Credibility assessment of implicit finite element models for coronary stent fatigue and radial strength under a risk-based V&V framework

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Abstract

Objective: To quantify and report the credibility of an implicit finite element analysis (FEA) program for a balloon-expandable cobalt–chromium coronary stent, focused on pulsatile fatigue and radial crush strength, under a medium-risk Context of Use (COU) within a V&V40-aligned, risk-based framework. Scope: Two computational models were assessed: Model U, a periodic strut–connector unit-cell used to compute stabilized cyclic strain/stress amplitudes and local fatigue safety factors; and Model S, a full stent model tracing crimp–expand–release with residual stress carryover, followed by quasi-static radial compression and physiologic pulsatile loading to compute radial strength, recoil, stress distributions, and fatigue hotspots. Mechanisms covered include (i) pulsatile fatigue of struts and connectors, (ii) radial crush strength, and (iii) crimp/expansion plasticity and residual stress. Methods: The credibility plan defined a private-scale Credibility Attainment Score (CAS) from 0–5 with predefined acceptance thresholds per factor for a Medium model risk. For each mechanism–model pair, activities addressed spatial resolution, numerical iteration/stepping, treatment of model parameters and loads, alignment to test measurements, the alignment of those measurements to the COU, and process assurance for the modeling workflow. Vendor numerical code verification documentation and internal spot checks were noted. Validation employed bench radial compression tests across three sizes, pulsatile fatigue segment tests with run-out at 10^8 cycles, and deployment strain imaging. Results: For pulsatile fatigue, Model U stabilized hotspot equivalent strain amplitude changed by 1.4% between the two finest unit-cell meshes and by 0.4% with time-step refinement, while Model S hotspot amplitude changed by 2.3% under mesh refinement and 0.9% under tighter convergence settings. Across three stent sizes, simulated minimum radial strength agreed with bench measurements with a mean absolute error of 3.8% and R^2 = 0.97, and the converged mesh changed the predicted force at 10% OD reduction by 1.7% from the next-finer mesh. Deployment imaging showed that the spatial distribution of post-expansion plastic strain matched simulations with a Dice overlap of 0.78 and a 6% average magnitude difference in regions above 2% plastic strain. Material property uncertainty from 12 Co–Cr L605 heat-lot specimens propagated to a 0.08–0.15 spread in predicted fatigue safety factor at the most severe location, while process parameters (balloon overshoot ±5%, friction 0.05–0.20) shifted mean stress by 8–15 MPa and radial recoil by 0.3%. Process assurance covered 73 regression cases executed automatically; no failures were recorded across 12 months and four releases. The single credibility summary table reports CAS for 42 rows (2 models × 3 mechanisms × 7 factors). Conclusions: Within the stated Medium-risk COU, evidence supports the sufficiency of the implicit FEA models to inform design down-selection and to set pre-test acceptance bands for fatigue and radial strength, in conjunction with mandatory bench testing. Dominant uncertainty contributors are the cyclic plasticity characterization and deployment process parameters. Recommendations are provided to sustain and extend the evidence base in future submissions.

Keywords: finite element analysis, coronary stent, V&V40

1. Introduction

Implicit finite element analysis (FEA) is now a routine component of the development of balloon-expandable coronary stents. When appropriately anchored to experimental measurements and conducted under controlled procedures, simulations can reduce design-cycle time, frame candidate geometries for physical test campaigns, and target factors most affecting durability and acute mechanical performance. While clinical decisions for individual patients lie firmly outside the remit of the present modeling activities, design choices informed by simulations can influence which geometric variants are tested, the acceptance bands that govern preliminary verification, and the likelihood that a device family meets standards-based mechanical performance requirements. As such, a structured credibility assessment is warranted to clarify how much confidence to place in computational outputs along the relevant pathways of use.

This paper reports the credibility of a two-model program for a modern cobalt–chromium, balloon-expandable coronary stent. The intent is narrowly defined: quantify the confidence for two decision variables—local fatigue safety factors under physiologic pulsatile loading and minimum radial strength under quasi-static radial compression—under a risk-based framework aligned to the principles of V&V40. The stent's fatigue and radial crush mechanisms are prioritized because they bear directly on lumen patency and structural durability, and because they anchor the test programs for design verification and standards compliance. By contrast, other phenomena such as drug elution or acute thrombogenicity are outside the scope.

We assess two complementary simulations. Model U is a periodic strut–connector unit-cell that delivers stabilized cyclic equivalent strain/stress amplitudes, mean stress at critical locations, and local fatigue safety factors given representative in vivo load cycles. Model S is a system-level, full stent model that resolves crimp, balloon expansion and release with carryover of residual stress, followed by quasi-static radial compression and application of a cardiac-like pulsatile pressure waveform to compute radial strength, recoil, global stress distributions, and candidate fatigue hotspots. Together, they span local and global scales and provide both quantitative predictions and qualitative maps that guide bench testing.

We abide by the central premise of V&V40: credibility is commensurate with model risk. Here, the model risk is categorized as Medium, because the simulations directly influence design down-selection and pre-test acceptance bands yet are complemented by standards-based bench testing that remains the release gate. We describe the Context of Use (COU), justify the model risk, map each model to three mechanisms of interest, and provide factor-by-factor activities and results. A single credibility summary table reports a private-scale Credibility Attainment Score (CAS) on a 0–5 scale for each factor across each model–mechanism pair, with predefined thresholds for acceptability.

In keeping with the discipline required of high-consequence modeling, we restricted the set of credibility factors to those specified in the plan and implemented practices to preserve traceability: inputs are tied to empirical sources or internal specifications, workflow changes are tracked, and model-to-test comparisons are reported with uncertainty estimates and sample sizes. The resulting body of evidence is synthesized to inform regulatory submissions and future design work within the declared scope.

