Establishing model credibility for a dental implant under osseointegration loading: Two implicit FEA models across two mechanisms using a numeric evidence scale

A. L. Vance, PhD[a], R. K. Molina, MS[b], S. T. Park, PhD[c], E. J. Hart, DDS, MS[1], M. Zhou, PhD[1]

[a]*Center for Computational Medicine, Meridian Institute of Technology, Boston, MA, USA,*
[b]*Department of Mechanical Engineering, Great Lakes University, Madison, WI, USA,*
[c]*Division of Periodontology, Hale Dental School, New York, NY, USA,*

Abstract

Finite element analysis (FEA) is routinely used to investigate mechanical conditions around dental implants during early healing, yet decision-making on early loading requires model credibility commensurate with clinical risk. Following the ASME V&V 40 intent for medical device modeling, this study implements a numeric evidence scale to assess the credibility of two implicit FEA models for an endosseous implant with a healing abutment. The Micro-Region Interface Model (MRIM) resolves thread geometry and a bonded surrogate interface layer in a local segment of peri-implant bone to compute interfacial micromotion, peri-implant strain energy density (SED), and cortical crest principal strains. The Segmental Jaw Continuum Model (SJCM) simulates a mandibular segment including heterogeneous cortical–trabecular bone, delivering the global construct stiffness, abutment displacement, and cortical load transfer. Both models are evaluated under two clinically relevant mechanisms: axial centric loading and oblique lateral excursion during early healing. We score evidence per model–mechanism pair on a 0–4 scale (0 insufficient; 4 extensive) across six factors: mesh-induced effects, agreement with benchtop measurements, decision-linked appropriateness of the outputs, alignment of the test conditions to the clinical scenario, controls on the modeling toolchain, and human-process reliability. The program includes mesh-refinement studies, benchtop testing with instrumented mandibular segments, and replication by independent analysts. Under axial centric loading, MRIM predicted interfacial micromotion within 14% of stereo digital image correlation (DIC) estimates and cortical crest strains within 12% of strain-gage data; SJCM predicted abutment displacement within 6% and construct stiffness within 6% of measured values. Under oblique lateral excursion, differences increased: MRIM cortical crest strain differed by up to 21% and SJCM stiffness by 15% from measurements, reflecting sensitivity to off-axis boundary compliance. Across both models and mechanisms, mesh-induced changes in quantities of interest were below 2.1% between the two finest meshes. The benchtop fixtures and load vectors matched the intended early-healing use case within 10% for axial and 14% for oblique in terms of boundary compliance and directionality. The software toolchain enforced version control and automated testing (121 unit tests and 23 regressions; 97% coverage for post-processing scripts), and two analysts reproduced key outputs within 2.1% following a written workflow. Credibility tables per model present the full factor-by-mechanism scoring and one-line bases with numbers. The results support risk-informed use of MRIM and SJCM to inform early-loading decisions when constrained to loads, geometries, and material states consistent with the validation experiments, with greater confidence under axial centric loading than oblique lateral excursion.

Keywords: osseointegration, finite element analysis, model credibility

1. Introduction

The first weeks after placement of an endosseous dental implant are marked by a delicate balance between establishing primary stability and allowing biological processes to create a durable interface. While conventional protocols defer occlusal function until osseointegration matures, practice patterns increasingly consider immediate or early loading with a healing abutment when insertion torque and stability appear favorable. In this window, mechanical conditions at the bone–implant contact influence micromotion, tissue differentiation, and remodeling trajectories. Finite element analysis (FEA) can noninvasively resolve stress and strain fields inaccessible to sensors, but clinical decisions require that model predictions be trustworthy for the specific context of early loading. The ASME V&V 40 framework promotes a risk-informed approach: identify a clear question of interest and a context of use (COU), then gather and grade evidence that relates model outputs to reality at a level commensurate with the decision risk.

Evidence accumulation blends analyses and experiments. On the analysis side, numerical approximations should be stable with respect to discretization, and inputs, boundary conditions, and outputs must be defined in a traceable manner. On the experimental side, measurements must relate to model outputs and emulate the decision context. The literature on dental implant FEA is extensive, yet reported studies vary widely in how and whether their model-to-test relationships have been quantified. Moreover, the transition from long-term steady-state osseointegration to early healing poses additional modeling challenges, including partial interlock and time-dependent tissue properties not captured by classical bonded-contact assumptions.

This work establishes a credibility program for two complementary implicit FEA models of an internal-connection implant with a healing abutment. The Micro-Region Interface Model (MRIM) resolves explicit thread geometry and a surrogate interface layer at the scale of tens to hundreds of micrometers around the implant, and outputs interfacial motion, peri-implant strain energy density (SED), and cortical crest principal strains. The Segmental Jaw Continuum Model (SJCM) represents a mandibular segment with heterogeneous cortical–trabecular material properties, and outputs the global construct stiffness, abutment displacement, and the distribution of load borne by the cortical shell at the crest. Two load mechanisms are examined, each with clinical salience: axial centric loading and oblique lateral excursion during early healing.

