Risk-based credibility assessment of two implicit finite element models for external fixator construct stiffness under ASME V&V 40

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Abstract

Objective: To evaluate the credibility of two implicit finite element models that predict construct stiffness of a modular unilateral tibial external fixator under prescribed axial compression and frontal-plane bending, following ASME V&V 40 with a medium model-risk posture and a private 0–5 Credibility Index (CI) scale. Methods: We developed a high-fidelity model (HF-Contact) resolving frictional contact at pin–cortex and clamp interfaces and an efficient reduced-order model (RB-Beam) using beam and spring idealizations. The context of use (CoU) is to support design verification and preclinical evidence planning; model outputs inform design iteration and bench test priorities but do not directly infer clinical performance. The quantities of interest (QoIs) are construct stiffness in axial compression (N/mm) and frontal-plane bending (N·mm/deg) under standardized loading fixtures mapped to ASTM F1541-style conditions. We examined six credibility factors: discretization, input mapping, code-oriented checks, solution convergence behavior, the alignment of the QoIs with decisions, and the breadth and representativeness of bench constructs. Structured procedures included mesh and time incrementation studies, benchmark problems, metrological mapping of physical inputs to model parameters, and comparison to eight-construct test series per mechanism. Results: HF-Contact's finest practical meshes produced grid-convergence indices below 1.6% (axial) and 2.4% (bending). RB-Beam reached <1.0% refinement uncertainty for both mechanisms. Input mapping differences between measured and modeled hardware properties were held within 3% for HF-Contact and within 5% for RB-Beam through spring and connector calibration. Code-oriented checks reproduced linear elastic and Hertzian contact benchmarks within 0.5–1.2%. Nonlinear static solves attained force residuals < 10^-8 of the applied load and contact penetrations < 3 μm; RB-Beam linear solves achieved machine-precision residuals. The QoIs coincide directly with design verification metrics, supporting prioritization and planning. Eight physical constructs per mechanism (five repeated assemblies and three manufactured duplicates) were tested; coefficients of variation were 6–8%, with controlled fixture alignment and clamp torque. HF-Contact predicted axial stiffness of 310 N/mm versus test 302 ± 18 N/mm and bending rotational stiffness of 2150 N·mm/deg versus test 2200 ± 130 N·mm/deg. RB-Beam predicted 295 N/mm and 2100 N·mm/deg, respectively. On the 0–5 CI scale with acceptance at CI ≥ 3.0 for medium model risk, all factor scores met acceptance for both mechanisms and models, with HF-Contact higher for input mapping and solution behavior and RB-Beam higher for refinement efficiency. Conclusions: Under the stated CoU and medium model risk, both HF-Contact and RB-Beam provide credible stiffness predictions for axial compression and frontal-plane bending of a modular unilateral tibial external fixator. HF-Contact is preferred when sensitivity to clamp and interface details is critical; RB-Beam offers rapid screening for design iteration. The factor-by-factor CI scoring supports their combined use: HF-Contact for high-fidelity design verification and RB-Beam for early-stage configuration narrowing, with mandatory bench testing bounding any residual modeling uncertainty.

Keywords: external fixation, model credibility, ASME V&V 40

1. Introduction

External fixation remains a mainstay for provisional and definitive stabilization of diaphyseal tibial fractures, where modular unilateral frames must provide dependable stability in axial compression and frontal-plane bending. Frame stiffness contributes to the evolving strain environment at the fracture gap, shaping callus formation and influencing alignment control under physiologic loads. Computational models offer a means to explore design variants rapidly, prioritize test conditions, and anticipate performance across a realistic range of configurations, provided their credibility is established for the decisions they aim to support.

This study applies the ASME V&V 40 framework to two finite element analysis (FEA) models that predict construct stiffness for a modular unilateral tibial fixator. The first, HF-Contact, resolves contact and friction at pin–cortex, clamp–bar, and clamp–pin interfaces while accounting for bar–clamp compliance in an implicit static solution. The second, RB-Beam, is a reduced-order formulation using classical beam elements and springs with rigid connectors to represent hardware and compliant joints, solved implicitly with small-displacement kinematics. Both are configured to calculate stiffness under standardized axial compression and frontal-plane bending fixtures analogous to those used in ASTM F1541-style bench testing.

We adopt a medium model risk position: predictions guide design iteration, screening of frame configurations, and prioritization of bench test matrices. Mechanical testing and design controls remain the principal means of regulatory assurance. We define a private 0–5 Credibility Index (CI) with acceptance at CI ≥ 3.0 for the stated risk level. The credibility factors examined are discretization, mapping of physical inputs to model parameters, checks tied to software correctness, solution behavior under nonlinear and contact conditions, the closeness of the QoIs to the decision needs, and the appropriateness of the bench constructs used to anchor inferences. The body of evidence is organized by mechanism to reflect the ways loads enter the frame and fracture span.

We emphasize practical matters that often dominate external-fixator modeling: how clamp preloads translate to joint stiffness, how pin–cortex friction and seating govern load paths, and how bar geometry and connectors shape overall flexibility. The comparative assessment is designed to support a combined modeling strategy in which an efficient reduced-order model guides early choices and a higher-fidelity model refines final verification predictions before physical tests are run.

Relevance of the quantities of interest — gradation.

a. Level 0: Model outputs are tangential to the decision and not expressed in design or test metrics.

b. Level 1: Outputs overlap qualitatively with design metrics but require major transformation and assumptions for use.

c. Level 3: Outputs are directly expressed in the same units and boundary conditions as design verification tests.

d. Level 5: Outputs are identical to the acceptance metrics in scope, units, boundaries, and measurement definitions.

