Results and Synthesis.

17. Credibility assessment table for Model C: Partitioned FSI with compliant aortic root and mortar contact

The following table lists the Credibility Index gradations for Model C across all three mechanisms and six factors, with basis statements aligned to the quantitative data reported under Results and Synthesis.

18. Synthesis across mechanisms: weakest-link appraisal against acceptance criteria

Across the three solvers and three mechanisms, halving characteristic mesh spacing and timestep altered peak principal stress by less than 3.0% for Mechanisms 1–2 and up to 3.8% for closure, and coaptation area by less than 2.3%, indicating that numerical resolution was sufficient for the questions asked.

Tightening nonlinear and interface tolerances by two orders of magnitude shifted key outputs by under 0.6% in sustained diastole and at peak systole, and by up to 2.2% during the closure transient in the immersed boundary solver, with similar behavior in the other models, consistent with solver residuals being subdominant contributors to errors.

The closure event was not captured with the desired faithfulness: all three implementations underpredicted the pressure spike over the pre-closure value by 20–36% and produced rebound onsets 6–12 ms late, with stress overshoots smaller than measured, signaling that the combination of wall compliance, compressibility, and contact dynamics in this fast transient was inadequately represented.

Boundary-load and material parameter sets lay within physiologic and measured ranges, but uncertainty in the polymer's loss factor and reinforcement width generated a 8.3–12.1% spread in predicted closure amplification and a 6–10 ms spread in rebound timing across the models, which dominated the output variability for Mechanism 3 relative to Mechanisms 1–2.

The hydrodynamic loop reproduced target aortic pressure and flow waveforms with RMS deviations of 3.2–4.6% across the cycle and maintained peak and mean flows within 0.5 and 0.3 L/min, respectively; however, during deceleration the aortic pressure overshot by 9%, which limits the fidelity of closure-event comparisons.

Two of the six leaflet sets exhibited 4–6% drift in coaptation area across preconditioning cycles and microscopy revealed a reinforcement width variability of ±0.18 mm, so the tested constructs did not fully reflect the intended design uniformity and add confounding variability to the backflow and coaptation metrics.

Under the acceptance rule (all factors 75 or greater and none below 60 for every model–mechanism pair), several weak links emerge. For Mechanism 3, Model A's and Model B's physics representation scores fall below 60 due to large underpredictions of water-hammer amplification and delayed rebound timing; for all models and mechanisms, representativeness of the tested constructs is marginal, with values near or below 60 for the closure transient. Even where factor scores exceed 75 in sustained diastole and peak systole, the overall decision is governed by the minimum across the set, enforcing a conservative conclusion appropriate to the risk.

This weakest-link appraisal is emphasized by the tabulated Credibility Index values: Model A is brought below threshold by the physics of closure and by construct variability; Model B is noncompliant in physics for closure and marginal for stress in the open state; Model C, while strongest in closure among the three, still fails the closure physics threshold and suffers from the same construct limitations. The deliberately strict acceptance criterion ensures that confidence must be uniformly high, rather than allowing excellence in one mechanism to mask fragility in another.

Synthesis and decision logic transparency — gradation.

a.
Narrative synthesis without explicit weakest-link analysis.

b.
Weakest-link analysis anecdotal; limited linkage to scores.

c.
Weakest-link analysis quantified and linked to tabulated scores.

d.
Weakest-link analysis quantified with direct mapping to acceptance rule and risk posture.

19. Conclusion: Not accepted due to inadequate model form for the closure transient and unrepresentative test samples leading to failing Credibility Index scores in multiple model–mechanism pairs

We executed a V&V 40-aligned, mechanism-focused credibility assessment for three FSI models of a trileaflet polymeric aortic valve with edge reinforcement. The models—ALE anisotropic shell with contact, immersed boundary with homogenized leaflet material, and partitioned FSI with a compliant root and mortar contact—were interrogated against three mechanisms of interest. Evidence was assembled and scored for six factors per model–mechanism pair on a 0–100 Credibility Index with a strict acceptance rule requiring all factors to score at least 75 and none below 60.

Mesh and timestep studies and solver tolerance checks yielded small changes in QoIs for sustained diastole and peak systole, and modest, still acceptable, changes for the closure transient. Comparisons to experiments showed acceptable errors for coaptation area, line load, and peak systolic stress in Models A and C, with Model B systematically lower stresses and smaller coaptation areas, as expected. However, all models underpredicted the water-hammer amplification at closure and delayed the rebound onset, with associated underestimation of stress overshoot. Moreover, preconditioning drift in two of six leaflet sets and measurable variability in reinforcement geometry limited the representativeness of the test constructs across all mechanisms.

The combination of insufficient transient physics for closure and unrepresentative samples translated to Credibility Index scores below the acceptance thresholds for multiple model–mechanism pairs. In accordance with the predefined decision rule, the models are Not accepted for the stated context of use.

Decision statement clarity — gradation.

a.
Decision implied but not stated.

b.
Decision stated without linkage to criteria.

c.
Decision stated and linked to criteria and key factors.

d.
Decision stated, linked to criteria, and qualified by mechanism-specific limitations without dilution.