CAS scale for Medium-risk COU — gradation.

a.
CAS 0: No organized evidence; undocumented analysis; no link to COU decisions.

b.
CAS 2: Limited, quantitative evidence on some aspects; ad hoc comparisons; incomplete traceability.

c.
CAS 3: Adequate quantitative evidence for key decisions; documented procedures; bounded uncertainties.

d.
CAS 5: Comprehensive, multi-source quantitative evidence with formal uncertainty quantification; mature procedures with automated checks and full traceability.

2. Device and computational models

The device is a balloon-expandable coronary stent manufactured from cold-worked Co–Cr L605 alloy, laser-cut from tubing and electropolished. The strut thickness is 90 μm and width is 80–95 μm depending on cell orientation. The nominal expanded diameters assessed are 2.5, 3.0, and 3.5 mm, with a 16 mm working length. Connector geometry alternates between S-shaped and dogbone-type links to manage longitudinal flexibility while preserving hoop support. Manufacturing pretreatments and postprocessing steps (stress relief and electropolishing) are part of the physical device but are represented implicitly in the computational program via material characterization and deployment simulation procedures.

Model U: The unit-cell model comprises a periodic strut segment and an adjacent connector, with periodic boundary conditions applied at the four bounding faces to emulate an infinite lattice. The geometry is extracted from the native CAD of the 3.0 mm size and parameterized by strut width and connector radius. The model resolves the through-thickness gradient using two hexahedral elements across the 90 μm thickness, with local refinement at inner radii of curvature. The elasto-plastic constitutive model is a von Mises J2 plasticity with nonlinear isotropic and kinematic hardening calibrated to cyclic stabilization from L605 specimens, including ratcheting response under mean stress. Strain-life (ϵ–N) parameters are employed for fatigue predictions, with Morrow mean stress correction. The loading protocol applies a multi-axial cyclic deformation field representative of a superimposed pressure pulsation and vessel bending, constructed from kinematic boundary conditions yielding target nominal hoop strain excursions of 250–350 $\mu\epsilon$ about a post-expansion mean strain state.

Model S: The full stent model represents the complete device lattice at the system scale and resolves the deployment sequence. The stent is meshed with 8-node hexahedral elements (reduced integration with hourglass control) with two elements through thickness and local refinement at strut crowns and connectors. Element counts are approximately 1.2M (coarse), 1.8M (fine), and 3.4M (superfine) for the 3.0 mm size. Crimping is modeled by imposing radial displacement via a rigid cylindrical surface with low friction (μ = 0.05) until a specified crimp diameter is reached. Balloon expansion is represented by prescribed radial displacement of an analytical surface following a pressure-diameter curve with a controlled overshoot to simulate clinical deployment dynamics; the balloon is not explicitly meshed. After expansion to the nominal diameter, the balloon is retracted and the vessel is represented by a rigid cylinder with μ = 0.10–0.15 at the stent–wall interface for the final release and seating. Residual stress is carried forward to subsequent loading.

For quasi-static radial strength, Model S is then subjected to external compression within an annular gauge per ISO 25539-2 analog conditions. The minimum radial strength is computed as the force per unit length at 10% outer diameter reduction on the descending portion of the force–diameter curve, after accounting for device-specific compliance correction. For pulsatile fatigue at system level, a physiologic pulsatile pressure waveform (mean 100 mmHg, amplitude 40 mmHg) is applied for 10 cardiac cycles

Figure 1: Overview of the two-model program and the V&V40-aligned evidence flow: mapping from device features through mechanisms to model outputs, verification activities, validation comparators, and COU decisions.

with heart rate 60–90 bpm; stabilized response is used to identify hotspots. A modest bending curvature (radius 20 mm) is applied about the stent axis to represent vessel tortuosity in sensitivity analyses.

Material characterization leverages uniaxial tension, cyclic stabilized hysteresis, and fully reversed strain-controlled tests on L605 coupons from the same heat lot as production tubing (n = 12). Elastic modulus is 240 ± 8 GPa, Poisson's ratio 0.30, 0.2% offset yield 780 ± 35 MPa, ultimate tensile strength 1570 ± 60 MPa. Cyclic hardening follows a combined nonlinear model fitted to capture the Bauschinger effect and mean stress relaxation over 100 cycles: K = 1510 MPa, n = 0.12; kinematic hardening saturation C = 7500 MPa, γ = 75, with specimen-to-specimen scatter. Strain-life parameters (fit to N = 10^4–10^7 cycles) are: σf = 1820 MPa, b = 0.09; ϵf = 0.25, c = 0.60; validated at R = 0 and R = 1 conditions. Translation to multiaxial states employs critical plane criteria via equivalent strain amplitude with Morrow mean stress correction, consistent with common coronary stent practice.

All analyses use an industry-standard implicit structural solver on double-precision, with default Newton–Raphson iteration and line search. Contact is enforced by a penalty formulation. For deployment steps, incremental stabilization is applied only during severe contact transitions and is reduced to zero prior to extraction of residual state. Quasi-static load stepping employs an adaptive arc-length-like controller to maintain a target convergence rate while respecting element-level strain limits. For pulsatile cycles, a time increment of 0.5 ms is used for bulk runs, with sensitivity at 0.1 ms for select cases.

3. Context of Use (COU)

The intended use of the simulations is quantitative and prescriptive within the device development lifecycle but not clinical. Specifically, the models are used to (i) predict local fatigue safety factors at strut and connector hotspots under representative pulsatile loading and (ii) predict minimum radial strength under quasi-static compression across a family of stent sizes. In both roles, the models inform design down-selection and establish pre-test acceptance bands for subsequent bench testing. Formal device release and regulatory verification are governed by standards-compliant physical testing; simulation outputs do not substitute for those tests.

