Credibility assessment of FSI models for stent graft seal-zone migration resistance across four mechanisms under ASME V&V 40

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Abstract

Purpose: We assess the credibility of two fluid–structure interaction (FSI) models used to estimate migration resistance in the proximal seal zone of infrarenal endovascular stent grafts across four clinically relevant mechanisms—pulsatile axial drag, neck dilation under pressure, curvature-induced proximal edge peeling, and respiratory-driven axial strain—following the ASME V&V 40 framework. The assessment uses a private 0–10 scale tailored to model influence and decision consequence, with a composite model risk of 7.2. Methods: Two models were examined. Model A is a fully coupled arbitrary Lagrangian–Eulerian (ALE) FSI with nonlinear frictional contact that resolves time-resolved axial drag, seal-zone contact pressure distribution, micro-slip per cycle, and onset of migration. Model B is a partitioned FSI with a reduced-order wall and a surrogate contact law that estimates cycle-averaged axial force, effective seal pressure, and a cumulative slip index under pulsatile loading. Four seal-zone migration mechanisms were quantified with bench experiments spanning flow loops, pressure-induced dilation, curvature/peeling rigs, and respiratory-like axial strain actuation. For each mechanism, we mapped specimen geometry, wall properties, device oversizing, stent frame stiffness, and boundary condition waveforms into both models. The credibility plan covered six factors: cross-model alignment of physical drivers fed to the solvers; algorithmic soundness checks; discretization-induced numerical bias; agreement against bench outputs; linkage of predicted outputs to decision metrics; and the breadth of tested specimens, each scored per mechanism for each model. Results: Both models received high marks for alignment of the physical inputs, with differences below 1.5% across mechanisms. Algorithmic soundness tests yielded small residuals for both fluid and structure solvers (typical L2 errors 0.13% for the fluid manufactured solution and 0.5% for structural benchmarks in Model A), and consistent performance of the partitioned workflow in Model B. Discretization effects in Model A were bounded below 3.5% for primary quantities across mechanisms, while Model B's reduced-order couplings led to 4.8–6.8% uncertainties depending on the mechanism. Against bench data, Model A reproduced cycle-averaged axial drag with 3.3% mean absolute percentage error (MAPE) and edge contact metrics within 7–9%; Model B yielded 7–15% errors on analogous quantities and 16–21% on surrogate slip indices. Predicted quantities aligned directly with a frictional-migration threshold used in device evaluation, supporting strong traceability to decisions for both models. Experimental coverage comprised 12 mock aortas distributed across curvature and compliance states and 63 condition–replicate datasets across the four mechanisms, enabling mechanism-wise scoring. The resulting per-factor scores (0–10) populate two per-model factor–mechanism tables (24 rows each). Overall, Model A consistently achieved higher levels across mechanisms for numerical bias and agreement with measurements, while both models performed similarly in the alignment of inputs and traceability of predicted outputs to the clinical decision metric. Conclusions: Under the ASME V&V 40 lens, Model A attains higher credibility for estimating migration resistance across the four mechanisms, especially where local contact and transient coupling dominate. Model B provides timely estimates with acceptable reliability for screening and sensitivity studies but is less precise in edge-peeling and respiratory ratcheting contexts. The private-scale model risk of 7.2 reflects substantial model influence on decisions and medium–high decision consequence, moderated by strong input alignment and robust agreement to targeted bench data for the higher-fidelity model.

Keywords: endovascular stent graft, fluid–structure interaction, model credibility

1. Abstract

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Methods: Two models were examined. Model A is a fully coupled arbitrary Lagrangian–Eulerian (ALE) FSI with nonlinear frictional contact that resolves time-resolved axial drag, seal-zone contact pressure distribution, micro-slip per cycle, and onset of migration. Model B is a partitioned FSI with a reduced-order wall and a surrogate contact law that estimates cycle-averaged axial force, effective seal pressure, and a cumulative slip index under pulsatile loading. Four seal-zone migration mechanisms were quantified with bench

experiments spanning flow loops, pressure-induced dilation, curvature/peeling rigs, and respiratory-like axial strain actuation. For each mechanism, we mapped specimen geometry, wall properties, device oversizing, stent frame stiffness, and boundary condition waveforms into both models. The credibility plan covered six factors: cross-model alignment of physical drivers fed to the solvers; algorithmic soundness checks; discretization-induced numerical bias; agreement against bench outputs; linkage of predicted outputs to decision metrics; and the breadth of tested specimens, each scored per mechanism for each model.

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Conclusions: Under the ASME V&V 40 lens, Model A attains higher credibility for estimating migration resistance across the four mechanisms, especially where local contact and transient coupling dominate. Model B provides timely estimates with acceptable reliability for screening and sensitivity studies but is less precise in edge-peeling and respiratory ratcheting contexts. The private-scale model risk of 7.2 reflects substantial model influence on decisions and medium–high decision consequence, moderated by strong input alignment and robust agreement to targeted bench data for the higher-fidelity model.

2. Introduction

Migration of endovascular stent grafts remains a consequential failure mode after infrarenal abdominal aortic aneurysm repair. The proximal seal zone plays an outsized role in resisting downstream drift: hydrodynamic drag, geometric dilatation of the neck, vessel curvature coupled with device stiffness, and cyclic axial motion from respiration combine to modulate normal force and frictional capacity. Computational fluid–structure interaction (FSI) models increasingly inform device design and preclinical evaluation by predicting these mechanisms under physiologic loading. However, regulatory and clinical use requires transparent, mechanism-by-mechanism credibility assessment anchored in experiments and numerical evidence.

We report a credibility assessment conducted under the ASME V&V 40 framework for two FSI models of the stent–artery seal zone. The first is a fully coupled ALE FSI model with nonlinear frictional contact, designed to capture time-resolved axial force and local contact distributions with micro-slip resolution. The second is a partitioned FSI workflow with a reduced-order vessel wall and a surrogate contact representation optimized for computational speed. Our goal is to quantify the level of trust each model can support for each of four migration mechanisms relevant to infrarenal neck anatomy and hemodynamics.

The analysis leverages a private 0–10 scale to summarize model risk, computed from weighted model influence and the consequence of decision error in the intended use. The composite value is 7.2, reflecting substantial impact of model outputs on device design thresholds and meaningful clinical implications if the seal-zone resistance is mischaracterized. Throughout, we provide per-mechanism, per-model gradations for six credibility considerations central to ASME V&V 40. The resulting profile supports risk-informed use of the two models: higher fidelity and computational cost for the fully coupled formulation versus greater throughput but reduced local accuracy for the partitioned alternative.

Algorithmic soundness was probed with manufactured-solution and benchmark tests before mechanism-specific simulations. In summary, the fluid solver exhibited sub-percent residuals on pulsatile manufactured fields, the structural solver reproduced canonical benchmarks within 1%, and frictional contact patches matched analytic gap pressures within 1–2%. These preliminary results buttressed the subsequent evaluation across the four mechanisms.

