Credibility Assessment of Implicit Finite Element Models for a Distal Radius Plate Under Screw Angulation

Eleni Markou, PhD[a], Rahul Menon, MS[b], Catherine D. Hart, PhD[c], Miguel Alvarez, MD[1], Samantha L. Pierce, PE[1]

[a] *Computational Orthopaedics Laboratory, OrthoSim Analytics, Boston, MA, USA,*
[b] *Department of Mechanical Engineering, Northeastern University, Boston, MA, USA,*
[c] *Department of Orthopaedic Surgery, Boston General Hospital, Boston, MA, USA,*

Abstract

Background: Volar locking plates for distal radius fractures are implanted with variable-angle screws that may approach the far cortex or lever the plate away from bone when angulated off-axis. Finite element analysis (FEA) can quantify angulation limits that preserve anatomical clearance and construct stability, but decisions that rely on computational results require an explicit account of credibility. Objective: To evaluate three static implicit finite element model forms for a volar plated distal radius across two clinically important mechanisms—(i) cortical breach at a distal screw tip and (ii) plate–bone lift-off that could jeopardize reduction—using a structured, ordinal 0–4 scale with descriptive anchors. Methods: We assessed three models: M1 (linear construct with bonded hardware), M2 (deformable plate with frictional interfaces), and M3 (thread-embedded nonlinear bone response with cohesive thread surrogate and trabecular plasticity). Each model predicts stress/strain fields, screw-tip proximity to cortex, and plate–bone gap as functions of screw angulation. We developed metrics for tip clearance and plate separation, performed numerical code checks, set solver controls and convergence criteria, executed mesh-refinement studies, and mapped validation tests to the intended application. We then graded eight factors across the model–mechanism space: development governance, mesh-induced error, model adequacy, solver implementation checks, step-to-step numerical accuracy, applicability of experiments to the intended decision, sensitivity/robustness of outputs, and controls on the software lifecycle. Findings: Across common boundary conditions and identical angulation sweeps, mesh refinement from 0.6 mm to 0.3 mm in the cortical shell altered minimum far-cortex tip clearance by 0.08 mm (2.6%) and peak plate stress by 3.1%, and further halving to 0.15 mm changed these by no more than 1.1%. Manufactured-solution and patch checks yielded 0.37% L2 displacement error with an observed convergence rate of 1.98 and sub-nanonewton contact/cohesive force balance. Residual norms at convergence were 1e-6 or lower, with contact penetrations below 0.5 micrometers and energy balance error within 0.2% across all load steps. Cadaveric constructs matched device geometry and screw patterns at 10°, 20°, and 30° angulations, with micro-CT clearance mapping aligned to post-processing within 0.1 mm. In a 120-point Latin hypercube spanning ±20% trabecular modulus and ±10% friction, the directionality of angulation effects on clearance and lift-off was preserved; the median clearance slope was 0.31 mm per 10° (interquartile range 0.27–0.36), and lift-off increased 22 μm per 10° (18–26). Representing threads explicitly versus bonding the shank changed a pullout surrogate by 14–18% in the trabecular region but altered tip proximity at 15° by only 0.2 mm. Toolchain controls included automated testing (172 unit and 31 integration checks) with 99–100% pass rates over the last three releases and zero critical findings in static analysis. Conclusions: For cortical breach and plate lift-off, M2 achieves higher overall confidence than M1, while M3 exhibits the most realistic bone–thread response but lower numerical stability and less targeted experimental mapping for the breach and lift-off readouts. The assessment identifies specific shortfalls—particularly in model adequacy for M1 at larger angulations and in the experimental alignment and numerical stability for M3—that preclude adoption at this time. Decision: Not accepted.

Keywords: distal radius, computational credibility, screw angulation

1. Introduction

Locked volar plates are widely implanted for unstable distal radius fractures, enabling fixed-angle, subchondral support with polyaxial screws that can be directed to capture specific fragments. Angulation freedom in these systems comes with risks: a distal screw that advances too close to the far cortex can breach and injure adjacent soft tissue, and off-axis locking can lever the plate away from the volar cortex, compromising reduction and increasing motion at the fracture. As such, product teams and clinicians seek quantitative limits that ensure screws remain within a safe proximity to the far cortex while the plate remains apposed under given loading and bone qualities.

Static implicit finite element analysis provides a framework to explore how screw angulation changes internal force transfer between plate, screws, and bone and how these changes affect two readouts of clinical interest: minimum cortical clearance at the screw tip and maximum plate–bone separation under physiologic-like loading. The computational question of interest is whether the modeled response across 10–30 degrees of screw angulation predicts changes in these readouts with sufficient reliability to guide design rules and surgical technique recommendations for the specified plate.

The present work examines three finite element model forms that have become common in the orthopaedic device community for this class of constructs: a linearized bonded construct; a deformable, frictional construct; and a thread-sensitive, nonlinear bone response construct using an equivalent cohesive representation of the helical thread with elasto-plastic trabecular response. We assess their credibility against a structured set of considerations tailored to the distal radius plate use context and report model–mechanism scores on an ordinal 0–4 scale, where higher values indicate stronger support.

Two mechanisms anchor the analysis. First, a distal screw's proximity to the far cortex as angulation increases determines the risk of cortex breach or near-breach that could threaten flexor tendons and neurovascular structures. Second, plate–bone lift-off as angulation increases signals the potential for loss of reduction and elevated interfragmentary motion. We define readouts to quantify these mechanisms, develop and verify numerical procedures, align experimental activities to the intended application, and probe robustness across material and interface variations.

To keep the assessment usable, we separate numerical implementation evidence from experimental mapping to the intended use, use a single, ordinal scale to grade each consideration for each model–mechanism pair, and print one model per matrix to preserve readability, reflecting how practitioners consume credibility summaries in real development settings.

Relevance of the validation activities to the intended application — gradation.

a.
No experimental constructs or loading reflect the clinical device or its boundary conditions; metrics are surrogate-only.

b.
Some geometry or load similarity exists, but alignment on screw patterns, angulations, or readouts is partial.

c.
Construct geometry, screw patterns, and angulations are matched; primary readouts are measured with known uncertainty.

d.
End-to-end mapping from surgical configuration to lab measurement to simulation post-processing is demonstrated with quantified alignment error and pre-specified acceptance limits.

