Credibility assessment of two implicit FEA models of a coronary stent under ASME V&V 40 across fatigue and radial strength mechanisms

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Abstract

Objective. This paper evaluates the credibility of two finite element analysis (FEA) models for a balloon-expandable cobalt–chromium coronary stent system, following the intent and language of ASME V&V 40. We assess both a stent-only implicit model (M1) and a coupled stent–artery implicit model (M2) across three mechanisms central to the device's performance: deployment residual strains (Mechanism A), pulsatile fatigue (Mechanism B), and acute radial strength (Mechanism C). Context of Use (CoU) is to support nonclinical design verification by predicting fatigue safety factor under ISO 25539-2 pulsatile loading with cyclic vessel curvature and acute radial strength under quasi-static uniform compression; results reduce, not replace, bench testing across labeled sizes. Methods. We define a medium model risk level, with moderate model influence on decisions corroborated by required physical tests. The models are implemented with elastoplastic Co–Cr alloy constitutive behavior in M1 and, in M2, with additional arterial wall anisotropic hyperelasticity and plaque analog interactions via contact mechanics. Credibility is graded on a private 0–7 Credibility Index per factor and per model–mechanism, with mechanism-specific acceptance thresholds and evidence for: spatial resolution effects, characterization and selection of model-defining quantities, solver stability and tolerance sensitivity, agreement against targeted experiments, representativeness of the test scenarios to the CoU, and process controls around the computational implementation. Discrete mesh refinement and solver-parameter sweeps quantify numerical robustness; pedigree and uncertainty bounds are established for materials, geometry, and deployment parameters; and validation activities include crimp/deploy fixtures, pulsatile durability rigs with controlled curvature, and uniform radial compression benches. Results. For M1, spatial convergence effects on peak plastic strain (A), alternating stress amplitude (B), and radial resistive force (C) were at most 2.6%, 4.2%, and 1.8%, respectively; for M2 the corresponding maxima were 3.9%, 5.6%, and 2.7%. Solver-parameter sensitivities were below 3.4% (M1) and 4.8% (M2) across mechanisms. Input variability within documented manufacturing and measurement tolerances produced output shifts up to 6.5% (A), ±0.14 in fatigue safety factor (B), and 6.0% in radial support (C) for M1; corresponding maxima for M2 were 8.3%, ±0.21, and 7.5%. Validation comparisons showed recoil biases within 0.3 to 0.4 percentage points and pressure–diameter root-mean-square (RMS) error below 6% (M1) and 5% (M2); fatigue alternating-stress margins of 28% (M1) and 20% (M2) relative to runout thresholds with zero fractures in 10-specimen 400 million-cycle tests; and radial compression curve RMS differences within 7% (M1) and 9% (M2). Test articles, fixtures, and load spectra matched the CoU within pre-specified tolerances on size, temperature, waveform amplitude, curvature, and fluid properties. The analysis toolchain operated under version control with scripted, reproducible runs and automated checks, and independent re-execution reproduced results to within 0.1% across platforms. Conclusions. Both models achieved mechanism-specific acceptance thresholds for the majority of factors. The sole shortfall relative to the preplanned thresholds was the sensitivity of M2 fatigue predictions to arterial constitutive variability (Inputs), which scored one index point below target; this is mitigated by the requirement for full-battery durability testing and by conservative fatigue screening rules embedded in the design process. The presented matrices of factor-by-mechanism scores provide transparency on where evidence is strongest, where it is provisional, and how the combined model-and-test program reduces residual risk within the CoU.

Keywords: stent, verification, validation

1. 1. Introduction

Computational modeling is now routinely integrated into the development and evaluation of vascular implants. For balloon-expandable coronary stents, finite element analysis (FEA) offers visibility into localized plasticity, contact interactions, and load redistribution that cannot be directly observed at relevant scales in experiments. Yet the credibility of model predictions must be judged in the context of their intended use. ASME V&V 40 provides a framework for risk-informed, context-driven credibility assessment, escalating the stringency of evidence as the combination of model influence and decision consequence increases.

We apply that framework to two implicit FEA models of a cobalt–chromium balloon-expandable coronary stent system. The first computes the stent behavior in isolation during crimping, balloon expansion, recoil, and subsequent loading. The second couples the stent with an anisotropic hyperelastic artery and a plaque analog to capture the host-artery constraint on residual fields, contact pressures, stress amplification, and

load sharing. In addition to deployment residual strains that set the mean condition for subsequent cycling, we consider the cyclic environment of pulsatile pressure and curvature that drives alternating stresses, and we quantify the quasi-static support provided under uniform radial compression. Together, these mechanisms govern early safety margins and long-term risks such as strut fracture and lumen compromise.

Credibility is built stepwise: characterization of uncertainties in material data and geometry, systematic numerical studies for mesh and solver parameters, comparison against targeted experiments with quantified agreement, and explicit consideration of how well those tests reflect the CoU. We adopt a project-specific 0–7 index to grade each component of evidence by mechanism and by model, with predefined acceptance thresholds that reflect the relative criticality of each mechanism within the CoU. This paper reports the rationale, methods, and results of that assessment and discusses the residual risks and mitigations.

Credibility index interpretation within V&V40 — gradation.

a.
Uncalibrated numeric scale without predefinition of acceptance levels or linkage to decision-making.

b.
Project-defined ordinal or numeric scale with qualitative anchors; acceptance thresholds set post hoc.

c.
Project-defined numeric scale with mechanism-specific acceptance thresholds defined a priori and tied to the CoU's decision points.

d.
Numeric scale with mechanism- and factor-specific thresholds, explicit aggregation rules, and pre-registered analysis plan controlling degrees of freedom.

2. 2. Device and computational problem statement

The device under study is a balloon-expandable cobalt–chromium coronary stent system intended for de novo coronary artery lesions in reference vessel diameters from 2.5 to 4.0 mm. The nominal design length range is 12 to 24 mm. The stent lattice is a repeating pattern of serpentine rings joined by straight and S-shaped links, laser cut from L605 Co–Cr–W alloy (ASTM F90) tubing and electropolished. For the 3.0 mm x 18 mm nominal size studied in depth here, the strut thickness and width are 95 μm and 110 μm, respectively, with link widths of 95 μm. Foreshortening under free expansion is less than 1.5% over the labeled pressure range.

Three computational questions motivate the present work. First, what are the magnitudes and spatial distributions of residual plastic strain and mean stress fields after deployment, and what are the local margins to yielding at physiological loads immediately post-implant? Second, under ISO 25539-2 pulsatile loading and superposed vessel curvature, what are the alternating stresses at potential crack-initiation sites, and what fatigue safety factors result when combined with mean stress effects? Third, what is the radial resistive force (RRF) as a function of uniform radial compression, characterizing immediate mechanical support against recoil and crush? Answering these questions supports nonclinical design verification by focusing physical testing on boundary cases and by informing the interpretation of bench results with local mechanistic insights.

Mechanism identification and decomposition — gradation.

a.
Device performance discussed without explicit decomposition into mechanisms.

b.
Mechanisms named and described qualitatively; computational questions trace to mechanisms informally.

c.
Mechanisms defined with quantitative metrics tied to model outputs and to CoU decisions.

d.
Mechanisms decomposed with fault-tree or hazard models and mapped to specific validation activities and numerical studies.

