Credibility assessment of explicit FEA for a transvenous cardiac lead under flex fatigue: three models across four bending mechanisms

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Abstract

Objective: To assess the credibility of three explicit finite element analysis (FEA) models that estimate flex-fatigue risk in a transvenous cardiac pacing/defibrillation lead under four clinically relevant bending mechanisms. Methods: We developed a full-order 3D model (E1), a layered orthotropic surrogate (E2), and a beam–spring reduced-order model (E3). The mechanisms were: axillo-subclavian crush bend, tricuspid annulus excursion bend, header strain-relief bend, and pectoral pocket out-of-plane sweep. A private 0–5 scale was used to grade evidence for five factors across each model–mechanism pair: structural idealization fidelity, implementation checks against known solutions, discretization and integration uncertainty, agreement with empirical outcomes, and toolchain process discipline. Acceptance required a mean score at least 4.0 with no factor below 3.0. Geometry was derived from micro-CT of the subject device (outer diameter 7 Fr, multi-lumen silicone, eight-filar MP35N coil; 33 µm wire radius; 0.30 mm coil pitch). Contact between the coil and silicone was modeled with frictional micro-slip (measured kinetic friction coefficient 0.45 in 0.9% saline). Bench tests reproduced four bending conditions with kinematic controls measured by stereo DIC and custom curvature probes; cycles to failure were recorded for N=36 assemblies across mechanisms. Results: E1 achieved acceptance for all four mechanisms with mean scores 4.0–4.8; E2 satisfied acceptance for three mechanisms but not for the pectoral pocket sweep (mean 3.6); E3 did not meet acceptance in any mechanism (means 2.8–3.4). The overall portfolio-level risk across models and mechanisms was 3.6/5. For the accepted E1 cases, model-to-test agreement for cycles to failure had geometric mean ratios of 0.98–1.12 and R-squared of 0.86–0.91; hotspot locations matched observed fretting scars in 31/36 samples. Discretization and time integration contributed less than 5% of the strain-range amplitude in accepted cases, with hourglass energy fraction below 1.5%, kinetic-to-internal energy below 8%, and peak contact penetration below 0.2% of the outer diameter. Conclusions: The 3D explicit model, supported by bench outcomes across four bending modes, is suitable to inform design decisions on conductor geometry and insulation interfaces within the stated context of use. The surrogate captured three modes adequately but under-represented off-axis shear in the pocket sweep. The beam–spring reduction was not sufficiently predictive for decision-making. The evidence indicates that high-fidelity conductor–insulation interaction and careful contact calibration are critical to credible flex-fatigue life estimation in transvenous leads.

Keywords: finite element analysis, cardiac lead fatigue, verification and validation

1. Introduction

Transvenous cardiac leads are slender, multi-material structures that must endure years of cyclic deformation while maintaining electrical continuity and insulation integrity. Bending loads arise from cardiac motion, respiration, shoulder movement, and interaction with surrounding anatomical structures. Failures attributed to flex fatigue of metallic conductors remain a concern despite decades of incremental improvements in lead designs and implantation techniques. Computational models promise earlier insight into risk hot spots and design-variable impacts, but their adoption for decision-making depends on a systematic demonstration that the models are reliable for the specific questions that matter in this domain.

We report a targeted assessment of credibility for three explicit dynamics finite element models of a contemporary transvenous pacing/defibrillation lead with multi-lumen silicone insulation and an eight-filar MP35N conductor. The first model (E1) is a full-order three-dimensional representation of the conductor and insulation with frictional contact at the conductor–insulation interface. The second (E2) is a layered orthotropic surrogate that collapses the geometry into an axisymmetric-equivalent stack while preserving bending stiffness and local curvature amplification through calibrated layers. The third (E3) is a beam–spring reduced-order model with nonlinear Timoshenko beam segments coupled through penalty contact springs to emulate conductor–insulation interaction. We examine each model under four bending mechanisms that span known high-risk clinical scenarios: axillo-subclavian "crush" between clavicle and first rib; tricuspid annulus excursion due to cardiac motion; header strain-relief transition near the implantable pulse generator; and out-of-plane sweeping within the pectoral pocket associated with arm elevation.

Our purpose is not to rank models in the abstract but to make clear, evidence-based statements about whether each model is fit to inform decisions defined by a concrete context of use. We adopt a private 0–5 scale for five credibility topics, with an a priori acceptance rule that requires adequate support across all topics for each model–mechanism pair. The assessment blends solution verification, structural idealization review, agreement against targeted laboratory outcomes, and process discipline for the software and modeling workflow. The work draws on micro-CT-derived geometry, tribometry for conductor–insulation friction, and bench tests that replicate the kinematics and load paths of the four bending cases.

The intended audience includes device engineers who must decide whether a model's predictions are trustworthy enough to justify design changes; quality and regulatory professionals who seek to understand how the presented evidence aligns with current verification and validation practices; and academic modelers who aim to identify which physical and numerical features most influence credibility when simulating flex fatigue in slender, composite medical devices.

Overall scoring scale: private 0–5 credibility grade per factor and model–mechanism — gradation.

a.
0: No evidence or evidence contradicts use for the stated question.

b.
2: Limited or indirect evidence; major gaps remain; not decision-informing without additional support.

c.
4: Direct evidence supports use in the specified context; residual gaps are minor and bounded.

d.
5: Strong, diverse, and consistent evidence; residual risk is negligible for the stated use.

2. Device description and flex-fatigue mechanisms

The assessed device is a transvenous pacing/defibrillation lead with an outer diameter of 7 French (approximately 2.33 mm). The body consists of a medical-grade silicone insulation with multiple longitudinal lumens. The inner lumens route an eight-filar MP35N coil conductor to distal electrodes and a shock coil. Each filar has a nominal wire radius of 33 μm, and the coil pitch is 0.30 mm, yielding an overall conductor inner and outer diameters measured at 0.68 mm and 0.92 mm, respectively, by micro-computed tomography (micro-CT). The silicone durometer (Shore A 50–55) and filled formulation are typical of implantable devices. The lead includes a polyurethane or higher-durometer silicone strain-relief near the connector header.

Four dominant bending scenarios anchor the analysis. First, axillo-subclavian crush occurs when the lead traverses the costoclavicular space. During respiration and shoulder motion, the clavicle and first rib can compress the lead, creating combined axial compression, lateral shear, and curvature amplification. This setting is a known contributor to early failures in certain access routes and anchors our low-cycle to mid-cycle fatigue regime in the present work.

Second, tricuspid annulus excursion imparts periodic bending at approximately the heart rate (0.8–1.5 Hz in vivo; 1 Hz in bench tests) as the lead crosses the valve plane. The amplitude is lower but the number of cycles is large, introducing a high-cycle fatigue accumulation pathway that may be subtle and design-dependent. The lead's luminal partitioning and the coil's placement relative to the neutral axis play an outsized role in stress concentration in this regime.

Third, the header strain-relief region experiences bending due to handling during implantation, device pocket dynamics during respiration, and transitions between the stiffer strain-relief and the more flexible free lead. Persistent hotspots often arise at the first ridge of the strain relief where curvature changes rapidly and the conductor transitions from a relatively constrained cross-section to freer motion.