2. Device Description and Computational Scope

The device under consideration is a volar distal radius plate with variable-angle locking technology and a cluster of four distal threaded holes designed to accept 2.4–2.7 mm screws. The plate footprint spans 47 mm in length with a 17 mm distal width and a 2.2 mm nominal thickness in the shaft region, thickening to 2.6 mm in the distal segment. Screw trajectories are nominally orthogonal to the distal plate at 0 degrees and allowed to angulate up to ±15 degrees relative to the nominal axis within the locking feature geometry. Plates are manufactured from Ti-6Al-4V ELI with a specified yield strength of 795 MPa and an elastic modulus of 110 GPa; cortical bone is represented as an orthotropic shell 1.2–1.6 mm thick overlying a trabecular core with apparent density 0.20–0.35 g/cm3 for the cadaveric specimens used in the associated experiments.

We simulate a distal simple transverse fracture reduced and supported by the plate with two proximal locking screws in the shaft and a four-screw distal cluster placed to support the subchondral region. The ulna is not modeled. Boundary conditions reflect a pin-supported proximal radius with a distributed joint-reaction surrogate at the distal articular surface directed along the long axis (positive axial compression) with a superimposed palmar bending moment. Loads span 100–150 N with a 2.0–2.5 N·m bending moment chosen to elicit tensile stresses on the volar aspect sufficient to probe lift-off without inducing wholesale loss of contact across the full distal footprint.

To align simulations and experiments, screw angulations were swept at 10, 20, and 30 degrees from the nominal axis for the most distal radial and ulnar holes in the cluster while other screws remained at 0 degrees. The same plate, screw diameters, and distal row pattern were used in both domains. The experimental metric of interest for the first mechanism was the minimum distance from the tip of the most distal screw to the far cortex, measured by high-resolution micro-CT after loading. For the second mechanism, the metric was the maximum plate–bone separation measured by digital image correlation markers bonded to the bone and visible through windows in the plate.

The cadaveric tests mirrored the intended clinical configuration and loading of the distal cluster: the same device geometry and screw patterns were deployed at 10, 20, and 30 degrees of angulation, and the micro-CT-based cortex clearance measurement mapped to the simulation post-processor with a 0.1 mm spatial alignment error after rigid registration of the distal fragment and plate.

Applicability of experiments to the modeled question — gradation.

a.
Setups and measures differ materially from the clinical question or the finite element outputs.

b.
Some elements match (e.g., plate or screw pattern), but load path or readouts diverge.

c.
Device geometry, screw positioning, and angulation schedules match; readouts are similar but not identical.

d.
Device, loading, angulations, and readouts are matched end-to-end, with measurement-to-simulation mapping quantified.

3. Models M1–M3: Formulations, Material Laws, and Boundary Conditions

M1: Linear Construct with Bonded Hardware. This model treats the plate as a rigid body to minimize degrees of freedom

Figure 1: Schematic of the volar distal radius plate with distal screw cluster showing nominal axes and off-axis angulation cones for the most distal radial and ulnar holes; inset depicts measurement definitions for minimum tip-to-cortex distance and maximum plate–bone separation used in both test and simulation.

Table 1: Device and loading parameters used in models and experiments

Credibility factor	Level	Basis
Plate material and thickness	—	Ti-6Al-4V ELI; 2.2 mm shaft thickness (2.6 mm distal)
Screw diameters and angulation limits	—	2.4–2.7 mm; ±15° locking feature nominal; simulated 10°, 20°, 30° for distal pair
Cortical shell representation	—	Orthotropic shell, 1.2–1.6 mm thickness (specimen-specific)
Trabecular core	—	Apparent density 0.20–0.35 g/cm3; elastic or elasto-plastic depending on model
Loads	—	Axial 100–150 N and palmar bending 2.0–2.5 N·m
Boundary conditions	—	Proximal pin support; distal articular surface distributed load
Primary mechanisms and readouts	—	Minimum screw-tip to far-cortex distance; maximum plate–bone separation

and attributes all deformation to the screws and bone. Bone is linear elastic and homogeneous within each compartment: cortical shell with orthotropic elasticity (E1 = 17.0 GPa, E2 = 12.0 GPa, E3 = 20.0 GPa; ν12 = 0.35, ν23 = 0.30; G12 = 3.8 GPa, G23 = 4.2 GPa) and trabecular core isotropic with modulus 350–650 MPa and Poisson's ratio 0.24. Screw–plate and screw–bone interfaces are tied, emulating locked engagement and a fully bonded interface within bone. Loads are applied as in the device description, and screw angulations are geometric transformations of the nominal axis within the locking cone. The post-processor computes stress/strain fields within bone, plate–bone gap via minimum normal separation of nodes along the plate underside and cortical surface, and the minimum tip-to-far-cortex distance along the screw axis.

M2: Deformable Plate with Frictional Interfaces. The plate is deformable with isotropic linear elasticity (E = 110 GPa, ν = 0.34), and the screw head–plate interface is modeled as a locking constraint with a compliant locking head approximation that accommodates off-axis engagement within the allowed cone. Screw shanks are tied to the screw head but interact with bone through surface-to-surface contact with Coulomb friction; friction coefficients are 0.30 on cortical interfaces and 0.20 within trabecular contacts. The cortical shell and trabecular core are as in M1 but partitioned to allow distinct contact with the screw shanks. Plate–bone interaction is contact with a low-friction interface (μ = 0.05) that allows lift-off when bending moments are applied. Outputs include interface normal and tangential resultants, local strain energy density in bone, screw-tip proximity, and separation under the plate as functions of angulation.

M3: Thread-Embedded Nonlinear Bone Response. To capture local thread engagement without the meshing complexity of helical geometry, M3 embeds an equivalent cohesive zone along the screw–trabecular interface with a traction–separation law calibrated to screw diameter, pitch, and average bone density. The law includes an initial elastic stiffness, peak traction reflecting shear strength, and a softening branch to mimic thread stripping; cortical engagement at the near cortex remains a no-penetration contact with friction. Trabecular bone follows an elasto-plastic model with isotropic hardening (yield at 6.5 MPa, tangent modulus 50 MPa, saturation at 12 MPa) and a damage variable that degrades stiffness upon plastic work accumulation. Plate–bone contact is retained as in M2. Computed outputs include surrogates for axial screw resistance and pullout (peak axial force transfer prior to softening), local plastic strain accumulation within trabecular bone, lift-off magnitude, and tip proximity.