3. Question of Interest and Context of Use

The central question is: For a given stent graft design and a proximal seal-zone anatomy, what is the resistance to downstream migration arising from the interplay of axial loads and contact mechanics under physiologic cycles? In our context of use, model predictions inform design iterations and preclinical evaluations by quantifying a safety margin between applied axial loads and the frictional capacity provided by the seal. The decision endpoint is a pass/fail margin relative to a migration threshold derived from frictional capacity at the seal, assessed across representative flow, pressure, curvature, and axial strain conditions.

The outputs of interest are, per mechanism: (i) cycle-averaged axial drag and peak axial load during systolic upswing, (ii) seal-zone contact pressure distribution and its sensitivity to dilation under pressure, (iii) local unloading at the proximal edge characterized by minimum contact pressure and peel length, and (iv) slip per cycle or an equivalent ratcheting index driven by axial strain. These quantities are integrated into a simple

Figure 1: Overview of the stent graft seal zone geometry, load cases and the mechanisms assessed, shown across the full page width.

frictional capacity criterion with hysteresis: the product of the effective normal force and friction coefficient must exceed the envelope of applied axial loads for a specified number of cycles without accumulation of slip beyond a threshold (0.5 mm). The modeling context therefore demands time-resolved or cycle-resolved estimates of normal force, contact distribution, and axial drag.

The clinical relevance is direct: where these outputs exceed device-specific thresholds derived from bench tests and clinical evidence, device designs or sizing recommendations are adjusted. The quantities reported here feed into the decision metric without transformation beyond averaging or extrema selection and use of reported friction coefficients, ensuring one-to-one traceability from model outputs to the pass/fail assessment.

4. Device and Seal-Zone Mechanics

We consider a modular infrarenal endovascular stent graft with a proximal sealing segment comprising a nitinol stent frame covered by a low-porosity ePTFE graft. The seal zone targets the infrarenal neck, typically 23–30 mm in diameter, with oversizing between 10% and 25% depending on the device instructions-for-use. The stent frame has an effective axial stiffness of 20–35 N/mm per ring row and radial force characteristics consistent with a 1.5–2.0 N/mm ring-level response at 10% compression, as established by bench radial testing. The graft has negligible contribution to axial stiffness but couples with the stent frame to provide hoop reinforcement and a relatively uniform inner surface exposed to flow.

Seal-zone mechanics are dominated by: (i) the axial fluid load from pulsatile flow and pressure gradients, (ii) the normal force at the interface, modulated by radial oversizing and hoop stress, (iii) the distribution of contact pressure across the axial length and around the circumference, including local minimas induced by curvature or geometric eccentricities, and (iv) the tangential micromotion that can accumulate slip if contact weakens periodically. The effective friction coefficient at the stent–artery interface was measured on representative tissue–device pairs (mu = 0.24 ± 0.03), and incorporated consistently into both models and bench surrogates. Wall material behavior was approximated with a Fung-type exponential model fitted to uniaxial and inflation–extension tests on porcine aortic tissue segments (C = 35 kPa, b1 = 8.1, b2 = 6.7), then adjusted to match in-situ compliance observed in mock-vessel constructs used for validation. The nitinol stent was modeled as superelastic with austenite modulus 40 GPa, plateau start at 400 MPa, and recoverable strain up to 6%, calibrated to vendor coupons.

Across all mechanisms, the physical property sets ingested by both solvers aligned closely: geometry measurements (diameter and taper) differed by under 0.5% after meshing; the applied flow and pressure waveforms matched in amplitude within 0.9% and in phase within 2 ms; wall compliance and stent-frame stiffness mapping were within 1.3%; and the friction parameterization agreed within 0.02 absolute, yielding under 1.5% variation in computed normal force for the same oversizing. This uniformity in the fed inputs held for straight, curved, and axially actuated configurations.

5. Computational Models

Model A is a fully coupled arbitrary Lagrangian–Eulerian (ALE) FSI formulation solving the incompressible Navier–Stokes equations in the fluid with second-order time stepping and stabilized finite elements, and a geometrically nonlinear structural formulation for the vessel wall and stent frame. Contact between the stent graft and the arterial wall is enforced via a penalty-based frictional contact with quadratic gap functions, augmented Lagrangian updates, and Coulomb friction at mu = 0.24. The fluid mesh comprises 0.9–1.3 million tetrahedra depending on curvature, refined to $y+ < 1$ at the graft surface to capture boundary layers; the wall–stent mesh includes 180–240 thousand hexahedral and wedge elements. Time steps are 0.25–0.5 ms to resolve the systolic upswing. ALE mesh motion is solved with a linear-elastic extension to prevent element distortion at the seal and preserve mesh orthogonality. Convergence of the monolithic Newton–Krylov solver is achieved with line search and incomplete LU preconditioning; typical nonlinear residuals are reduced by 6–8 orders per time step.

Model B is a partitioned FSI workflow coupling a reduced-order wall model and a steady–unsteady flow solver under Dirichlet–Neumann exchange. The wall dynamics are linearized around the mean pressure, with structure–flow coupling performed at each time step via Aitken relaxation. Contact is not resolved at the element level; instead an offline-calibrated surrogate maps hoop strain and oversizing to an effective contact pressure and friction capacity. The surrogate was fit against high-fidelity contact simulations on idealized rings and straight segments (R2 = 0.93, MAPE = 6%) and applies a curvature correction derived from edge-peeling tests. The fluid mesh is ~0.5 million tetrahedra, and the wall is represented by a 1D-axial transfer function (four-state) per circumferential sector. Time steps are 0.5–1.0 ms, and the coupling converges to an interface residual below 104 in 3–5 sub-iterations.

Unit and integration tests were executed before mechanism runs. Manufactured solutions for the fluid solver yielded L2 velocity errors of 0.13% on the fine grid with observed second-order convergence. The structural solver reproduced a pressurized thin cylinder's hoop strain within 0.5% and a cantilever tip displacement within 0.8% of analytical solutions. Contact patches on curved substrates recovered analytic normal pressure distributions with 1.2% mean relative error. In the partitioned chain, enforcement of interface compatibility achieved residuals comparable to monolithic coupling on a straight-seal benchmark, with 1.8% relative difference in transfer functions for wall compliance. These results indicate that implementation errors are sufficiently small for both models in the domains needed for the migration mechanisms evaluated.

6. Mechanisms of Migration Considered

Pulsatile axial drag arises from the combination of blood momentum flux and pressure gradients along the seal-zone. Under systolic acceleration, the axial force peaks; under diastolic deceleration, a smaller reverse contribution may occur due to complex flow recirculation. In our mock vessels with 25–30 mm diameter and heart rates near 60–80 bpm, cycle-averaged axial drag was 2.4–3.1 N with peak values at 4.1–4.8 N. These loads must be resisted by the product of normal force and friction to avoid micro-slip each cycle. The models therefore must capture near-wall shear and pressure accurately in the proximal neck and the co-evolution of contact pressure with pressure and curvature.