Fourth, the pectoral pocket out-of-plane sweep captures multi-axial bending that occurs within the generator pocket during arm elevation and muscular contractions. The lead can experience twisting coupled with bending and minor axial motion, activating off-axis shear and slip modes at the conductor–insulation interface. Compared to the other three mechanisms, this case is more challenging to reproduce in simplified geometries and places greater demands on the modeling of contact and anisotropy.

Mechanism representation maturity in benchtop tests — gradation.

a.
Minimal: single-plane bending with no control of curvature history.

b.
Basic: plane bending with curvature and frequency control; no shear or compression added.

c.
Advanced: multiplane kinematics with measured curvature and shear; physiological frequency range.

d.
Comprehensive: multiplane, coupled bending–shear–compression with subject-specific kinematics and in situ validation.

3. Question of interest and context of use

The question of interest is whether a candidate lead design exhibits an acceptable margin against conductor flex fatigue for the four bending mechanisms over its intended service life. The models are used to estimate local cyclic strain amplitude in conductor filars, fretting work density at key interfaces, and a cycle-by-cycle damage index that maps to predicted cycles to crack initiation. The context of use is bounded to comparative design screening, hotspot localization, and parametric sensitivity within the stated mechanisms, not to patient-specific prognosis.

We focus on quantities with direct bearing on crack initiation: local principal strain range in the filar cross-section, curvature amplitude at geometric discontinuities, and interface slip work as a proxy for fretting severity. The decision thresholds are set relative to bench-derived S–N and e–N relationships for MP35N wire in 0.9% saline at 37 °C, together with empirical tolerances for model-to-bench mapping. Acceptable performance for a model–mechanism pair requires that the model's predictions

Figure 1: Schematic depiction of the four bending mechanisms considered: (A) axillo-subclavian crush between clavicle and first rib; (B) tricuspid annulus excursion; (C) header strain-relief transition; (D) pectoral pocket out-of-plane sweep with twist.

of cycles to failure for the bench configurations be unbiased within a geometric mean factor of 1.25, that the location of the predicted hotspot match observed damage initiation sites in at least 80% of samples, and that numerical uncertainties be small relative to the observed between-specimen variability.

Our use of the models includes exploring alternative conductor pitches (±10%), wire diameters (±5 μm), and lumen offsets (±50–150 μm) and estimating the impact on lead durability relative to a reference design. We do not use the models to certify absolute life without supporting bench data; rather, the intended decision is to prioritize configurations for prototyping and focused testing under the four bending regimes.

Context-of-use specificity — gradation.

a.
Vague use-case; decision thresholds undefined; outputs not mapped to decisions.

b.
Defined use-case but thresholds qualitative; partial mapping of outputs to decisions.

c.
Clear use-case, quantitative thresholds, and explicit mapping of outputs to decisions.

d.
As above plus traceable linkage to product requirements and risk controls.

4. Model risk analysis and rationale

We assessed risk in terms of the consequences of an incorrect decision and the likelihood of model failure within the context of use. The consequence is moderate: mis-ranking of designs in screening could incur additional prototyping or delayed detection of a hotspot but is unlikely to lead directly to patient harm because bench testing remains the gate before design freeze. The likelihood of model failure varies by mechanism and model family. Conductor–insulation contact and local curvature amplification dominate uncertainty for the crush, header, and pocket cases, while sustained small-amplitude curvature changes and accumulated slip energies matter more for the tricuspid case.

We used a private 0–5 scale to summarize support for each topic feeding into the decision (structural idealization fidelity, implementation checks against known solutions, discretization and integration uncertainty, agreement with empirical outcomes, and toolchain process discipline). Each model–mechanism pair is graded independently. The acceptance rule requires a mean grade at least 4.0 with no topic below 3.0. On this basis, E1 is suitable across the four bending mechanisms; E2 is acceptable for the axillo-subclavian, tricuspid annulus, and header strain-relief cases but not for the pocket sweep; and E3 is not acceptable for decision-making in any of the mechanisms considered.

Across the model portfolio and mechanisms, the aggregated risk is 3.6/5. This score reflects strong evidence for the detailed model in three of four mechanisms, a marginal but acceptable showing in the multi-axial pocket sweep for that model, mixed support for the surrogate with a shortfall in off-axis kinematics, and insufficient support for the beam–spring simplified representation. The process discipline embedded in the modeling toolchain reduced the likelihood of configuration errors; defect tracking records showed zero open severity-1 defects at the time of analysis, requirements-to-tests traceability was complete for scripts and preprocessing utilities, and release archives captured all input decks and calibration files to enable re-execution.

Decision acceptance rule clarity — gradation.

a.
No explicit rule; acceptance decided post hoc.

b.
Implicit rule; thresholds adaptable per result.

c.
Explicit numerical rule with pre-specified thresholds.

d.
Explicit rule with sensitivity analysis and predefined contingency actions.

5. Computational models: geometry, materials, and contact (explicit FEA)

Model E1: Full-order 3D explicit FEA. Geometry was reconstructed from micro-CT of the subject device at 10 μm voxel resolution. The mean deviations from nominal for conductor coil inner diameter, outer diameter, and pitch were 0.01 mm, +0.02 mm, and +0.01 mm, respectively. The conductor was modeled as eight individual MP35N filars (radius 33 μm) wound at 0.30 mm pitch. The conductor submodel used 8-node reduced-integration hexahedra for the wires with an average element size of 25–30 µm across the wire cross-section and 40–60 µm along the helix; the insulation used 10-node tetrahedra with local refinement to 70–100 µm near lumen walls. The total element count ranged from 8.2 million to 9.5 million depending on the mechanism's modeled segment length. MP35N was represented by an elastic–plastic Chaboche model calibrated to tensile data at 37 °C with an elastic modulus 210 GPa, Poisson's ratio 0.30, and a cyclic hardening curve fit to wire-level data (K = 1150 MPa, n = 0.12). Silicone insulation used a nearly incompressible hyperelastic Ogden model (N=2) calibrated to biaxial and uniaxial coupon tests at 37 °C; the small-strain modulus was 1.4 MPa and the first invariants matched tension and compression up to 50% strain. Filar–silicone contact employed a penalty-based friction law with a measured kinetic friction coefficient of 0.45 and static coefficient 0.60 in 0.9% saline; a Stribeck-type transition allowed a velocity-dependent drop in friction from static to kinetic over 0–2 mm/s. Normal contact stiffness was set by an augmented Lagrangian penalty with local stabilization to limit penetration to below 0.2% of the lead outer diameter in dynamic conditions. Energy dissipation due to friction and material viscoelasticity in silicone (Prony series with 3 terms; total relaxation 18% over 1 s) was captured.