We adopt a numeric 0–4 evidence scale to grade the strength of evidence for each model–mechanism pair across six factors central to trust in early-loading decisions: mesh-induced effects, agreement with benchtop measurements, decision-linked appropriateness of the quantities of interest (QOIs), alignment of the test conditions to the COU, controls on the modeling toolchain, and human-process reliability. Each factor is scored separately for axial and oblique mechanisms, and each model is summarized in its own table. We further emphasize transparency by reproducing key numbers in the prose and tables, enabling independent readers to align their interpretation of the evidence with their own risk tolerances.

Our intent is not to exhaustively model all aspects of early healing, which includes complex biology and time-dependent mechanics, nor to predict long-term peri-implant bone remodeling. The COU is deliberately narrow: to inform early-loading decisions for a single mandibular implant with a healing abutment under modest functional forces in the first two to four weeks, using mechanistic outputs directly tied to accepted thresholds for micromotion and cortical strain, and construct-level stiffness and displacement accessible to benchtop testing. The subsequent sections define the COU and question of interest, describe both models, detail mechanisms and boundary conditions, specify QOIs and measurement definitions, present the credibility plan and scoring system, and then report verification, validation, relevance arguments, software and human-process controls, and results including factor-by-mechanism scores for each model.

Overall numeric evidence scale for risk-informed modeling — gradation.

a.
0: No organized plan for evidence; ad hoc or anecdotal justification.

b.
1: Informal plan; partial mapping between evidence and the decision; sparse quantification.

c.
2: Documented plan; explicit mapping to the decision; several quantitative checks; gaps acknowledged.

d.
3: Structured plan; quantitative checks across all selected factors; consistency demonstrated across mechanisms.

e.
4: Structured plan with pre-specified thresholds; quantitative checks repeated independently; traceable linkage to the decision and risk posture.

2. Question of Interest and Context of Use

The question of interest is whether an internal-connection dental implant with a healing abutment, placed in a mandibular segment with typical adult bone quality, can be subjected to early functional loading without exceeding mechanical thresholds believed to endanger osseointegration. The decision is framed as a go/no-go judgment for two families of actions during the first two to four weeks: (i) allowing controlled axial centric contacts on the healing abutment during swallowing or light clenching, and (ii) allowing lateral excursions that generate off-axis shear and bending.

The COU bounds geometry, loading, materials, and outputs. Geometry is limited to a single implant (nominal diameter 4.1 mm, length 10 mm) with an internal conical connection and a healing abutment 4 mm in height, set in a mandibular segment spanning from the cortical crest to the inferior border with a 10–12 mm buccal–lingual width. Loading is limited to (a) axial centric forces up to 100 N applied to the healing abutment and (b) a combined normal-shear resultant of 70 N at 20 degrees from the implant axis to emulate lateral excursion. Materials reflect early healing: bone is modeled as linear elastic and heterogeneous at the cortical and trabecular levels (cortical elastic modulus 14.0 GPa, trabecular 0.35 GPa; Poisson's ratio 0.30), and the implant and abutment as Ti-6Al-4V (elastic modulus 110 GPa; Poisson's ratio 0.34). Outputs are limited to measurable or decision-linked quantities: interfacial micromotion (micrometers), peri-implant SED (microjoules per cubic millimeter), cortical crest principal strains (microstrain), global construct stiffness (kN/mm), abutment displacement (micrometers), and the proportion of load transferred through the cortical shell at the level of the crest.

The models are not intended to simulate viscoelastic behavior, time-evolving osteoid formation, microdamage accumulation, or long-term remodeling. Rather, they aim to characterize mechanical states in a narrow time window where geometry and material properties can be reasonably approximated as static, and where conservative limits for micromotion and cortical strain can be invoked based on the literature. The COU anticipates a practitioner or manufacturer looking to justify or challenge early function of a healing abutment under controlled forces, and a modeling team assessing whether their models provide sufficiently trustworthy outputs for that decision.

Mapping of COU to decision needs — gradation.

a.
0: Intended use not clearly defined; outputs not mapped to the decision.

b.
1: Intended use stated; partial mapping of outputs to decision thresholds.

c.
2: Intended use documented with bounds on geometry,

Figure 1: Overview of the dental implant geometry, load cases and the mechanisms assessed, shown across the full page width.

loads, and materials; outputs traceably linked to decision thresholds.

d.
3: Intended use documented and bounded; outputs linked to decision thresholds and to available measurements.

e.
4: Intended use documented and bounded; outputs linked to decision thresholds, to measurements, and to pre-specified tolerances for agreement.

3. Model Risk Analysis

We consider the consequence of an incorrect go/no-go recommendation for early loading to be moderate: premature mechanical challenge could increase micromotion or concentrated cortical strains enough to impair osseointegration, potentially leading to marginal bone loss or implant failure. Conversely, overly conservative recommendations may reduce patient function unnecessarily during the early healing period. With decision impact in the moderate range, the evidence burden must ensure that model outputs have demonstrated stability to numerical settings, correspondence with measurements under relevant loads and fixtures, and strong linkage between outputs and the clinical thresholds used in decision-making.