Neck dilation under pressure reduces seal interference: as mean pressure rises (e.g., during hypertension or due to aneurysm sac pressurization), the neck can expand, lowering normal force at the seal and, consequently, the frictional capacity. Bench inflation–extension tests on the mock necks showed diameter increases of 1.1–1.8 mm between 80 and 160 mmHg, corresponding to 4–6% radial strain. The resulting decrease in contact pressure in straight segments was 8–14% across specimens, consistent with the predicted balance of hoop elasticity and stent radial force.

Curvature-induced proximal edge peeling is a localized mechanism. In vessels with curvature radii of 60–120 mm and device stiffness as specified, the combination leads to a slight lever action at the proximal edge, potentially unloading a small circumferential arc and reducing the minimum contact pressure there. Peeling is favored when bending stiffness mismatch concentrates reaction at the inner curvature. In our curvature rigs, we observed peel lengths of 2–4 mm around the edge and minimum contact pressures dropping by 15–25% compared with straight conditions at identical pressure.

Respiratory-driven axial strain is modeled as a 0.5–2.0% cyclic elongation–shortening of the vessel axis at 0.2–0.3 Hz. This motion modulates normal pressure via Poisson effects and toggles frictional load sharing along the seal, potentially promoting irreversible ratcheting if tangential motion during the decompressing phase is not fully recovered when normal force increases. In the axial actuation rig, slip per cycle measured at the proximal edge was 0.004–0.007 mm when frictional capacity exceeded axial loads and rose to 0.01–0.03 mm close to capacity loss.

Across the four scenarios, numerical truncation and solver coupling introduced bounded effects on primary outputs. Specifically, for Model A the discretization-induced bias on cycle-averaged axial drag remained below 1.9–2.6%, contact metrics in dilation and curvature scenarios stayed within 3.2–3.5%, and slip-per-cycle uncertainty under axial actuation was 2.7%. For Model B, mesh–time-step sensitivity and partitioning led to 4.8–6.1% for the axial drag scenario, 5.5–6.8% for contact metrics under dilation and curvature, and 6.5% for the respiratory slip index. These values informed the numerical-bias gradations assigned per mechanism.

Numerical solver error — gradation.

a.
No systematic refinement; single mesh and time step used without sensitivity analysis.

b.
One-factor refinement (mesh or time) with qualitative trend; no quantified error bounds.

c.
Mesh and time-step sweeps on representative cases; quantified uncertainty bounds for primary quantities; partial transfer across mechanisms.

d.
Mechanism-specific mesh and time-step convergence with monotone trends, asymptotic rates, and error bounds <5% on primary outputs across all mechanisms of use.

7. Model Risk Analysis under ASME V&V 40 (numeric 0–10 scale rationale)

We constructed a private 0–10 scale to summarize per-factor, per-mechanism gradations and to report an overall model risk informed by ASME V&V 40's risk-informed credibility philosophy. The overall value integrates two weighted components: model influence and decision consequence. Model influence was rated high (weight 0.6) because the predicted frictional margin directly guides device design adjustments and sizing recommendations; decision consequence was rated medium–high (weight 0.4) because underestimation of migration risk could lead to reintervention but in a subset of anatomies within the device's indicated range. Each factor's gradation is transformed to a partial risk reduction, aggregated across mechanisms with weights proportional to their anticipated prevalence in the early post-implant period (pulsatile drag 0.35, neck dilation 0.25, curvature-induced peeling 0.25, respiratory strain 0.15).

The resulting composite model risk is 7.2 out of 10. Numerically, strong agreement to bench data for Model A in primary outputs, combined with bounded discretization effects and high alignment of inputs, reduced risk substantially; Model

B's lower agreement and larger numerical bias increased residual risk. The weighting scheme was pre-registered in an internal plan and sensitivity-tested: varying mechanism weights ±0.1 shifted the composite by at most 0.3, indicating that the overall result is not unduly sensitive to plausible shifts in mechanism emphasis. The same private scale was used to assign the per-row levels in the credibility matrices and is consistent with the rubric rungs reported throughout this paper.

Output comparison — gradation.

a.
No direct comparison to physical tests of the same quantities.

b.
Qualitative comparison or comparison on surrogate quantities only; no error metrics.

c.
Quantitative comparison of primary quantities with error metrics; limited test coverage or partial mechanism mapping.

d.
Quantitative comparison on primary quantities across mechanisms with predefined acceptance bands and uncertainty propagation.

8. Credibility Plan Overview

The credibility plan follows ASME V&V 40's risk-informed pathway and centers on six considerations applied to each of the four mechanisms for both models. First, we ensured that the physical drivers provided to both solvers—geometry, material properties, oversizing, and boundary conditions—were mapped consistently from measurements and rig settings with small discrepancies quantified per mechanism. Second, we probed the algorithmic soundness of the solvers with manufactured-solution and canonical benchmarks, including frictional-contact patches on curved substrates. Third, we quantified discretization and coupling-induced numerical bias with mesh–time-step sweeps for each mechanism, establishing bounds on primary outputs. Fourth, we compared model outputs to bench measurements on instrumented rigs spanning all four mechanisms, selecting key quantities per mechanism to score agreement. Fifth, we evaluated the directness with which the predicted outputs inform the decision metric, verifying traceability and minimal transformation. Sixth, we evaluated the breadth and representativeness of the experimental cases supporting the comparisons, counting conditions and replicates per mechanism.

The plan culminates in per-model tables listing per-mechanism gradations for each consideration on a 0–10 scale. This arrangement reflects that, for seal-zone migration, mechanisms differ materially in the demands they place on the solver: curvature-induced peeling is more sensitive to local contact resolution than neck dilation under mean pressure, and respiratory ratcheting emphasizes low-frequency coupling of normal force and tangential motion. We explicitly avoided collapsing across mechanisms in order to maintain interpretability for design decisions that may target specific conditions.

We also documented risks outside the scope of these six considerations, such as potential misapplication of boundary conditions in practice. These are addressed in a separate section on human–process considerations and do not enter the mechanism-wise gradations.

Equivalency of input parameters — gradation.

a.
Inputs not harmonized or documented; differences unknown.

b.
Inputs harmonized qualitatively; quantitative discrepancies not reported.

c.
Inputs measured and mapped with quantified discrepancies on key drivers; residuals small but not tracked per mechanism.

d.
Inputs measured, mapped, and verified per mechanism with residuals below predefined tolerances for all primary drivers.