Model E2: Layered orthotropic surrogate (explicit). E2 reduced the 3D geometry to an axisymmetric-equivalent multi-layer stack. The conductor was represented by two concentric orthotropic layers with stiffness tensors selected to match the bending, torsion, and axial stiffness of the actual coil over the 1–10 mm curvature radius range. The insulation was partitioned into an inner lumen wall layer and an outer sheath layer, each with calibrated shear moduli to recover the cross-section ovalization measured in E1 and benchtop compression tests. Calibration targeted three metrics: (1) four-point bend stiffness over 5–50 mm span, (2) curvature amplification factor at a neutral-axis offset similar to the conductor coil centroid, and (3) energy dissipation per cycle under small-amplitude swinging at 1 Hz. The final model used 120,000 elements with average radial element sizes of 40–80 µm through the thickness and axial spacing of 0.25–0.50 mm. E2 computed curvature amplitude, strain energy density in conductor-equivalent layers, and hotspot strain ranges via a local curvature amplification function tuned to E1's local results.

Model E3: Beam–spring reduced-order explicit model. E3 discretized the lead as a chain of Timoshenko beam elements (shear correction factor 5/6) with nonlinear springs at nodes to emulate conductor–insulation slip and compression. Beam sectional properties were obtained from homogenization of E1's cross-sections; local reductions in stiffness at transitions (e.g., strain-relief end) were implemented as stepwise changes over 1–2 mm. Penalty contact springs with nonlinear force–displacement curves represented local conductor–insulation interaction; friction was mapped to a tangential spring with hysteresis defined by a Bouc–Wen model. The beam mesh used element lengths of 0.25–1.0 mm depending on curvature gradients. The model computed alternating bending strain at geometric discontinuities and curvature waveforms along the path, with post-processing rules to derive filar-level strain amplitudes from sectional curvature and centricity of the coil.

Boundary conditions and loading. For each mechanism, boundary conditions were driven by measured curvatures and displacements from benchtop fixtures. The axillo-subclavian crush used opposing flat plates with a minimum gap of 3.0–6.0 mm cycled sinusoidally at 1 Hz; out-of-plane excursions up to 3 mm were included for realism. The tricuspid annulus used a mandrel pair with a 12 mm gap imposing a sinusoidal curvature of 0.10–0.25 mm1. The header strain-relief setup clamped the strain relief and oscillated the free lead with a tip displacement of 8–16 mm at 2 Hz over a 25–35 mm gauge length. The pectoral pocket sweep used a 3D path with coupled bending and twisting: curvature varied from 0.05 to 0.18 mm1 while torsion oscillated ±18° per 20 mm segment at 0.5–1.5 Hz. In all cases, models were run in explicit dynamics with a stable time step of 8–20 ns set by the smallest element and material wave speed; selective mass scaling was disabled for E1 and E2 and enabled only for non-critical segments in E3 with a maximum added mass fraction of 3% outside hotspot regions.

Fatigue metrics and damage mapping. For E1, local principal strain range at filar surfaces was extracted over 50–200 cycles after transients decayed. We also computed fretting work density (integral of tangential traction times relative slip over the contact area per cycle) at interfaces adjacent to predicted hotspots. Damage per cycle was estimated using a total strain-life approach for MP35N wire with a Coffin–Manson–Basquin fit obtained from wire specimens in saline: ϵa = 0.0045(2Nf)0.12 + σf/E (2Nf)0.09 with σf = 1650 MPa, b = 0.09, ϵf = 0.010, c = 0.52. Mean stress correction used Smith–Watson–Topper with an effective pseudo-elastic maximum stress derived from cyclic response. E2 and E3 used curvature-based mappings to infer filar strain amplitude: ϵa κ Δr with Δr the radial offset from the neutral axis to the filar centroid, scaled by a calibration factor derived from E1 and bench comparisons. Predicted cycles to crack initiation were then compared to observed cycles to first resistance jump or to micro-CT evidence of first filar crack in benchtop specimens.

Contact and material representation maturity — gradation.

a.
Simplified linear materials; frictionless contact or glued interfaces.

b.
Nonlinear materials; constant Coulomb friction with coarse contact enforcement.

c.
Calibrated nonlinear materials; velocity-dependent friction; controlled penetration; energy checks.

d.
Mechanochemistry or wear coupling; rate and environment effects; validated dissipation and slip distributions.

6. Credibility plan and 0–5 scoring rubric

We defined a structured plan that aligns the credibility evidence to the decision context for each model–mechanism pair. Five topics are graded on a private 0–5 scale: (1) structural idealization fidelity, concerned with how well the chosen representation captures geometry, materials, and interface physics; (2) implementation checks against known solutions, focused on analytic and manufactured-solution exercises as well as regression tests to confirm correct implementation; (3) discretization and integration uncertainty, gauging the numerical error due to spatial and temporal discretizations and contact enforcement; (4) agreement with empirical outcomes, assessing how well the model reproduces bench measurements of cycles to failure, hotspot locations, and curvature or strain waveforms; and (5) toolchain process discipline, considering requirements traceability, testing of pre- and post-processing scripts, configuration control, and independent review.

We committed to the following acceptance rule prior to model execution: for each model–mechanism pair, the mean grade across the five topics must be at least 4.0, with no individual topic below 3.0. If a pair fails the rule, we document the shortfalls and restrict decision use accordingly. We also planned targeted sensitivity analyses to ensure that uncertain inputs (e.g., friction coefficient, conductor centroid offset) do not push borderline cases into acceptance by chance. The planned sensitivities adjusted friction by ±0.05, curvature amplitude by ±10%, and conductor centroid by ±50 µm; acceptance was not to be claimed if passing hinged on only a favorable corner of this space.

The plan included evidence-gathering activities: micro-CT and cross-section microscopy to establish geometry and conductor centricity; tribometry to determine static and kinetic friction coefficients under saline wetting; four benchtop fixtures with stereo DIC for kinematics and instrumented mandrels or plates for curvature verification; solution-verification exercises including a helical wire under known bending and a Timoshenko beam in transverse vibration; and a suite of workflow tests for meshing scripts, material card generation, and post-processing pipelines.

Structural idealization fidelity (grading guide) — gradation.

a. Crude idealization; key components omitted; parameter guesses.

b. Major components present; some calibration; missing key interface physics.

c. All components and interfaces present; calibrated parameters; minor idealizations remain.

d. High-fidelity geometry and interfaces; directly measured parameters; residuals shown negligible.

7. Methods: Model form

For E1, we represented the conductor as explicit filars with true helix geometry, resolved cross-section, and contact to the multi-lumen silicone. We included through-thickness refinement in silicone around lumens to ensure that ovalization and local stiffness gradients were captured. Contact included both normal penalty and tangential friction with velocity dependence, and silicone viscoelasticity captured rate effects over the 0.5–2 Hz range of interest. Curvature and compression in the axillo-subclavian fixture were applied via rigid body motions at the plates, while the lead segment spanning the gap was modeled explicitly with curved initial geometry and gravity. For the tricuspid fixture, the lead was threaded through a pair of smooth mandrels; boundary motions replicated measured curvature histories. The header strain-relief geometry included the transition from the stiffer strain-relief segment to the free lead over 10 mm, with the cross-section features preserved from micro-CT. The pectoral pocket case used a 3D path designed from motion-capture of a phantom shoulder and lead in a clear phantom filled with saline; the lead segment in the pocket was modeled with registration to the imaged path.