Mechanistic pathways differ between the two mechanisms. For axial centric forces, the response is dominated by compressive load sharing between trabecular and cortical bone and by the elastic compliance of the implant–abutment assembly; interfacial relative motion is driven primarily by normal separation and small tangential slip. For oblique forces during lateral excursion, the response includes bending of the fixture, shear at the interface, and localization of tension–compression pairs in the cortical crest. The oblique mechanism is thus more sensitive to local geometric details and boundary compliance. These distinctions motivate collecting evidence for each model–mechanism pair separately rather than inferring behavior across mechanisms.

Risk also depends on the clarity of the thresholds invoked. Literature commonly cites interfacial relative motion below 50–150 micrometers as protective of stable osseointegration during early healing, recognizing variability across animal and human studies. Mechanostat concepts place 2000–4000 microstrain within physiological ranges for cortical bone and suggest that peak cortical crest strains above roughly 7000 microstrain under repetitive loads may be undesirable, although local remodeling and microstructure complicate these thresholds. Construct-level stiffness and abutment displacement provide accessible surrogates that integrate both interface and bulk bone mechanics. The present credibility plan therefore places emphasis on quantities that can be measured or that have accepted decision thresholds.

Risk-informed evidence sufficiency — gradation.

a.
0: No explicit risk consideration; single minimal check irrespective of decision impact.

b.
1: Qualitative risk consideration; limited checks only loosely tied to decision impact.

c.
2: Decision impact characterized; checks prioritize the most critical mechanisms.

d.
3: Decision impact characterized; checks separated by mechanism; thresholds for acceptance proposed.

e.
4: Decision impact characterized; checks separated by mechanism; thresholds for acceptance pre-specified and met or variances justified.

4. Computational Models

Two complementary implicit FEA models were constructed using a commercial structural solver (Abaqus/Standard 2023; Dassault Systemes) and custom pre- and post-processing scripts written in Python 3.11. Geometries were created from manufacturer-provided implant and abutment CAD and from a representative mandibular segment segmented from a de-identified CT dataset (0.3 mm isotropic voxel size) followed by cortical–trabecular separation based on density thresholds. Titanium alloy components were modeled as linear elastic, homogeneous, and isotropic (E = 110 GPa, ν = 0.34). Bone was modeled as linear elastic and isotropic with region-specific properties: cortical E = 14.0 GPa, ν = 0.30; trabecular E = 0.35 GPa, ν = 0.30. While orthotropy in cortical bone is known, isotropy was selected to align with the level of characterization available in benchtop testing and to avoid introducing additional parameters not constrained by the data in the present COU.

Micro-Region Interface Model (MRIM). The MRIM domain consists of a cylindrical segment of bone centered on the implant axis extending 8 mm radially and 12 mm apico-coronally, with explicit representation of the implant outer geometry including threads at the manufacturer-specified pitch and flank angles. A zero-thickness surrogate interface layer separates the implant and bone surfaces to enable computation of relative motion while enforcing continuity of traction. The layer is implemented using cohesive contact with very high normal penalty stiffness (1.0 × 10^6 N/mm^3) to suppress interpenetration, coupled with an elastic tangential penalty stiffness (5.0 × 10^4 N/mm^3) to allow small, proportional slips that represent the early fibrous interlock. No damage or decohesion was permitted within the COU loads. Ten-node quadratic tetrahedral elements (C3D10) were used for bone and implant components. Mesh refinement was concentrated near the interface: element edge lengths were 0.05 mm at the interface, transitioning to 0.25 mm within 1.0 mm of the implant, and coarsening further to 0.6 mm at the outer boundaries. The medium mesh had 14.2 million degrees of freedom (DOF); the fine mesh had 24.5 million DOF. Boundary constraints were applied on the outer cylindrical surface (radial constraint) and the apical face (axial constraint) to emulate continuity with surrounding bone outside the modeled micro-region.

Segmental Jaw Continuum Model (SJCM). The SJCM domain is a mandibular segment with buccal and lingual cortical shells and trabecular core, spanning 30 mm mesio-distally and 20 mm apico-coronally, with an implant positioned centrally. The healing abutment is included and loaded as in the benchtop tests. The model uses an embedded region approach: an outer structured brick mesh for the cortical shells (C3D8R) with 0.5 mm elements and an inner tetrahedral mesh for the trabecular core (C3D10) with 0.7 mm average elements, refined to 0.1–0.2 mm around the implant–bone contact region to capture local compliance changes. Bone–implant contact is modeled as perfectly bonded to represent the effective stiffness of early interlock under small displacements; sensitivity to tangential compliance was explored in a separate analysis and was found to change abutment displacements by less than 4% under the axial mechanism within the COU loads. The inferior border of the mandible segment is constrained in three translations to emulate fixation in the test rig; mesial and distal faces are left free except for contact with the test fixture plates as described later. The medium mesh had 3.4 million DOF; the fine mesh had 5.6 million DOF.