The rationale for this COU is twofold. First, the models directly affect which geometric variants survive to bench testing and thus shape the design space, creating a moderate degree of influence on decisions that ultimately bear on patient safety through structural integrity. Second, these decisions are buffered by mandatory bench tests (e.g., radial compression, fatigue segment evaluation) that operate as independent gates, limiting the consequence of model error. The models are not tuned to individual patients or used to make per-patient clinical recommendations. Rather, they are embedded in an engineering process that synthesizes simulation, bench data, and manufacturing knowledge to meet device-level requirements.

4. Model risk level and rationale

We categorize the model risk as Medium. The decision consequence is moderate: if the simulations materially under-predict fatigue damage at a connector crown, a design with a latent defect might progress further into bench testing; however, standards-based verification remains a barrier to market, providing an opportunity to detect unacceptable designs prior to patient exposure. The model influence is moderate-to-high: the models bound the design space and may allow early retirement of some bench iterations, and they define preliminary acceptance bands for minimum radial strength across sizes that shape the subsequent test plans.

In terms of device function, the two modeled mechanisms—fatigue durability and radial crush strength—are directly tied to lumen support and structural integrity. Failures in these attributes can precipitate loss of scaffolding, restenosis, or acute complications. We therefore require that supporting evidence for simulations used to influence these attributes meets a defined threshold for Medium risk. Because multiple evidence streams (simulation, standardized bench tests, manufacturing inspections) inform the final decisions, very high rigor reserved for high-risk, simulation-only decisions is not strictly necessary, but a coherent body of quantitative support is. We operationalize this requirement through the CAS thresholds and the factor-specific activities outlined below.

5. Mechanisms and mapping of models to mechanisms

Three mechanisms are within scope. Pulsatile fatigue of struts and connectors is represented by cyclic stress and strain amplitudes at sites of geometric curvature or connector articulation. Outputs include stabilized equivalent strain amplitude, mean stress across the cycle, and derived local fatigue safety factor at critical locations. Radial crush strength is represented by the minimum radial force (per unit length) at a specified percentage reduction in outer diameter under quasi-static compression in an annular gauge, along with device recoil upon unloading. Crimp/expansion plasticity and residual stress is represented by the distribution of plastic strain induced during crimp, balloon pressurization to nominal diameter with overshoot, and balloon withdrawal and seating against a vessel analog; outputs include maps of equivalent plastic strain and residual hoop stress, as well as global recoil.

Model U is mapped primarily to the fatigue mechanism. It computes stabilized cyclic response under a reduced, periodic representation and outputs local fatigue safety factors, enabling rapid exploration of connector radius, strut width, and link topology. Model S is mapped to all three mechanisms. It delivers the deployment-induced stress and strain history, which sets the initial damage state for fatigue; it supports full-system pulsatile loading to localize hotspots and quantify amplitudes in context; and it provides a direct prediction of radial crush strength and recoil consistent with the standardized bench configuration. Where Model U is not applicable by construction (e.g., radial crush strength, system-level deployment), we still document the evidence status and score it accordingly.

6. Credibility plan and acceptance criteria

The credibility plan addresses seven factors across each model–mechanism pair: spatial resolution, parameterization of materials and loads, iteration/stepping numerical performance, comparison to bench measurements for outputs of interest, alignment of those measurements to the decisions in the COU, numerical code verification, and process assurance for the modeling workflow. We report a Credibility Attainment Score (CAS) on a private, 0–5 numeric scale for each factor and pair, with predefined thresholds tailored to a Medium-risk COU:

CAS thresholds: For spatial resolution, the acceptance criterion is a change of less than 5% in the mechanism-relevant output when moving from the fine to the superfine mesh (and less than 3% preferred), with at least three levels tested at the most severe case; the threshold for acceptance is CAS ≥ 3. For iteration/stepping performance, acceptance requires that tightening tolerances or refining steps by factors of 5–10 changes the mechanism-relevant output by less than 1% (less than 0.5% preferred), with CAS ≥ 3. For parameterization of materials and loads, acceptance requires quantified sources and sample sizes with propagated impact on outputs; CAS ≥ 3. For model-to-test alignment on outputs, acceptance requires pre-specified agreement bands based on measurement uncertainty: less than 10% MAE for radial strength across sizes and greater than 90% correct prediction of runout vs. failure for fatigue segments (or equivalently, safety factors consistently above unity for runouts and below for failures), with CAS ≥ 3. The alignment of selected tests to the COU requires that the tested sizes, loading amplitudes, and boundary conditions bracket at least 90% of the expected operating envelope across the design family; CAS ≥ 3. For numerical code verification, we rely on vendor documentation and internal spot checks; given the indirect nature of the evidence and the Medium-risk COU buffered by bench testing, the minimum acceptable CAS is 1 provided other factors meet their thresholds. For process assurance, acceptance requires configuration control, requirements traceability, and an automated regression suite with regular execution; CAS ≥ 3.

Evidentiary artifacts include: mesh convergence decks and logs, tolerance and stepping sensitivity logs, material coupon datasets with fits and confidence intervals, deployment process parameter specifications and logs, fatigue segment test reports including strain measurements and runout/failure outcomes, radial compression test reports across sizes with force–diameter curves, deployment strain imaging reports with spatial comparison metrics, configuration management records, and solver vendor code verification summaries. We maintain a traceability matrix linking each artifact to the factor, mechanism, model, and COU decision it supports.

To avoid overfitting and leakage of test measurements into model calibration, we segregated datasets by role: material coupon data inform constitutive parameters; fatigue segment outcomes and radial compression curves are reserved solely for model-to-test alignment; deployment imaging is used to assess the reasonableness of post-expansion strain maps; no tuning to fatigue or radial strength outputs is performed after initial parameterization.

Agreement rigor for output–test alignment — gradation.

a.
Qualitative correspondence only; no pre-specified metrics or bands; opportunistic matching.

b.
Quantitative metrics with post hoc bands; partial uncertainty accounting; small sample.

c.
Pre-specified metrics and bands; uncertainty-aware statistics; multiple sizes or conditions.

d.
Cross-validated, pre-specified metrics; comprehensive uncertainty propagation; broad coverage of sizes and conditions.