2. Device and decision problem

The device is a modular unilateral external fixator intended for stabilization of mid-diaphyseal tibial fractures. The frame comprises an anodized aluminum bar, adjustable stainless-steel clamps, and threaded Schanz pins (self-tapping cortical thread) affixed to the tibial diaphysis proximal and distal to a standardized fracture gap. The bar length and clamp positions are set to reflect typical surgical builds for midshaft tibial fixation. A double-stack of clamps per segment is possible but not used in the primary builds; the assessment emphasizes a single-bar, four-pin configuration that is widely adopted in clinical practice.

The decision problem is to support design verification and preclinical evidence with computed construct stiffness for axial compression and frontal-plane bending. Specifically, model outputs are used to: (1) screen candidate bar diameters, pin diameters, and clamp preloads for their influence on construct stiffness; (2) prioritize which configurations merit bench measurement; and (3) reduce rework in the design verification test matrix by anticipating boundary conditions with heightened sensitivity. The models are not used to demonstrate clinical performance or directly substitute for required mechanical testing; rather, they serve as decision aids within design controls.

Table 1: Representative device and test configuration parameters used for modeling and bench tests (not credibility factors).

Credibility factor	Level
Bar outer diameter / wall thickness	12 mm / 2.5 mm
Bar material (measured E)	Aluminum 6061-T6 (68.5 GPa measured; (
Schanz pin diameter / thread	5.0 mm / cortical thread; stainless steel 316L (199 GPa
Clamp torque (target)	6 N·m (measured ±0.2 N·m; applied wit
Pin spread (each segment)	46 mm center-to-center (proximal), 4
Bar–bone offset	35 mm (pin–bar centerline dis
Standardized gap	10 mm osteotomy gap in tibia s
Axial compression load	500 N quasi-static
Frontal-plane bending moment	7.5 N·m varus and valgus (applied at

A standard bench setup is assumed: a sawbone tibia surrogate with a midshaft osteotomy gap is mounted in a rigid test frame. For axial compression, load is applied collinearly with the anatomic axis. For frontal-plane bending, a mediolateral couple produces varus–valgus rotation about the gap. Measurements of frame displacement or rotation are used to compute linearized stiffness in units of N/mm for axial compression and N·mm/deg for frontal-plane bending. The same fixtures and definitions are replicated in silico to maintain alignment with design verification protocols.

Equivalency of input parameters — gradation.

a. Level 0: No mapping of device, specimen, or fixture properties to model inputs.

b. Level 1: Qualitative linkage of inputs; key dimensions and preloads are approximated without measurement.

c. Level 3: Dimensions and materials are measured; clamps and interfaces are represented with calibrated lumped parameters.

d. Level 5: All geometric, material, and interface parameters are measured or inferred from tightly controlled component tests, with uncertainty bounds propagated to the model.

3. Context of use (CoU): Use of model-predicted construct stiffness to support design verification and preclinical evidence for a modular unilateral external fixator; clinical performance is not directly inferred

The models are used to estimate construct stiffness under test-specific loading conditions that mirror design verification

Figure 1: Schematic of the unilateral tibial external fixator used in this study, showing bar, clamps, and four Schanz pins spanning a standardized diaphyseal gap; inset illustrates the bench fixtures for axial compression and frontal-plane bending.

and early preclinical assessments. Outputs from the models inform whether incremental changes to the bar diameter, clamp strategy, or pin size materially influence stiffness and whether a given configuration warrants bench testing. They also help determine which boundary conditions in axial compression and frontal-plane bending exhibit the largest changes in response to assembly and geometry, thereby optimizing the test matrix.

The CoU does not include predicting healing trajectories, evaluating patient-specific loading histories, or estimating complication risk. The models are device-centric; they abstract away muscular forces, gait variability, and in vivo soft-tissue constraints. Consequently, clinical effectiveness or safety is not inferred directly from the model results. Rather, the models function upstream of mandatory testing to refine design decisions and to make bench experimentation more efficient without replacing it.

The chosen CoU bounds model complexity. For example, the RB-Beam model deliberately reduces contact interfaces to linear springs and rigid links, facilitating rapid turnaround when many design permutations must be explored. The HF-Contact model brings in greater constitutive detail only where it materially affects the global compliance under the standardized fixtures defined for the bench.

Relevance of the quantities of interest — gradation.

a. Level 0: Outputs do not map to any design gate or verification criterion.

b. Level 2: Outputs partly map to verification criteria but omit key aspects of boundary conditions or units.

c. Level 4: Outputs match verification criteria in form and boundary conditions; minor differences exist in how measurements are defined.

d. Level 5: Outputs coincide exactly with the verification metrics, including measurement definitions, fixtures, and reporting units.

4. Model risk level and rationale: Medium model risk because predictions guide design iteration and bench test planning but are not the sole basis for regulatory clearance or clinical decisions; erroneous outputs are bounded by mandatory mechanical testing and design controls

A medium risk classification is justified by the role of the models in design controls. The outputs support prioritization of design iterations, selection of candidate builds, and configuration of bench test plans. Mechanical testing remains the arbiter of compliance with specifications, and no regulatory submission relies solely on computational results in this CoU. The consequences of incorrect predictions are mitigated by the requirement to demonstrate performance on physical fixtures; biases or errors are likely to be detected through test-to-model comparisons prior to any device release.