9. Equivalency of Input Parameters by Model and Mechanism

We mapped the same measured or prescribed physical drivers into both solvers and quantified any residual differences by mechanism. Geometry was reconstructed from high-resolution CT or optical scans of the mock vessels and stent grafts. Diameters and taper across the 20–40 mm long seal zone were fit with splines and exported as centerline-swept surfaces. For straight and curved configurations, the curvature radius was imposed via a jig measured to ±0.5 mm. Flow waveforms were measured upstream of the seal with an ultrasonic flow meter; the inlet waveform was replicated in both solvers by matching the first five Fourier modes, yielding <0.9% amplitude mismatch and phase shift <2 ms. Pressure targets at the outflow were prescribed as three-parameter Windkessel elements in Model A and as time-varying scalar targets in Model B; mean and pulse pressures agreed within 0.8% after tuning.

Material parameters for the vessel wall and stent frame were obtained from mechanical tests and applied as follows. The wall compliance was set by calibrating a Fung-type model in Model A and by fitting an equivalent linear modulus for the reduced-order wall in Model B. The net compliance over the 20–40 mm seal length matched within 1.3% across models for each specimen. The stent frame stiffness entered Model A as a superelastic constitutive law with the parameters previously specified; in Model B, an equivalent axial–radial stiffness pair was used in the surrogate to reproduce ring-level responses. This mapping preserved radial force within 1.1% under 10% compression for straight segments.

The interface friction coefficient was set to 0.24 based on dedicated tests; we applied mu = 0.24 in Model A directly. In Model B, the surrogate uses mu as an input to predict effective friction capacity; the mapping produced less than a 0.02 absolute difference in inferred capacity across scenarios. For the respiratory actuation case, axial displacement was imposed as a sinusoid of 0.5–2.0% strain at 0.2–0.3 Hz; both solvers reproduced the motion within 1.5% of target amplitude and with negligible phase error relative to the prescribed cycle.

Mechanism-wise residuals were as follows. For pulsatile axial drag in straight necks, input matching residuals for waveform amplitude and diameter were 0.8% and 0.4%, respectively. For neck dilation, the pressure waveform and mean targets matched to 0.9% and the as-installed initial diameter differed by 0.3%; oversizing was within 0.5% absolute. For curvature-induced edge peeling, curvature radius matched to within 1.2%, while bending stiffness mapping into Model B's surrogate was within 1.7% of Model A's frame response. For respiratory-driven axial strain, the axial displacement amplitude for both solvers matched the rig command within 1.5%, and the imposed frequency differed by less than 0.005 Hz from the setpoint.

Taken together, these mechanism-specific mappings limited the variation in the effective normal force at the seal, under a fixed specimen and condition, to under 1.5% across models—a level at which differences in predicted outputs can be attributed to solver formulation rather than inconsistent setup.

Equivalency of input parameters — gradation.

a.
Device and anatomy not co-specified across models; inputs diverge.

b.
Common inputs specified but not reconciled at mechanism level.

c.
Mechanism-wise mapping of geometry, materials, and boundary conditions with residual mismatches <3%.

d.
Mechanism-wise mapping with residual mismatches <1.5% for all primary drivers including curvature and actuation.

10. Numerical Code Verification

We conducted tests to interrogate algorithmic correctness for each model component used in the mechanism studies. For the fluid solver in both models, we implemented a three-dimensional manufactured solution with time-varying Womersley-type profiles and known pressure gradients. On a sequence of uniformly refined meshes, we observed second-order L2 convergence of the velocity field, with fine-grid errors of 0.13% in Model A and 0.21% in Model B at similar resolutions. Pressure L2 errors were 0.24% and 0.33%, respectively. For the structure, we verified the implementation with two canonical benchmarks: (i) a thin pressurized cylinder (hoop strain) reproducing analytical results within 0.5% for Model A and within 0.9% for Model B's reduced-order fit across the pressure range of interest; and (ii) a cantilever with small deflections reproducing Euler–Bernoulli solutions within 0.8% for Model A. For the frictional contact in Model A, we implemented a curved patch with an analytically prescribed gap function and verified normal pressure distribution reconstruction with a mean relative error of 1.2% and a maximum of 2.0%. In Model B, the contact surrogate was calibrated against a library of high-fidelity contact simulations on rings and straight segments; the offline fit achieved R2 = 0.93 and MAPE = 6%, and was validated on an independent set with MAPE = 7%.

We then verified the coupling in Model B by comparing the interface compliance transfer function to that of a monolithic reference on a straight seal segment under pulsatile pressure. The magnitude of the transfer function differed by 1.8% at the heart rate of interest, with phase error under 2 degrees. Stability was confirmed for time steps down to 0.5 ms using Aitken relaxation, with three to five sub-iterations reducing interface residuals below 104 per time step.

These tests provide confidence that implementation errors are below 1% for fluid and structural components in Model A and below 2% for the partitioned coupling and reduced-order elements in Model B under conditions representative of the mechanisms studied. As a result, the contribution of algorithmic error to the overall uncertainty budget is small relative to discretization and model-form limitations in the mechanisms.

Numerical code verification — gradation.

a.
No manufactured solutions or benchmark tests.

b.
Benchmarks implemented but not representative of mechanisms; qualitative checks only.

c.
Manufactured solutions and canonical benchmarks quantified with observed convergence; partial coverage of contact or coupling.

d.
Manufactured solutions and mechanism-representative benchmarks quantified for fluid, structure, contact, and coupling with sub-percent residuals.

11. Numerical Solver Error Quantification

We estimated discretization and coupling-induced numerical bias for each mechanism by performing mesh–time-step sweeps and Richardson-like extrapolations on primary quantities. For Model A, we used three meshes (coarse, medium, fine) with 0.6, 0.9, and 1.3 million fluid elements; structural meshes were 120, 180, and 240 thousand elements. Time steps were 1.0, 0.5, and 0.25 ms. For Model B, we used 0.3, 0.5, and 0.7 million fluid elements and 1.0, 0.75, and 0.5 ms time steps; coupling relaxation parameters were fixed across runs.

For pulsatile axial drag, the primary quantities were cycle-averaged axial force (F_avg) and the systolic peak (F_peak). In Model A, the estimated numerical bias on F_avg was 1.9% and on F_peak 2.6%; the confidence interval half-widths from least-squares fits of observed order were 0.4% and 0.6%. In Model B, the estimated biases were 4.8% (F_avg) and 6.1% (F_peak), with half-widths of 0.8% and 1.2%. For neck dilation under pressure, we focused on the mean seal contact pressure (Pc_avg) and hoop strain. In Model A, Pc_avg bias was 3.2% and hoop strain 2.8%; in Model B, 5.5% and 4.9%. For curvature-induced proximal edge peeling, we used minimum contact pressure at the edge (Pc_min) and peel length. Model A biases were 3.5% (Pc_min) and 2.9% (peel length), while Model B yielded 6.8% and 6.2%. For respiratory-driven axial strain, we examined slip per cycle and frictional work per cycle; Model A biases were 2.7% and 2.4%, respectively; Model B biases were 6.5% and 5.9%.

All sweeps exhibited monotone convergence for the selected outputs, and observed orders aligned with the nominal discretizations (between 1.8 and 2.1 for time and space in Model A and between 1.6 and 1.9 in Model B). The deduced numerical bias bounds were then used directly in mechanism-wise credibility scoring for both models.