For both models, quasi-static analyses were performed with implicit solution procedures. Nonlinearities stem from contact and material heterogeneity rather than material nonlinearity. A load ramp of 20 steps was used to reach the target forces. Convergence criteria were displacement-based with relative tolerances of 1 × 10^-6 and maximum residual force of 2% of the applied load at each increment. Solver settings, including time incrementation and contact stabilization (0.5% artificial damping), were held constant across meshes to isolate the effect of discretization on QOIs. Post-processing used element-wise extrapolation of strains to integration points and volume-averaged SED within a 0.5 mm annular region surrounding the first thread engagement.

Geometric and material representation sufficiency for early loading — gradation.

a.
0: Major geometric or material features affecting early loading omitted; no justification.

b.
1: Some features omitted; qualitative justification provided.

c.
2: Primary features included (threads, cortical–trabecular distinction); simplifications justified relative to COU.

d.
3: Primary features included; interface representation chosen to match COU loads; sensitivity to key simplifications explored.

e.
4: Primary features included; interface and bone anisotropy characterized experimentally for the specimens; sensitivity quantified and bounded.

5. Mechanisms and Boundary Conditions

Two loading mechanisms were applied consistently across models. For axial centric loading, a vertical compressive force of 100 N was applied to the superior face of the healing abutment via a rigid cap that distributed the load uniformly over the abutment top, consistent with the benchtop indenter. The load orientation was aligned within 0.5 degrees of the implant axis. For oblique lateral excursion, a resultant of 70 N was applied at the abutment cap at 20 degrees from the implant axis in the buccal–lingual plane, with the tangential component directed buccally. A small torsional component (≤3 N·mm) was measured in the benchtop tests due to fixture friction; the models included a corresponding moment at the abutment to match the measured resultant within 5%.

In MRIM, the outer cylindrical boundary was constrained to prevent rigid-body motion while allowing deformation consistent with the surrounding jaw. Specifically, radial displacements were fixed on the outer surface, axial displacements were fixed on the apical face, and tangential constraints were left free to avoid artificial stiffening in torsion. Contact between the implant and bone occurred through the cohesive layer described earlier, allowing computation of relative displacements at the interface nodes. Thread engagement was modeled explicitly, with initial gaps set to zero to represent a well-seated implant.

In SJCM, boundary conditions were defined to emulate the test rig and to provide sufficient support while preserving realistic compliance. The inferior border of the mandible segment was fixed in translation; rotations were unconstrained. The mesial and distal cut faces were left traction-free, in line with the physical specimen preparation. The abutment load was applied through a rigid cap tied to the abutment top. No attempt was made to model periodontal ligament or adjacent teeth, consistent with the specimen preparation that removed neighboring dentition.

Friction at the abutment–cap contact in the benchtop tests was reduced using PTFE interfaces; the residual friction coefficient was measured at 0.06 ± 0.02 and neglected in the models. The implant–abutment connection was treated as perfectly seated with no microgap and no bolt preload, consistent with the torqued healing abutment that remained in place during all tests. Sensitivity to a ±10% variation in cortical elastic modulus was explored in SJCM to bound the effect of interspecimen variability, and resulted in a ±7% change in global stiffness under the axial mechanism and a ±9% change under the oblique mechanism, informing interpretation of model–measurement differences.

Boundary condition traceability to experiments — gradation.

a.
0: Boundary conditions do not correspond to any documented test configuration.

b.
1: Boundary conditions approximate the test qualitatively; directions and magnitudes matched to first order.

c.
2: Boundary conditions derived from test logs with quantified load directions and magnitudes; fixture compliance approximated.

d.
3: Boundary conditions derived from test logs; fixture compliance measured and represented; parasitic moments accounted for.

e.
4: Boundary conditions derived from synchronized load–displacement–image records; full fixture structural model coupled to specimen.

6. Quantities of Interest and Measurement Definitions

Interfacial micromotion (MRIM) was defined as the vector magnitude of relative displacement between paired nodes on the implant and bone sides of the cohesive contact, evaluated at integration points mapped to the midline of the first three threads and averaged over a 120-degree sector centered buccally, where oblique loads concentrate shear. The reported value is the 95th percentile of the magnitude distribution in that sector to capture peak but robust behavior. Peri-implant strain energy density (SED) was computed as the volume-average within a 0.5 mm-thick annulus immediately outside the outermost edges of the first thread, centered at the buccal aspect. Cortical crest principal strains were evaluated at the outer cortical surface within a 1.0 mm by 1.0 mm region of interest (ROI) aligned with the crest; the maximum principal strain was reported based on extrapolated nodal values from integration points.

Construct stiffness (SJCM) was defined as the slope of the force–displacement curve at the abutment top between 10% and 90% of the target force, averaged over the loading phase. Abutment displacement was the total translation of the abutment top in the direction of applied force at the target load. Cortical load transfer proportion was computed as the ratio of reaction forces carried by a ring of elements in the cortical shell at the level of the crest to the total reaction at the implant–bone interface, with the ring defined by a 0.5 mm thickness spanning the shell.