Given this risk posture, the tolerance for residual uncertainty is moderate. We accept a private 0–5 CI scale with acceptance at CI ≥ 3.0, reflecting that factors with imperfect evidence can be acceptable as long as no single weakness dominates decision making and downstream tests bound the remaining uncertainty. Higher CIs are sought where the models will be relied upon more heavily, such as pre-screening design options when substantial test resources are at stake.

Test samples — gradation.

a. Level 0: No relevant constructs are measured.

b. Level 2: Limited constructs are tested with uncertain assembly conditions and sparse repeats.

c. Level 3: A moderate number of constructs are tested with controlled assembly and documented measurement uncertainty.

d. Level 5: A large, diverse construct set is tested with rigorous control of assembly variables and full traceability.

5. Computational models: HF-Contact and RB-Beam (implicit analyses, pre- and post-processing workflows)

The HF-Contact model consists of a detailed assembly derived from device CAD and metrology. The bar is meshed with second-order brick elements with reduced integration to balance accuracy and computational cost. Clamps and pin shanks are modeled with solid elements, while pin threads in the cortical segment are represented with conformal surfaces that transmit shear and normal traction via frictional contact laws. Bar–clamp and pin–clamp interfaces include tangential contact with regularized Coulomb friction and augmented Lagrange enforcement in the normal direction. The tibial diaphyseal surrogate is represented as an orthotropic elastic material in the cortical region (E_longitudinal 17 GPa, E_transverse 11 GPa, G_LT 3.5 GPa; Poisson's ν_LT 0.33) with a cancellous fill modeled as a low-modulus core to stabilize computation without materially affecting global stiffness. Pins engage the cortical shell with a seating pretension produced by a simplified torque-to-axial force relation; sensitivity to this pretension is included in post-processing. The solver operates in a static step with nonlinear geometry activated; arc-length control is not required due to monotonic loading, but line search and automatic stabilization damping of 0.5% critical are available and disabled by default for baseline runs.

The RB-Beam model uses Timoshenko beam elements for the bar and pin shafts and discrete springs at the joints to emulate clamp and interface compliance. Pin–cortex interaction is captured by an axial slip spring and a torsional spring representing thread engagement compliance. Bar–clamp interfaces are constructed with rotational springs about the bar axis and lateral translational springs calibrated from component tests. Rigid connectors enforce idealized alignment between beam centrelines and clamp reference frames. Small-strain, small-rotation kinematics are assumed, and the system is solved by a linear implicit static method. The model is assembled parametrically, enabling rapid exploration of bar diameter, pin diameter, and bar–bone offset. Governing outputs are nodal displacements and relative rotations at the osteotomy plane under the prescribed loads.

For both models, pre-processing automates geometry parameterization, mesh generation or beam-element instantiation, contact pair assignment (HF-Contact), and batch creation of load cases. Post-processing extracts force–displacement and moment–rotation curves, fits linear stiffness over a 10–100% load window for repeatability, and computes reported stiffness metrics in N/mm (axial) and N·mm/deg (bending). The same kinematic references used in bench measurements are implemented in analysis scripts to ensure traceability from raw solver outputs to reported QoIs.

Numerical solver error — gradation.

a.
Level 0: No check of equilibrium residuals or constraint satisfaction.

b.
Level 2: Residuals monitored but not tied to convergence tolerances linked to QoIs.

c.
Level 3: Residuals, contact closure, and constraint violations are bounded to levels shown not to change QoIs beyond set tolerances.

d.
Level 5: Multiple convergence controls (force, displacement, work) and path checks are used; QoIs are unchanged across tightened tolerances and alternative solution controls.

6. Mechanisms of interest: Axial compression and frontal-plane bending

Two loading mechanisms are examined. Axial compression applies a collinear force through fixtures aligned with the tibial diaphyseal axis, producing nearly uniform compressive loading across the bar and through the pin assemblies. This load path primarily probes the vertical compliance of the bar–clamp stack and the axial slip at the pin–cortex interfaces, with relatively small contributions from rotational freedoms. It is sensitive to the effective axial stiffness of pins and the bar, and to clamp joint seating.

Frontal-plane bending imposes a mediolateral couple that causes varus–valgus rotation about the fracture gap. Under this mechanism, the bar behaves as a laterally loaded beam segment with boundary conditions dictated by clamp flexibility and the pinned cortices. The load path reveals the rotational and lateral translational compliance of joints and highlights any asymmetry in pin spread or bar–bone offset. Differences in the fidelity of clamp and interface modeling have a larger influence under this mechanism because joint rotations and slips contribute strongly to the frame response.

Test samples — gradation.

a.
Level 0: No mechanism-specific testing.

b.
Level 2: Single mechanism tested with few replicates and uncontrolled alignment.

c.
Level 3: Both mechanisms tested with controlled fixtures and repeated assemblies.

d.
Level 5: Extensive mechanism-by-mechanism testing with randomized assemblies, calibrated fixtures, and comprehensive uncertainty analysis.

7. Quantities of interest and their relevance to the decision

The primary outputs are linearized construct stiffness under standardized loads: axial stiffness in N/mm from the slope of the load–displacement response over the 50–500 N interval and rotational stiffness in N·mm/deg from the slope of the moment–angle response over the 1–7.5 N·m interval in frontal-plane bending. These quantities are extracted at reference locations and axes matching the bench fixtures and gauge definitions. For axial compression, the displacement is taken at the distal fixture relative to the proximal fixation frame; for bending, the relative varus–valgus rotation about the osteotomy mid-plane is computed from fixture-mounted reference triads.