Across all models, we discretize the cortical shell and plate with predominantly linear hexahedral and wedge elements to accommodate curvature, while screws are meshed with linear tetrahedra to ease conformal contact. The typical nominal edge length in the distal region is 0.3–0.6 mm for plate and cortex, with local refinements around screw tips. Load steps are advanced quasi-statically with Newton–Raphson iterations to prescribed residual and energy tolerances; M3 also uses line search and adaptive stabilization in softening regimes.

To provide an implementation-level check that model equations are correctly assembled and solved, a manufactured-solution benchmark on an orthotropic hollow cylinder under mixed boundary conditions was run using the same element types and contact algorithms. The resulting L2 displacement error was 0.37%, and the observed convergence order for linear elements was 1.98 under mesh refinement; contact and cohesive balance were verified by patch problems with net residual forces below 1e-10 N in equilibrium.

Model adequacy for the stated mechanisms — gradation.

a.
Simplifying assumptions obscure the mechanism of interest; key interactions are absent.

b.
Core interactions are present but simplified; sensitivity to omitted physics is not characterized.

c.
Interactions most relevant to the readouts are represented; expected biases are discussed and bounded.

d.
All interactions that materially affect the readouts are represented with calibrated or validated submodels within stated uncertainty.

4. Mechanisms: Definitions and Quantification Metrics

Cortical breach at the screw tip is operationally defined as the condition where the minimum distance from the screw tip to the far cortex is zero or negative after load application. The model readout is the minimum signed distance along the screw axis between the distal-most vertex of the screw and the triangulated far-cortex surface; positive values indicate clearance, zero indicates tangent contact, and negative indicates penetration. This metric is computed for each screw that is angulated off-axis and is plotted as a function of angulation and load. In the experiments, micro-CT provided a volumetric reconstruction of the distal radius segment, enabling a direct measurement of the same signed tip-to-cortex distance with a voxel size of 60 μm. A registration step aligned the plate and distal fragment from the CT volume to the finite element geometry to compare like with like.

Plate–bone lift-off is characterized as the maximum gap across the nominal contact region between the plate underside and the outer cortical surface after load application. Numerically, the underside of the plate is sampled by nodes on the inner plate surface, and the closest normal distance to the cortex is calculated; positive values correspond to separation. In the cadaveric study, high-contrast fiducial markers were placed on the bone and imaged through milled windows in the plate to estimate relative motion, which, after calibration, yields the peak separation along the volar cortex under the distal footprint.

To reduce confounding due to mesh dependence for a signed-distance metric, local refinements were applied in regions within 1.5 mm of screw tips and under the distal plate edge. The computational measurement routine was verified against analytic geometries for reference screws at known clearance to ensure numerical determinism independent of element face tessellation.

Refining cortical shell and plate elements from 0.6 mm to 0.3 mm at the distal cluster changed the minimum far-cortex tip clearance by 0.08 mm (2.6%) and the peak plate von Mises stress by 3.1%; halving again to 0.15 mm changed both quantities by no more than 1.1% across all angulations tested.

Across parameter variations chosen to reflect clinical spread—trabecular modulus ±20%, cortical shell thickness ±0.2 mm, friction coefficients ±10% around nominal values, and angulation spanning 10–30 degrees—the direction of the effect of angulation on clearance and lift-off did not switch. The median change in tip-to-cortex clearance was 0.31 mm per 10 degrees of angulation (IQR 0.27–0.36), and lift-off increased 22 μm per 10 degrees (IQR 18–26), indicating that although magnitudes shifted with tissue and interface parameters, the qualitative trends remained stable.

Mesh-induced error control — gradation.

a.
Single mesh, no study; metrics known to be mesh-sensitive are not localized.

b.
One refinement study in a subset of domains; change in key outputs is reported but not used to set target meshes.

c.
Systematic local refinement around sensitive features with reported change in readouts and rationale for chosen mesh sizes.

d.
Global and local refinement studies with extrapolation or estimator-based targets and monitoring of mesh quality metrics.

5. Numerical Code Verification and Software Quality Assurance

We employed crafted boundary conditions and known analytic fields to exercise the element formulations, contact resolution, and cohesive implementation used across M1–M3. Meshes spanned at least three characteristic sizes with consistent refinements to enable observation of order. Contact and cohesive interfaces were tested on ring shear and cylinder pullout patches to confirm that interface tractions balance and that solver residuals vanish at equilibrium independent of partitioning.

Tooling consistency was maintained by locked solver and mesher versions across all runs that contributed to the credibility assessment. The modeling scripts, pre-processing notebooks, and post-processing routines were held in a controlled repository with branch protection and automated checks. Test assets validated geometry import, partitioning, and contact pair assignment as stable under angular transformations. Build and test status were recorded at each merge to the protected branch, and trace links ensured that any pipeline failure was investigated before accepting new results into the assessment corpus.

While we emphasize numerical model performance here, we note that process-level controls for the software environment were planned in concert with modeling milestones to ensure that computational outputs were reproducible and that environment drift did not confound the assessment.

Implementation checks and quality controls — gradation.

a.
Ad hoc spot checks; no automated verification.

b.
Basic unit tests exist but do not cover contact or nonlinear subroutines.

c.
Automated tests cover core element routines, contact, and cohesion; failures block merges.

d.
Continuous integration with coverage targets; static analysis and periodic defect review inform release readiness.

6. Numerical Solver Error Controls and Convergence Criteria

All static analyses were run with a full Newton–Raphson iteration scheme with line search enabled for steps where contact engaged or disengaged. For M2 and M3, augmented Lagrangian contact was used with penalty updates to keep normal penetrations below micrometer scales, and a consistent tangent was assembled for frictional slip. The solver residual tolerance was set to 1e-6 in normalized form, with an energy norm assessment at the end of each step; if the energy imbalance exceeded 0.5%, the step was repeated with smaller increments and tightened contact stabilization.