7. Verification activities — spatial resolution

We performed spatial resolution studies tailored to each mechanism–model pair. For Model U applied to pulsatile fatigue, three hexahedral meshes were constructed for the periodic strut–connector cell: coarse (approximately 110,000 elements), fine (approximately 180,000 elements), and superfine (approximately 310,000 elements), each with two elements through thickness and graded refinement at inner radii. The loading protocol and material parameters were held constant. The stabilized equivalent strain amplitude at the most severe crown and the derived local safety factor were monitored. Between the fine and superfine meshes, the hotspot equivalent strain amplitude decreased from 0.00286 to 0.00282 (Δ = 1.4%), and the local safety factor shifted from 1.32 to 1.30 (Δ = 0.02). The second-most severe location changed by 0.7% in amplitude.

For Model S under pulsatile loading, three meshes for the 3.0 mm size were used: 1.2M (coarse), 1.8M (fine), and 3.4M (superfine) elements. Under a 40 mmHg pressure oscillation about 100 mmHg mean and mild curvature (radius 20 mm), stabilized hotspot equivalent strain amplitudes at the crown near the proximal connector were 0.00274 (coarse), 0.00266 (fine), and 0.00260 (superfine). The change from fine to superfine was 2.3%. Mean stress at the hotspot differed by 10 MPa (from 520 to 510 MPa). The set of top five hotspots was invariant between fine and superfine meshes.

For radial crush strength with Model S, mesh studies focused on the radial force at 10% outer diameter reduction. The fine-to-superfine change in the 3.0 mm device was from 0.402 to 0.395 N/mm (Δ = 1.7%). Force–diameter curves across sizes exhibited similar convergence: at 3.5 mm, the change was 2.1%; at 2.5 mm, 1.5%. The location of first local buckling during compression was consistent across fine and superfine meshes, and the post-buckling branch was smooth and monotonic.

For crimp/expansion plasticity and residual stress with Model S, convergence was examined on the maximum equivalent plastic strain at crown intrados and on residual hoop stress distribution after balloon withdrawal and seating. Maximum plastic strain at the most severe crown decreased from 0.062 to 0.060 moving from fine to superfine (Δ = 3.1%). The L2-norm of the difference in residual hoop stress fields (normalized by the field norm) between fine and superfine was 2.5% over the stent lattice. Recoil after balloon withdrawal differed by 0.2% absolute diameter between the two finest meshes.

Model U is not used for radial crush strength or for crimp/expansion in the COU; no spatial resolution studies were run for those mechanisms in that model (0 cases). We document this absence of evidence explicitly and score accordingly in the summary table.

Spatial resolution rigor — gradation.

a.
Single mesh; no sensitivity; unknown impact on outputs.

b.
Two meshes at one condition; qualitative assessment; limited metric tracking.

c.
Three or more meshes at severe conditions; change in outputs under 5% between finest; local hotspot checks.

d.
Multiple meshes across sizes; output change under 3% at finest; hotspot set invariance; documented local error indicators.

8. Verification activities — numerical iteration and stepping

We assessed sensitivity to solver controls and step sizes. For Model U under pulsatile cyclic loading, the time increment was reduced from 0.5 ms to 0.1 ms for ten cycles, and the Newton residual convergence tolerance was tightened from 10^5 to 10^7 on the norm of the out-of-balance forces. The resulting change in stabilized hotspot equivalent strain amplitude was 0.4%, and the change in local safety factor was under 0.01. Contact stabilization is not present in Model U due to the periodic nature of the boundary conditions and lack of contact pairs; thus, no stabilization parameters were varied.

For Model S pulsatile cases, the time increment was reduced from 0.5 ms to 0.1 ms for ten cycles, accompanied by tightening the force residual tolerance from 10^5 to 10^7 and the maximum number of iterations per increment increased from 25 to 50. The stabilized hotspot equivalent strain amplitude decreased from 0.00266 to 0.00264 (Δ = 0.9%). The mean stress shifted by 4 MPa. Varying the penalty contact stiffness by ±50% during pulsatile cycles altered the hotspot amplitude by 0.3%. Damping and stabilization terms used during deployment were verified to be fully removed before pulsatile cycles began; repeating the cycles without any residual stabilization terms yielded differences under 0.1% in amplitude.

For Model S radial compression, a quasi-static arc-length controller was compared with a displacement-controlled step at matched convergence tolerances. The difference in minimum radial strength at 10% OD reduction was 0.6% (0.398 vs. 0.395 N/mm) on the superfine mesh, and the force–diameter curve overlay was visually indistinguishable over the loading path within plotting resolution. Reducing the residual tolerance from 10^5 to 10^7 changed the minimum radial force by 0.3%. Varying contact penalty by ±50% changed the radial force at 10% OD by 0.5%.

For deployment (crimp/expand/release) in Model S, line search was toggled and the time stepping during balloon pressurization was halved to ensure monotonic convergence in regions with extensive contact changes. The maximum equivalent plastic strain change under these controls was 0.003 absolute (from 0.060 to 0.057 at the worst crown), and residual hoop stress at the same location changed by 7 MPa. These changes are within the acceptance bands for numerical stepping sensitivity but not negligible; we retained the tighter controls for production runs.

Model U is not used for radial compression or deployment; therefore, no iteration or stepping studies were conducted for those pairs (0 cases).

Solver control and stepping rigor — gradation.

a.
Default solver settings; no sensitivity analysis; potential hidden nonconvergence.

b.
Single sensitivity on tolerance or step; partial metric tracking; no contact sensitivity.

c.
Multiple sensitivities on tolerances and steps; contact parameters varied; output change under 1%; production settings justified.

d.
Systematic sensitivities across mechanisms and sizes; output change under 0.5%; documentation of residual histories and energy balance.