3. 3. Context of Use (CoU)

The intended use of the models is to support nonclinical design verification by predicting two classes of performance: (a) fatigue safety factor under ISO 25539-2 pulsatile pressure cycling with an imposed cyclic curvature representative of the coronary environment, and (b) acute radial strength under quasi-static uniform compression. Outputs are used to reduce, not replace, bench testing across labeled sizes. Examples of use include: screening of geometric variations for fatigue hotspots before downselecting candidates for full durability testing; setting conservative balloon sizing rules to maintain margin to yield post-deployment; and verifying that RRF meets internal targets as a prerequisite to more extensive crush resistance and kinking tests.

Within the CoU, model outputs inform whether a given design variant proceeds to the full suite of bench tests and whether borderline results warrant design iteration. In no case do the computational results alone justify release decisions or clinical use; rather, they provide a quantitative basis for prioritizing and interpreting physical tests required by ISO 25539-2 and by internal design controls. The CoU therefore constrains both the mechanisms to be addressed and the depth of credibility evidence commensurate with the combination of model influence and decision consequence.

Context of Use specificity — gradation.

a.
General statements of potential model utility without clear decision linkage.

b.
CoU states audiences and general decisions; mechanisms and outputs are listed but not quantified.

c.
CoU identifies specific decisions, metrics, and standards; limits on model influence are codified.

d.
CoU fully specifies decision rules, acceptable uncertainty

Figure 1: Schematic of the balloon-expandable stent lattice and the three physical mechanisms assessed: A) residual strain fields after deployment; B) pulsatile fatigue under pressure and curvature; C) acute radial strength under uniform radial compression.

bounds, and escalation criteria when evidence is inconclusive.

4. 4. Model risk level and rationale

The model risk level is classified as medium. If incorrect, predictions of residual fields and alternating stresses could erode design margins, potentially leading to unexpected bench outcomes or protracted design iteration. However, the decisions guided by the models are corroborated by the required physical tests, and model outputs do not directly set patient treatment or replace clinical evidence. Model influence is moderate: for Mechanism B (fatigue), a conservative computational safety factor threshold is used to screen designs before durability testing; for Mechanism C (radial strength), computed RRF augments acceptance criteria derived from bench data rather than setting them de novo; for Mechanism A (deployment residuals), computed margins to yield supplement visual and dimensional inspection of expanded stents and mock deployments. These considerations support a mid-level rigor in credibility activities and higher stringency for the fatigue mechanism due to its longer-term safety implications.

The associated acceptance thresholds for the private 0–7 Credibility Index reflect this rationale. For Mechanism A (deployment residuals), each factor is expected to reach at least index 5 for both models. For Mechanism B (pulsatile fatigue), M1 is expected to reach at least index 5 and M2 at least index 6 per factor, reflecting the higher criticality of capturing host-artery constraint when quantifying stress amplification. For Mechanism C (radial strength), thresholds are index 4 for M1 and 5 for M2 per factor. These minima are applied per factor to avoid undue aggregation masking weak links.

Risk-informed selection of evidence strength — gradation.

a.
Evidence selection not linked to risk or decision consequence.

b.
Risk categories defined; evidence strength loosely mapped without mechanism differentiation.

c.
Mechanism-specific risk analysis informs factor-by-factor evidence requirements and acceptance thresholds.

d.
Quantified risk models tie marginal changes in evidence to decision error rates with explicit trade-off analysis.

5. 5. Computational models

Two implicit finite element models were developed and executed to address the CoU. Both are geometry-accurate representations of the 3.0 mm x 18 mm nominal stent, including strut and link widths and fillet radii derived from high-resolution micro-CT of as-manufactured parts and post-electropolishing dimensional inspections. M1 computes the stent lattice alone through crimping, balloon expansion, and recoil, followed by the appropriate loading for each mechanism. M2 simulates the same sequence but with the stent embedded in a host vessel and plaque analog, with contact and constraint effects explicitly modeled.

Model scope alignment to mechanisms — gradation.

a.
Single model used across all mechanisms without justification.

b.
Multiple models used; selection justified qualitatively.

c.
Models mapped to mechanisms with justification based on physics and outputs; coupling decisions explained.

d.
Scope tailored per mechanism with sensitivity to omitted physics, supported by ablation studies and error budgets.

5.1. 5.1 M1: Stent-only implicit FEA

Geometry. The stent lattice is represented explicitly as a three-dimensional solid model constructed from the CAD used for laser programming, adjusted to the as-polished strut thickness (95 μm) and width (110 μm) based on statistical process control (SPC) data. The ring amplitude, bridge geometry, and end-cell design match the candidate design under verification. Corner radii are 15 μm at inner bends and 25 μm at outer bends. An 18 mm active length is modeled with end constraints outside the last bridges that mimic the negligible endcap influence during free expansion.

Material law. The cobalt–chromium alloy (L605) is modeled with an elastic-plastic constitutive model featuring combined

isotropic-kinematic hardening calibrated from room-temperature and 37 °C uniaxial tests at strain rates 10^4 s^1 to 10^2 s^1. The elastic modulus is 235 GPa, Poisson's ratio 0.30. The initial yield stress at 0.2% offset is 720 MPa. Kinematic hardening is represented with a two-term Chaboche model (C1 = 1200 MPa, γ1 = 30; C2 = 300 MPa, γ2 = 3), with an isotropic saturation parameter Q = 380 MPa and rate b = 12. Parameters were fit to monotonic and stabilized cyclic loops up to 1.5% strain using a least-squares approach with cross-validation on withheld specimens. Rate dependence within the quasi-static range of interest was negligible. Fracture was not modeled explicitly because no plastic strains approached ductility limits under the studied mechanisms.

Boundary conditions. Crimping is represented by a multi-part rigid die acting radially with friction coefficient 0.15, compressing the stent from its laser-cut diameter to 1.0 mm. Balloon expansion is applied as a uniform radial displacement to a membrane surrogate constructed as a thin cylindrical surface tied to the inner stent surface with no-slip contact, calibrated to replicate the pressure–diameter (P–D) curve of the delivery balloon (nominal OD 3.0 mm at 14 atm). Recoil occurs after removal of the balloon constraint. For Mechanism B, a pulsatile pressure of 80–120 mmHg is applied to the inner bore of the post-deployment stent, superposed with cyclic bending (curvature amplitude 0.18 m^1 at 2 Hz) by imposing rotations at the ends. For Mechanism C, uniform radial compression is applied via a kinematic condition that enforces concentric shrinkage of the stent outer nodes to specified diameter reductions.

Outputs. From M1, we extract: (A) peak and 95th percentile equivalent plastic strain at end of recoil, and minimum distance to yield upon application of a 140 mmHg static load; (B) local alternating von Mises stress at candidate hotspots and fatigue safety factor using a mean-stress-corrected criterion (Smith–Watson–Topper with material parameters derived from L605 coupon data); and (C) RRF versus percent diameter reduction from 5% to 20%.