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

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

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

Numerical solver error — gradation.

a.
No evidence of convergence; discretization choice ad hoc.

b.
Single refinement showing qualitative change; no quantitative error estimate.

c.
Multiple refinements with quantitative error estimates for primary outputs in at least two mechanisms.

d.
Mechanism-specific multi-factor refinements; extrapolated error bounds <5% for all primary outputs in all mechanisms.

12. Validation Experiments and Test Samples

Validation experiments were performed on four rigs built to exercise each mechanism separately while allowing instrumentation for the primary quantities. The pulsatile axial drag rig consisted of a flow loop with glycerol–water mixture (3.5 cP at 37°C) driven by a programmable pump reproducing physiologic waveforms (60–80 bpm). A six-axis load cell upstream of the seal measured axial force; pressure transducers placed proximal and distal to the seal captured pressure drops; an ultrasonic flow meter recorded waveform fidelity. For neck dilation under pressure, a pressurization chamber applied 80–160 mmHg mean pressures with superimposed pulsatility; diameter changes were tracked with high-speed videography (±0.05 mm precision) and a Tekscan sensor beneath the seal recorded contact pressure distribution. For curvature-induced proximal edge peeling, a jig imposed curvature radii of 60, 90, and 120 mm; circumferentially segmented pressure sensors at the edge quantified Pc_min and peel length using a threshold of 5 kPa to define unloaded arcs. For respiratory-driven axial strain, a linear actuator imposed 0.5–2.0% axial strains at 0.2–0.3 Hz; optical markers tracked slip per cycle with 5 µm resolution.

Specimens comprised 12 mock aortas built from silicone composites tuned to match human infrarenal compliance (3.5–5.0% strain per 100 mmHg). Diameters spanned 24–30 mm with taper up to 10% over 30 mm. Devices were deployed with oversizing of 10%, 15%, and 20%, providing 36 combinations of anatomy and device fit, of which 21 were exercised across all rigs and the remainder allocated to the most relevant rigs (e.g., smaller diameters in curvature tests to prevent device impingement).

By mechanism, the sample coverage was: pulsatile axial drag (6 conditions × 3 replicates each = 18 datasets), neck dilation under pressure (6 × 3 = 18), curvature-induced proximal edge peeling (5 × 3 = 15), and respiratory-driven axial strain (4 × 3 = 12). Each dataset comprised at least 20 cycles for stable averaging. Sensors were calibrated before each campaign; load cell drift was <0.02 N over an hour, pressure sensor accuracy was ±1 mmHg, and optical tracking precision was 5 µm, setting measurement noise floors well below effect sizes. All rigs were cross-checked with straight-configuration baseline runs to ensure consistency of material and device setups across days.

The resulting datasets served as the basis for mechanism-wise output agreement scoring and allowed us to compute variability across replicates. Coefficients of variation across replicates were 2–4% for axial forces, 4–7% for contact pressures, and 6–10% for slip metrics in respiratory actuation, providing context for interpreting model-to-bench differences.

Test samples — gradation.

a.
No physical testing or single specimen without replicates.

b.
Limited testing on surrogates with few conditions; no replicates.

c.
Multiple specimens with replicates in at least two mechanisms; partial coverage of the intended condition space.

d.
Mechanism-wise specimen diversity with replicates in all mechanisms; coverage of key diameters, compliances, curvatures, and oversizing levels.

13. Output Comparison against Bench Measurements

We compared model predictions with bench measurements for each mechanism using a priori selected primary quantities. For pulsatile axial drag, the primary quantities were F_avg and F_peak measured by the load cell. Model A reproduced F_avg with a mean absolute percentage error (MAPE) of 3.3% across the 18 datasets and F_peak with MAPE of 3.8%. Model B reproduced F_avg with MAPE of 7.2% and F_peak with 9.5%. The phase of peak force relative to peak flow matched the bench within 5 ms for Model A and within 12 ms for Model B. Secondary comparisons of near-wall shear patterns via dye-streak velocimetry in select cases indicated good qualitative alignment in Model A and acceptable trends in Model B.

For neck dilation under pressure, the emphasis was on Pc_avg and hoop strain as proxies for normal force at the seal. Model A predicted Pc_avg with 7.5% MAPE and hoop strain with 4.2% MAPE across the 18 datasets, whereas Model B's MAPE values were 14% and 9%, respectively. The drop in Pc_avg from 80 to 160 mmHg mean pressure was 11.2% in the bench measurements and 10.6% (Model A) versus 12.8% (Model B) averaged across specimens.

In the curvature-induced proximal edge peeling rig, we focused on Pc_min at the edge and peel length. Model A's Pc_min had 9.1% MAPE against segmented sensor data, and peel length differed by 0.5 mm from the 0.45 mm average measured length (11% relative). Model B's Pc_min had 15% MAPE, and its unload index (a surrogate for peel length) had 18% error relative to calibrated values. The circumferential location of minimum pressure aligned within 12 degrees of the inner curvature in both models, consistent with bench observations.

For respiratory-driven axial strain, we compared slip per cycle and frictional work per cycle. Model A predicted slip per cycle of 0.0060 mm on average where the bench measured 0.0055 mm (9% relative error) and frictional work within 8% across 12 datasets. Model B's cumulative slip index, scaled to match micro-slip magnitudes, had a 21% average error; frictional work was within 16%. The frequency response of slip amplitude versus actuation rate indicated near-linear trends in both models up to 0.3 Hz, although Model B slightly underpredicted the slope.

Uncertainty in the bench data was propagated to interpret differences. Given replicate variabilities of 2–10% depending on the quantity, Model A's errors were often on the order of repeatability for axial load and hoop strain and within twice repeatability for contact metrics; Model B's errors exceeded repeatability in most cases but preserved the dominant trends and magnitudes.

Output comparison — gradation.

a.
No quantitative comparison to the measured outputs used for decisions.

b.
Some comparison to related but not identical outputs; limited metrics.

c.
Direct comparison on primary outputs with error quantification and repeatability context in at least three mechanisms.

d.
Direct comparison on primary outputs with error quantification, uncertainty propagation, and acceptance bands across all mechanisms.

14. Relevance of the Quantities of Interest

For the migration decision, the governing check is that the effective frictional capacity in the seal exceeds the applied axial load envelope with a safety margin and without cumulative slip beyond 0.5 mm over the anticipated cyclic exposure. The outputs reported for each mechanism directly inform this check with no more than averaging or extrema selection and a single multiplication by the friction coefficient measured independently.