To probe sensitivity to iteration controls, a subset of cases was repeated with residual tolerances relaxed by an order of magnitude and with line search disabled. We observed that disabling line search increased the number of iterations by 25–40% for contact-dominated steps in M2 and M3 and increased the likelihood of cutbacks in M3 near softening onset. The response of the bonded M1 model was nearly invariant to these settings, as expected.

The treatment of softening in M3 included viscous regularization with a characteristic time of 0.001 s in the quasi-static formulation to avoid snapback, coupled with a cap on the maximum damage increment per iteration. These settings were chosen after preliminary sweeps demonstrated that higher regularization biased peak force transfer noticeably, while lower values led to excessive cutbacks.

Step length control followed a conservative schedule for large angulations: initial steps at 5% of the load ramp increased geometrically to 25% for later steps once contact states stabilized. Residual histories were archived for all runs contributing to final scores.
Control of numerical solution accuracy — gradation.

a.
Default tolerances and step sizes; no sensitivity checks.

b.
Some tuning of tolerances; limited assessment of impact on outputs.

c.
Target tolerances established; sensitivity sweeps show small effect on readouts.

d.
Tolerances tied to output error targets; error indicators drive adaptive stepping with documented residual and balance histories.

7. Discretization Error Studies and Mesh-Refinement Strategy

We approached spatial resolution systematically, focusing effort where the readouts are most sensitive. The far-cortex proximity of a screw tip is a classical geometric sensitivity to local element size and face tessellation; we therefore performed nested h-refinements around the distal tips of the off-axis screws and under the distal plate footprint. The mesh families targeted element edge lengths of 0.6 mm, 0.3 mm, and 0.15 mm in refined regions while holding a coarser background to control cost. Element quality metrics, including aspect ratio and Jacobian determinants, were monitored to ensure that refinement did not introduce inverted or overly skewed elements in areas of strong curvature.

To cross-check whether mesh-bias in contact enforcement altered plate–bone lift-off, we constructed two alternative meshes with shifted node locations along the plate underside and repeated the 20-degree angulation case. The peak separation moved by less than 6 µm across these variants for M2 and by 9–12 µm for M3, consistent with contact formulations' sensitivity to local discretization. For M1, lift-off is constrained by bonded contact and is therefore identically zero by construction, making mesh adequacy for this readout moot.

We did not use extrapolation to a zero-size mesh because local constitutive nonlinearity in M3 and contact state changes in M2 and M3 introduce piecewise-smooth behavior. Instead, we set a target local element size of 0.3 mm in the distal region by requiring that a halving of the size cause no more than a 3% change in peak distal plate stress and no more than a 0.1 mm change in tip clearance at 20 degrees in M2; this target was then used consistently in all runs supporting the credibility matrices.
Spatial resolution sufficiency — gradation.

a.
No rationale for element sizes; no local refinement.

b.
Rationale based on rules of thumb; one refinement check on a key output.

c.
Local refinement concentrated around sensitive features with quantified change in outputs and a stated acceptance threshold.

d.
Refinement guided by estimators or extrapolation; mesh metrics tracked; acceptance thresholds pre-specified and met.

8. Model Form Justification and Assumption Audit

The three model forms are intended to bracket complexity and computational cost while anchoring two readouts. M1 enables rapid sweeps because it removes plate compliance and enforces perfect engagement between screws and the surrounding bone. It therefore serves as an upper-bound on construct stiffness and a lower-bound on plate–bone separation. Its use for cortical proximity relies on the assumption that, for the distal cluster and loads considered, plate flexibility and interface sliding make only second-order contributions to tip position relative to the far cortex. M1's obvious limitation is that it cannot produce lift-off, and it does not include load redistribution effects arising from differential frictional engagement among screws.

M2 relaxes these constraints by allowing the plate to flex and introducing slip at the screw–bone interface and plate–bone interface. The purpose is to capture the mechanism by which off-axis locking induces a bending moment in the distal segment of the plate and alters the load path through the screws. This mechanism directly impacts lift-off and indirectly modulates screw-tip position by allowing small screw reorientations and head-seat compliance. We retained linear elastic bone in M2 because the loads and deformations required to challenge fracture reduction are below levels that would produce widespread trabecular plasticity, and because the readouts are primarily geometric distances and separations rather than damage measures.

M3 is brought in to address cases where local thread engagement and trabecular yielding could influence the readouts, particularly in low-density metaphyseal bone or with high angulation that concentrates load on the distal thread flanks. The cohesive zone approximation allows the model to represent screw axial resistance and the onset of stripping without the meshing costs of helical threads. The price is added numerical stiffness nonlinearity and a need to calibrate cohesive parameters to density, which we performed using separate data not detailed here. While M3 can produce the same readouts as M2 and includes mechanisms M2 cannot, it introduces parameter dependencies that broaden output uncertainty.

We catalogued all assumptions in a structured audit, identifying which materially affect the readouts and which are expected to be benign. For example, neglecting the ulna is innocuous for the two readouts under the applied loads; treating cartilage as a homogeneous compressible layer is likewise innocuous because the load is applied as a distribution, not transmitted through conforming contact. In contrast, the choice to tie screw shanks to the bone in M1 is a first-order limiter on realism for lift-off, and plate rigidity in M1 increases confidence only for the cortical proximity readout when compared at the same angulation and load.

Alignment of simplifying assumptions with readouts — gradation.

a. Assumptions conflict with the physics of the readouts.

b. Assumptions are plausible but their impact on readouts is not discussed.

c. Assumptions are mapped to expected biases on the readouts with qualitative justification.

d. Assumptions are mapped and quantified for their impact on the readouts with bounds or compensating analyses.

9. Validation Activities and Their Relevance to the Intended Application

Cadaveric testing used fresh-frozen distal radii prepared with the same volar plate and screw set as in the computational models. Screws were placed in the same distal holes, and their angulations were set with jigs to target 10°, 20°, and 30° from the nominal axis. The shafts received two proximal locking screws at 0° to mirror the finite element models. Specimens were potted proximally and loaded in a servohydraulic frame to apply a compressive force and superimposed bending moment representing a resisted grip with palmar flexion. The plate–bone interface was imaged through plate windows to capture separation, and each specimen was micro-CT scanned post-test for a geometric reconstruction of the distal segment and screws.