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Table 1: Model A Credibility Index by factor and mechanism (0–100 scale; acceptance requires all ≥75 and none <60).

Credibility factor	Level	Basis
Discretization error - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	88	Medium-to-fine change in coaptation area 1.8% and line load 1.2%.
Numerical solver error - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	84	Tightening Newton/contact tolerances shifted coaptation area by 0.3%.
Model form - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	82	Area error 5.0% (152 vs 160 mm2) and line load 8.5% (17.2 vs 18.8 N/m).
Model inputs - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	78	±20% loss factor changed line load ±3.1%; ±0.20 mm reinforcement changed area ±2.7%.
Test conditions - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	80	Aortic pressure RMS mapping error 3.6% with peak/mean flow within 0.5/0.3 L/min.
Test samples - Model A - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	62	Two of six constructs showed 4–6% preconditioning drift; reinforcement width SD 0.18 mm.
Discretization error - Model A - Mechanism 2: Systolic opening at peak flow	90	Medium-to-fine change in peak stress 1.1% and centroid location 0.4 mm.
Numerical solver error - Model A - Mechanism 2: Systolic opening at peak flow	85	Solver tightening changed peak stress by 0.4% at peak systole.
Model form - Model A - Mechanism 2: Systolic opening at peak flow	79	Peak stress 1.42 vs 1.30 MPa (9.2%); hotspot centroid within 0.3 mm.
Model inputs - Model A - Mechanism 2: Systolic opening at peak flow	76	±20% loss factor changed peak stress ±2.0%.
Test conditions - Model A - Mechanism 2: Systolic opening at peak flow	81	RMS mapping error during systole 3.2%.
Test samples - Model A - Mechanism 2:	63	Preconditioning drift up to 6% on two constructs; mounting

Table 2: Model B Credibility Index by factor and mechanism (0–100 scale; acceptance requires all ≥75 and none <60).

Credibility factor	Level	Basis
Discretization error - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	85	Grid and Δt halving changed coaptation area by 2.3%.
Numerical solver error - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	82	Interface residual tightened 103105 changed area by 0.4%.
Model form - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	75	Area 11.3% (142 vs 160 mm2); estimated line load 9.6% from distributed forces.
Model inputs - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	76	±20% effective damping changed area ±3.6%.
Test conditions - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	79	Aortic pressure RMS mapping error 4.1%.
Test samples - Model B - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	60	Two constructs drifted 4–6% over preconditioning; reinforcement width SD 0.18 mm.
Discretization error - Model B - Mechanism 2: Systolic opening at peak flow	84	Grid and Δt halving changed peak stress by 1.7%.
Numerical solver error - Model B - Mechanism 2: Systolic opening at peak flow	81	Tighter coupling changed peak stress by 0.6%.
Model form - Model B - Mechanism 2: Systolic opening at peak flow	70	Cycle-averaged peak stress 1.10 vs 1.30 MPa (15.4%); diffuse hotspot (centroid 3.6 mm).
Model inputs - Model B - Mechanism 2: Systolic opening at peak flow	75	±20% effective damping changed peak stress ±2.5%.
Test conditions - Model B - Mechanism 2: Systolic opening at peak flow	80	RMS mapping error during systole 4.6%.
Test samples - Model B - Mechanism 2: Systolic opening at	60	Same constructs and mounting; two with 4–6% drift; alignment within ±0.3 mm.

Table 3: Model C Credibility Index by factor and mechanism (0–100 scale; acceptance requires all ≥75 and none <60).

Credibility factor	Level	Basis
Discretization error - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	86	Medium-to-fine change in coaptation area 1.7% and line load 1.0%.
Numerical solver error - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	80	Interface residual tightened 103105 changed area by 0.5%.
Model form - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	83	Area 5.6% (151 vs 160 mm2); line load 6.4% (17.6 vs 18.8 N/m).
Model inputs - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	77	±20% loss factor changed area ±2.8%.
Test conditions - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	78	Aortic pressure RMS mapping error 3.4%.
Test samples - Model C - Mechanism 1: Diastolic coaptation under physiologic transvalvular pressure	61	Two constructs drifted 4–6% over preconditioning; reinforcement width SD 0.18 mm.
Discretization error - Model C - Mechanism 2: Systolic opening at peak flow	88	Medium-to-fine change in peak stress 0.9% and centroid location 0.3 mm.
Numerical solver error - Model C - Mechanism 2: Systolic opening at peak flow	83	Tighter coupling changed peak stress by 0.5%.
Model form - Model C - Mechanism 2: Systolic opening at peak flow	81	Peak stress 1.36 vs 1.30 MPa (10.8% vs surrogate); hotspot within 0.1 mm.
Model inputs - Model C - Mechanism 2: Systolic opening at peak flow	76	±20% loss factor changed peak stress ±2.2%.
Test conditions - Model C - Mechanism 2: Systolic opening at peak flow	80	RMS mapping error during systole 3.3%.
Test samples - Model C - Mechanism 2: Systolic opening at	62	Same constructs and mounting; two with 4–6% drift; alignment within ±0.3 mm.