These outputs map directly to design verification criteria employed in our internal test protocols, both in form and in reporting practice. Acceptance specifications are stated in identical units and under the same fixtures. Because the models predict stiffness under those fixtures, design iteration and test planning can be carried out without reinterpreting or transforming outputs. The capability to calculate stiffness across configurations allows rapid identification of combinations that are likely to succeed or fail verification tests, thereby focusing bench resources. When paired with physical measurements, the outputs also enable straightforward calculation of prediction error margins to prioritize additional testing where discrepancies are largest.

Relevance of the quantities of interest — gradation.

a.
Level 0: Output units and fixtures differ from those used in decisions.

b.
Level 1: Qualitative overlap with decision metrics; major reinterpretation needed.

c.
Level 3: Same units and similar fixtures; minor reinterpretation required.

d.
Level 5: Exact match to decision metrics, including load paths, fixtures, and reporting conventions.

8. Equivalency of input parameters between models, physical tests, and device configuration

The models and bench fixtures share the same device geometry and hardware settings to the extent practicable. Device CAD is reconciled with metrology on manufactured components. Bar outer diameter and wall thickness are confirmed by optical and micrometer measurements; the elastic modulus of the bar alloy is obtained by tensile coupon testing. Pins are measured for straightness, diameter, and thread geometry, and the measured elastic modulus of the alloy is used in both models. Clamp screws are torqued to a target value in bench assemblies using a calibrated torque wrench. In the HF-Contact model, clamp preloads are represented by contact seating and friction at the bar–clamp and pin–clamp interfaces; in RB-Beam, clamp compliance is captured by tuned rotational and translational springs.

The surrogate tibia geometry is reproduced from the supplier's CAD, with the osteotomy modeled as a 10 mm uniform gap. In HF-Contact, the cortical shell and cancellous core are represented to stabilize computation and to route load through the pin–cortex region in a manner consistent with physical specimens. In RB-Beam, the bone serves primarily as a kinematic reference for pin anchorage, with thread engagement represented via lumped stiffness elements at pin locations. The bench fixtures' stiffness is selected to be orders of magnitude higher than the frame stiffness; residual flexibility of fixtures is verified experimentally and neglected in both models as it is small compared to frame compliance.

Interface properties are calibrated from component-level tests where direct measurement is not possible. For example, the effective rotational compliance of a single clamp at the bar interface is measured by applying a known couple and recording angular displacement, generating an average of 1500 N·mm/deg at 6 N·m screw torque across five clamps. This value seeds the corresponding rotational spring in RB-Beam and informs the friction parameters in HF-Contact, ensuring that clamp behavior in the model aligns with the observed joint response under similar loads.

Equivalency of input parameters — gradation.

a.
Level 0: Inputs chosen from catalog values without measurement or calibration.

b.
Level 2: Major dimensions measured; interfaces assigned typical literature values without calibration.

c.
Level 3: Most dimensions and materials measured; interfaces calibrated from component tests; remaining gaps documented.

d.
Level 5: All relevant dimensions, materials, interface behaviors, and preloads measured or calibrated with uncertainty propagation to predictions.

9. Numerical code verification

We exercised benchmark problems to check that the software infrastructure and element formulations used in both models produce correct solutions for canonical cases. Linear elastic checks include a cantilever beam under end load and a three-point bending plate, both with closed-form solutions. For HF-Contact, which uses solid elements and frictional contact, we implemented a cylinder-on-plane normal contact problem and a sphere indentation problem to compare normal pressures and deformations to Hertzian predictions in the small-deformation limit.

For RB-Beam, we verified beam element stiffness and shear correction in Timoshenko theory using standard test cases: simply supported and clamped beams with uniform loads and end moments, verifying deflections and rotations to within 0.5% of analytical values when element aspect ratios were maintained within recommended limits. We also verified the assembly of springs and rigid connectors by constructing a small portal frame with known lateral stiffness and rotation under an applied couple; the model reproduced the expected compliance within 0.6% across a series of spring stiffness values spanning three decades.

Within HF-Contact, contact enforcement was verified by matching normal approach and contact pressure to analytical predictions for smooth convex bodies at low loads (small strains), giving $<1.2\%$ relative error at the finest mesh density. Frictional tangential response was compared to Cattaneo–Mindlin behavior qualitatively through load–unload loops at low slip; the observed stick–slip transition in the code was consistent with expectations. These checks do not assess model form appropriateness for the fixator but establish that the employed elements and contact routines behave as intended for the classes of problems they are asked to solve.

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

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

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

Numerical code verification — gradation.

a. Level 0: No benchmark or analytic checks performed.

b. Level 2: A few basic linear benchmarks exercised; no contact or nonlinear checks.

c. Level 3: Linear benchmarks and selected nonlinear/contact benchmarks run with errors reported.

d. Level 5: Extensive benchmark suite covering linear, nonlinear, and contact problems with quantified errors and cross-code comparisons.

10. Numerical solver error assessment for implicit static solutions

HF-Contact uses an implicit static solver with nonlinear geometry and augmented Lagrange contact. Convergence is tracked via force and displacement norms, with tolerances tightened until further reductions do not change the QoIs beyond pre-specified thresholds. Load increments are applied in 20 uniform steps to the target load in axial compression and 25 steps to the target couple in bending. At each increment, we verify that the ratio of the residual force norm to the external load norm falls below 10^-8 and that the displacement correction norm stabilizes. Contact penetration is monitored as the maximum normal approach at the pin–cortex interface and kept below 3 μm at the final increments. The line search algorithm is enabled automatically if convergence stalls; in these runs it was not required.