FEA test cases were constructed to reflect the same position and angulation of screws, and the same load steps were applied. The closest point calculation for screw tip clearance used the CT-derived cortex surface after a rigid transformation registered the CT plate to the model plate, thereby ensuring that the measured minimum distance mapped to the modeled measure with a known residual error from registration.

Representing threads explicitly versus bonding the shank changed the pullout surrogate by 14–18% in trabecular regions while changing the screw-tip proximity at 15 degrees angulation by only 0.2 mm under the same loading, indicating that the detailed thread engagement mechanism is more critical for strength-like outcomes than for geometric proximity in the tested range of loads and angles.

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

$$\varepsilon_{rel} = \frac{\sum_{i=1}^{n} w_i x_i}{\sum_{i=1}^{n} w_i} \quad (2)$$

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

Experimental-to-simulation readout mapping — gradation.

a. Readouts differ and require surrogates without quantified linkage.

b. Readouts are similar and a qualitative mapping is provided.

c. Readouts are matched and mapping uncertainty is estimated.

d. Readouts are matched and mapping uncertainty is measured and incorporated in acceptance criteria.

10. Results Robustness: Parameter and Angulation Sensitivities

We sampled model inputs that plausibly vary across patients and surgical technique. For bone properties, trabecular modulus varied ±20% around nominal, and cortical thickness varied by ±0.2 mm to reflect anatomical spread. Friction coefficients at the screw–bone and plate–bone interfaces varied ±10% to emulate lubrication changes, surface finishing, and tissue hydration. Screw angulation was swept from 10° to 30° in 5° increments for the two distal screws in the cluster while holding the others at 0°. For M3, cohesive peak traction was varied by ±15% in accord with density scatter not captured by the apparent-density estimate.

The resulting surfaces of clearance and lift-off versus angle and property variations were analyzed for monotonicity with respect to angle and for the stability of slopes across the sampled space. For all three models, clearance decreased with angle and lift-off increased with angle across the sampled cases; slope distributions tightened for models that allowed interface slip and plate compliance, reflecting an improved load transfer mechanism representation. The strongest dispersion appeared in M3, consistent with its richer parameterization of trabecular yielding and damage.

As an additional check, we perturbed solver step sizes, residual tolerances, and line search settings in a subset of cases to ensure that qualitative trends did not depend on numerical control parameters. Trends were consistent across these perturbations, and the changes stayed within the expected bound for numerical noise under the stated tolerances.

Output stability under plausible input variation — gradation.

a. No sensitivity analysis; anecdotal checks only.

b. One-factor-at-a-time variations explored at nominal angulation.

c. Multi-parameter sampling (e.g., Latin hypercube) with trend analysis and dispersion reporting.

d. Global sensitivity with uncertainty propagation tied to input distributions and decision thresholds.

11. Development Process, Product Management, and Technical Reviews

Model planning was integrated with device development gates so that model maturation and decision needs were aligned. Requirements were captured before solution implementation, mapped to the readouts and mechanisms, and sequenced such that basic physics came online before parameterized sweeps. A configuration managed the plate geometry, mesh templates, and boundary conditions, with approvals required to alter any of these assets during the assessment phase.

Stakeholder checkpoints included design-focused discussions to reconcile modeling assumptions with the device features. Internal specialists in computational mechanics and in experimental testing coordinated to ensure that angulation jigs and loading configurations could be replicated in silico. Documentation encompassed model intent, limitations, and rationale for the chosen complexity in each of M1–M3.

A development technical review occurred after initial results from M2 to vet whether frictional interfaces were tuned appropriately and whether additional calibration data were needed for the cohesive approximation in M3. Notes from that session informed expanded sensitivities but did not alter the stated scope.

Governance of the modeling lifecycle — gradation.

a. No plan; model evolves ad hoc with undocumented changes.

b. High-level milestones exist; limited documentation of decisions.

c. Stage gates with documented decisions and change control on key assets.

d. Fully traceable lifecycle with independent reviews at major gates and impact assessment for any scope changes.

12. Use History and Prior Applications

Components of the modeling approach have been used previously in finite element analyses of volar plates for different fracture patterns, and the cohesive approach for thread engagement has appeared in studies of cancellous screw pullout in the proximal humerus and tibial metaphysis. These earlier applications informed parameter ranges and numerical stabilizations, but direct transposition is limited by anatomical and loading differences in the distal radius.

The software environment, including solver, mesher, and post-processing scripts, was maintained under version control with automated checks across the repository. The test suite comprised 172 unit tests and 31 integration tests executed on each protected-branch merge, with the last three releases recording pass rates of 100%, 100%, and 99%, and static analysis reporting zero critical defects.

Prior users have reported that mesh templates and contact settings developed for distal plates shorten setup time for metacarpal and olecranon constructs, though outside the present scope we did not enumerate those experiences into formal credibility evidence.

Controls on software lifecycle — gradation.

a. Tools and scripts not versioned; no automated checks.

b. Version control present; spot checks on scripts.

c. Automated unit and integration tests with gating for merges; periodic static analysis.

d. Continuous quality controls with coverage metrics, defect classification, and release audits.

13. Credibility Scoring Methodology (0–4 Scale) and Evidence Mapping

We used an integral 0–4 ordinal scale with descriptive anchors for each consideration. A 0 indicates no credible evidence for the intended decision, 1 indicates minimal evidence or significant mismatches that undermine use, 2 indicates partial support with material gaps or uncertainties, 3 indicates strong support with minor, bounded limitations, and 4 indicates very strong support with comprehensive evidence. The scale is private to this assessment and is intended to be interpretable by design and clinical stakeholders.

Evidence mapping followed a one-to-many approach: a single piece of evidence may support multiple model–mechanism pairs when it applies broadly (e.g., mesh sensitivity quantification), but each factor's decisive statement appears once in the prose, and tables restate that finding succinctly for each scored case. This structure prevents double counting and ensures that the reader can trace any score to the argument supporting it.

We present one table per model to keep each matrix to a readable size. Rows enumerate all eight considerations for each of the two mechanisms. The level column holds only the ordinal score, facilitating sorting or filtering by readers who may wish to compare, for example, model adequacy across the mechanisms. *Scoring transparency and traceability — gradation.*

a. Scores presented without explanation.

b. Narrative justification without clear mapping to scores.

c. Scores linked to specific findings and sections.

d. Scores linked to specific quantitative findings with location identifiers and consistent restatement.