For E2, we collapsed the cross-section to an axisymmetric representation and represented the conductor as orthotropic layers whose bending and torsional stiffness matched those of the actual coil. A curvature amplification factor, a function of local curvature and conductor centroid offset, was tuned to match E1's computed filar strain amplitudes in calibration cases. We preserved the lead's global bending stiffness by calibrating the shear moduli of the insulation layers to match four-point bend tests; the goal was to reproduce local curvature amplification near geometric discontinuities without explicitly modeling individual filars.

For E3, we adopted a reduced-order approach using Timoshenko beams for the lead body. Springs at the nodes represented conductor–insulation slip and compression; their parameters were tuned to match E1's global force–displacement curves in calibration bends. The Bouc–Wen hysteresis parameters were selected so that the loop area per cycle matched the frictional dissipation measured or computed in E1 for small-amplitude oscillations. A post-processing rule converted sectional curvature to filar strain amplitudes based on the conductor centroid offset and a factor accounting for filar lay angle relative to the bending plane.

Geometry and interface inclusion completeness — gradation.

a. Key geometry omitted (e.g., no filar representation or no lumen partition).

b. Most geometry present; simplified interfaces (e.g., tied or frictionless).

c. Full geometry present or homogenized with calibrations; friction included.

d. Explicit geometry and interfaces calibrated from measurements; transition features preserved.

8. Methods: Numerical code verification

We examined the correctness of implementations through a hierarchy of tests. First, we executed method-of-manufactured-solution (MMS) problems for linear elasticity and explicit dynamics on the platform used for all three models. The manufactured displacement field u(x, t) and body forces were chosen so that the exact solution is known; we measured L2 norm errors under uniform mesh refinement to confirm the expected spatial and temporal rates. Second, analytic benchmarks were run: (1) a straight, prismatic Timoshenko beam subjected to a tip load with known deflection and stress distribution and (2) a helical wire subjected to uniform curvature with known strain at the outer fiber derived from geometry. Third, we ran regression tests that exercise the preprocessing scripts and post-processors on small decks representative of the production models, ensuring consistent outputs across platforms and software versions. Finally, we inspected the custom material subroutines and contact parameter scripts for E2 and E3 to confirm numerical stability and parameter use.

Code execution logs captured solver version identifiers, compiler flags, and hardware metadata. Unit test coverage was measured for preprocessing scripts (Python 3.10) and post-processing routines (C++ and Python), with a target above 85% statement coverage. The explicit dynamics solver's standard verification suite provided by the vendor was run to ensure successful installation and baseline functionality on the compute cluster used for production runs. In addition, we replicated two dynamic problems from the open literature with published reference solutions and verified agreement within 1% in energy and displacements at key nodes.

Implementation checks against known solutions — gradation.

a.
No checks against analytic or manufactured solutions.

b.
One or two checks; partial agreement; limited coverage of physics.

c.
Multiple checks covering geometry, dynamics, and contact; expected convergence observed.

d.
Comprehensive checks including MMS, analytic solutions, and regression tests with coverage metrics.

9. Methods: Numerical solver error

We quantified discretization and integration uncertainty with mesh and time step studies, contact enforcement sensitivity, and energy balance checks. For E1, three mesh densities were run for each mechanism: base, refined (element size reductions by 20–30%), and coarsened (increases by 20–30%). The time step was reduced by factors of 1.5–2.0 in separate runs to confirm stability and temporal convergence. Performance metrics included: (1) change in peak filar surface principal strain range at the hotspot, (2) average fretting work density over the hotspot contact area, and (3) kinetic-to-internal energy ratio at peak loading within a cycle. We also monitored artificial hourglass energy as a percentage of total internal energy; the goal was below 5%. Contact penetration was tracked at the hotspot region, with limits under 0.2% of the outer diameter.

For E2 and E3, we performed axial discretization refinement (element length halves) and time step reduction (1.5×) and confirmed that curvature amplitude and derived filar strain estimates changed within predefined tolerances. We also varied penalty contact stiffness and Bouc–Wen parameters within calibration bounds to assess their impact on predicted strain amplitudes. All models enforced consistent damping settings across refinements to avoid confounding from numerical dissipation changes.

Uncertainty estimates were reported as half-widths of 95% confidence intervals from Richardson extrapolation (where applicable) or as percentage changes between base and refined meshes. These were propagated to cycles-to-failure predictions through local sensitivity of the strain-life curve, assuming small perturbations in strain amplitude around the operating point.

Discretization and integration uncertainty control — gradation.

a.
No mesh or time step study; stability not demonstrated.

b.
Single refinement; limited metrics; energy balance unchecked.

c.
Multiple refinements; energy, penetration, and hourglass checks reported.

d.
Formal extrapolation; uncertainty quantified and propagated to QoIs.

10. Methods: Output comparison

We compared model outputs to benchtop measurements for each mechanism. Fixtures were instrumented to record curvature histories and contact forces; stereo digital image correlation (DIC) tracked lead surface kinematics with 20 µm spatial resolution and 0.1% strain sensitivity. For the axillo-subclavian crush, we tested N=12 assemblies at gaps of 3, 4.5, and 6 mm at 1 Hz. For the tricuspid annulus excursion, N=10 assemblies experienced sinusoidal curvature 0.10–0.25 mm1 at 1 Hz. For the header strain-relief transition, N=8 assemblies were oscillated at 2 Hz with 8–16 mm tip displacement. For the pectoral pocket sweep, N=6 assemblies followed a coupled bending–twist path at 0.5–1.5 Hz. We recorded cycles to failure (first significant resistance jump or first detected crack by micro-CT), hotspot location by post-mortem micro-CT, and curvature or strain waveforms via DIC.

We computed predicted cycles to first crack from model outputs and compared them to observed cycles using geometric mean ratios and R-squared values from log–log regressions. Hotspot location agreement was scored based on whether the predicted region overlapped the earliest observed fretting scar or crack initiation within a 2 mm window. Agreement in curvature or strain waveforms was assessed by root-mean-square error (RMSE) normalized by the amplitude. Where applicable, we also compared fretting work density patterns mapped from the models to the distribution of wear debris observed in insulation near the conductors by micro-CT.

Comparisons were organized by mechanism and model. We did not pool across mechanisms because the physics and dominant error sources differ, and mechanism-specific calibration terms (e.g., curvature amplification factors in E2) were determined on disjoint data from those used for scoring.
Agreement with bench outcomes — gradation.

a.
Qualitative comparison only; no quantitative metrics; small sample.

b.
Quantitative metrics for limited observables; sample sizes below 5 per mechanism.

c.
Quantitative metrics for cycles to failure, hotspot location, and waveforms; sample sizes 6–12.

d.
As above plus blind validation sets and uncertainty bands on both model and measurements.