RB-Beam, being linear under small-strain assumptions, is solved in a single step with a sparse direct solver. The residuals are at machine precision for the problem scales considered, and constraint equations enforced by rigid connectors are satisfied to within 10^-12 m or rad. Sensitivity to spring stiffness magnitudes is evaluated to avoid ill-conditioning; we found that using spring values at least two orders of magnitude below the stiffness of their connected beams avoids numerical dominance and ensures stable conditioning. The QoIs were unchanged at the third significant figure when spring stiffnesses were varied within a factor of two around their calibrated values.

We also performed solution control sensitivity checks for HF-Contact. Tightening the force residual tolerance by one order of magnitude and halving the maximum increment size led to changes in axial stiffness of 0.1% and in bending rotational stiffness of 0.2%. Alternative normal contact enforcement (pure penalty versus augmented Lagrange) produced differences of 0.3% in axial and 0.4% in bending stiffness metrics. These changes are below our discretization uncertainties and are therefore acceptable within this CoU.

Numerical solver error — gradation.

a. Level 0: Solver convergence not assessed.

b. Level 2: Convergence reported but not linked to impact on outputs.

c. Level 3: Convergence criteria and alternative solver controls explored; changes in outputs quantified.

d. Level 5: Multiple solution strategies exercised with unchanged outputs to within tighter-than-required tolerances.

11. Discretization error estimation and mesh convergence procedures

We prepared mesh families for each model and mechanism to estimate refinement uncertainty. For HF-Contact, three hexahedral meshes were generated with characteristic element sizes of approximately 2.5 mm, 1.7 mm, and 1.2 mm in the bar and clamp solids, with local refinement to 0.4 mm near pin–cortex contact patches. The resulting degrees of freedom were approximately 1.3 million (coarse), 2.9 million (medium), and 5.7 million (fine). For RB-Beam, bar and pin beams were discretized with 2, 5, and 10 elements per member, and the joints retained the same lumped parameters.

Richardson extrapolation was applied to the three-level sequences where monotonic convergence was observed, using an apparent order estimated from the data. For HF-Contact under axial compression, stiffness values for coarse, medium, and fine meshes were 303, 309, and 311 N/mm, respectively. The extrapolated infinite-resolution value was 312 N/mm with a Grid Convergence Index (GCI) on the fine mesh of 1.6% at a 95% confidence factor. For frontal-plane bending, rotational stiffnesses were 2120, 2140, and 2152 N·mm/deg, with an extrapolated value of 2158 N·mm/deg and a fine-mesh GCI of 2.4%.

For RB-Beam, axial stiffness was 291, 294, and 295 N/mm for 2, 5, and 10 elements per member, respectively, with an extrapolated value of 296 N/mm and a fine-mesh GCI of 0.7%. Frontal-plane rotational stiffness was 2060, 2090, and 2100 N·mm/deg, with an extrapolated value of 2104 N·mm/deg and a fine-mesh GCI of 1.1%. These refinement procedures were repeated for both mechanisms to ensure that the discretization choices do not mask or exaggerate differences between configurations. For HF-Contact, contact patch refinement controlled variation in local stresses but had

only minor effects on global stiffness once the patch was resolved to sub-millimeter scale.
Discretization error — gradation.

a.
Level 0: Single mesh with no refinement study.

b.
Level 2: Two-mesh comparison without extrapolation or confidence assessment.

c.
Level 3: Three-level refinement with monotonic convergence and reported uncertainty bounds.

d.
Level 5: Three or more refinement levels with convergence proof, extrapolation, confidence intervals, and sensitivity to localized refinement at critical regions.

12. Test samples and loading configurations for mechanism-specific comparisons

We constructed eight physical frames for each mechanism. Five were repeated assemblies of the same parts built by two technicians across separate days to sample assembly variability; three were duplicates of the manufactured hardware to capture part-to-part variability. All assemblies followed a detailed work instruction specifying pin spacing, bar–bone offset, clamp torque, and fixture alignment. Torque application was verified with a calibrated digital torque wrench; final torque values were within ±0.2 N·m of the 6 N·m target. Pin spread was verified with calipers to within ±0.5 mm. Fixture alignment was checked by dial indicator to ensure axial alignment within ±0.3°, and bending fixture offsets were centered to within ±0.2 mm.

For axial compression, a 500 N load was applied in displacement control at 10 N/s, and displacements were recorded by a 1 μm-resolution LVDT. Stiffness was computed as the slope of the least-squares line between 50 N and 500 N to avoid seating artifacts at very low load. The mean axial stiffness across eight builds was 302 N/mm with a standard deviation of 18 N/mm, giving a coefficient of variation of 6.0%. For frontal-plane bending, a 7.5 N·m moment was applied in varus and valgus; the varus–valgus rotation about the osteotomy was measured by a digital inclinometer at the distal fixture. Rotational stiffness was computed as the slope of the moment–angle curve over 1–7.5 N·m; the mean was 2200 N·mm/deg with a standard deviation of 130 N·mm/deg.

Measurement system analysis included repeatability and reproducibility checks. The LVDT showed 0.8% repeatability error at 500 N; the inclinometer showed 0.6% repeatability at 7.5 N·m. Between-operator reproducibility added 0.5% for both instruments. Combined measurement uncertainty remained below 1.5% for both mechanisms. Environmental effects were minimized by conducting tests at 22 ± 1 °C and 45 ± 5% relative humidity. No specimen showed evidence of plastic deformation or slippage during testing, and all fixtures exceeded 10 times the frame stiffness by independent verification, supporting the assumption of rigid boundary conditions in the models.
Test samples — gradation.

a.
Level 0: No physical tests of the target constructs or mechanisms.

b.
Level 2: Minimal tests with uncontrolled assembly variables and unknown measurement error.

c.
Level 3: A moderate set of tests with controlled variables and documented measurement uncertainty.

d.
Level 5: Robust set of tests with both assembly and part-to-part variability sampled, instrument calibration, and environmental control.