Corresponding measurements were defined in the benchtop program. Interfacial relative motion was not directly observable; instead, stereo digital image correlation (DIC) of the exposed cortical crest provided high-resolution surface strains and displacements, while a previously published compliance calibration mapped abutment displacement to an estimated interfacial micromotion via a transfer function derived from MRIM geometry families. Cortical crest strains were measured by miniature rectangular strain gages (gauge length 1.0 mm) adhered at the buccal crest with alignment verified via micro-CT and by DIC, with DIC serving to corroborate rosette solutions for principal strains. Abutment displacements were measured by a laser triangulation sensor with 1 μm resolution and 2 μm repeatability over the loading range; global stiffness was computed from the measured force and displacement. Fixture compliance was measured separately by loading a steel dummy abutment of known stiffness and subtracting its contribution from the combined displacement.

Traceability of QOIs to measurements — gradation.

a.
0: QOIs have no experimental analog or mapping.

b.
1: QOIs conceptually correspond to measured quantities; mapping informal.

c.
2: QOIs correspond to measured quantities; mapping defined and documented; uncertainties estimated.

d.
3: QOIs correspond to measured quantities; mapping validated on similar geometries; uncertainties propagated.

e.
4: QOIs correspond to measured quantities; mapping validated on the same geometries; uncertainties propagated and reported with predictions.

7. Credibility Plan and Scoring Rubric (0–4 scale)

We graded evidence on a five-rung 0–4 scale, where 0 indicates insufficient evidence to make a judgment, 1 limited evidence, 2 adequate evidence, 3 strong evidence, and 4 extensive evidence. Scores were determined for each model–mechanism pair across six factors chosen for their relevance to early-loading decisions and for their tractability within our program: mesh-induced effects; agreement with benchtop measurements; alignment of the outputs to decision thresholds; alignment of the tests to the COU; controls on the modeling toolchain; and reliability of human processes. Each factor had pre-specified numerical targets where applicable, such as a ≤3% change in QOIs upon mesh refinement between the two finest meshes for the first factor, and agreement within 15% for core outputs under axial loading for the second factor, recognizing that oblique loading may tolerate larger residuals.

The plan called for independent mesh-refinement studies for each model and mechanism, laboratory testing with at least five specimens prepared to emulate the COU, replicated analyses by two analysts following a written workflow, and a software pipeline under version control with both unit and regression testing. The tables later in the paper repeat the scores and summarize the numeric bases for each model–mechanism pair. The rubric ladders embedded throughout the paper provide criteria for judging rigor on each factor.

Scoring rigor for agreement with benchtop tests — gradation.

a.
0: No direct comparison to measurements.

b.
1: One or two comparisons; no uncertainty; qualitative matching only.

c.
2: Multiple comparisons on relevant outputs; central tendency used; uncertainty acknowledged.

d.
3: Multiple comparisons; uncertainty reported; acceptance ranges pre-specified and mostly met.

e.
4: Multiple comparisons; uncertainty reported; acceptance ranges pre-specified and met; independent replication of tests or analyses.

8. Verification: Discretization Error for Each Model–Mechanism Pair

We performed mesh-refinement studies for MRIM and SJCM under both mechanisms using three systematically refined meshes per model. For MRIM, the coarse mesh had 8.7 million DOF, the medium 14.2 million DOF, and the fine 24.5 million DOF. For SJCM, the coarse mesh had 1.9 million DOF, the medium 3.4 million DOF, and the fine 5.6 million DOF. Element sizes near the bone–implant contact were refined by approximately 40–60% from medium to fine, while outer regions remained coarser to contain the computational cost. All other modeling settings, including contact parameters, load ramping, and solver tolerances, were held constant across meshes.

Under axial centric loading, MRIM predicted an interfacial micromotion P95 of 24.6 μm on the medium mesh and 24.3 μm on the fine mesh (a change of 1.2%). The peri-implant SED within the 0.5 mm annulus decreased from 0.48 μJ/mm^3 to 0.47 μJ/mm^3 (2.1%). The maximum principal strain at the buccal cortical crest within the 1.0 mm by 1.0 mm ROI changed from 2,200 $\mu\epsilon$ to 2,165 $\mu\epsilon$ (1.6%). Under oblique lateral excursion, the MRIM interfacial micromotion P95 was 78.0 μm on the medium mesh and 76.7 μm on the fine mesh (1.7%), SED decreased from 0.91 μJ/mm^3 to 0.89 μJ/mm^3 (2.2%), and the crest maximum principal strain changed from 5,600 $\mu\epsilon$ to 5,480 $\mu\epsilon$ (2.1%). The slight increase in percent change for oblique loads reflects stronger gradients in the cortical crest region.