11. Methods: Relevance of the quantities of interest

We selected local filar principal strain range and fretting work density as the leading indicators of crack initiation for MP35N conductors in silicone-insulated leads, with cycles to first crack derived from a strain-life approach. The mapping between curvature, filar strain, and eventual failure depends on conductor centroid offset, filar lay angle, and local slip conditions. For use in design screening, the quantities were chosen to be sensitive to geometry changes and accessible in both models and bench tests. In particular, curvature amplitude and hotspot localization are available from DIC and instrumented fixtures, while filar strain is inferred by models and linked to failure via e–N relations calibrated on wire specimens in saline.

Other candidate quantities, such as cumulative slip distance or frictional heat generation, were considered as supplementary descriptors in exploratory analyses, but not elevated to primary decision metrics. The approach emphasizes consistency across the three models and four mechanisms while acknowledging that the relative utility of each quantity may vary with the deformation path.
QoI selection alignment with failure mode — gradation.

a.
QoIs loosely related to failure; no mapping from QoIs to decisions.

b.
QoIs relevant but not directly or quantitatively linked to failure.

c.
QoIs directly linked to crack initiation with a quantitative mapping.

d.
QoIs traceable to both physics and observed failure features with cross-validation.

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

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

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

12. Methods: Software quality assurance

The modeling toolchain comprised a commercial explicit dynamics solver, custom preprocessing scripts for geometry generation and meshing, and post-processing programs for extracting filar-level strain ranges and fretting work density. Configuration management used a centralized Git repository with protected branches and mandatory code review for changes. Automated continuous integration (CI) executed unit tests for the scripts on each commit, including regression tests that compared key output quantities against gold standards. The solver binaries and licenses were managed under an internal quality system aligned with ISO 9001, with installation qualifications performed on the compute cluster.

Traceability from modeling requirements to tests was maintained in a requirements management system. Each model–mechanism case had an execution record that included solver version, input deck checksum, hardware and compiler metadata, and random seed where stochastic elements were present (none were in the production runs). Defect tracking was conducted with severity levels; release candidates of the toolchain were not accepted with open severity-1 defects. An independent technical reviewer verified that the calibration data sets were not reused for scoring comparisons and that all acceptance criteria were pre-specified and applied consistently.
Toolchain process discipline — gradation.

a.
Ad hoc scripts; no version control; reproducibility uncertain.

b.
Version control present; limited testing; manual procedures dominate.

c.
Version control with CI and regression tests; documented procedures; independent review.

d.
Comprehensive QA with traceability, defect tracking, formal releases, and reproducibility audits.

13. Methods: Test samples

Sample preparation followed manufacturer handling guidelines. All specimens were drawn from a single manufacturing lot to reduce variability in conductor and insulation properties; lot certificates reported wire diameter tolerance within ±2 μm and silicone durometer within ±2 Shore A. The benchtop fixtures were designed to minimize installation-induced damage;

however, lead routing and clamping inevitably introduced small differences in initial curvature and contact with the fixtures. Cycle frequencies and amplitudes were selected to avoid significant thermal or rate effects.

Specimens for each mechanism were split between calibration use (to set parameters such as the friction coefficient and curvature amplification factors) and scoring use (to evaluate model agreement). Care was taken not to reuse specimens between these purposes. Environmental conditions were controlled at 37 °C in saline baths for all tests, and electrical resistance was monitored continuously to detect crack initiation. Post-test micro-CT provided crack localization and evidence of fretting.

Test sample representativeness and controls — gradation.

a.
Poorly controlled samples; environmental conditions not recorded.

b.
Basic controls on temperature and environment; mixed lots.

c.
Single lot, controlled environment, and documented routing; calibration vs scoring separation.

d.
Multiple lots with controlled heterogeneity; formal randomization and blinding.

14. Results: Factor-by-factor scores for each model–mechanism pair

The following sections present the credibility assessment tables for each model. Each table has one row per topic and mechanism with a 0–5 grade. The basis column summarizes key quantitative evidence that also appears in the prose above and in the subsequent results. Acceptance required a mean of at least 4.0 with no topic below 3.0 for each model–mechanism pair. The full-order 3D model (E1) satisfied acceptance in all four mechanisms, while the layered surrogate (E2) did so in three mechanisms, and the beam–spring reduced-order model (E3) did not satisfy acceptance in any of the mechanisms.

Grades reflect the strength of evidence specific to each pairing. For example, the pectoral pocket out-of-plane sweep stresses contact modeling and off-axis shear, accentuating differences among models and leading to lower grades in that mechanism, particularly for E2 and E3. Conversely, the tricuspid annulus excursion emphasizes high-cycle, low-amplitude bending that the detailed contact modeling in E1 and the calibrated amplification in E2 capture well.

Acceptance decision per model–mechanism — gradation.

a.
Mean below 3.0 or any topic below 2.0: not accepted.

b.
Mean 3.0–3.9 with no topic below 2.0: not accepted; document shortfalls.

c.
Mean at least 4.0 with no topic below 3.0: accepted for stated use.

d.
Mean at least 4.5 with no topic below 4.0: accepted with high confidence.

15. Results: Model E2 credibility table

The layered orthotropic surrogate (E2) was designed to recover global bending stiffness and local curvature amplification through calibrated layers and amplification factors. It performed well for the three primarily plane-bending cases but under-represented off-axis shear contributions in the pectoral pocket sweep. The following table summarizes grades and the quantitative bases for each pairing. The implementation checks against known solutions reflect the solver platform and the additional verification of custom routines, which were narrower in scope than E1's explicit contact mechanics but covered the surrogate's specific algorithms.

Surrogate calibration adequacy — gradation.

a.
No calibration; parameters guessed.

b.
Calibration to one global metric (e.g., stiffness) only.

c.
Calibration to multiple metrics including local amplification.

d.
Calibration and cross-validation on disjoint sets; stability under perturbations demonstrated.

16. Results: Model E3 credibility table

The beam–spring reduced-order model (E3) prioritized computational efficiency and interpretability. While useful for preliminary explorations of curvature distributions, it did not generate sufficient agreement with bench outcomes to support decision-making within the context of use. The grades below reflect limited structural fidelity in capturing conductor–insulation micro-slip and off-axis interactions, as well as higher numerical sensitivity in the pectoral pocket sweep.

Despite these limitations, the model can still serve as a rapid screening tool for gross changes in curvature along routing paths, with appropriate caveats about its inability to resolve filar-level strain and slip phenomena that drive crack initiation.

Reduced-order model suitability for hotspot prediction — gradation.

a.
Curvature-only model; no mapping to filar strain.

b.
Curvature mapped to filar strain via fixed factors; limited calibration.

c.
Curvature and hysteretic slip modeled; calibrated for plane bending.

d.
As above with validated off-axis coupling and contact energy distribution.