13. Software quality assurance summary

Analyses were executed using maintained versions of commercial FEA software with standard update and patch policies; in-house scripts for pre- and post-processing underwent peer review prior to use. Version control and issue tracking were in place for model templates and automation scripts. Broader organizational processes for software lifecycle management follow internal SOPs appropriate for engineering tools.

14. Scoring rubric: 0–5 Credibility Index for each factor and model–mechanism pair, acceptance threshold for medium risk

We score each credibility factor on a private 0–5 Credibility Index (CI) scale with acceptance at CI ≥ 3.0 for the declared medium model risk. The scale is ordinal, where 0 denotes absent evidence, 1 denotes minimal qualitative support, 2 denotes partial quantitative support with notable gaps, 3 denotes adequate quantitative support aligned to the CoU, 4 denotes strong quantitative support with minor residual gaps, and 5 denotes comprehensive, mechanism-specific support with quantified uncertainties and cross-checks. Scores are assigned per model and per mechanism to reflect differences in load paths and the relevance of specific checks.

To maintain transparency, we anchor each score to specific evidence and numbers, as reported in subsequent sections. The acceptance threshold is justified by the presence of mandatory bench tests and design controls that bound residual uncertainty for this CoU. Factors with inadequate scores would trigger targeted mitigation prior to relying on model outputs for design decisions or test planning.
Discretization error — gradation.

a.
Level 0: No refinement or uncertainty quantification.

b.
Level 2: Two-level refinement without error estimation.

c.
Level 3: Three-level refinement with estimated order and uncertainty bounds for global QoIs.

d.
Level 5: Three-plus levels, localized refinement at

stressors, and formal uncertainty bounds below decision thresholds.

15. Factor scores by model–mechanism pair (0–5 CI): consolidated findings

Mesh studies showed that the most refined HF-Contact meshes yielded 1.6% uncertainty in axial stiffness and 2.4% in rotational stiffness for frontal-plane bending, based on Richardson extrapolation and GCI calculations. The RB-Beam refinement sequence converged faster in terms of global compliance, with 0.7% and 1.1% uncertainty for axial and bending stiffness, respectively, at 10 elements per member. These results indicate that the discretization choices do not materially bias the QoIs within the decision tolerances adopted for this CoU.

Mapping of device and fixture characteristics to model inputs was tight in both models but more literal in HF-Contact. Measured bar modulus (68.5 GPa) and geometric dimensions were used directly, and clamp joint behavior was inferred from component tests. In HF-Contact, the difference between measured and modeled bar bending stiffness was held within 2.2%, and clamp rotational response was within 3.4% of the mean of component tests. In RB-Beam, spring values tuned to match component-level torsional response reached within 5.0% of measured values, and beam properties reconstructed the measured bar bending stiffness within 1.6%. Effective pin–cortex engagement length was set at 22 mm based on surrogate sectioning; the resulting axial slip stiffness in RB-Beam, 55 kN/mm, reproduced observed load–displacement response within 4.7% under isolated pin loading.

Checks of the underlying formulations reproduced canonical solutions. Linear beam and plate problems matched analytic solutions within 0.5% across both models' element sets. For HF-Contact, the small-deformation Hertzian contact cases agreed within 1.2% on the finest mesh for normal pressure and approach; frictional tangential response showed the expected transition behavior under load–unload cycles. These checks support confidence that the software primitives perform as intended in the regimes exercised by the fixator analyses.

Solution behavior was well controlled. In HF-Contact, the ratio of residual to applied force norm fell below 10^-8 at the final increments, and contact penetration at the pin–cortex interface remained below 3 µm. Tightening solver tolerances by an order of magnitude and halving the maximum increment size changed axial stiffness by 0.1% and bending stiffness by 0.2%. Switching normal contact enforcement from augmented Lagrange to penalty changed stiffness by ≤0.4%. In RB-Beam, which solves linearly in one step, constraints were satisfied to within 10^-12 and QoIs were unchanged to three significant figures when spring values were perturbed by a factor of two. These results indicate negligible influence of solution controls on the reported stiffnesses.

The reported outputs correspond exactly to the metrics used in design verification, expressed in N/mm and N·mm/deg under the same fixtures and load application points. Because they are the same quantities extracted from the same kinematic definitions, there is no need for transformation or reinterpretation when moving between model predictions and bench acceptance criteria. This alignment enables direct comparison and prioritization of builds for testing.

The bench dataset comprised eight constructs per mechanism, spanning repeated assemblies and manufactured duplicates, built under controlled torque and alignment. The axial stiffness mean and standard deviation were 302 ± 18 N/mm, and the frontal-plane rotational stiffness was 2200 ± 130 N·mm/deg. Instrumentation repeatability and reproducibility together were below 1.5% for both mechanisms. This breadth and control support credible mechanism-specific comparisons and constrained estimation of prediction error.

With these inputs and controls in place, the HF-Contact model predicted an axial stiffness of 310 N/mm and a frontal-plane rotational stiffness of 2150 N·mm/deg for the reference configuration. The RB-Beam model predicted 295 N/mm and 2100 N·mm/deg, respectively. Relative to test means, the HF-Contact predictions deviated by 2.6% (axial) and 2.3% (bending), while RB-Beam predictions deviated by 2.3% (axial) and 4.5% (bending). All deviations were within the observed spread of bench measurements and within the refinement uncertainties reported.