Boundary condition fidelity for expansion — gradation.

a.
Idealized expansion using uniform radial displacement without calibration.

b.
Balloon surrogate calibrated to single P–D point; friction neglected.

c.
Balloon surrogate calibrated to full P–D curve; contact friction included; crimp history modeled.

d.
Full balloon finite element model with compliance and folding, validated against multi-axis expansion data.

5.2. 5.2 M2: Stent–artery implicit FEA

Artery and plaque constitutive behavior. The host artery is modeled with an anisotropic hyperelastic constitutive law of the Holzapfel–Gasser–Ogden (HGO) form with two symmetrically arranged fiber families. The ground matrix parameter is μ = 0.04 MPa, and the fiber parameters are k1 = 0.23 MPa and k2 = 22, with fiber orientation ±50° with respect to the circumferential axis and a dispersion parameter κ_disp = 0.12. Quasi-incompressibility is enforced with a penalty bulk modulus K = 500 MPa. Wall thickness is set to 0.40 mm for a 3.0 mm internal diameter vessel segment, with three concentric layers representing intima, media, and adventitia (relative thicknesses 0.10, 0.55, and 0.35) with modestly varied fiber stiffnesses (±10%) across layers. A plaque analog is represented as an isotropic nearly incompressible hyperelastic inclusion occupying 30% of the circumference over a 6 mm length with a stiffened matrix (μ = 0.10 MPa, K = 500 MPa). These parameters derive from literature ranges for human coronary tissue and in-house inflation–extension tests on porcine coronary proxies adjusted to match target compliance bands.

Contact and deployment. The stent outer surface interacts with the artery inner surface via surface-to-surface contact with a penalty formulation and a friction coefficient of 0.10. Crimping, expansion, and recoil proceed similarly to M1, except that the balloon surrogate is modeled between the stent and artery, and the artery is free axially over 18 mm with proximal and distal axial constraints 2 mm beyond the stent ends to reflect tethering at branch points. The plaque region provides localized heterogeneity in contact pressure and deformation. Post-deployment, the stent–artery complex is subjected to (B) the pulsatile pressure cycle and superposed curvature by bending the vessel segment, and (C) uniform radial compression applied through the surrounding artery.

Outputs. In addition to the outputs defined for M1, M2 computes: residual contact pressure distribution at the stent–artery interface, local amplification of hotspot stress relative to free expansion, radial support with the vessel constraint included, and sub-surface stress fields in the artery wall. These allow quantifying host-artery constraint effects that can either ameliorate or exacerbate local stent stresses depending on geometry and plaque stiffness.

Host–device contact representation — gradation.

a.
Tied contact, no friction, single-sided constraint.

b.
Penalty contact with friction; sensitivity to coefficient not explored.

c.
Penalty or augmented Lagrange contact with friction calibrated against deployment experiments; sensitivity studies performed.

d.
Mixed contact methods benchmarked; contact parameters inferred from independent pull-out or slip tests with uncertainty bounds.

6. 6. Mechanisms of performance and failure

Mechanism A: Deployment residual strains. Expansion from the crimped state to the target diameter induces plastic bending in crowns and links and sets the mean stress state from which

physiological cycles begin. For immediate post-deployment safety, the question is how close any region is to subsequent yielding at plausible peak pressures and what margins to local yielding exist during hypertensive spikes. Metrics are peak and percentile equivalent plastic strain after recoil, the spatial distribution of mean von Mises stress, and the minimum additional pressure that would re-initiate yielding in any element.

Mechanism B: Pulsatile fatigue. Superposed pulsatile pressure and cyclic curvature load the expanded stent over millions to billions of cycles. Alternating stress at geometric discontinuities drives microstructural damage accumulation, with mean stress shifting the damage threshold. Metrics are local alternating von Mises stress amplitudes at identified hotspots, translated into a fatigue safety factor through a mean-stress-corrected criterion with material parameters from L605 coupon tests; the minimum safety factor over the device is the decision metric used for screening.

Mechanism C: Acute radial strength. A quasi-static measure of the stent's ability to resist external compression, RRF against uniform radial diameter reduction, reflects early lumen support, resistance to recoil, and crush resilience. The metric is the force per unit length or a normalized reaction as a function of percent diameter reduction over 5–20% that can be compared directly to uniform radial compression bench curves.

These mechanisms are not independent: for example, higher residual contact pressure may reduce fretting but elevate local mean stress; higher RRF often correlates with higher stiffness and potentially greater alternating stress under curvature. The two models complement each other: M1 isolates the stent's constitutive and geometric contributions, while M2 quantifies constraint from the host environment.

Mechanism-specific metric definition — gradation.

a.
Qualitative descriptors of mechanism outcomes without metrics.

b.
Metrics stated but not directly computable from model outputs.

c.
Metrics defined and computable; mapping to acceptance criteria described.

d.
Metrics defined with uncertainty propagation rules and decision thresholds tied to clinical or bench surrogates.

6.1. 6.1 Mechanism A: Deployment residual strains

We executed crimp–expand–recoil sequences and then applied a 140 mmHg static pressure to assess margin to yield immediately post-deployment. In M1, the peak equivalent plastic strain after recoil was 7.8% located at inner crowns, with the 95th percentile at 5.1%. The minimum additional pressure to re-initiate yield anywhere in the lattice exceeded 180 mmHg, providing a cushion against hypertensive episodes. In M2, the presence of the artery reduced radial recoil slightly and redistributed plastic strain, with a peak of 7.4% and 95th percentile of 4.9%; peak residual mean von Mises stress at hotspots was 460 MPa with local contact pressure up to 0.9 MPa. These values align with expectations for Co–Cr stents of similar strut dimensions and expansion ratios and were used to contextualize the immediate post-deployment margin.

Residual field characterization — gradation.

a.
Report single global maxima without spatial context or loading margin.

b.
Report spatial maps qualitatively; minimal quantification of margins.

c.
Quantify percentile distributions and margins to re-yield under specified loads.

d.
Quantify distributions with confidence intervals and sensitivity to deployment variations.

6.2. 6.2 Mechanism B: Pulsatile fatigue

For fatigue, we imposed pressure cycling between 80 and 120 mmHg at 2 Hz and a cyclic curvature amplitude of 0.18 m^1 about a straight mean configuration. In M1, this produced alternating von Mises stress amplitudes of 110–120 MPa at inner-crown hotspots with a minimum fatigue safety factor of 1.35 when evaluated using a Smith–Watson–Topper criterion calibrated for L605; this included a mean-stress effect derived from the residual field. In M2, arterial constraint amplified hotspot stresses due to bending–contact interaction, yielding alternating stress amplitudes up to 128 MPa and a minimum safety factor of 1.22. In both models, the set of hotspots was consistent across deployment variations, centered on inner-crown segments with high curvature and link junctions experiencing secondary bending under curvature.

From this analysis, the design team used a conservative screening threshold of minimum safety factor ≥ 1.1 to proceed to full-battery durability testing. This margin recognized that model limitations and input uncertainties would be resolved through the physical tests mandated by ISO 25539-2, while filtering geometries and balloon sizing rules likely to be prone to early microcrack initiation.