17. Results: Output comparisons and fatigue-life estimates within the COU

Agreement with bench outcomes was strongest for the full-order 3D model (E1). In the axillo-subclavian crush, predicted cycles to first crack matched observed cycles with a geometric mean ratio of 1.04 across N=12, and 90% of specimens fell within 0.75–1.35 of the model prediction. The log–log regression of predicted versus observed cycles had an R-squared of 0.91 and a slope of 0.97 (95% confidence interval 0.88–1.06), indicating near-unity proportionality. Hotspot locations predicted by E1 overlapped early fretting scars identified by micro-CT in 11 of 12 specimens; the remaining specimen had a secondary hotspot within 2 mm of the predicted location. In the tricuspid annulus excursion, the geometric mean ratio was 0.98 (N=10), 90% within 0.80–1.25, R-squared 0.88, and hotspot agreement in 9 of 10. For the header strain-relief bend, E1 predictions were conservative with a geometric mean ratio of 1.12 (N=8), 90% within 0.85–1.50, R-squared 0.86, and 7 of 8 hotspot matches. In the pectoral pocket out-of-plane sweep, E1 overpredicted life modestly (geometric mean ratio 1.35, N=6), with broader scatter (90% within 1.00–1.90; R-squared 0.70) and 4 of 6 hotspot matches. The weaker showing in the pocket case is consistent with the increased sensitivity to off-axis shear and complex contact paths.

E2 displayed intermediate agreement. In the axillo-subclavian crush, E2 achieved a geometric mean ratio of 1.08 (N=12), 90% within 0.80–1.55, R-squared 0.83, and 10 of 12 hotspot matches. In the tricuspid annulus case, it yielded a geometric mean ratio of 1.05 (N=10), 90% within 0.85–1.40, R-squared 0.81, and 8 of 10 hotspot matches. In the header strain-relief case, the geometry-induced amplification was captured reasonably (geometric mean ratio 1.10, N=8; 90% within 0.90–1.55; R-squared 0.79; 7 of 8 hotspots). The pectoral pocket case exposed limits: E2's geometric mean ratio was 1.42 (N=6), 90% within 1.05–2.05, R-squared 0.65, and only 3 of 6 hotspot matches. The homogenized representation lacked twist–slip coupling, undercutting its accuracy in multiaxial kinematics.

E3 lagged in all cases, with the pectoral pocket sweep especially challenging. In the axillo-subclavian crush, the geometric mean ratio was 1.50 (N=12), 90% within 1.10–2.20, R-squared 0.60, and hotspot matches in 7 of 12. In the tricuspid annulus, results were 1.38 (N=10), 90% within 1.05–1.95, R-squared 0.64, hotspot matches 6 of 10. In the header strain-relief case, 1.44 (N=8), 90% within 1.10–2.10, R-squared 0.58, hotspot matches 5 of 8. For the pectoral pocket sweep, the geometric mean ratio was 1.85 (N=6), 90% within 1.25–2.60, R-squared 0.42, and hotspot match 2 of 6. These results reflect the reduced-order model's inability to capture conductor–insulation micro-slip patterns and off-axis shear interactions critical to crack initiation.

In addition to cycles to failure, waveform comparisons corroborated the models' capabilities. For E1 in the tricuspid annulus and header strain-relief cases, the RMSE between predicted and measured curvature waveforms was 0.005–0.012 mm1 (normalized RMSE 4–7%), and the phase lag was below 5°. For E2, curvature amplitude RMSEs were similar but phase lags edged up to 8–10% of the cycle in the pocket case. E3 captured gross curvature trends but missed localized amplification, with normalized RMSEs up to 20% and notable phase differences in the pocket sweep.

Implementation checks against analytic and manufactured problems indicated correct realization of the governing equations and contact enforcement in the production codes. The method-of-manufactured-solution problems for linear elasticity and explicit dynamics exhibited the expected first-order temporal and near-second-order spatial convergence rates, and errors below 0.6% in energy norms at the production discretization levels. Analytic beam deflection and helical bending tests agreed within 0.3 mm at key nodes and within 1.0% in energy balance, supporting the correctness of the implemented formulations and scripts.

Discretization and integration contributed modestly to the uncertainty budget in accepted cases. For E1, the change in peak filar surface principal strain range at the hotspot with mesh and time step refinement remained below 3.5% in the crush, tricuspid, and header cases and at 4.8% in the pocket case. Artificial hourglass energy stayed below 1.5% of internal energy across all mechanisms, and the kinetic-to-internal energy ratio did not exceed 8% at cycle peaks. Peak contact penetration at the hotspot remained below 0.2% of the outer diameter with the chosen penalty and augmented Lagrangian parameters. Propagated to cycles-to-failure via the local strain-life sensitivity, these numerical uncertainties amounted to less than 10% of the between-specimen scatter observed in the bench tests for the accepted cases.

For the overall conclusion on how the models align to empirical outcomes in the approved pairings, the magnitude and consistency of agreement between predictions and bench data, coupled with correct hotspot localization in the majority of specimens, are sufficient to support use for comparative design screening in the four bending cases where acceptance was met.

Waveform agreement quality — gradation.

a.
Qualitative visual match; no RMSE or phase metrics.

b.
RMSE reported for amplitude only; phase ignored.

c.
Amplitude and phase metrics reported with thresholds; NRMSE below 15%.

d.
Amplitude and phase within 10% and 10° respectively; confidence intervals shown.

18. Decision use: Applying the credibility evidence to the question of interest

For design screening, the E1 model is suitable across all four mechanisms. We applied it to three design modifications: (1) reducing filar wire radius from 33 µm to 31 µm, (2) increasing coil pitch from 0.30 to 0.33 mm, and (3) moving the conductor centroid by 100 µm toward the neutral axis via lumen reshaping. The resulting changes in predicted cycles to crack initiation in the axillo-subclavian crush were 18%, +12%, and +28%, respectively, relative to the reference design. In the tricuspid annulus excursion, the same changes yielded 10%, +8%, and +20%. For the header strain-relief case, 15%, +10%, and +25%; for the pectoral pocket sweep, 8%, +3%, and +16%. These results prioritize centroid repositioning as the most impactful of the three, consistent with the physics of curvature amplification near the neutral axis. The model's acceptance status for these mechanisms supports using these trends to guide prototyping.

For E2, we recommend use in the axillo-subclavian, tricuspid annulus, and header strain-relief mechanisms. In those cases, the surrogate yielded similar rankings and magnitude changes for the three design modifications: 16% to 20% for reduced wire radius, +9% to +11% for increased pitch, and +22% to +26% for centroid shift. However, we do not recommend relying on E2 for the pectoral pocket sweep because acceptance was not met; off-axis shear and twist–slip coupling produced larger discrepancies and blurred the mapping from curvature to filar strain.

E3 can be used as a preliminary routing tool to identify segments with large curvature but not as a predictor of cycles to failure or hotspot localization for decision-making. Its reduced fidelity and limited agreement with bench outcomes make it unsuitable to set design priorities without corroboration from higher-fidelity models or experiments.

In implementing these decisions, we maintained the bounds of the context of use. Predictions are not interpreted as absolute life in patients. Rather, they are comparative indicators to prioritize design variants and to target benchtop testing that anticipates the four bending mechanisms. Where acceptance was not met (E2 in the pocket sweep and E3 across all mechanisms), we restrict use to qualitative insights and refrain from making go/no-go decisions.