Together, these findings support CI scores at or above the acceptance threshold for all factors across both mechanisms and both models. HF-Contact attains higher scores for input mapping and solution behavior due to its explicit treatment of contact and joint seating, whereas RB-Beam attains higher scores for refinement efficiency due to its reduced-order nature. The alignment of QoIs with the decision needs and the availability of mechanism-specific bench data underpin high scores in those domains for both models.
Numerical code verification — gradation.

a.
Level 0: No evidence of code-oriented checks.

b.
Level 2: Limited checks with qualitative comparisons.

c.
Level 3: Quantified comparisons to analytic solutions for relevant primitives.

d.
Level 5: Quantified comparisons including contact, with error budgets tied to model QoIs.

16. Credibility summary table – HF-Contact

Scores for HF-Contact reflect strong support from mesh refinement, tight mapping of inputs, robust solution controls for contact-rich assemblies, direct QoI alignment with design verification, and an adequate bench corpus per mechanism. The basis lines summarize the evidence with the same numbers discussed in the consolidated findings.

17. Credibility summary table – RB-Beam

Scores for RB-Beam reflect excellent refinement efficiency, good mapping of inputs with calibrated springs, straightforward linear solution behavior, direct QoI alignment with verification metrics, and the same bench dataset for comparison. Reduced scores in input mapping for frontal-plane bending reflect the limitations of lumped representations in capturing joint nuances under lateral loading.

18. Discussion and implications for the stated CoU

The comparative credibility assessment indicates that both HF-Contact and RB-Beam are suitable for the stated CoU: informing design iteration and bench test planning for a modular unilateral tibial external fixator. The analyses demonstrate that under the standardized fixtures and measurement definitions, the output stiffnesses from both models align closely with bench results and are stable with respect to numerical choices. This creates a dependable basis for decisions about bar diameter, pin selection, clamp torque strategy, and fixture setups when allocating test resources.

The high-fidelity model's explicit treatment of contact and interface friction allows more nuanced exploration of assembly effects and sensitivity to clamp torque or pin seating. For example, when clamp torque is varied from 4 to 8 N·m in HF-Contact, the axial stiffness increased by 6.5% and bending stiffness by 8.3%, revealing a practical range over which assembly practice can influence outcomes. RB-Beam can represent such effects only through adjustments to lumped spring values, which is adequate for screening but less predictive if joint behavior departs from idealized rotational and translational compliance. As a result, while RB-Beam achieved slightly better refinement efficiency and perfect linear solver behavior, HF-Contact better captures the mechanisms that most affect lateral response.

Under axial compression, both models approximate the bench data well, with RB-Beam within 2.3% and HF-Contact within 2.6% of the test mean. The governing load path in axial compression is dominated by bar and pin axial stiffness, with relatively smaller contributions from joint rotation or slip, which explains why the reduced-order representation performs strongly. In frontal-plane bending, HF-Contact's explicit joint representation produces predictions closer to test means (2.3% deviation) than RB-Beam (4.5% deviation), consistent with the higher sensitivity of lateral response to interface details. The discrepancy is still within the observed test spread, but it suggests that HF-Contact is the preferred basis for final verification predictions when lateral stability is critical.

The numerical evidence is sufficiently strong to meet the acceptance threshold for all factors. Mesh and element choices were shown not to dominate the results; solver behaviors did not influence QoIs beyond tenths of a percent. Code-oriented checks offer confidence in underlying formulations across linear, nonlinear, and contact behaviors. The mapping from physical configuration to model parameters is carefully constructed, with calibrated interfaces; where simplifications exist in RB-Beam, they are transparent and bounded by comparisons to component tests and the full-assembly bench results. The bench dataset is of moderate size with controlled assembly variables, providing a reliable reference for mechanism-specific comparisons in this CoU.

Practically, we recommend a staged use of the models. Early in design, RB-Beam can evaluate the influence of bar diameter (e.g., 10–14 mm), pin choice (4–6 mm), and bar–bone offset (25–45 mm) quickly across a grid of options, filtering out combinations that are unlikely to meet stiffness targets. For shortlisted configurations, HF-Contact should then be applied to confirm axial and lateral stiffness predictions under the exact fixtures used for verification, including sensitivity to clamp torque and pin seating. This two-model approach balances speed and detail, and it leverages complementary strengths established by the credibility assessment.

Limitations include the reliance on a tibial surrogate rather than cadaveric bone in bench data and the focus on a single reference configuration for detailed numerical studies. Future work should extend the credibility assessment to alternative frame geometries, double-stacked clamps, and multi-bar constructs. Additional component tests could refine the mapping from clamp torque to joint stiffness under multi-axial loading. Finally, while software lifecycle processes are in place for the tools used, formal quality assurance not specific to these models was not the subject of this assessment.

Equivalency of input parameters — gradation.

a. Level 0: Unmeasured or assumed inputs dominate.

b. Level 2: Some measurements; key interfaces remain assumed.

c. Level 3: Calibrated interfaces and measured materials for the reference builds.

d. Level 5: Calibrated and measured inputs across the intended configuration space with uncertainty propagation.

19. Conclusions

Under ASME V&V 40 with a declared medium model risk and a private 0–5 CI scale, both HF-Contact and RB-Beam achieved acceptable credibility for predicting construct stiffness of a modular unilateral tibial external fixator under axial compression and frontal-plane bending. HF-Contact offers higher-fidelity representation of joint and contact behaviors, yielding closer agreement to bench data in lateral response and enabling sensitivity analyses tied to assembly practice. RB-Beam provides rapid, reliable estimates for axial stiffness and sufficiently accurate lateral stiffness for screening, with exceptional refinement efficiency and trivial solver errors. Both models benefit from having QoIs identical to design verification metrics and from a controlled, mechanism-specific test dataset.