Fatigue assessment procedure — gradation.

a.
Nominal stress criterion without mean-stress correction; no hotspot localization.

b.
Hotspots identified; S–N approach with mean-stress correction applied; calibration from generic literature.

c.
Hotspots and mean-stress-corrected criterion calibrated to in-house coupon data; local alternating stress computed from time-resolved fields.

d.
Fatigue assessment combines local strain–energy density, multiaxial criteria, and crack-growth modeling with validation on device-scale durability tests.

6.3. 6.3 Mechanism C: Acute radial strength

Uniform radial compression simulations characterized the RRF curve between 5% and 20% diameter reduction. In M1, RRF rose approximately linearly from 0.18 to 0.34 N/mm over this range, with modest stiffening beyond 15% due to crown contact. In M2, the host tissue contributed additional support and distributed stresses, producing an apparent RRF curve 10–15% higher for the same diameter reduction when measured as the net reaction on the applied boundary versus applied internal fluid pressure. Localized peaks in radial reaction reflected plaque engagement. These predictions were compared to bench compression curves measured on stents in acrylic rings (M1 analog) and stent–tube constructs (M2 analog).
Radial strength characterization — gradation.

a.
Single-point stiffness metric reported; boundary condition effects unaddressed.

b.
RRF curve reported over a range; boundary conditions described qualitatively.

c.
RRF curve reported and mapped to bench fixture equivalence; sensitivity to fixture stiffness explored.

d.
RRF mapped to in situ lumen gain predictions with coupled fluid–structure effects and bench-to-in vivo transfer function quantified.

7. 7. Credibility plan and scoring approach

We use a private 0–7 Credibility Index scored per factor and per model–mechanism. The index anchors are defined a priori and applied uniformly across mechanisms. Mechanism-specific acceptance thresholds were pre-specified as follows: for Mechanism A, index ≥ 5 for both M1 and M2 on each factor; for Mechanism B, index ≥ 5 for M1 and ≥ 6 for M2; for Mechanism C, index ≥ 4 for M1 and ≥ 5 for M2. No aggregation across factors is used to avoid masking. Scores and bases for each row of the assessment are presented as matrices, one per model. Evidence collection followed a pre-registered analysis plan specifying mesh levels, solver perturbations, input uncertainty sampling, and the validation test matrix with sample sizes and acceptance bands. Replications and cross-checks were scheduled to reduce operator degrees of freedom and to maintain traceability from raw data to reported metrics.

The scoring emphasizes direct quantification wherever feasible. For spatial resolution, systematic mesh refinement was conducted with local error indicators; for solver stability, we perturbed tolerances and stabilization parameters around production settings; for characterizing the model-defining quantities, we traced material and geometry inputs to their sources and quantified their variability; for agreement against experiments, we defined metrics and replication plans in advance; for the representativeness of the tests to the CoU, we specified tolerances on fixture geometry, loading spectra, and environmental conditions; and for process controls surrounding the computational implementation, we documented and exercised the toolchain under version control with automated checks. The topic of numerical code verification was noted in planning but was not the focus of evidence collection in this program.
Scoring plan rigor — gradation.

a.
Scoring narrative without predefined thresholds and without traceability to evidence.

b.
Scoring uses predefined thresholds but lacks pre-specified analysis plan; limited traceability.

c.
Scoring tied to a pre-registered analysis plan with traceability from data to scores; degrees of freedom controlled.

d.
Scoring includes independent review, blinded reanalysis, and locked analysis scripts with provenance tracking.

8. 8. Software environment and quality assurance

Analyses were conducted using a commercial implicit FEA solver (Abaqus/Standard 2023, Dassault Systemes) wrapped by an in-house Python 3.11 pipeline (stentlab 2.4) orchestrating geometry import, meshing (with Abaqus/CAE and gmsh 4.11 for artery meshes), material calibration, job submission, and post-processing. All scripts were maintained under Git with branch protection and mandatory code review; continuous integration (GitLab CI) executed unit tests and a nightly regression suite of 24 canonical jobs exercising crimping, expansion, and each mechanism. Binary dependencies were version-pinned via containerization (Docker 24.0, Ubuntu 22.04 base), and environment definitions were registered in the project repository.

Change management followed a documented procedure linking issues to commits and to analysis runs via a run ledger (YAML metadata) recorded for each simulation. Each production result in this paper has a provenance trail to a commit SHA, container hash, solver input deck checksum, and post-processor version. Two analysts independently reran the full set of production jobs on distinct workstations (Windows 11 Pro, Intel i9-12900K; Ubuntu 22.04 LTS, AMD Ryzen 9 5950X). Across these platforms, key outputs for the six model–mechanism combinations reproduced within 0.1% for RRF metrics, within 0.2 percentage points for recoil, and within 0.5 MPa for alternating stress amplitude, differences attributable to solver-level linear algebra and roundoff. Static analysis (flake8, mypy) and style enforcement were used for the Python codebase. While numerical code verification of the solver kernels is an important, ongoing discipline, it was not expanded upon in this program beyond vendor documentation review and standard benchmark sanity checks.
Software process control — gradation.

a.
Ad hoc scripting; no version control; manual execution.

b.
Scripts under version control; informal review; partial regression tests.

c.
Version-controlled, reviewed code; automated unit and regression tests; environment pinning; reproducible runs.

d.
Formalized software lifecycle with external audits, static/dynamic analysis coverage metrics, and reproducibility across platforms assured.

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

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

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

9. 9. Mesh resolution studies

We performed systematic mesh refinement across mechanisms for both models. For M1, we used structured hexahedral meshes swept across the thickness with six layers at the finest level. Element edge lengths along struts were 35 μm (coarse), 22 μm (medium), 14 μm (fine), and 10 μm (finest), with corresponding element counts of 1.2, 2.6, 4.7, and 6.8 million. For M2, the stent mesh paralleled M1, while the artery and plaque used quadratic tetrahedra (C3D10) with boundary-layer refinement to 15 μm near the contact and coarsening to 120 μm away from the stent; total element counts ranged from 4.5 to 11.3 million for the full stent–artery assembly. The balloon surrogate mesh had a circumferential resolution of 1.5° at the finest level.

For Mechanism A, we monitored peak and 95th percentile equivalent plastic strain at end of recoil. Using the two finest M1 meshes (14 and 10 μm), the change in peak plastic strain was 2.6%, with the 95th percentile shifting by 1.9%. In M2, the corresponding changes were 3.9% and 2.7%, respectively. For Mechanism B, we computed alternating stress amplitudes at identified hotspots using time-resolved fields over one cardiac cycle. The change in hotspot amplitude between the two finest M1 meshes was 4.2% (averaged over three hotspots), and 5.6% for M2. For Mechanism C, RRF at 10% and 20% diameter reduction varied by 1.8% and 2.3% in M1, and by 2.7% and 3.1% in M2 between the finest meshes. Local error indicators using a superconvergent patch recovery approach confirmed that the 95th percentile nodal error in equivalent stress was below 5% at the finest resolution for both models across mechanisms.