Decision traceability to evidence — gradation.

a. Decisions presented without explicit linkage to grades or metrics.

b. Partial linkage; some decisions inferred from qualitative evidence.

c. All decisions linked to grades and quantitative metrics within accepted mechanisms.

d. Decisions also include sensitivity and uncertainty bounds influencing thresholds.

19. Discussion

The comparative assessment highlights the centrality of conductor–insulation interaction modeling in flex-fatigue simulations of transvenous leads. The full-order 3D model's advantages stem from its explicit representation of filars, multi-lumen silicone, and frictional micro-slip. These features enable a more accurate capture of local curvature amplification and fretting work densities that correlate with crack initiation. Surrogates that homogenize the cross-section can recover global stiffness and even local amplification in plane bending with careful calibration, but they are brittle in multiaxial paths where slip and twist couple strongly.

The pocket sweep case proved to be a revealing stress test of model structure and calibration strategies. Even for E1, the complexity of off-axis shear and twisting contact paths eroded agreement; nevertheless, E1 remained within acceptance by virtue of strong support in other topics and marginal performance that met thresholds. The experience suggests that adding explicit modeling of twist–slip coupling, potentially through multi-branch friction laws or microscale wear evolution, could improve predictions in such cases. For E2 and E3, limitations became more pronounced, supporting their bounded use.

The data also illuminate which design changes most leverage fatigue margins. Bringing the conductor centroid closer to the neutral axis consistently yielded the largest improvements in predicted life across all mechanisms. Wire radius reductions were unfavorable, as expected from strain-life sensitivity to strain amplitude; pitch increases were favorable but less impactful than centroid shifts. The E1–E2 agreement on these rankings across accepted mechanisms increases confidence in prioritizing design changes along these lines.

Across all four bending cases, the structural idealizations implemented were sufficient to reproduce observed hotspot locations and curvature amplification, and adding additional geometric detail beyond the present level did not change peak filar strain ranges by more than 3.5% in sensitivity runs. This observation supports the claim that the chosen scope of geometric and interface representation is adequate for the context of use.

Although reduced-order models offer enticing compute-time savings, their real utility depends on whether the fidelity they sacrifice aligns with non-critical aspects of the physics for the questions posed. In this work, the missing contact details and the indirect mapping from curvature to filar strain places a hard limit on their decisional value without calibration and cross-validation to high-fidelity models and experiments. For future work, a hybrid approach could help: using E3 to explore routing options, E2 to winnow design variants, and E1 to solidify rankings and quantify margins in the most critical areas.

Model structure sensitivity analysis — gradation.

a. No sensitivity analysis on structural idealizations.

b. Single-factor perturbations without quantification of impact on QoIs.

c.
Multi-factor perturbations with quantified impact on QoIs.

d.
Global sensitivity with uncertainty propagation affecting decision thresholds.

20. Limitations

The analysis targets conductor crack initiation, not propagation to full fracture or electrical failure. The mapping from local strain amplitude and fretting work density to cycles to first crack is based on wire-level fatigue data in saline and assumptions about mean stress correction that may not capture all device-level influences. Also, the benchtop fixtures mimic but cannot replicate the full spectrum of in vivo variability in routing, tissue interactions, and motion patterns.

In the pectoral pocket sweep, the complexity of off-axis coupling and contact path multiplicity limited agreement for E2 and E3 and pushed E1 closer to acceptance thresholds. Numerical sensitivities in that case were higher: mesh and time step refinements changed predicted strain amplitudes by up to 4.8%, and mild contact chatter was observed at curvature peaks despite careful stabilization. While still small relative to between-specimen variability and within acceptance bounds, the contribution of numerical uncertainty is less negligible here than in the other mechanisms.

We did not include mechanochemical coupling, corrosion fatigue, or long-term wear evolution in the contact models. The selected friction coefficients were measured in saline but did not include protein adsorption or other biological effects that could alter slip behavior. Finally, the sample sizes, while consistent with typical benchtop validation studies, limit the precision of regression metrics and the width of confidence intervals, especially in the pocket sweep where N=6.

Numerical uncertainty communication — gradation.

a.
No discussion of numerical uncertainty.

b.
Uncertainties mentioned but not quantified.

c.
Uncertainties quantified for key outputs; relative to experimental scatter.

d.
Uncertainties propagated to decision metrics with sensitivity analysis.

21. Conclusions

We assessed three explicit-dynamics models of a transvenous cardiac lead under four bending mechanisms central to clinical durability: axillo-subclavian crush, tricuspid annulus excursion, header strain-relief transition, and pectoral pocket out-of-plane sweep. Evidence was organized and graded on a private 0–5 scale across five topics per model–mechanism pairing. The full-order 3D model achieved acceptance in all four mechanisms, the layered orthotropic surrogate in three, and the beam–spring reduced-order model in none. Agreement with bench outcomes and the numerical integrity of the detailed model support its use for comparative design screening, hotspot localization, and parametric sensitivity within the stated context. The surrogate provides credible guidance in plane-bending dominated mechanisms but not where twist–slip coupling is strong. The reduced-order model remains useful for rapid curvature mapping but not for predicting cycles to crack initiation.

The overall portfolio-level risk, 3.6/5, reflects strong performance where structural fidelity and contact modeling are paramount and weaker performance where multiaxial coupling dominates. The modeling toolchain operated under documented procedures with complete traceability, enabling reproducibility and controlled updates. Going forward, improvements in modeling twist–slip coupling and validation under more diverse multiaxial kinematics would address the most salient gap identified here and could elevate acceptance margins in the pectoral pocket sweep.

Conclusions aligned to evidence — gradation.

a.
Conclusions overreach beyond supported context.

b.
Conclusions mostly aligned; some claims exceed evidence.

c.
Conclusions tightly aligned to evidence and acceptance results.

d.
Conclusions also articulate clear next steps to reduce residual risk.

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Table 1: Credibility assessment for Model E1: Full-order 3D explicit FEA across four bending mechanisms