14. Credibility Matrix for M1

M1 serves as a computationally efficient bound on construct stiffness and as a first-order indicator for screw-tip proximity under the given loads and geometries. Because interfaces are bonded and the plate is rigid, M1 cannot exhibit lift-off; accordingly, the assessment for the lift-off mechanism emphasizes model adequacy as a known limitation but considers other considerations such as numerical implementation and mesh-induced error where applicable. Evidence for code correctness, numerical controls, and applicability of the experimental setup runs across models; scores for these considerations reflect the same underlying findings but are interpreted within the context of M1's simplifying assumptions.

15. Credibility Matrix for M2

M2 introduces deformable plate behavior and frictional interfaces to capture the mechanisms of plate bending and interface slip that influence both cortical proximity and lift-off. Because M2 retains linear bone elasticity and does not incorporate explicit thread engagement, it represents an intermediate fidelity intended to improve realism for the two readouts without incurring the parameter and stability burdens of nonlinear bone response. The same global evidence for numerical implementation and experimental applicability applies here and is interpreted in light of M2's capability to represent both mechanisms in principle.

16. Credibility Matrix for M3

M3 enriches the representation of screw–bone engagement by embedding a cohesive zone and allowing trabecular plasticity and damage. This model captures phenomena that are likely to matter in low-density bone or at large angulation, such as local yielding near thread flanks and softening under sustained load. However, these features introduce additional numerical stiffness, parameter dependencies, and potential mesh sensitivity that must be balanced against the value they bring to the two readouts considered. The same numerical and experimental evidence applies to M3 but with attention to how nonlinearities affect solver performance and the alignment of laboratory measures with the outputs.

Because the experiments were not designed to observe the onset of thread stripping or measure local plastic dissipation, the mapping between experimental and modeled measures is less direct for M3 than for M2 regarding the two chosen readouts, especially for lift-off where plate compliance and interface slip dominate. We reflect that limitation in the scoring.

17. Discussion: Deficiencies, Elevation Strategies, and Next Steps

This assessment indicates that incorporating deformable plate behavior and frictional interfaces (M2) substantially improves alignment with the physical mechanisms underlying the two readouts of interest, relative to a bonded, rigid-plate abstraction (M1). The ability to transmit bending moments through the plate and to permit small slips at the screw–bone interface generates lift-off magnitudes and trends with angulation that match qualitative expectations from the bench and clinic. For cortical proximity, all models predict decreasing clearance with angle; the relative insensitivity of the tip-to-cortex metric to detailed thread mechanics under the studied loads and angles clarifies why a bonded abstraction may still be informative in that specific context, though our scores reflect its incapacity to produce lift-off by construction.

The nonlinear, thread-aware model (M3) has value for strength-like outcomes and for cases where distal threads in low-density bone might yield locally. For the present decision, however, its added nonlinearity does not map directly to the two readouts chosen for angulation guidance. The experimental activities were not designed to capture cohesive softening or trabecular plastic dissipation, and the readouts remain geometric distances and separations that are dominated by plate compliance and contact kinematics. The scoring thus acknowledges that

M3's additional physics are not leveraged by the available validation data for these readouts, and the associated numerical stiffness reduces solution margins without adding commensurate support for the decision at hand.

Several targeted elevation strategies emerge. First, for M1, replace the rigid-plate abstraction with a linear elastic plate while keeping bonded interfaces to retain computational efficiency; this would recover most bending kinematics at little cost and eliminate the structural impossibility of plate separation, improving the alignment of the model with the lift-off readout. Second, for M2, focus on measurement alignment by adding in situ measurements of screw head-seat compliance and plate underside pressure in the bench setup to validate interface tractions and the onset of separation; these would deepen the evidence for the mechanism most responsible for lift-off. Third, for M3, design an experiment specifically to observe local yielding and post-yield slip near the distal threads of off-axis screws—e.g., by incorporating digital volume correlation around the screw flanks during loading or by using instrumented screws to measure axial transfer under angulation—so that the cohesive and plasticity parameters are directly constrained for the angulated configuration.

Refining the confidence in numerical implementation and spatial resolution is comparatively straightforward. The h-refinement study already indicates that a 0.3 mm target local size near screw tips and under the distal plate keeps changes in key readouts within 3%; a confirmatory study at the 0.2 mm scale in a limited number of cases would compress remaining uncertainty further, particularly for M3 where softening localization can be sensitive to mesh. Solver control strategies could be strengthened for M3 by implementing an energy-based step accept/reject criterion tied to a target change in the cohesive damage variable, thereby formalizing the line search and cutback behavior in softening steps.

From a process standpoint, the modeling lifecycle executed in this study demonstrates the intended discipline for a design-facing computational program. The development followed a stage-gated plan with four formal milestones and two independent reviews, decision logs linked each requirement to verification artifacts with 100% coverage across 37 requirements, and only three change requests were approved before the analysis set was frozen.

Finally, although results are stable in sign across sampled parameter spreads and the mapping between laboratory measurements and simulation readouts is tight for the two chosen metrics, the decision to set quantitative angulation limits using these models would be strengthened by two additions: (i) adding a measurement of flexor tendon proximity under the most distal screw location in the cadaveric series to complement the cortex clearance metric and (ii) expanding the angulation sweep in the lab to include 25° and 35° to bound the trend curvature that appears in M2 at the high end of the simulated range.

Actionability of elevation plan — gradation.

a.
Gaps identified without concrete steps.

b.
High-level steps noted without success criteria.

c.
Concrete steps with measurable targets tied to the readouts.

d.
Concrete steps with targets, timelines, and decision impacts quantified.

18. Decision

The composite of evidence across model forms and mechanisms does not yet meet the threshold for adopting any of the models to set quantitative angulation limits for the device. In particular, M1 is structurally incapable of representing lift-off and overconstrains interface behavior; M2, while the most balanced for the present readouts, requires additional experimental alignment around interface tractions and pressures; and M3, although physically richer, lacks direct validation mapping for the chosen readouts and exhibits tighter numerical margins. On balance, and consistent with the scale and matrices reported, the outcome of this assessment is Not accepted.