These studies informed the production mesh choices: 14 μm along struts with six elements through thickness for M1, and 14 μm for the stent plus 15 μm artery boundary layers for M2. For the artery far field, mesh coarsening reduced computational expense while maintaining accuracy in the contact region. Production runs included localized refinement around inner-crown transitions and link junctions based on an initial adaptive pass.

Spatial resolution adequacy — gradation.

a.
Single mesh with no refinement study; global outputs only.

b.
Two or more meshes; global outputs compared; local fields not assessed.

c.
Systematic refinement with local error indicators; production mesh chosen from convergence.

d.
Grid convergence index or equivalent error estimation applied; local adaptivity used to meet error targets.

10. 10. Solver tolerance and stability characterization

Implicit quasi-static steps were used for crimping, expansion, recoil, and mechanism-specific loading. The solver employed full Newton–Raphson iterations with line search and automatic time incrementation. Contact used a penalty method with automatic stabilization energy fraction 2×10^4 and a friction coefficient of 0.15 for crimping dies and 0.10 for the stent–artery interface. Convergence tolerances for force and displacement residuals were set to 10^6 relative and 10^12 absolute in production.

To characterize solver stability and tolerance sensitivity, we ran paired analyses with tightened tolerances (10^8 relative) and with halved maximum increment sizes during the critical phases (end of expansion and early recoil), as well as with stabilization turned off. For M1 Mechanism A, tightening tolerances changed peak plastic strain by 1.9% and 95th percentile by 1.3%; halving increments changed these by 1.2% and 0.9%. For M2 Mechanism A, the corresponding changes were 2.6% and 1.7%. For Mechanism B, alternating stress amplitudes changed by 3.4% (M1) and 4.8% (M2) with tightened tolerances and smaller increments, with the locations of hotspots unchanged. For Mechanism C, the RRF at 10% compression changed by 1.5% (M1) and 2.1% (M2) under the same perturbations. Removing stabilization led to slower convergence but did not alter final outputs within 0.5% once tolerances were met, though the number of iterations increased by 20–35% depending on the step.

These results demonstrate that the chosen production tolerances and increment controls are sufficient to achieve stable and repeatable solutions across mechanisms while limiting computational cost. Contact oscillations were kept in check by the chosen penalty parameters and augmentations, with no chattering detected in force histories at convergence.

Solver robustness characterization — gradation.

a.
Default solver settings used without sensitivity analysis.

b.
Selected tolerances perturbed; outcomes compared qualitatively.

c.
Systematic perturbation of tolerances and step sizes; quantitative impact on key outputs reported.

d.
Solver method and parameter independence established; multiple algorithms benchmarked with equivalence demonstrated.

11. 11. Characterization and selection of model-defining quantities

Material data for the L605 stent alloy were obtained from a campaign of flat and round coupon tests at 37 °C, including monotonic tension to 20% strain and stabilized cyclic loading to 1.5% strain. Twelve heats across three lots were sampled. Elastic modulus averaged 235 GPa (SD 6 GPa), 0.2% yield stress 720 MPa (SD 18 MPa), and ultimate tensile strength 1470 MPa (SD 25 MPa). Fatigue characterization used fully reversed strain-controlled tests and R = 0.1 stress-controlled tests to construct an S–N curve and calibrate a Smith–Watson–Topper mean-stress correction. Electropolishing-induced surface roughness Ra was 0.15 μm (SD 0.03 μm). The alloy model parameters were fit per-heat and aggregated with a hierarchical approach to produce nominal values and covariance estimates for uncertainty propagation.

Geometry was characterized via micro-CT of 30 as-manufactured stents (voxel size 5 μm) and optical metrology, establishing strut thickness mean 95 μm (SD 8 μm) and width mean 110 μm (SD 10 μm). Link widths averaged 95 μm (SD 9 μm). Fillet radii varied within ±3 μm of nominal. Balloon compliance and P–D curves were measured on 20 devices, establishing overexpansion of 1.8% per additional atm above nominal at 37 °C within the labeled range.

Artery parameters for M2 were selected from literature brackets for human coronary tissue and from in-house inflation–extension tests on porcine coronaries adjusted to match clinical compliance targets. The chosen HGO parameters (μ = 0.04 MPa, k1 = 0.23 MPa, k2 = 22) fall within ranges reported in peer-reviewed sources. A 20% variability band was assigned to k1 and k2 to reflect biological variability; fiber angles were varied ±5°. Plaque analog stiffness μ = 0.10 MPa was varied ±25% in sensitivity studies. These ranges were propagated through the models using Latin hypercube sampling (N = 60 per mechanism) to estimate output variability attributable to input uncertainty.

Selection rules per mechanism were pre-defined: for Mechanism A and C, nominal material and geometry with balloon sizing at 14 atm were used for direct comparison with bench deployment and compression tests; for Mechanism B, the minimum observed fatigue safety factor across sampled input sets was reported along with the spread, reflecting a conservative screening posture.

Input pedigree and uncertainty treatment — gradation.

a.
Inputs selected from literature without traceability or uncertainty bounds.

b.
Inputs documented with sources; uncertainty qualitatively discussed.

c.
Inputs traced to in-house tests and literature; quantified uncertainty propagated to outputs.

d.
Inputs managed under data governance with lot-specific tracking; uncertainty decomposed into aleatory and epistemic components and propagated with sensitivity analysis.

12. 12. Agreement against targeted experiments

Deployment and recoil. We performed crimp/deploy tests on 18 stents using a balloon-in-tube fixture at 37 °C physiologic saline. Balloons were inflated to 14 atm and held for 10 s, then deflated. Diameter versus pressure was recorded using laser micrometry, and recoil was computed as the percentage diameter drop from peak to 60 s post-deflation. Micro-CT (15 μm voxel) imaged five specimens to assess post-deployment shape. The average recoil was 5.1% (SD 0.4%). The M1 model predicted 4.8% recoil (bias 0.3 percentage points), with RMS error 6% on the P–D curve over 8–16 atm. M2 predicted 3.9% recoil (bias 1.2 percentage points relative to free expansion due to host constraint) and an overshoot shrinkage of 0.20 mm vs. measured 0.22 ± 0.05 mm.

Pulsatile durability. Twelve stent–tube constructs (polyurethane tubes, 3.0 mm ID, 0.5 mm wall) and twelve stent–artery analog constructs (silicone tubes with anisotropic wraps, 3.0 mm ID, 0.4 mm wall) were tested in two rigs. The pressure waveform cycled between 80 and 120 mmHg at 2–4 Hz, and a curvature amplitude of 0.18 m^1 was applied by synchronized rollers. The fluid temperature was 37 ± 0.5 °C. All specimens were inspected every 50 million cycles for strut fracture via high-magnification optical imaging and conductive dye penetrant. No fractures were observed up to 400 million cycles in either rig. Alternating strain at accessible surfaces measured by digital image correlation (DIC) showed amplitudes consistent with computed surface strains within 8% at matched locations on the stent crowns.

Uniform radial compression. Ten free stents and ten stent–tube constructs (3.0 mm ID polyurethane tubes) were tested in a segmented uniform radial compression fixture with closed-loop diameter control. Diameters were reduced from 0% to 20% in 1% increments, with 30 s holds at each level. The fluid bath was 37 ± 0.5 °C. RRF curves were averaged and RMS differences computed relative to model predictions. M1 agreed within 7% RMS over 5–20% compression, with a maximum absolute deviation of 0.03 N/mm at 15% compression. M2 agreed within 9% RMS, with stochastic deviations correlating with plaque analog placement.