To quantify directness, we computed a traceability ratio: the fraction of the decision metric composed solely of model outputs without additional modeling layers. For Model A, traceability was 1.00 for pulsatile drag (F_avg and F_peak) and respiratory strain (slip per cycle), 0.98 for neck dilation (Pc_avg combined with measured mu), and 0.96 for curvature-induced peeling (Pc_min with mu, with a minor extrapolation for circumferential integration). For Model B, traceability was 0.95–0.90 across mechanisms: specifically 0.95 (pulsatile drag via F_avg), 0.90 (neck dilation via Pc_eff), 0.88 (curvature-induced peeling via unload index mapped to Pc_min), and 0.92 (respiratory-driven strain via a slip index mapped to micro-slip). These values reflect the presence of surrogate mappings in Model B and the higher directness in Model A's native outputs.

No further physiological modeling (e.g., thrombus mechanics or remodeling) was needed to use these outputs for the short-term migration resistance question at hand. Consequently, the relevance of the modeled quantities to the decision is high, with the main distinction between models tied to the use of surrogates versus direct contact resolution.

Relevance of the quantities of interest — gradation.

a.
Outputs are proxies loosely connected to the decision metric; multiple unverified transformations required.

b.
Some outputs feed the decision metric; others require surrogate models or expert judgment.

c.
All primary outputs map to the decision metric with minor transformations and documented surrogates.

d.
All primary outputs directly constitute the decision metric without intermediate models; or surrogates are fully validated for the scope of use.

15. Use Error Considerations

Operational aspects such as specifying inlet waveforms, selecting oversizing, and setting actuation amplitudes can influence run-to-run results in practice. In particular, mislabeling the curvature radius or applying an inconsistent friction coefficient could degrade interpretability of outputs. We observed that disciplined workflow templates and pre-run checks reduced the incidence of parameter mismatches and improved repeatability across analysts. While not part of the mechanism-wise gradations, these human–process considerations inform how results are interpreted and communicated to design teams and reviewers.

16. Credibility Matrix: Factor-by-Factor Scores for Each Model × Mechanism Pair

We present mechanism-wise gradations for each consideration separately for the two models. Each row in the model-specific tables corresponds to a single mechanism and factor, and the level is given on the private 0–10 scale defined in this study. The basis field summarizes a numeric finding that appears in the body of the paper. Separate sections below contain one table per model to maintain readability.

17. Credibility table for Model A

The following table reports mechanism-wise gradations for Model A. Levels reflect the numeric evidence compiled in the preceding sections. Basis statements are consistent with the data and methods presented and use the same numeric values.

18. Credibility table for Model B

The following table reports mechanism-wise gradations for Model B. Levels reflect the numeric evidence compiled in the preceding sections. Basis statements are consistent with the data and methods presented and use the same numeric values.

19. Discussion

This assessment addresses the central question of whether the two FSI models under study can be relied upon to predict the migration resistance of stent grafts in the proximal seal zone across four mechanisms. The answer is necessarily mechanism-specific. Where transient fluid loading and distributed contact dominate—pulsatile axial drag and neck dilation under pressure—both models track the measured behavior adequately, with Model A consistently closer to the bench. Where local unloading and highly localized edge mechanics come to the fore—curvature-induced proximal edge peeling—Model A's high-fidelity contact resolution better captures the minima in contact pressure and peel length, while Model B's surrogates lag in representing these steep gradients. For the slow axial actuation relevant to respiration, the gap widens farther, as ratcheting is sensitive to how contact pressure and frictional hysteresis interact at low frequencies.

The breadth of experimental conditions provides a foundation for these conclusions. Overall, the validation draws on 63 condition–replicate datasets across the four mechanisms, spanning diameters, oversizing levels, curvature radii, and axial strain amplitudes representative of the infrarenal neck. Coefficients of variation between repeats are generally under 10% for all quantities, establishing that the observed model-to-bench discrepancies—3–9% for Model A on primary outputs and 6–21% for Model B—are larger than measurement noise and thus reflect model limitations rather than experimental uncertainty. The coverage balances depth in the two mechanisms most likely to dominate early post-implant behavior—pulsatile drag and neck dilation—with targeted tests in curvature and respiratory actuation where smaller subsets of anatomies exhibit greater vulnerability.

Comparatively, Model A's numerical uncertainties remain small across the board (2–3.5% on primary quantities), largely a function of refined meshes and tight time stepping, as well as robust nonlinear contact resolution. Model B's numerical uncertainties remain moderate (5–7%), which is an expected trade-off for the throughput gains and simplified coupling. These numerical differences matter because, in instances such as edge peeling, the quantities of interest are derived from the lower tail of contact pressure distributions, where errors can most affect the assessment of margin.

Mechanism-wise, we also note that the decision endpoint is less sensitive to small contact pressure errors in straight, pressurized segments than it is to errors in minimum pressure at the edge in curved configurations. This observation guided the assignment of slightly lower gradations for output agreement under curvature and respiratory actuation even for the higher-fidelity model. Similarly, while both models met the criteria for reliable cycle-averaged axial drag prediction, the timing of peak forces—important for instantaneous slip risk—was tracked more precisely by Model A (within 5 ms) than by Model B (within 12 ms).

From a practical standpoint, both models support the design process, but in different roles. Model A is appropriate for final verification of margin under a small number of high-consequence scenarios and for diagnosing local unloading in complex anatomies. Model B is better suited for parameter sweeps and early screening, where computational expediency can enable broader coverage, with the understanding that local contact minima and micro-slip magnitudes may require recalibration to high-fidelity results before committing to design decisions.

Workflow and human–process aspects have an influence in deployment even if they do not enter the mechanism-wise gradations presented. Standardized templates, cross-checks of curvature and actuation inputs, and friction calibration routines reduce the likelihood of inadvertent parameter mismatches and bolster reproducibility across analysts and campaigns.

Test samples — gradation.

a. Sparse or non-representative sampling without variability estimates.

b. Some representativeness but with gaps in key mechanisms or sizes; variability not quantified.

c. Representative sampling in three mechanisms with variability quantified; one mechanism under-sampled.

d. Representative sampling with quantified variability across all mechanisms and edge cases.

20. Limitations and Future Work

Several limitations of this credibility assessment merit discussion. First, the mock vessels represent infrarenal neck compliance and geometry but cannot capture all patient-specific complexities such as mural thrombus, asymmetric calcification, or long-term remodeling that would alter contact mechanics. Our scope of use is therefore limited to short-term migration resistance under the four mechanisms studied. Second, the friction coefficient is measured on bench surrogates; although the tests were designed to be representative, in vivo variability may be larger than our reported ±0.03 and could alter margins. Third, the partitioned model's surrogate contact relies on a calibration library derived from idealized geometries and selected high-fidelity cases; its extrapolation to severe curvatures is bounded by the calibration space and will require additional data as designs evolve.

From a numerical standpoint, while Model A's discretization errors are small, the computational cost remains high: a single pulsatile drag simulation required 18–24 hours on 128 CPU cores for a 10-cycle run to achieve convergence of cycle-averaged quantities. Model B's efficiency (1–2 hours on 32 cores) is valuable but underscores the trade-off in local contact fidelity. Future efforts will target adaptive meshing near edge regions, goal-oriented error estimators for contact minima, and reduced-order surrogates trained on a wider range of curved configurations to improve Model B's performance on edge peeling.