9. Verification activities — numerical code verification

We consulted the solver vendor's numerical verification documentation (release 2025.1), which summarizes 290 verification tests spanning linear and nonlinear statics, contact, and plasticity. In addition, we executed five internal spot checks relevant to our use cases: two patch tests on single elements under uniaxial and pure shear with J2 plasticity (residual forces below 1e9 N), a contact block-sliding test with penalty enforcement (measured slip within 0.2% of analytical), and two small benchmark frames with combined isotropic–kinematic hardening under strain control (stabilized loop area within 3% of reference). No dedicated method-of-manufactured-solutions (MMS) exercises were conducted for our exact model configurations, and we did not run code-level verifications of the cyclic hardening algorithm beyond the mentioned spot checks. The solver version used in production analyses matches the vendor-verified build.

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

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

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

Numerical code verification evidence — gradation.

a.
No evidence; solver treated as a black box; no reference to verification.

b.
Vendor verification summary referenced; minimal internal spot checks; no problem-specific MMS.

c.
Vendor verification plus problem-relevant MMS or analytical benchmarks; traceability to solver build.

d.
Comprehensive MMS or analytical verification for model features used; independent reproduction; continuous monitoring of solver changes.

10. Model inputs: materials, deployment, boundary conditions, and load spectra

The constitutive response is parameterized from 12 L605 specimens out of the same heat lot used for production tubing. We report means and standard deviations for elastic and plastic parameters and fit strain-life parameters with 95% confidence intervals using nonlinear least squares on log-transformed fatigue life. To propagate input variability, we drew 200 Latin hypercube samples within the joint confidence region of σf, b, ϵf, c, and kinematic saturation parameters (C, γ) and evaluated their impact on the computed safety factor at the most severe crown. The standard deviation of the predicted safety factor was 0.12 in Model U and 0.15 in Model S when holding geometry fixed. Sensitivity indices based on linear regression of outputs on inputs indicated that σf and c dominate the uncertainty budget (combined 68% of variance).

Deployment parameters were selected from internal balloon test fixtures: the overshoot during pressurization was modeled as 5% of the nominal pressure with an uncertainty band of ±5%, and the withdrawal rate was set to match the median time recorded in bench deployments. The friction coefficient between stent and balloon or vessel analogs was set between 0.05 and 0.20 based on surface roughness comparators and literature values for Co–Cr on polymer or endothelium-mimicking surfaces. Sensitivity runs showed that balloon overshoot changed the maximum equivalent plastic strain by up to 0.04 absolute, while friction variations changed it by up to 0.005 absolute. Residual hoop stress in the most stressed crown varied by 12 MPa across the friction range.

Boundary conditions and load spectra for pulsatile loading are tied to physiologic bounds: a mean arterial pressure of 100 mmHg with an amplitude of 40 mmHg (range 35–50 mmHg in sensitivity checks), and heart rates between 60 and 90 bpm. Mild vessel curvature was simulated with a radius of 20 mm (range 15–25 mm) to explore bending-induced modulation. The combined effect on hotspot equivalent strain amplitude was up to 0.0003 across the ranges, and the effect on local safety factors was up to 0.07 in Model S and 0.05 in Model U. These values are included in the uncertainty budget reported with decision variables.

Input uncertainty quantification — gradation.

a.
Nominal inputs only; no variability or source documentation; no propagation.

b.
Documented sources with ranges; one-factor-at-a-time sensitivity; qualitative impacts.

c.
Statistical characterization with confidence intervals; multi-parameter sampling; quantitative impact on outputs.

d.
Comprehensive joint uncertainty modeling; global sensitivity analysis; uncertainty carried through to COU decisions.

11. Validation — alignment to bench measurements for outputs

Radial compression tests were executed on three sizes (2.5, 3.0, 3.5 mm), five devices per size, using an annular gauge with calibration per internal procedure aligned to ISO 25539-2. For each device, force–diameter curves were recorded on loading and unloading. Minimum radial strength was computed as the force per unit length at 10% outer diameter reduction on the loading path. Simulations reproduced the gauge configuration and compliance. Across sizes, the mean absolute error between simulated and measured minimum radial strength was 3.8%, with R^2 = 0.97 when pooling devices. By size, MAE was 4.1% (2.5 mm), 3.2% (3.0 mm), and 4.0% (3.5 mm). The 95% limits of agreement encompassed the simulation–test differences, and the simulation-to-test bias was 0.01 N/mm overall.

Pulsatile fatigue segment tests were designed to bound the local cyclic environment at critical strut/connector locations. We excised rings and connector segments from expanded stents and mounted them in a fixture imposing cyclic bending and axial stretch tuned to match strain amplitudes measured in system-level simulations at the top two hotspots. Twelve segments were tested to run-out at 10^8 cycles or to failure, with in situ digital image correlation (DIC) providing targeted strain amplitudes (±50 $\mu\epsilon$ uncertainty). Model U and Model S predicted stabilized equivalent strain amplitudes at corresponding sites under the same nominal cyclic conditions. The root-mean-square difference between predicted and DIC-measured strain amplitudes across segments was 8%. Using the strain-life model with Morrow correction, the models correctly classified 11 of 12 outcomes as run-out (safety factor > 1 at 10^8 cycles) or failure (safety factor < 1), with one false positive (predicted fail, observed run-out) at the margin (predicted SF 0.98, observed run-out at 10^8).

Deployment strain imaging comparisons used stents expanded in a transparent gel vessel analog with refractive index matching. A stereo DIC system recorded full-field surface strains during and after balloon expansion to nominal diameter with overshoot. We compared the post-expansion equivalent plastic strain fields to Model S predictions for the same deployment parameters. We computed a Dice similarity coefficient on binary masks of regions exceeding 2% plastic strain and obtained 0.78. The mean absolute difference in equivalent plastic strain magnitude within the overlap was 6%. Spatial alignment errors due to optical distortion were quantified at 0.1 mm and accounted for in the analysis. The trend and rank ordering of most severe crowns matched between simulation and imaging.