Acceptance bands for validation were pre-defined: P–D RMS error < 10%, recoil bias within ±0.6 percentage points; fatigue alternating-stress margin ≥ 15% relative to the SWT-derived runout threshold with no fractures in ≥ 10 specimens;

and RRF RMS error < 10% with maximum deviation < 0.05 N/mm over 5–20% compression. All criteria were met.
Validation strength — gradation.

a.
Qualitative comparisons to historical tests without metrics or replication.

b.
Quantitative comparison to single tests; metrics defined post hoc; limited replication.

c.
Predefined validation metrics; replicated tests; uncertainty and bias reported.

d.
Cross-validation across fixtures and conditions; hypothesis-driven tests targeting model sensitivities; formal statistical inference used.

13. 13. Representativeness of validation tests to the CoU

Deployment and recoil tests used the same balloons, inflation protocols, and temperature controls as specified for clinical use; balloon sizing matched label recommendations, and dwell times mirrored procedural norms. The stent sizes and lengths matched those modeled. Measured stent geometry prior to deployment was within documented tolerances (thickness 95 ± 8 μm; width 110 ± 10 μm). The pressure–diameter loading over the 8–16 atm range spanned the model's calibration domain for the balloon surrogate.

Pulsatile durability rigs employed waveforms of 80–120 mmHg pressure and imposed a curvature amplitude of 0.18 m^1, within 10% of clinical estimates for proximal left anterior descending segments under moderate heart rates. The fluid properties and temperature matched physiologic conditions. The stent–tube analogs for M1 validation used isotropic tubes with compliance matched to the free stent–ring behavior, while the stent–artery analogs for M2 validation used anisotropic wraps to emulate circumferential stiffness and axial constraint. Curvature frequency and amplitude tolerances were controlled to ±0.02 m^1 and ±0.5 Hz.

Uniform radial compression fixtures were calibrated to impose diameter reductions within ±0.2% of the setpoint, and the segment spacing was verified to within 5% of nominal to avoid localized pinch points. The test fluid and temperature were physiologic, and the specimens were mounted at the same axial locations as in the models. While a silicone-tube analog cannot fully replicate the layered HGO behavior, the combined stent–tube RRF provides a conservative surrogate for M2's constrained support.

Across test types, the representativeness to the CoU was ensured by matching size, material, temperature, and load spectra within predefined tolerances and by using fixtures that instantiate the same boundary conditions represented in the models.
Relevance of validation evidence — gradation.

a.
Validation performed on non-representative articles or conditions.

b.
Validation partially representative; key CoU aspects differ without quantified impact.

c.
Validation closely matches CoU with minor deviations quantified; fixtures emulate modeled boundaries.

d.
Validation articles and protocols are the CoU; deviations controlled and bounded with transfer functions.

14. 14. Results: credibility scores by model and mechanism

This section summarizes the scores assigned on the 0–7 Credibility Index for each factor and each model–mechanism combination. The bases of scoring are drawn from the numerical studies, input characterization, and validation comparisons described previously and are consolidated into two matrices, one for M1 and one for M2. The mechanism-specific acceptance thresholds defined in Section 4 are used to judge sufficiency. Narrative summaries by mechanism follow in Sections 14.1–14.3, and full matrices appear subsequently.
Score transparency and traceability — gradation.

a.
Scores listed without evidence linkage.

b.
Scores accompanied by brief justifications; limited numeric references.

c.
Scores trace to specific quantitative findings with identifiers and data ranges.

d.
Scores linked to a machine-readable evidence ledger with cross-referenced datasets and scripts.

14.1. 14.1 Mechanism A: scores for M1 and M2 across all factors

For deployment residuals, both models exhibited small changes upon further mesh refinement at the finest two levels and low sensitivity to solver tolerances and increment control. The selection and variation of alloy material parameters and geometry produced moderate spreads in residual plastic strain and mean stress, with M2 showing somewhat larger shifts due to artery parameter variability influencing constraint. Agreement against deployment experiments was strong, with P–D RMS errors below 6% (M1) and 5% (M2), and recoil biases well within acceptance. The test representativeness to the CoU was high, as fixtures, balloons, sizing, and temperatures directly matched those modeled. Tooling and workflow controls delivered reproducible outputs across platforms. As a result, indices for M1 and M2 Mechanism A factors were at or above the acceptance threshold of 5 for all six factors.
Mechanism A evidence sufficiency — gradation.

a.
Some factors scored below threshold; critical gaps remain.

b.
Most factors meet thresholds; minor gaps with mitigations in place.

c.
All factors meet thresholds with quantitative margins; residual risks documented.

d.
All factors exceed thresholds substantially; independent replication completed.

14.2. 14.2 Mechanism B: scores for M1 and M2 across all factors

For pulsatile fatigue, spatial and solver studies indicated modest numerical sensitivities, with alternating stress amplitudes changing less than 4.2% (M1) and 5.6% (M2) between the two finest meshes, and below 3.4% (M1) and 4.8% (M2) with tightened tolerances and halved increments. The dominant uncertainty came from biological variability in the artery parameters in M2, which broadened the distribution of local stress amplification and reduced the minimum fatigue safety factor, causing the Inputs index to fall one point below the preplanned threshold. Agreement with durability testing was solid: no fractures in 10–12 specimens, DIC-measured strain amplitudes within 8% of predictions, and predicted alternating stress margins relative to SWT-derived runout thresholds of 28% (M1) and 20% (M2). The rigs' relevance to the CoU was strong for pressure waveform and curvature amplitude and frequency. Process controls ensured reproducibility. Overall, Mechanism B indices met thresholds for M1 and met or were within one point of thresholds for M2, with mitigation by mandatory durability testing.

This blend of strengths and a single shortfall shapes the decision posture: computational screening for fatigue is retained, while physical durability testing remains the definitive gate in the development process.

Mechanism B evidence sufficiency — gradation.

a.
Key factors below threshold; computational results unsuitable for screening without further evidence.

b.
Thresholds met for numerical and validation factors; input variability exceeds planned limits; mitigations required.

c.
Thresholds met for all factors; margins acceptable; computational screening supported.

d.
Thresholds exceeded with independent durability test replication and probabilistic predictions aligned to bench statistics.

14.3. 14.3 Mechanism C: scores for M1 and M2 across all factors

For acute radial strength, numerical studies showed very small sensitivity to mesh and solver settings across both models. Inputs were well-characterized for the stent geometry and for the tube analogs; artery parameter variability influenced M2's apparent RRF less than it affected fatigue hotspots. Agreement to segmented uniform radial compression curves was within 7% RMS for M1 and 9% for M2. The fixtures closely matched the model boundary conditions and environmental controls, and computational workflow reproducibility was established. All factor indices met or exceeded the mechanism-specific thresholds (4 for M1 and 5 for M2).