Decision readiness based on computational evidence — gradation.

a.
Evidence is insufficient; important factors unaddressed.

b.
Evidence addresses some factors; key gaps remain for decision use.

c.
Evidence addresses most factors with bounded limitations acceptable for decision context.

d.
Evidence comprehensively addresses factors with quantified uncertainty aligned to decision risk.

References

[1] S. Jankowski, M. Halvorsen, S. Halvorsen, Mesh density effects on contact pressure in computational models, Int. J. Numer. Methods 28 (2008) 90–585.

[2] W. Zetterberg, G. Kaur, P. Yilmaz, R. Tanaka, P. Tanaka, Boundary condition effects on stress range in computational models, Comput. Methods Biomech. 115 (2022) 382–709.

[3] C. Lindqvist, B. Zetterberg, T. Abbott, Flow rate effects on peak force in computational models, Comput. Methods Biomech. 28 (2009) 37–530.

[4] L. Vasquez, M. Quintero, G. Ueda, N. Kaur, Wall roughness effects on shear stress in computational models, Int. J. Numer. Methods 103 (2007) 206–411.

[5] G. Zetterberg, N. Nakamura, Flow rate effects on head displacement in computational models, Med. Eng. Phys. 100 (2006) 392–737.

[6] A. Duarte, D. Grigoryan, Inlet profile effects on cortical strain in computational models, Comput. Fluids 27 (2011) 109–538.

[7] P. Yilmaz, D. Eriksen, K. Abbott, E. Lindqvist, A. Abbott, Load path effects on hemolysis index in computational models, Med. Eng. Phys. 25 (2021) 8–505.

[8] R. Nakamura, A. Castellano, A. Wojcik, Contact stiffness effects on rib deflection in computational models, J. Verif. Valid. Uncertain. 148 (2018) 363–570.

[9] C. Eriksen, A. Zetterberg, G. Abbott, K. Pettersson, Mesh density effects on hemolysis index in computational models, Int. J. Numer. Methods 36 (2009) 16–871.

[10] B. Moreau, S. Ishikawa, M. Silva, L. Duarte, H. Pettersson, Element type effects on cortical strain in computational models, J. Verif. Valid. Uncertain. 46 (2012) 130–816.

[11] T. Ishikawa, C. Zetterberg, M. Kaur, T. Ueda, D. Wojcik, Solver tolerance effects on shear stress in computational models, Comput. Fluids 100 (2020) 248–792.

[12] N. Castellano, N. Moreau, H. Wojcik, Material model effects on cortical strain in computational models, Med. Eng. Phys. 43 (2017) 109–809.

[13] T. Zetterberg, A. Abbott, Bone density effects on cortical strain in computational models, Ann. Biomed. Eng. 71 (2019) 227–715.

[14] E. Yilmaz, T. Grigoryan, Friction effects on contact pressure in computational models, J. Verif. Valid. Uncertain. 57 (2014) 215–608.

[15] P. Lindqvist, D. Zetterberg, L. Okonkwo, M. Bergman, J. Moreau, Damping effects on shear stress in computational models, J. Verif. Valid. Uncertain. 87 (2023) 240–840.

[16] S. Eriksen, D. Moreau, Time step effects on cortical strain in computational models, Med. Eng. Phys. 25 (2019) 346–584.

[17] H. Wojcik, T. Pettersson, P. Quintero, D. Ishikawa, Cement mantle effects on rib deflection in computational models, J. Mech. Behav. Biomed. Mater. 109 (2005) 26–567.

[18] D. Castellano, G. Kaur, L. Jankowski, Material model effects on head displacement in computational models, J. Verif. Valid. Uncertain. 95 (2007) 367–596.

[19] A. Moreau, F. Bergman, G. Vasquez, G. Lindqvist, H. Quintero, Solver tolerance effects on contact pressure in computational models, Med. Eng. Phys. 132 (2018) 197–731.

[20] T. Silva, P. Zetterberg, H. Pettersson, Inlet profile effects on hemolysis index in computational models, Med. Eng. Phys. 37 (2020) 162–825.

[21] D. Halvorsen, R. Eriksen, N. Yilmaz, Bone density effects on flow split in computational models, Comput. Methods Biomech. 130 (2009) 221–444.

[22] J. Eriksen, B. Jankowski, B. Silva, D. Vasquez, L. Tanaka, Load path effects on peak force in computational models, J. Verif. Valid. Uncertain. 77 (2014) 52–755.

[23] W. Moreau, J. Ueda, L. Nakamura, Solver tolerance effects on rib deflection in computational models, J. Verif. Valid. Uncertain. 110 (2006) 61–621.

[24] B. Lindqvist, J. Bergman, Load path effects on head displacement in computational models, J. Verif. Valid. Uncertain. 27 (2007) 233–652.

[25] R. Wojcik, L. Okonkwo, Flow rate effects on head displacement in computational models, Int. J. Numer. Methods 106 (2011) 17–742.

[26] M. Duarte, F. Abbott, E. Grigoryan, M. Abbott, Inlet profile effects on contact pressure in computational models, J. Verif. Valid. Uncertain. 85 (2022) 97–588.

[27] H. Silva, T. Castellano, Gap size effects on outlet velocity in computational models, Ann. Biomed. Eng. 23 (2012) 392–857.

[28] S. Moreau, F. Vasquez, H. Halvorsen, E. Castellano, R. Ueda, Bone density effects on rib deflection in computational models, J. Mech. Behav. Biomed. Mater. 137 (2007) 387–453.

[29] W. Lindqvist, F. Okonkwo, Solver tolerance effects on rib deflection in computational models, Int. J. Numer. Methods 99 (2017) 279–864.

[30] R. Okonkwo, S. Pettersson, C. Fontaine, D. Tanaka, L. Ishikawa, Contact stiffness effects on rib deflection in computational models, J. Biomech. Eng. 133 (2016) 173–755.

[31] K. Ueda, T. Jankowski, M. Lindqvist, W. Pettersson, Mesh density effects on outlet velocity in computational models, J. Verif. Valid. Uncertain. 139 (2021) 253–804.

[32] B. Jankowski, M. Pettersson, P. Moreau, F. Zetterberg, J. Pettersson, Element type effects on stress range in computational models, Int. J. Numer. Methods 130 (2015) 243–867.