These validation exercises are limited to bench surrogates of in vivo loading but are chosen to target the same outputs that underpin COU decisions: local strain amplitudes for fatigue and minimum radial strength for crush resistance. Statistical analyses used pre-specified metrics and acceptance bands, with uncertainties in measurements propagated to assess compatibility with simulation predictions.

Output alignment rigor — gradation.

a.
Qualitative alignment; visual overlay only; no error quantification.

b.
Quantitative but post hoc-defined metrics; small N; partial uncertainty treatment.

c.
Pre-specified metrics and bands; moderate N; uncertainty-informed interpretation; multi-size coverage.

d.
Cross-condition and cross-size validation; pre-registered metrics; uncertainty propagation through decision variables.

12. Validation — alignment of selected tests to the COU

We evaluated whether the chosen validation tests span the operating envelope relevant to the COU. For fatigue, the cyclic amplitudes and heart rates employed in segment tests (strain amplitudes 200–350 $\mu\epsilon$; heart rates 60–90 bpm) overlap the ranges used in simulations and represent the 5th–95th percentile of physiologic cycles expected in proximal coronary segments. Connector geometries tested in segments correspond to the two most severe link topologies identified by Model S. For radial strength, the annular gauge replicates the standardized condition in ISO 25539-2 and uses stents at the same three nominal sizes in the design family. The compliance of the gauge and the correction applied in data reduction are consistent between simulation and test, and the 10% outer diameter reduction criterion matches the COU decision variable definition.

Deployment strain imaging employs a gel vessel analog with stiffness near the low end of coronary tissue, biasing comparisons to a conservative overestimation of plastic strain in regions of high curvature. The balloon pressurization sequence and overshoot in imaging runs are derived from internal deployment logs. While the imaging medium is not a perfect surrogate for an artery, the primary purpose is to appraise the reasonableness of the spatial pattern and magnitude of residual plastic strain that seeds fatigue. Collectively, these tests exercise the same decision variables and loading conditions used in the COU and encompass the central body of expected operation with margin at the extremities.

COU coverage by validation — gradation.

a.
Tests cover a narrow subset of operating conditions; weak link to decisions.

b.
Tests map to some decision variables; partial coverage of sizes or loads; limited rationale.

c.
Tests directly cover decision variables and sizes; bracket typical operating ranges; rationale documented.

d.
Tests comprehensively span sizes, loads, and boundary conditions; include stressor combinations; explicit mapping to all decision variables.

13. Software quality assurance for the modeling workflow

We placed the modeling workflow under configuration control. Input decks, material parameter files, and solver control scripts are versioned in a Git repository with branch protection and code review for all changes affecting production runs. Requirements for each model–mechanism pair are documented as testable items, and a traceability matrix links them to specific analyses and validation artifacts. An automated regression suite with 73 cases runs nightly on a dedicated cluster node via a continuous integration (CI) service; the suite includes reduced-size variants of the production models to exercise meshing, boundary conditions, contact, deployment sequences,

pulsatile cycles, and radial compression. Over 12 months and four minor releases of the modeling workflow, there were zero regressions that affected mechanism-relevant outputs; two incidental regressions affected postprocessing only and were corrected within 48 hours. All production runs are tagged to the solver build (2025.1) and to a specific commit of the workflow repository. Data retention and reproducibility are supported by immutable artifacts stored in a controlled bucket with metadata including solver version, run date, and parameter hashes.
Process assurance maturity — gradation.

a.
Ad hoc scripts; no version control; manual execution; no regression checks.

b.
Version control for some assets; informal peer review; occasional manual checks.

c.
Comprehensive version control; documented requirements; automated regression suite; CI in place.

d.
Full lifecycle QA with formal verification of tools; change impact analysis; audited releases; continuous monitoring with metrics.

14. Results

We summarize the outcome of the credibility activities using the Credibility Attainment Score (CAS) on a 0–5 scale for each factor, model, and mechanism. Scores reflect the quantitative observations reported in the preceding sections and the predefined thresholds for a Medium-risk COU. Acceptance status was judged per factor, per pair, against those thresholds and is indicated in the narrative below.

Evidence synthesized across the program supports the following key points relevant to the COU. First, when comparing the finest two meshes used in production for each case, element refinement altered the mechanism-relevant outputs by less than 3% for all Model S results and by less than 2% for Model U results at fatigue hotspots, indicating that the chosen discretizations are sufficiently refined for the intended use. Second, tightening the iteration tolerances by two orders of magnitude or refining time steps by a factor of five led to changes below 1% in the primary outputs for pulsatile and radial simulations, within pre-specified acceptance bands for numerical iteration and stepping. Third, in quantitative comparisons to bench measurements, the simulated minimum radial strength agreed with annular gauge tests within 3.8% mean absolute error across three sizes (R^2 = 0.97), and fatigue segment predictions matched DIC-measured strain amplitudes with 8% RMS error while correctly classifying 11 of 12 outcomes at 10^8 cycles. Fourth, variability in L605 cyclic parameters observed across 12 heat-lot specimens propagated to a 0.08–0.15 spread in predicted fatigue safety factor at the most severe location, and realistic deployment parameter ranges shifted mean stress by 8–15 MPa and radial recoil by 0.3%; these effects are explicitly carried as uncertainty margins on the decision variables. Fifth, the selected validation activities span the stent sizes and loading ranges used in design decisions and bracket at least 90% of the expected operating envelope; this alignment justifies using the validation results to judge model performance under the COU. Sixth, the modeling workflow operated under configuration control with an automated 73-case regression suite that recorded zero mechanism-impacting failures across 12 months and four releases, demonstrating procedural robustness.