For SJCM under axial centric loading, the global construct stiffness was 3.36 kN/mm on the medium mesh and 3.39 kN/mm on the fine mesh (0.9% increase), corresponding to abutment displacements of 29.8 μm and 29.5 μm at 100 N (1.0% decrease). The proportion of load transferred through the cortical shell at the crest shifted from 62% to 63% (absolute change 1%). Under oblique lateral excursion, stiffness was 1.07 kN/mm on the medium mesh and 1.06 kN/mm on the fine mesh (1.3% difference), abutment displacement at 70 N resultant changed from 65.4 μm to 66.0 μm (0.9%), and the cortical load transfer proportion changed from 74% to 75% (absolute change 1%).

To complement the percent-change metrics, we estimated apparent order of accuracy using a simple two-mesh estimate for the dominant QOIs. Assuming asymptotic convergence in the mesh density parameter h, we computed an estimated convergence rate p for MRIM micromotion under axial loading of 1.8 and under oblique loading of 1.9, consistent with the use of quadratic tetrahedra and contact nonlinearity. For SJCM stiffness, p estimates were 2.0–2.1. Given that between-mesh QOI changes were all below 2.2% for MRIM and below 1.3% for SJCM when comparing medium to fine meshes, we used the fine-mesh values as representative and assigned mesh-induced uncertainty bounds accordingly in the validation comparisons.

Mesh refinement rigor — gradation.

a.
0: Single mesh; no sensitivity reported.

b.
1: Two meshes; coarse qualitative check of stability.

c.
2: Three meshes; quantitative percent-change reported on key outputs.

d.
3: Three meshes; quantitative percent-change and estimated order of accuracy reported; finest-mesh uncertainty bounded.

e.
4: Four or more meshes; grid-convergence index reported; uncertainty propagated to validation metrics.

9. Validation: Output Comparison to Physical Tests

Benchtop testing used six fresh-frozen porcine mandibular segments prepared to approximate the human adult cortical–trabecular proportions after de-fleshing and drilling to accommodate the same implant and healing abutment used in the models. Specimens were potted in PMMA at the inferior border and mounted in a custom frame with an instrumented upper indenter applying either axial or oblique loads through a PTFE-capped plate contacting the abutment top. Force was measured by a six-axis load cell (capacity 1 kN; resolution 0.1 N), and abutment displacement was measured by a laser triangulation sensor aligned with the load direction (resolution 1 μm). Cortical crest strain was measured with three-element rosettes (120°) adhered at the buccal crest adjacent to the implant and registered by micro-CT to the MRIM ROI. Stereo DIC provided a secondary estimate of principal strains over a 5 × 5 mm field of view at the crest, with speckle pattern applied by airbrushing matte paint.

Axial centric loading. At 100 N, the measured construct stiffness after fixture compliance subtraction was 3.60 ± 0.21 kN/mm (mean ± SD across six specimens), corresponding to abutment displacements of 27.8 ± 1.6 μm. The SJCM predicted

3.39 kN/mm stiffness and 29.5 µm abutment displacement for the CT-derived geometry used in the model, giving differences of 5.8% (stiffness) and 6.1% (displacement) relative to the specimen means, within the pre-specified axial acceptance of 15%. Surface principal strains at the buccal crest measured by rosettes were 2,010 ± 230 $\mu\epsilon$; the MRIM predicted 2,165 $\mu\epsilon$ in the corresponding ROI, a 7.7% difference. Interfacial micromotion was estimated from abutment displacement using a previously calibrated transfer function derived from a suite of MRIM geometries encompassing thread pitch ±10% and cortical thickness 1.0–2.5 mm; at 100 N, the estimated micromotion was 26 ± 5 µm, while MRIM predicted 24.3 µm, a 6.5% difference from the mean, acknowledging the additional uncertainty of the mapping.

Oblique lateral excursion. At a 70 N resultant applied 20 degrees from the implant axis, measured stiffness was 1.25 ± 0.14 kN/mm and abutment displacement was 56.0 ± 6.3 µm in the load direction after fixture compliance subtraction. The SJCM predicted 1.06 kN/mm and 66.0 µm, differences of 15.2% (stiffness) and 17.9% (displacement) relative to means. The corresponding maximum principal strains at the buccal crest measured by rosettes were 6,940 ± 780 $\mu\epsilon$; MRIM predicted 5,480 $\mu\epsilon$ in the ROI, a 21.0% difference relative to the mean. The interfacial micromotion estimate from the transfer function was 81 ± 9 µm, versus MRIM's 76.7 µm, a 5.3% difference. Peri-implant SED could not be measured directly but was indirectly related to the strain fields captured by DIC; MRIM-predicted SED changes between mechanisms tracked the relative DIC strain magnitudes.

Uncertainties in the measurements were characterized and used to interpret differences. For abutment displacement, the combined uncertainty from laser sensor calibration, alignment, and fixture compliance subtraction was estimated at 3 µm (coverage factor k = 2). For rosette strains, uncertainty arose from gage factor tolerance (±0.5%), adhesive creep (estimated <2% over the short load hold), and alignment errors (±3 degrees), propagating to approximately 6% relative uncertainty in principal strain. For the micromotion transfer function, cross-validation across the geometry suite yielded a root-mean-square error of 4.8 µm over the 20–100 µm range. While these uncertainties do not account for all biological variability between porcine and human bone, they provide a quantitative context for the observed differences.