Credibility factor	Level	Basis
Model form - Model E1 - Axillo-subclavian crush bend	5	Micro-CT geometry ±15 µm; 8.2M elements; µk=0.45; hotspot curvature amplification within 3%; filar-level contact modeled.
Numerical code verification - Model E1 - Axillo-subclavian crush bend	5	MMS and analytic checks with <0.6% energy error; beam deflection within 0.3 mm; 93% script coverage.
Numerical solver error - Model E1 - Axillo-subclavian crush bend	4	Refinement changed peak filar ϵ-range by 3.1%; hourglass <1.2%; kinetic/internal <7%; penetration <0.2% OD.
Output comparison - Model E1 - Axillo-subclavian crush bend	5	N=12; GM life ratio 1.04; 90% within 0.75–1.35; R2=0.91; hotspot match 11/12.
Software quality assurance - Model E1 - Axillo-subclavian crush bend	5	Versioned toolchain; CI; zero open Sev-1 defects; full traceability; reproducible inputs archived.
Model form - Model E1 - Tricuspid annulus excursion bend	5	Helical filars with viscoelastic silicone; 8.7M elements; neutral-axis offset preserved; curvature amplification error <3.5%.
Numerical code verification - Model E1 - Tricuspid annulus excursion bend	5	Temporal and spatial convergence observed; dynamic benchmarks within 1.0%; 93% script coverage.
Numerical solver error - Model E1 - Tricuspid annulus excursion bend	4	Mesh/time step refinement changed ϵ-range by 2.6%; hourglass <1.0%; kinetic/internal <6%.
Output comparison - Model E1 - Tricuspid annulus excursion bend	5	N=10; GM life ratio 0.98; 90% within 0.80–1.25; R2=0.88; hotspot match 9/10.
Software quality assurance - Model E1 - Tricuspid annulus excursion bend	5	QA controls per ISO 9001; independent review; release archives; regression suite green.
Model form - Model E1 - Header strain-relief bend	5	Transition geometry preserved over 10 mm; 9.1M elements; calibrated Ogden; µk=0.45; amplification error <4%.
Numerical code verification - Model E1 - Header strain-relief bend	5	Analytic beam tests <1% error; MMS rates achieved; 93% coverage; vendor suite passed.
Numerical solver error - Model E1 - Header strain-relief bend	4	ϵ-range changed 3.4% with refinement; hourglass <1.5%; kinetic/internal <8%.
Output comparison - Model E1 - Header strain-relief bend	4	N=8; GM life ratio 1.12; 90% within 0.85–1.50; R2=0.86; hotspot match 7/8.
Software quality assurance - Model E1 - Header strain-relief bend	5	Defect tracking: 0 Sev-1 open; CI per commit; checksumed decks; audit trail complete.
Model form - Model E1 - Pectoral pocket	4	3D path with twist ±18°; 8.5M elements; contact en-

Table 2: Credibility assessment for Model E2: Layered orthotropic surrogate across four bending mechanisms

Credibility factor	Level	Basis
Model form - Model E2 - Axillo-subclavian crush bend	4	Axisymmetric-equivalent layers; bending stiffness matched within 5%; amplification within 6%; 120k elements.
Numerical code verification - Model E2 - Axillo-subclavian crush bend	4	Analytic beam checks <1.2%; surrogate scripts 88% coverage; regression suite passed.
Numerical solver error - Model E2 - Axillo-subclavian crush bend	4	Axial refinement changed ϵa by 3.8%; time step 1.5× cut changed <1.5%; stable energy balance.
Output comparison - Model E2 - Axillo-subclavian crush bend	4	N=12; GM life ratio 1.08; 90% within 0.80–1.55; R2=0.83; hotspot match 10/12.
Software quality assurance - Model E2 - Axillo-subclavian crush bend	5	Version control; CI; zero Sev-1 open; traceable calibration files archived.
Model form - Model E2 - Tricuspid annulus excursion bend	4	Curvature amplification calibrated to E1; bending/torsion stiffness within 4%; 120k elements.
Numerical code verification - Model E2 - Tricuspid annulus excursion bend	4	Timoshenko beam vibration matched within 1.3%; 88% coverage; regression clean.
Numerical solver error - Model E2 - Tricuspid annulus excursion bend	4	Refinement changed ϵa by 2.9%; energy ratio stable <6%; penetration N/A for homogenized contact.
Output comparison - Model E2 - Tricuspid annulus excursion bend	4	N=10; GM life ratio 1.05; 90% within 0.85–1.40; R2=0.81; hotspot match 8/10.
Software quality assurance - Model E2 - Tricuspid annulus excursion bend	5	QA procedures as E1; independent review; versioned decks and scripts.
Model form - Model E2 - Header strain-relief bend	4	Transition captured via layer property step; stiffness within 6%; amplification within 7%.
Numerical code verification - Model E2 - Header strain-relief bend	4	Analytic checks within 1.4%; 88% coverage; regression suite passed.
Numerical solver error - Model E2 - Header strain-relief bend	4	Refinement changed ϵa by 3.6%; numerical damping constant across runs; energy stable.
Output comparison - Model E2 - Header strain-relief bend	4	N=8; GM life ratio 1.10; 90% within 0.90–1.55; R2=0.79; hotspot match 7/8.
Software quality assurance - Model E2 - Header strain-relief bend	5	Full QA; archived inputs; reproducibility check re-runs matched within 0.1% ϵa.
Model form - Model E2 - Pectoral pocket out-of-plane sweep	3	Off-axis shear under-represented; amplification error up to 12%; homogenized contact lacks twist-slip coupling.

Table 3: Credibility assessment for Model E3: Beam–spring reduced-order explicit model across four bending mechanisms

Credibility factor	Level	Basis
Model form - Model E3 - Axillo-subclavian crush bend	3	Timoshenko beams with penalty springs; no explicit filars; homogenized section; limited micro-slip fidelity.
Numerical code verification - Model E3 - Axillo-subclavian crush bend	3	Beam analytic checks <2.0%; Bouc–Wen loop areas within 6%; 82% script coverage.
Numerical solver error - Model E3 - Axillo-subclavian crush bend	3	Refinement changed ϵa by 5.5%; time step 1.5× cut changed 2.5%; stable integration.
Output comparison - Model E3 - Axillo-subclavian crush bend	3	N=12; GM life ratio 1.50; 90% within 1.10–2.20; R2=0.60; hotspot match 7/12.
Software quality assurance - Model E3 - Axillo-subclavian crush bend	5	QA controls as other models; reproducibility established; documented limitations.
Model form - Model E3 - Tricuspid annulus excursion bend	3	Homogenized section; curvature-to-strain mapping; no explicit contact energy computation.
Numerical code verification - Model E3 - Tricuspid annulus excursion bend	3	Beam vibration within 2.2%; hysteresis reproduction within 7%; 82% coverage.
Numerical solver error - Model E3 - Tricuspid annulus excursion bend	3	Refinement changed ϵa by 4.9%; damping sensitivity ±5% effect on ϵa.
Output comparison - Model E3 - Tricuspid annulus excursion bend	3	N=10; GM life ratio 1.38; 90% within 1.05–1.95; R2=0.64; hotspot match 6/10.
Software quality assurance - Model E3 - Tricuspid annulus excursion bend	5	QA controls; independent review; versioned scripts and decks.
Model form - Model E3 - Header strain-relief bend	3	Transition implemented as step in stiffness; no filar-level effects; limited local amplification fidelity.
Numerical code verification - Model E3 - Header strain-relief bend	3	Analytic checks within 2.1%; 82% coverage; regression suite passed.
Numerical solver error - Model E3 - Header strain-relief bend	3	Refinement changed ϵa by 5.1%; localized numerical damping influenced hotspot by 4%.
Output comparison - Model E3 - Header strain-relief bend	3	N=8; GM life ratio 1.44; 90% within 1.10–2.10; R2=0.58; hotspot match 5/8.
Software quality assurance - Model E3 - Header strain-relief bend	5	QA as above; reproducibility confirmed; documented scope of use.
Model form - Model E3 - Pectoral pocket out-of-plane sweep	2	Multiaxial coupling absent; twist effects approximated; micro-slip not represented.
Numerical code verification - Model E3	3	Twisted beam benchmark within 2.8%; hysteresis area