The credibility summary table below enumerates 42 rows—every factor for each model–mechanism pair—along with the CAS and a basis that restates the numeric observations also reported in the prose. Rows where a model is not used for a mechanism are still listed and scored based on the actual state of evidence, which is minimal by design.

15. Discussion

A risk-based assessment emphasizes sufficiency for the intended use rather than perfection. For pulsatile fatigue, Model U and Model S together provide complementary insights. The unit-cell efficiently computes localized cyclic response with high spatial resolution and rigorous solver settings, while the system model anchors those local predictions to deployment-induced mean stress and to the context of global deformations and contact. The spatial resolution studies indicate that, for both models, refined meshes adequately resolve curvature-induced gradients at crowns and connectors; moving from fine to superfine altered amplitudes by 1.4% (Model U) and 2.3% (Model S), well within the 5% acceptance threshold and near the preferred 3% target for Model U. The solver control studies reinforce this picture: tightening convergence tolerances or refining time steps by factors of five to ten had sub-percent impacts on amplitudes, providing confidence that the reported cyclic metrics are numerically stable.

For radial crush strength, the system model provides a direct mapping to the annular gauge configuration and a pressure–diameter reduction criterion consistent with the COU. Mesh refinement sequences converged the minimum radial force at 10% OD reduction within 1.7–2.1% across sizes, and solver variations altered the force by less than 1%. The alignment to bench measurements is stronger here than for fatigue because the bench condition is a closer analog of the simulation boundary conditions: the MAE of 3.8% across sizes and an R^2 of 0.97 indicate both accuracy and consistency in trend. The small negative bias of 0.01 N/mm is negligible compared to the acceptance bands established a priori.

Deployment simulations in the system model are a linchpin because they set the initial residual stress and plastic strain from which fatigue accumulates. Spatial resolution and solver control sensitivities for deployment showed changes that, while within acceptance, are somewhat larger than those observed in pulsatile or radial simulations (e.g., 0.003 absolute change in equivalent plastic strain under tighter stepping). This is expected due to the complex contact transitions and rapid evolution of the plastic zone during balloon pressurization and withdrawal. The deployment strain imaging provided a consistency check on spatial patterns and magnitudes of plastic strain, with Dice overlap of 0.78 in regions exceeding 2% plastic strain and 6% magnitude difference in the overlap. These are reasonable levels of agreement given the stiffness and optical proxies in the imaging setup; they lend credence to the deployment-induced state used in fatigue calculations.

Model parameterization and loading are a dominant source of uncertainty for fatigue. The propagated uncertainty from L605 cyclic properties across the 12-specimen dataset contributes a 0.08–0.15 spread in local safety factor at the most severe location. This spread is not negligible relative to unity and must be considered when setting preliminary acceptance bands. Our sensitivity indices point to σf and c as the principal contributors, suggesting that future efforts to reduce uncertainty should emphasize improved constraints on the low-cycle to high-cycle transition and on the slope of the elastic strain-life branch. Deployment parameters, particularly balloon overshoot, are the second-order contributors to fatigue margins via their effect on mean stress; we quantified shifts of 8–15 MPa in mean stress across realistic overshoot and friction ranges. Because mean stress moderates fatigue strength through Morrow correction, this translates into shifts of safety factor on the order of 0.05–0.07, which is meaningful in marginal cases.

The validation evidence maps directly to the COU decisions. The annular gauge tests are essentially the same condition used to make radial strength decisions; agreement within 4% is comfortably inside the pre-specified 10% acceptance band and supports using simulation to set pre-test acceptance bands and to down-select designs before committing to a full suite of bench tests. For fatigue, the situation is more nuanced. The segment tests are not the entire stent and the imposed cyclic fields are a surrogate for in vivo multisource loading. However, the segments are derived from the most severe link topologies, and the imposed amplitudes and heart rates bracket the 5th–95th percentile operating conditions that matter for COU decisions. The 8% RMS error in strain amplitude and the 11/12 correct classification at 10^8 cycles provide a defensible basis for using simulations to cull designs with poor fatigue margins and to set cautious pre-test bands, provided that final release still hinges on standardized endurance testing.

Where the evidence is weak by design or outside the COU, we explicitly report it as such and score accordingly. The unit-cell model is not used for radial strength or deployment; it is inappropriate to claim credibility there. Likewise, numerical code verification is based on vendor documentation and limited internal spot checks; we do not claim problem-specific method-of-manufactured-solutions exercises. Because the COU is buffered by mandatory bench tests, the plan establishes a minimal acceptable CAS of 1 for this factor, and we meet that without overinterpreting its import.

The process by which simulations are developed and executed is a material contributor to credibility for any COU spanning multiple projects and submissions. The modeling workflow's configuration control, automated regression suite, and documented releases reduce the risk of silent changes and facilitate reproducibility. We highlight that over a 12-month period, 73 nightly regression cases ran without mechanism-impacting failures, an operational signal of process robustness that complements the technical evidence.

Finally, the program's structure—pairing a fast, high-resolution unit-cell model with a full stent model that resolves deployment and system-level loading—proved effective. The unit-cell model can be run for many geometric variants to map relative fatigue margins, while the system model supplies the global context and provides direct comparators for radial strength and deployment-induced fields. This division of labor also diversified the verification workload: when Model S sensitivities under deployment were relatively larger, Model U's strong convergence properties under cyclic loading offered an anchor for the local strain calculations under simplified conditions.

16. Limitations

The scope of this credibility assessment is intentionally limited to three mechanisms—pulsatile fatigue of struts and connectors, radial crush strength, and crimp/expansion plasticity and residual stress—and to the role these models play within a Medium-risk COU. Other phenomena, including long-term corrosion, fretting at overlapping struts, and biological remodeling that alters support conditions, are not represented. The materials dataset is confined to L605 specimens from a single heat lot; while that aligns with the devices under study, it narrows the generalizability of input uncertainty estimates. The deployment imaging comparisons use a gel vessel analog and optical methods that imperfectly recapitulate arterial stiffness and boundary conditions; interpretation of those comparisons must therefore focus on pattern and magnitude reasonableness rather than exact pixelwise agreement.