Measurement agreement quality — gradation.

a.
0: No measurements or only qualitative comparison.

b.
1: Single measurement type; central tendency only; no uncertainty.

c.
2: Multiple measurement types for some outputs; uncertainty estimates reported for instruments.

d.
3: Multiple measurement types for all key outputs; uncertainties propagated to comparison metrics.

e.
4: Multiple measurement types for all key outputs; uncertainties propagated; independent replication of both tests and analyses.

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

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

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

10. Relevance of QOIs to Early-Loading Decisions

The selected outputs are intended to connect directly to the mechanical criteria commonly used to judge early-loading safety. Interfacial micromotion at or below approximately 50–150 µm has been associated with favorable osseointegration outcomes in animal models; the present COU treats the upper end of that range (150 µm) as a conservative limit for single-load events on a healing abutment, with the understanding that repetition and healing status modulate risk. The MRIM interfacial micromotion predictions under the two mechanisms span 24–77 µm, remaining below this limit and thus informative for go/no-go judgments. The cortical crest principal strains quantify the risk of excessive local bone deformation; reports of physiologic activity around 2000–4000 $\mu\epsilon$ and adverse responses above 7000 $\mu\epsilon$ provide benchmarks. MRIM predictions of 2,165 $\mu\epsilon$ (axial) and 5,480 $\mu\epsilon$ (oblique) fall within or below these levels under the specified loads.

Construct stiffness and abutment displacement integrate the contributions of the interface, bone, and fixture into a single metric observable in benchtop testing and in some clinical measurement setups. A stiffness on the order of 3–4 kN/mm under a 100 N axial load implies abutment displacements of 25–33 µm, which are well below the 150 µm micromotion limit even if displacement is imperfectly correlated with interface slip. Similarly, oblique stiffness on the order of 1.0–1.3 kN/mm at 70 N implies displacements of 54–70 µm, which track with but do not exceed the micromotion limit. The cortical load transfer proportion in SJCM captures whether the cortical shell bears an excessive fraction of load, which could correlate with crest strain concentration.

These outputs were chosen because their measurement analogs or mappings were feasible with the benchtop setup. The mapping from abutment displacement to interfacial micromotion is sensitive to details of thread engagement and cortical thickness, motivating the calibration across geometries and the use of MRIM as a transfer model. The mapping uncertainty is explicitly considered in interpreting agreement. The strain and displacement outputs are also straightforward to report and explain to clinical stakeholders who make early-loading decisions.

Decision linkage of outputs — gradation.

a.
0: Outputs not tied to any decision threshold.

b.
1: Outputs tied qualitatively to decision thresholds.

c.
2: Outputs tied to published thresholds; ranges specified; clinical assumptions documented.

d.
3: Outputs tied to published thresholds; ranges specified; mappings to measurements defined and used.

e.
4: Outputs tied to published thresholds; mappings validated; thresholds customized to the specific specimens or patient groups.

11. Relevance of Validation Activities to the COU

The benchtop tests were designed to emulate the COU bounds on geometry and loading. The use of a healing abutment with the same dimensions and surface as in the models ensured comparable load application. The axial and oblique load magnitudes and directions matched the COU, with monitored parasitic moments minimized by low-friction interfaces. The potting method and inferior border fixation reproduced a common clinical boundary whereby the mandible is supported by musculature and soft tissues, albeit rigidly in the rig.

Geometrically, porcine bone differs from human mandibular bone in mineralization and microarchitecture; this choice was driven by availability and the need to instrument specimens. The trabecular core in porcine mandibles in the tested region presented elastic moduli within an order consistent with those assigned in the models, and the cortical thickness was in the 1.5–2.3 mm range measured by micro-CT. These characteristics approximate, though do not replicate, the human mandibular segments that motivate the COU. The fixture compliance was measured and subtracted, rather than modeled explicitly, to avoid confounding of model-to-test comparisons by fixture details. The abutment loading cap and alignment were matched to the model by using the same coordinate frames and by registering DIC fields to model ROIs.

Residual differences between tests and the COU include the lack of surrounding soft tissue, absence of adjacent teeth and ligamentous support, and substitution of porcine for human bone. These differences bias the interpretation toward caution: agreement with porcine-based tests may not guarantee the same level of agreement for human bone, but the measured stiffness and strains fall within ranges reported for cadaveric human segments tested under similar configurations in the literature.
COU alignment of validation tests — gradation.

a.
0: Tests unrelated to intended use; loads and fixtures do not match.

b.
1: Tests partially related; loads match in magnitude; fixtures differ substantially.

c.
2: Tests closely related; loads and directions match; fixtures approximated; materials differ.

d.
3: Tests closely related; loads, directions, and fixtures match; materials differ but are characterized.

e.
4: Tests replicate intended use in geometry, materials, loads, and fixtures.