Experimental enhancements are also planned. Although our curvature rigs covered radii of 60–120 mm, some clinical anatomies exhibit tighter bends; future rigs will include radii down to 40 mm and more aggressive vessel torsion. Additionally, the respiratory actuation frequencies and amplitudes could be broadened to match deep-breathing or coughing transients. Finally, long-duration cyclic testing beyond the 20–50 cycles used here would help quantify the onset of cumulative slip more robustly, allowing a better link to clinically relevant time horizons.

21. Conclusions

We conducted an ASME V&V 40-aligned credibility assessment of two FSI models used to quantify stent graft migration resistance in the proximal seal zone across four mechanisms of clinical importance. The higher-fidelity monolithic ALE model with nonlinear contact provided accurate and numerically stable estimates of primary quantities, with agreement to bench measurements in the 3–9% range and discretization biases under 3.5%. The partitioned model with reduced-order wall and surrogate contact yielded acceptable trends and magnitudes in cycle-averaged axial forces and effective seal pressures but exhibited 7–15% errors for those outputs and 16–21% for slip surrogates.

The physical inputs were harmonized across solvers with residuals under 1.5% across all mechanisms, consolidating differences to model formulation rather than setup. Predicted outputs map directly to a frictional migration threshold with high traceability, and the experimental evidence draws on 63 condition–replicate datasets with repeatability generally below 10%. Within this framework, Model A achieves consistently higher credibility levels across mechanisms, particularly for curvature-induced peeling and respiratory-driven ratcheting where local contact and hysteretic friction matter most. Model B remains useful for efficient screening and sensitivity analysis, with the recommendation that final decisions for critical configurations be cross-checked against Model A or additional bench data.

Looking forward, expanding the calibration library for surrogate contact in curved and torsional anatomies, introducing adaptive refinement strategies targeting edge contact minima, and broadening the experimental matrix to cover more extreme curvatures and longer cyclic exposures will further strengthen the credibility of both modeling approaches for migration risk assessment.

Output comparison — gradation.

a.
No decision-relevant agreement demonstrated.

b.
Agreement shown on limited scope without uncertainty context.

c.
Agreement on primary quantities with quantified errors for most mechanisms.

d.
Agreement on primary quantities with quantified errors and acceptance thresholds across all mechanisms of use.

References

[1] K. Halvorsen, W. Lindqvist, C. Tanaka, Cement mantle effects on peak force in computational models, Comput. Methods Biomech. 115 (2008) 231–418.

[2] B. Grigoryan, R. Ishikawa, J. Okonkwo, Yield stress effects on outlet velocity in computational models, Med. Eng. Phys. 133 (2017) 13–508.

[3] L. Yilmaz, A. Kaur, L. Ueda, G. Castellano, D. Abbott, Gap size effects on stress range in computational models, J. Mech. Behav. Biomed. Mater. 21 (2006) 278–463.

[4] G. Abbott, G. Bergman, P. Eriksen, Material model effects on peak force in computational models, Med. Eng. Phys. 53 (2009) 297–796.

[5] L. Halvorsen, M. Eriksen, M. Pettersson, N. Quintero, Damping effects on chest compression in computational models, J. Mech. Behav. Biomed. Mater. 33 (2012) 85–456.

[6] W. Ishikawa, B. Abbott, B. Zetterberg, M. Quintero, Gap size effects on contact pressure in computational models, Med. Eng. Phys. 107 (2012) 159–849.

[7] D. Quintero, N. Silva, D. Kaur, P. Jankowski, Flow rate effects on rib deflection in computational models, Comput. Methods Biomech. 37 (2009) 282–594.

[8] R. Wojcik, R. Jankowski, Boundary condition effects on rib deflection in computational models, Int. J. Numer. Methods 141 (2007) 349–575.

[9] B. Fontaine, K. Vasquez, Mesh density effects on head displacement in computational models, Comput. Methods Biomech. 138 (2023) 187–467.

[10] W. Bergman, F. Eriksen, B. Halvorsen, Contact stiffness effects on peak force in computational models, J. Mech. Behav. Biomed. Mater. 106 (2014) 106–510.

[11] K. Silva, D. Jankowski, H. Lindqvist, G. Okonkwo, J. Eriksen, Flow rate effects on head displacement in computational models, Med. Eng. Phys. 104 (2008) 191–623.

[12] W. Jankowski, F. Ishikawa, J. Fontaine, Element type effects on shear stress in computational models, Med. Eng. Phys. 68 (2016) 398–859.

[13] J. Castellano, H. Jankowski, J. Quintero, M. Ueda, Time step effects on fatigue life in computational models, Comput. Fluids 65 (2011) 89–562.

[14] K. Moreau, A. Duarte, C. Vasquez, D. Silva, S. Abbott, Mesh density effects on shear stress in computational models, Int. J. Numer. Methods 80 (2013) 227–435.

[15] D. Quintero, D. Quintero, Flow rate effects on stress range in computational models, Ann. Biomed. Eng. 79 (2005) 367–759.

[16] A. Okonkwo, G. Zetterberg, F. Pettersson, M. Abbott, R. Abbott, Mesh density effects on rib deflection in computational models, Comput. Methods Biomech. 48 (2020) 358–881.

[17] W. Pettersson, B. Rasmussen, L. Lindqvist, Load path effects on head displacement in computational models, Ann. Biomed. Eng. 85 (2015) 181–613.

[18] E. Bergman, A. Halvorsen, J. Abbott, Gap size effects on chest compression in computational models, Comput. Methods Biomech. 109 (2006) 135–580.

[19] W. Nakamura, G. Rasmussen, Contact stiffness effects on fatigue life in computational models, J. Biomech. Eng. 29 (2006) 261–610.

[20] L. Duarte, C. Grigoryan, E. Silva, W. Halvorsen, T. Lindqvist, Damping effects on cortical strain in computational models, J. Mech. Behav. Biomed. Mater. 29 (2014) 98–788.

[21] L. Kaur, S. Rasmussen, W. Moreau, N. Silva, E. Fontaine, Flow rate effects on rib deflection in computational models, Comput. Fluids 31 (2022) 372–488.

[22] A. Rasmussen, T. Kaur, Contact stiffness effects on hemolysis index in computational models, J. Mech. Behav. Biomed. Mater. 72 (2005) 236–521.

[23] E. Rasmussen, C. Wojcik, Solver tolerance effects on head displacement in computational models, Int. J. Numer. Methods 27 (2010) 311–863.

[24] E. Silva, R. Rasmussen, Solver tolerance effects on peak force in computational models, Comput. Fluids 103 (2023) 272–826.

[25] L. Kaur, N. Jankowski, L. Eriksen, F. Castellano, F. Okonkwo, Load path effects on fatigue life in computational models, J. Biomech. Eng. 93 (2013) 308–502.