For this CoU, we recommend deploying RB-Beam for early design exploration and HF-Contact for final verification predictions and detailed sensitivity analyses, all under the umbrella of mandatory bench testing. The factor-by-factor scores justify this combined strategy and provide a transparent

record of the evidence base. Extending the credibility assessment to additional configurations, enhanced component-level interface testing, and broader specimen sets will further strengthen the basis for using these models in future design programs.
Discretization error — gradation.

a.
Level 0: No quantification of mesh-induced uncertainty.

b.
Level 2: Partial studies without confidence bounds.

c.
Level 3: Mechanism-specific refinement with uncertainty estimates below observed test variability.

d.
Level 5: Refinement uncertainties shown to be negligible relative to decision thresholds across all mechanisms.

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Table 2: Credibility assessment summary for HF-Contact on a 0–5 Credibility Index (CI) scale (acceptance at CI ≥ 3.0).

Credibility factor	Level	Basis
Discretization error - HF-Contact - Axial compression	4	Three-level mesh study gave 303/309/311 N/mm with extrapolated 312 N/mm; fine-mesh GCI 1.6%.
Discretization error - HF-Contact - Frontal-plane bending	4	Rotational stiffness 2120/2140/2152 N·mm/deg; extrapolated 2158 N·mm/deg; fine-mesh GCI 2.4%.
Equivalency of input parameters - HF-Contact - Axial compression	4	Measured bar E 68.5 GPa; modeled 69.0 GPa (2.2% EI diff); clamp response within 3.4% of component tests.
Equivalency of input parameters - HF-Contact - Frontal-plane bending	4	Pin–cortex seating and clamp friction calibrated; global EI and joint stiffness within 3.4% of measurements.
Numerical code verification - HF-Contact - Axial compression	4	Linear beams/plates within 0.5% of analytic; Hertzian contact approach and pressure within 1.2% on fine mesh.
Numerical code verification - HF-Contact - Frontal-plane bending	4	Contact and friction checks reproduced expected responses; errors ≤1.2% in small-deformation limit.
Numerical solver error - HF-Contact - Axial compression	4	Force residual ratio <1e-8; tightening tolerances changed stiffness by 0.1%; contact penetration <3 µm.
Numerical solver error - HF-Contact - Frontal-plane bending	4	Residual ratio <1e-8; alternative contact enforcement changed stiffness by ≤0.4%.
Relevance of the quantities of interest - HF-Contact - Axial compression	5	Output is axial stiffness in N/mm under the same fixture and load window as verification tests.
Relevance of the quantities of interest - HF-Contact - Frontal-plane bending	5	Output is rotational stiffness in N·mm/deg with identical fixture definitions to bench protocols.
Test samples - HF-Contact - Axial compression	4	Eight constructs; 302 ± 18 N/mm; controlled torque (±0.2 N·m) and alignment (±0.3°); CV 6.0%.
Test samples - HF-Contact - Frontal-plane bending	4	Eight constructs; 2200 ± 130 N·mm/deg; fixture centering ±0.2 mm; instrument uncertainty <1.5%.

Table 3: Credibility assessment summary for RB-Beam on a 0–5 Credibility Index (CI) scale (acceptance at CI ≥ 3.0).

Credibility factor	Level	Basis
Discretization error - RB-Beam - Axial compression	5	2/5/10 elements per member gave 291/294/295 N/mm; extrapolated 296 N/mm; fine-mesh GCI 0.7%.
Discretization error - RB-Beam - Frontal-plane bending	5	2060/2090/2100 N·mm/deg; extrapolated 2104 N·mm/deg; fine-mesh GCI 1.1%.
Equivalency of input parameters - RB-Beam - Axial compression	3	Beam EI matched within 1.6%; axial slip spring 55 kN/mm reproduced pin loading within 4.7%.
Equivalency of input parameters - RB-Beam - Frontal-plane bending	3	Clamp rotational spring 1500 N·mm/deg (measured 1450); rigid connectors idealize joints under lateral load.
Numerical code verification - RB-Beam - Axial compression	4	Beam theory checks within 0.5% analytic; spring–rigid connector portal frame within 0.6%.
Numerical code verification - RB-Beam - Frontal-plane bending	4	Linear portal frame and end-moment cases reproduced within 0.5–0.6%.
Numerical solver error - RB-Beam - Axial compression	5	Single-step linear solve; constraints satisfied to 1e-12; QoIs unchanged to three significant figures under spring perturbations.
Numerical solver error - RB-Beam - Frontal-plane bending	5	Machine-precision residuals; no sensitivity to solver controls; stable conditioning maintained.
Relevance of the quantities of interest - RB-Beam - Axial compression	5	Output is axial stiffness in N/mm using the same fixture and slope definition as bench tests.
Relevance of the quantities of interest - RB-Beam - Frontal-plane bending	5	Output is rotational stiffness in N·mm/deg with the same moment–angle definition as verification protocols.
Test samples - RB-Beam - Axial compression	4	Eight constructs with controlled assembly; 302 ± 18 N/mm; instrument uncertainty <1.5%.
Test samples - RB-Beam - Frontal-plane bending	4	Eight constructs; 2200 ± 130 N·mm/deg; alignment and centering documented; CV 5.9%.