Mechanism C evidence sufficiency — gradation.

a.
Uncertain or inconsistent outcomes; thresholds missed for multiple factors.

b.
Most factors meet thresholds; small deviations understood; conservative use acceptable.

c.
All factors meet thresholds; evidence robust; model supports design verification use.

d.
All factors exceed thresholds; cross-fixture validation achieved; high confidence in transferability.

14.4. 14.4 Credibility matrix for M1

The table lists the 0–7 Credibility Index assignments and one-line bases for each factor across the three mechanisms for the stent-only model.

14.5. 14.5 Credibility matrix for M2

The table lists the 0–7 Credibility Index assignments and one-line bases for each factor across the three mechanisms for the stent–artery coupled model.

15. 15. Decision and residual risk within the CoU

Refining the spatial resolution beyond the production meshes altered key outputs by at most 2.6% (M1-A), 4.2% (M1-B), and 1.8% (M1-C) for the stent-only model and 3.9% (M2-A), 5.6% (M2-B), and 2.7% (M2-C) for the coupled model, establishing that further refinement would not change conclusions within the acceptance bands used for decisions.

Across sampled variation of alloy curves, strut gage, balloon sizing, and, for the coupled case, tissue mechanical parameters, the outputs shifted by 6.5% in peak plastic strain (M1-A), ±0.14 in minimum fatigue safety factor (M1-B) with corresponding alternating stress changes of 9%, and 6.0% in RRF (M1-C); the corresponding shifts for the coupled model were 8.3% (M2-A), ±0.21 (M2-B) with 12% alternating stress variation, and 7.5% (M2-C).

Tightening residual tolerances from 10^6 to 10^8 and halving increment sizes changed the deployment residual metrics

by 1.9% (M1-A) and 2.6% (M2-A), the alternating stress amplitudes by 3.4% (M1-B) and 4.8% (M2-B), and the RRF at 10% compression by 1.5% (M1-C) and 2.1% (M2-C), indicating that numerical procedure settings are not a dominant source of variation.

Against the physical tests, the predicted recoil differed by 0.3 percentage points with a 6% RMS error on the pressure–diameter curve for the stent-only model and by similar margins (3.9% recoil; 5% RMS) for the coupled case; in durability rigs, predicted alternating stress amplitudes at hotspots were 28% (M1) and 20% (M2) below the SWT-derived runout thresholds with zero fractures in 10–12 constructs to 400 million cycles; and in uniform radial compression, the RMS error was 7% (M1) and 9% (M2) with maximum absolute deviation 0.03 N/mm over 5–20% compression.

The tested constructs, fixtures, and load histories matched the modeled scenarios within the predefined tolerances on size (±0.01 mm gage), temperature (37 ± 0.5 °C), waveform amplitude (±2 mmHg), curvature amplitude (±0.02 m^1), and fixture spacing (±5%), supporting direct inferences to the CoU.

All analyses were executed through a scripted, version-controlled toolchain with automated checks and a run ledger; independent reruns on different platforms reproduced all six model–mechanism outputs within 0.1% for RRF, within 0.2 percentage points for recoil, and within 0.5 MPa for alternating stress amplitude.

Decision. With these results, both models are accepted for use within the CoU as follows. For Mechanism A, both models are used to assess immediate post-deployment margins and to evaluate balloon sizing rules; their factor scores meet or exceed the acceptance thresholds. For Mechanism B, the stent-only model is used for conservative screening with the minimum fatigue safety factor threshold of 1.1 to proceed to durability testing; the coupled model is used qualitatively to understand constraint-induced amplifications, noting that the sensitivity of results to arterial property uncertainties slightly underperforms the planned threshold on the Inputs index. For Mechanism C, both models inform RRF expectations, with the coupled model guiding interpretation when host constraint is a primary determinant of support. Residual risk from the single shortfall in the coupled fatigue case is mitigated by the mandatory full-battery durability testing on each design iteration, by using the lower of the stent-only and coupled safety factors for screening, and by conservatively bounding arterial stiffness in sensitivity analyses.

Decision integration of credibility — gradation.

a.
Decisions taken without explicit reference to factor scores or thresholds.

b.
Decisions reference scores qualitatively; mitigations not explicitly tied to shortfalls.

c.
Decisions tied to mechanism-specific thresholds; shortfalls mitigated by tests or conservative rules.

d.
Decisions driven by quantified error budgets and value-of-information analyses.

16. 16. Discussion

This work demonstrates a risk-aligned approach to model credibility for coronary stent FEA under the V&V 40 framework, implemented with a private 0–7 scale and mechanism-specific acceptance thresholds. The assessment spans two models and three mechanisms that bracket near-term deployment behavior and longer-term cyclic loading and support. Multiple dimensions of evidence are required to earn confidence: numerical robustness, fidelity and variation in the defining quantities, agreement with targeted experiments, alignment of those experiments to the CoU, and well-controlled software processes. By reporting scores and bases at the factor-by-mechanism level, we make transparent where evidence is strongest (e.g., radial strength) and where it remains provisional (e.g., the sensitivity of fatigue hotspots to arterial constitutive properties).

Limitations include representation of the host artery and plaque as continuum media with simplified fiber architecture and homogeneous layers. While the chosen HGO parameters and variability ranges capture a reasonable span of coronary behavior, patient-specific geometry and microstructure can differ in ways that would alter contact distributions and local stress amplification. The plaque analog lacks calcified inclusions or lipid pools with sharply contrasting stiffness; adding such features could produce local extremes in contact pressure and bending. Likewise, the balloon surrogate, while calibrated to the full P–D curve, does not explicitly capture folding or compliance anisotropy. In fatigue assessment, we used an S–N-based mean-stress-corrected criterion; a more detailed local strain–energy density or crack-growth approach could change screening results. The durability rigs, though carefully designed, inevitably abstract the in vivo environment.

The program did not extend to formal numerical code verification of the underlying solver kernels beyond vendor documentation and standard benchmarks. Future work could include method-of-manufactured-solutions tests or community benchmarks targeted to contact and large-deformation plasticity to further strengthen trust in the numerical implementation. That said, the solver stability and reproducibility results, combined with strong agreement to targeted experiments, indicate that the primary risks within the CoU are addressed.

The scoring method adopted here is not a substitute for judgment; rather, it structures that judgment so that assumptions, tolerances, and evidence can be weighed deliberately. The choice of acceptance thresholds balances the need for screening efficiency against the imperative to detect at-risk designs early. The single shortfall identified—greater-than-planned sensitivity of coupled fatigue results to arterial parameter selection—points to a tangible path forward: narrower arterial parameterization through patient-specific imaging- and pressure-derived compliance, additional validation targeting constraint-induced bending, and multi-model ensembles to explore method variance.

Generality to other sizes and patterns depends on geometric similarity and the scaling of bending and contact mechanics

with strut dimensions and ring/link topology. The procedures for mesh and solver studies, input characterization, and validation can be carried over directly, while numeric values will shift with size and architecture. In particular, thinner struts and more compliant linkages are expected to elevate alternating stresses under curvature but also to reduce RRF; thus, the trade-offs made here will differ for ultrathin-strut designs. The private index can be reused with updated thresholds tuned to the decision context of each program.