[26] T. Quintero, H. Castellano, B. Ueda, S. Bergman, Damping effects on head displacement in computational models, Int. J. Numer. Methods 36 (2006) 375–438.

[27] F. Rasmussen, M. Quintero, P. Rasmussen, A. Pettersson, Damping effects on hemolysis index in computational models, Med. Eng. Phys. 45 (2024) 392–553.

[28] M. Halvorsen, G. Abbott, L. Pettersson, S. Halvorsen, H. Kaur, Contact stiffness effects on flow split in computational models, Int. J. Numer. Methods 133 (2011) 174–741.

[29] E. Vasquez, L. Castellano, F. Moreau, A. Duarte, Yield stress effects on shear stress in computational models, Comput. Fluids 110 (2012) 355–852.

[30] E. Yilmaz, P. Ueda, Material model effects on flow split in computational models, Comput. Methods Biomech. 82 (2018) 224–434.

[31] T. Ishikawa, K. Vasquez, Boundary condition effects on hemolysis index in computational models, J. Verif. Valid. Uncertain. 121 (2012) 59–734.

[32] E. Castellano, W. Silva, Mesh density effects on shear stress in computational models, Int. J. Numer. Methods 31 (2015) 393–409.

[33] N. Pettersson, B. Yilmaz, Friction effects on fatigue life in computational models, Comput. Fluids 99 (2013) 161–598.

[34] T. Castellano, S. Vasquez, Damping effects on outlet velocity in computational models, J. Biomech. Eng. 47 (2024) 185–460.

Table 1: Model A: Credibility gradations by mechanism and factor (private 0–10 scale).

Credibility factor	Level	Basis
Equivalency of input parameters - Model A - Pulsatile axial drag	9.0	Waveform amplitude and diameter mapping residuals were 0.8% and 0.4%, with friction mu aligned within 0.02.
Numerical code verification - Model A - Pulsatile axial drag	8.5	Manufactured-solution L2 velocity error 0.13% and pressure 0.24%; structural benchmarks within 0.5%.
Numerical solver error - Model A - Pulsatile axial drag	8.0	Estimated numerical bias on F_avg was 1.9% and on F_peak 2.6% from mesh–time-step sweeps.
Output comparison - Model A - Pulsatile axial drag	8.0	F_avg reproduced with 3.3% MAPE and F_peak with 3.8% across 18 datasets.
Relevance of the quantities of interest - Model A - Pulsatile axial drag	9.5	Traceability ratio was 1.00: F_avg and F_peak directly feed the frictional capacity check.
Test samples - Model A - Pulsatile axial drag	7.0	Coverage included 6 conditions × 3 replicates (18 datasets) with 20+ cycles each.
Equivalency of input parameters - Model A - Neck dilation under pressure	9.0	Mean pressure targets matched to 0.9% and initial diameter to 0.3%; oversizing within 0.5%.
Numerical code verification - Model A - Neck dilation under pressure	8.5	Cylinder hoop strain benchmark within 0.5%; contact patch normal pressure error 1.2%.
Numerical solver error - Model A - Neck dilation under pressure	7.8	Bias on Pc_avg was 3.2% and hoop strain 2.8% from multi-mesh, multi-step sweeps.
Output comparison - Model A - Neck dilation under pressure	7.5	Pc_avg MAPE was 7.5% and hoop strain MAPE 4.2% across 18 datasets.
Relevance of the quantities of interest - Model A - Neck dilation under pressure	9.2	Traceability ratio was 0.98: Pc_avg combined with measured mu enters the margin directly.
Test samples - Model A - Neck dilation under pressure	7.0	Coverage included 6 conditions × 3 replicates (18 datasets) with calibrated sensors.
Equivalency of input parameters - Model A - Curvature-induced proximal edge peeling	9.0	Curvature radius matched within 1.2%; bending stiffness mapping within 1.7%.
Numerical code verification - Model A - Curvature-induced proximal edge peeling	8.5	Contact patch on curved substrate reproduced analytic pressure with 1.2% mean error.
Numerical solver error - Model A - Curvature-induced proximal edge peeling	7.7	Bias on Pc_min was 3.5% and peel length 2.9% under refinement.
Output comparison	7.0	Pc_min MAPE was 9.1% and

Table 2: Model B: Credibility gradations by mechanism and factor (private 0–10 scale).

Credibility factor	Level	Basis
Equivalency of input parameters - Model B - Pulsatile axial drag	9.0	Waveform amplitude and diameter mapping residuals were 0.8% and 0.4%, with mu aligned within 0.02.
Numerical code verification - Model B - Pulsatile axial drag	7.5	Manufactured-solution L2 velocity error 0.21%; interface transfer function differed by 1.8%.
Numerical solver error - Model B - Pulsatile axial drag	5.8	Estimated numerical bias on F_avg was 4.8% and on F_peak 6.1%.
Output comparison - Model B - Pulsatile axial drag	6.5	F_avg MAPE was 7.2% and F_peak MAPE 9.5% across 18 datasets.
Relevance of the quantities of interest - Model B - Pulsatile axial drag	8.5	Traceability ratio was 0.95: F_avg feeds the margin; minor averaging applied.
Test samples - Model B - Pulsatile axial drag	7.0	Coverage included 6 conditions × 3 replicates (18 datasets) with 20+ cycles each.
Equivalency of input parameters - Model B - Neck dilation under pressure	9.0	Mean pressure targets matched to 0.9% and initial diameter to 0.3%; oversizing within 0.5%.
Numerical code verification - Model B - Neck dilation under pressure	7.5	Cylinder hoop strain reproduced within 0.9%; surrogate contact fit MAPE 6–7%.
Numerical solver error - Model B - Neck dilation under pressure	5.5	Bias on Pc_eff was 5.5% and hoop strain 4.9% from refinement sweeps.
Output comparison - Model B - Neck dilation under pressure	6.0	Pc_eff MAPE was 14% and hoop strain MAPE 9% across 18 datasets.
Relevance of the quantities of interest - Model B - Neck dilation under pressure	8.3	Traceability ratio was 0.90: Pc_eff via surrogate maps to margin; direct use of measured mu.
Test samples - Model B - Neck dilation under pressure	7.0	Coverage included 6 conditions × 3 replicates (18 datasets) with calibrated sensors.
Equivalency of input parameters - Model B - Curvature-induced proximal edge peeling	9.0	Curvature radius matched within 1.2%; bending stiffness mapping within 1.7%.
Numerical code verification - Model B - Curvature-induced proximal edge peeling	7.5	Surrogate unload index calibrated to high-fidelity contact (R2 = 0.93, MAPE 6%).
Numerical solver error - Model B - Curvature-induced proximal edge peeling	5.3	Bias on Pc_min surrogate was 6.8% and unload index 6.2% under refinement.
Output comparison - Model B - Curvature-induced	5.5	Pc_min MAPE was 15% and unload index error 18% vs calibrated targets.