[33] B. Eriksen, H. Silva, F. Jankowski, N. Okonkwo, Solver tolerance effects on hemolysis index in computational models, J. Biomech. Eng. 61 (2011) 292–844.

[34] H. Lindqvist, L. Eriksen, E. Fontaine, Yield stress effects on rib deflection in computational models, Med. Eng. Phys. 35 (2014) 16–691.

Table 2: Credibility factors scored for M1 across two mechanisms

Credibility factor	Level	Basis
Development process and product management - M1 - Cortical breach at screw tip	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Development process and product management - M1 - Plate–bone lift-off and loss of reduction	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Discretization error - M1 - Cortical breach at screw tip	3	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Discretization error - M1 - Plate–bone lift-off and loss of reduction	3	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Model form - M1 - Cortical breach at screw tip	2	Threads vs bonded shank changed pullout 14–18% but tip proximity at 15° by only 0.2 mm under same loading.
Model form - M1 - Plate–bone lift-off and loss of reduction	1	Rigid plate and bonded interfaces preclude separation; mechanism cannot be represented for lift-off.
Numerical code verification - M1 - Cortical breach at screw tip	3	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical code verification - M1 - Plate–bone lift-off and loss of reduction	3	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical solver error - M1 - Cortical breach at screw tip	4	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 μm; solver sweeps changed outputs <0.5%.
Numerical solver error - M1 - Plate–bone lift-off and loss of reduction	4	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 μm; solver sweeps changed outputs <0.5%.
Relevance of the validation activities to the COU - M1 - Cortical breach at screw tip	2	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Relevance of the validation activities to the COU - M1 - Plate–bone lift-off and loss of reduction	2	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Results robustness - M1 - Cortical breach at screw tip	2	Across 120 LHS samples, clearance slope 0.31 mm/10° (IQR 0.27–0.36); sign preserved across ±20% E and ±10% μ.
Results robustness - M1 - Plate–bone lift-off and loss of reduction	2	Across 120 LHS samples, lift-off +22 μm/10° (IQR 18–26); sign preserved across ±20% E and ±10% μ.
Software quality assurance - M1 - Cor-	4	Toolchain under VC with 172 unit and 31 integration tests;

Table 3: Credibility factors scored for M2 across two mechanisms

Credibility factor	Level	Basis
Development process and product management - M2 - Cortical breach at screw tip	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Development process and product management - M2 - Plate–bone lift-off and loss of reduction	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Discretization error - M2 - Cortical breach at screw tip	3	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Discretization error - M2 - Plate–bone lift-off and loss of reduction	3	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Model form - M2 - Cortical breach at screw tip	3	Threads vs bonded shank changed pullout 14–18% but tip proximity at 15° by only 0.2 mm; frictional slip and plate flex captured.
Model form - M2 - Plate–bone lift-off and loss of reduction	3	Plate compliance and contact allow separation under bending; mechanism represented with frictional interfaces.
Numerical code verification - M2 - Cortical breach at screw tip	3	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical code verification - M2 - Plate–bone lift-off and loss of reduction	3	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical solver error - M2 - Cortical breach at screw tip	3	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 μm; solver sweeps changed outputs <0.5%.
Numerical solver error - M2 - Plate–bone lift-off and loss of reduction	3	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 μm; solver sweeps changed outputs <0.5%.
Relevance of the validation activities to the COU - M2 - Cortical breach at screw tip	3	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Relevance of the validation activities to the COU - M2 - Plate–bone lift-off and loss of reduction	3	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Results robustness - M2 - Cortical breach at screw tip	3	Across 120 LHS samples, clearance slope 0.31 mm/10° (IQR 0.27–0.36); sign preserved across ±20% E and ±10% μ.
Results robustness - M2 - Plate–bone lift-off and loss of reduction	3	Across 120 LHS samples, lift-off +22 μm/10° (IQR 18–26); sign preserved across ±20% E and ±10% μ.
Software quality as-	4	Toolchain under VC with 172

Table 4: Credibility factors scored for M3 across two mechanisms

Credibility factor	Level	Basis
Development process and product management - M3 - Cortical breach at screw tip	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Development process and product management - M3 - Plate–bone lift-off and loss of reduction	3	Stage-gated plan with 4 milestones and 100% trace across 37 requirements; 3 approved changes before freeze.
Discretization error - M3 - Cortical breach at screw tip	2	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Discretization error - M3 - Plate–bone lift-off and loss of reduction	2	Refining cortex/plate from 0.60.3 mm changed tip clearance 0.08 mm (2.6%) and peak plate stress 3.1%; halving again ≤1.1%.
Model form - M3 - Cortical breach at screw tip	3	Threads vs bonded shank changed pullout 14–18% but tip proximity at 15° by only 0.2 mm; plasticity adds realism in low-density bone.
Model form - M3 - Plate–bone lift-off and loss of reduction	3	Plate compliance and contact allow separation; cohesive and plasticity mainly affect strength-like outcomes.
Numerical code verification - M3 - Cortical breach at screw tip	2	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical code verification - M3 - Plate–bone lift-off and loss of reduction	2	Manufactured-solution L2 displacement error 0.37% with observed order 1.98; contact/cohesive patches <1e-10 N residual.
Numerical solver error - M3 - Cortical breach at screw tip	2	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 µm; solver sweeps changed outputs <0.5%.
Numerical solver error - M3 - Plate–bone lift-off and loss of reduction	2	Residual norms ≤1e-6, energy error ≤0.2%, contact penetration ≤0.5 µm; solver sweeps changed outputs <0.5%.
Relevance of the validation activities to the COU - M3 - Cortical breach at screw tip	2	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Relevance of the validation activities to the COU - M3 - Plate–bone lift-off and loss of reduction	2	Cadaveric constructs matched device geometry and 10°/20°/30° angulations; micro-CT clearance mapped with 0.1 mm alignment.
Results robustness - M3 - Cortical breach at screw tip	2	Across 120 LHS samples, clearance slope 0.31 mm/10° (IQR 0.27–0.36); sign preserved across ±20% E and ±10% µ.
Results robustness - M3 - Plate–bone lift-off and loss of reduction	2	Across 120 LHS samples, lift-off +22 µm/10° (IQR 18–26); sign preserved across ±20% E and ±10% µ.
Software quality as-	4	Toolchain under VC with 172