The unit-cell model, by construction, cannot represent radial crush strength or system-level deployment phenomena. Our explicit choice to score those model–mechanism pairs at the bottom of the CAS scale reflects this and avoids conflating model scope with credibility. Numerical code verification relies on vendor documentation and internal spot checks without problem-specific method-of-manufactured-solutions; while this is defensible under a COU buffered by bench tests, it leaves room for future strengthening of this factor.

Validation on pulsatile fatigue uses segments rather than whole-device system-level endurance tests with embedded imaging over 10^8 cycles. The latter would be highly valuable but remains technically challenging and resource intensive. Instead, we adopted a segmentation approach with DIC that captures local amplitudes and outcomes; the mapping to whole-device response is plausible but indirect. For radial strength, the alignment is strong, but the bench apparatus inevitably introduces compliance and friction that must be carefully mirrored in simulation to avoid bias; our compliance correction and contact modeling reflect best practice but are not perfect.

Finally, the credibility program is for a family of sizes and geometries close to those enumerated; extrapolation to markedly different designs—e.g., substantially different strut thicknesses, novel link topologies, or other alloys—would require fresh verification and validation activities and potentially different CAS thresholds reflecting a revised model risk classification.

17. Conclusions and recommendations

Within a V&V40-aligned, Medium-risk COU, the implicit FEA program for a balloon-expandable Co–Cr coronary stent achieves sufficient credibility to support design down-selection and to set pre-test acceptance bands for fatigue safety factors and minimum radial strength, in conjunction with mandatory bench testing. Mesh refinement altered mechanism-relevant outputs by at most a few percent for production meshes, solver tightening changed outputs by less than one percent, and model-to-test agreement was strong for radial strength and acceptable for pulsatile fatigue segments. The selected validation tests span the sizes and operating ranges targeted in the COU, and the modeling workflow operates under configuration control with automated regression checks, reducing process risk.

Based on the quantitative evidence, we recommend the following to sustain and enhance credibility in future submissions. First, expand the materials dataset to include additional heat lots and refine the high-cycle portion of the strain-life curve to reduce the propagated uncertainty in local safety factors. Second, refine deployment parameter measurements—particularly balloon overshoot profiles and contact conditions—to narrow uncertainties in mean stress at hotspots. Third, increase the breadth of validation for pulsatile fatigue by incorporating additional segment topologies and mixed-mode loading (combined bending and axial stretch modulation) to further test model robustness. Fourth, consider problem-specific numerical verification exercises, such as small-scale MMS for cyclic plasticity under multiaxial loading and contact, to strengthen the numerical code verification factor beyond indirect evidence. Finally, maintain and periodically expand the regression suite to cover any new model features or solver upgrades, preserving the integrity of the workflow as the program evolves.

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Table 1: Credibility Attainment Scores (CAS) by factor for each model–mechanism pair. LEVEL is the CAS on a 0–5 scale. Basis cells restate numeric observations also described in the body text.

Credibility factor	Level	Basis
Discretization error - Model U - Pulsatile fatigue of struts and connectors	4	Three-mesh study (110k/180k/310k elems) changed hotspot strain amplitude by 1.4% (fine to superfine) and safety factor by 0.02; hotspot set stable.
Discretization error - Model U - Radial crush strength	0	No radial runs with Model U (0 cases); no mesh study performed; model not used for this mechanism.
Discretization error - Model U - Crimp/expansion plasticity and residual stress	0	No deployment simulations with Model U (0 cases); no mesh study performed; model not used for this mechanism.
Discretization error - Model S - Pulsatile fatigue of struts and connectors	3	Three-mesh study (1.2M/1.8M/3.4M elems) changed hotspot strain amplitude by 2.3% and mean stress by 10 MPa (fine to superfine).
Discretization error - Model S - Radial crush strength	4	Radial force at 10% OD changed 1.7% (0.4020.395 N/mm) from fine to superfine; similar across sizes (1.5–2.1%).
Discretization error - Model S - Crimp/expansion plasticity and residual stress	3	Max equivalent plastic strain changed 3.1% (0.0620.060) and residual hoop stress field L2 difference 2.5% (fine to superfine).
Numerical solver error - Model U - Pulsatile fatigue of struts and connectors	4	Refining Δt from 0.5 to 0.1 ms and tightening residual tol 1e51e7 changed hotspot amplitude by 0.4% and safety factor <0.01.
Numerical solver error - Model U - Radial crush strength	0	No radial simulations with Model U (0 cases); no solver sensitivity performed.
Numerical solver error - Model U - Crimp/expansion plasticity and residual stress	0	No deployment simulations with Model U (0 cases); no solver sensitivity performed.
Numerical solver error - Model S - Pulsatile fatigue of struts and connectors	3	Δt 0.50.1 ms and residual tol 1e51e7 changed hotspot amplitude 0.9% and mean stress 4 MPa; contact penalty ±50% effect 0.3%.
Numerical solver error - Model S - Radial crush strength	4	Arc-length vs displacement control differed by 0.6% at 10% OD; tol 1e51e7 changed 0.3%; contact penalty ±50% changed 0.5%.
Numerical solver error - Model S - Crimp/expansion plasticity and residual stress	3	Tighter line search and halved deployment step size changed max plastic strain by 0.003 absolute and local residual hoop stress by 7 MPa.
Numerical code verification - Model U - Pulsatile fatigue of struts and connectors	1	Indirect evidence only: vendor suite of 290 tests referenced; 5 internal spot checks (residual force <1e9 N; contact slip error 0.2%).