Limitations and future work articulation — gradation.

a.
Limitations not discussed.

b.
Limitations listed qualitatively; no impact analysis.

c.
Limitations analyzed for plausible impact; future work prioritized.

d.
Limitations quantified via sensitivity or ablation studies; future work linked to decision risk reduction.

17. 17. Conclusions

We assessed the credibility of two implicit finite element models of a cobalt–chromium balloon-expandable coronary stent under ASME V&V 40 across three mechanisms: deployment residual strains, pulsatile fatigue, and acute radial strength. Using a private 0–7 Credibility Index with mechanism-specific acceptance thresholds aligned to a medium model risk level and a clearly defined CoU, we carried out systematic mesh and solver studies, characterized and propagated uncertainty in the model-defining quantities, compared predictions to targeted bench tests with predefined metrics and acceptance bands, established the representativeness of those tests to the CoU, and executed analyses under a controlled software process. The stent-only model (M1) met or exceeded thresholds across all factors and mechanisms relevant to the CoU. The coupled stent–artery model (M2) met thresholds for five of six factors across mechanisms, with a single point below the target on the Inputs index for fatigue due to arterial property variability; mitigations include mandatory durability testing and conservative screening rules. Both models are, therefore, appropriate for their intended roles in nonclinical design verification.

The structure of the assessment ensures that the strengths and limits of the computational evidence are clear and that decisions are insulated from overconfidence in any single component. By presenting one table per model summarizing factor-by-mechanism scores and by embedding the bases of those scores in a rigorous program of numerical characterization, input pedigree, validation, relevance, and process control, the paper exemplifies how V&V 40 can be applied to cardiovascular implants to reduce residual risk while maintaining efficiency in development.

Conclusion strength relative to evidence — gradation.

a.
Conclusions overreach the presented evidence.

b.
Conclusions generally aligned but omit caveats and mitigations.

c.
Conclusions explicitly tied to evidence strength and residual risks.

d.
Conclusions integrate quantified uncertainties and specify decision boundaries under varying assumptions.

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Table 1: Credibility Index scores for M1 (stent-only implicit FEA) across mechanisms A–C on the 0–7 private scale.

Credibility factor	Level	Basis
Discretization error - M1 - Mechanism A	6	Finest-two mesh change in peak plastic strain 2.6% (95th percentile 1.9%).
Numerical solver error - M1 - Mechanism A	6	Tightening tolerances and halving increments changed peak plastic strain by 1.9%.
Model inputs - M1 - Mechanism A	5	Material/geometry sampling shifted peak plastic strain by 6.5%.
Output comparison - M1 - Mechanism A	6	Recoil bias 0.3 pp; P–D RMS error 6% over 8–16 atm.
Relevance of the validation activities to the COU - M1 - Mechanism A	6	Fixtures, balloons, sizing, temperature matched modeled conditions within pre-set tolerances.
Software quality assurance - M1 - Mechanism A	6	Independent reruns reproduced outputs within 0.2 pp recoil difference.
Discretization error - M1 - Mechanism B	5	Alternating stress amplitude change 4.2% between finest two meshes.
Numerical solver error - M1 - Mechanism B	5	Tightened tolerances and increments altered hotspot amplitude by 3.4%.
Model inputs - M1 - Mechanism B	5	Input sampling yielded min fatigue SF shift of ±0.14 (alt stress ±9%).
Output comparison - M1 - Mechanism B	5	No fractures in 10–12 specimens to 400M cycles; DIC strains within 8%; SWT margin 28%.
Relevance of the validation activities to the COU - M1 - Mechanism B	5	Pressure 80–120 mmHg and curvature 0.18 m^1 matched CoU within 10%.
Software quality assurance - M1 - Mechanism B	6	Automated pipeline; cross-platform reruns matched alternating stress within 0.5 MPa.
Discretization error - M1 - Mechanism C	7	RRF at 10% and 20% compression changed 1.8% and 2.3% on mesh refinement.
Numerical solver error - M1 - Mechanism C	6	RRF at 10% compression changed 1.5% under tighter tolerances and smaller steps.
Model inputs - M1 - Mechanism C	5	Geometric/material variability shifted RRF by 6.0% across sampled sets.
Output comparison - M1 - Mechanism C	6	RRF RMS error 7% over 5–20% compression; max deviation 0.03 N/mm.
Relevance of the validation activities to the COU - M1 - Mechanism C	6	Segmented fixture and environment matched modeled boundary conditions within tolerance.
Software quality assurance - M1 - Mechanism C	6	Scripted runs; ledgered provenance; reruns matched RRF within 0.1%.

Table 2: Credibility Index scores for M2 (stent–artery implicit FEA) across mechanisms A–C on the 0–7 private scale.

Credibility factor	Level	Basis
Discretization error - M2 - Mechanism A	5	Finest-two mesh change in peak plastic strain 3.9% (95th percentile 2.7%).
Numerical solver error - M2 - Mechanism A	5	Tightening tolerances and halving increments changed peak plastic strain by 2.6%.
Model inputs - M2 - Mechanism A	5	Artery/stent sampling shifted peak plastic strain by 8.3%.
Output comparison - M2 - Mechanism A	6	Recoil 3.9% vs measured; P–D RMS error 5%; overshoot shrink 0.20 mm vs 0.22±0.05 mm.
Relevance of the validation activities to the COU - M2 - Mechanism A	6	Deployment fixtures and host-constraint analogs matched modeled conditions within tolerance.
Software quality assurance - M2 - Mechanism A	6	Cross-platform reruns reproduced outputs within 0.2 pp recoil and 0.1 MPa contact pressure.
Discretization error - M2 - Mechanism B	5	Alternating stress amplitude change 5.6% between finest two meshes.
Numerical solver error - M2 - Mechanism B	5	Tightened tolerances and increments altered hotspot amplitude by 4.8%.
Model inputs - M2 - Mechanism B	4	Artery/plaque variability drove min fatigue SF shift of ±0.21 (alt stress ±12%).
Output comparison - M2 - Mechanism B	5	No fractures to 400M cycles; DIC strains within 8%; SWT margin 20% at hotspots.
Relevance of the validation activities to the COU - M2 - Mechanism B	6	Waveform and curvature amplitude/frequency matched CoU within stated tolerances.
Software quality assurance - M2 - Mechanism B	6	Automated pipeline; reruns matched alternating stress within 0.5 MPa.
Discretization error - M2 - Mechanism C	6	RRF at 10% and 20% compression changed 2.7% and 3.1% on refinement.
Numerical solver error - M2 - Mechanism C	6	RRF at 10% compression changed 2.1% under tighter tolerances and smaller steps.
Model inputs - M2 - Mechanism C	5	Artery parameter variability shifted apparent RRF by 7.5%.
Output comparison - M2 - Mechanism C	5	RRF RMS error 9% over 5–20% compression; deviations linked to plaque placement.
Relevance of the validation activities to the COU - M2 - Mechanism C	6	Stent–tube analogs emulated host constraint; environment matched modeled boundary conditions.
Software quality assurance - M2 - Mechanism C	6	Scripted, versioned runs; provenance ledger; reruns matched RRF within 0.1%.