12. Software Quality Assurance for Pre- and Post-Processing

All modeling steps were performed under version control (Git) with issue tracking and mandatory code review before merging to the main branch. The solver was a commercial product (Abaqus/Standard 2023) with fixed versioning for all analyses reported here. Pre-processing scripts generated meshes, applied materials, and defined contacts and loads using the solver's Python API, with inputs stored in human-readable JSON templates to reduce manual transcription. Post-processing scripts extracted QOIs in a consistent manner, including mapping to ROIs and computing percentiles and averages as specified. A continuous integration (CI) pipeline executed static code analysis and automated test suites on each commit to the main branch.

The automated tests comprised 121 unit tests for individual functions (mesh generation parameters, ROI definitions, QOI calculations) and 23 regression tests verifying that end-to-end results for canonical small models (e.g., a simplified cylinder-in-cube contact problem) remained unchanged within a 0.5% tolerance. Code coverage for the post-processing repository was 97%, and for pre-processing 88%, as measured by branch coverage. The CI pipeline also checked that solver input decks conformed to a schema and that critical parameters (e.g., contact stiffness values, element types) matched the configuration documented for the COU. After each run, a SHA-256 hash of the input and a separate hash of the extracted QOIs were stored in a run ledger to detect divergence on reruns.

To guard against unintended deviations in the vendor solver settings, a script parsed the solver log to confirm the convergence tolerances, contact algorithms, and time incrementation were consistent with the COU defaults. For post-processing, numerical checks ensured that the number of nodes in the ROI matched expectations and that percentile calculations used the intended ordering and interpolation. The team used tagged releases for the toolchain to ensure that analyses contributing to validation or tables could be reproduced in the future.
Toolchain controls and testing — gradation.

a.
0: No version control; no tests; manual steps undocumented.

b.
1: Version control in use; limited tests; manual steps partially documented.

c.
2: Version control with branching; unit tests cover major functions; manual steps documented.

d.
3: Version control with protected main; unit and regression tests; continuous integration; run logs archived.

e.
4: Full CI/CD; high coverage; run-time checks on solver logs; cryptographic hashes for reproducibility.

13. Use Error Controls and Analyst Workflows

Analyst procedures were documented in a stepwise workflow, including model setup, mesh selection, boundary condition checks, solver settings, and QOI extraction. A two-person rule applied for boundary condition definition and ROI placement: one analyst executed the step, and a second performed a checklist-driven review. The checklists included specific items such as confirming the abutment load vector orientation within ±1 degree of target; verifying the cohesive layer parameters in MRIM; confirming the element type and sizes in the interface-near region; and verifying that solver logs indicated convergence under the configured tolerances with no automatic stabilization creep beyond 0.5%.

To probe robustness to human process variability, a replication exercise was conducted. Two analysts independently built the MRIM axial and SJCM axial models from the shared templates and executed the analyses blind to each other's results. For MRIM axial, the interfacial micromotion P95 differed by 2.1% between analysts (24.3 μm versus 24.8 μm), and the crest maximum principal strain differed by 1.5% (2,165 $\mu\epsilon$ versus 2,132 $\mu\epsilon$). For SJCM axial, the construct stiffness differed by 1.5% (3.39 versus 3.44 kN/mm), and the abutment displacement at 100 N differed by 1.8% (29.5 versus 29.0 μm). A seeded error test, in which one analyst deliberately misassigned the oblique load angle by 5 degrees, was caught by the checklist and by a scripted tolerance check on the load vector direction.

Training materials included quick-reference guides with annotated screenshots for the pre-processing GUI steps and exemplar scripts for common tasks. All data files used for validation comparison were stored in a structured repository with metadata describing specimen IDs, load cases, and instrument settings. The combination of documentation, checklists, replication, and data management was intended to reduce the probability that subtle human errors would propagate into validation or decision-support outputs.
Analyst reproducibility and process control — gradation.

a.
0: No documented procedures; single analyst performs all work.

b.
1: Procedures informally documented; occasional peer checks.

c.
2: Written procedures; checklists for critical steps; periodic peer review.

d.
3: Written procedures; mandatory peer checks; replication by a second analyst; error seeding and detection.

e.
4: Written procedures; mandatory peer checks; routine cross-lab replication; formal proficiency testing.

14. Test Samples and Physical Setup

Five to six porcine mandibular segments per mechanism were prepared using the same implant and healing abutment as in the models and mounted in a rigid test frame with a low-friction loading cap contacting the abutment top. Micro-CT was used to register cortical thickness and implant placement relative to the crest, and DIC was used to map surface strain fields during loading. The loading protocol applied preconditioning cycles followed by monotonic ramps to the target forces while recording force, displacement, and DIC image pairs. The strain gages and laser displacement sensors were calibrated before each test day using traceable standards. Specimens were kept hydrated with saline mist throughout testing.

The physical test fixtures included adjustments to accommodate variability in segment thickness and to maintain consistent abutment-to-cap alignment across specimens. Data acquisition was synchronized across the load cell, laser sensor, and DIC cameras. Fixture compliance was characterized by replacing the biological segment with a steel dummy and repeating the load protocol to separate fixture motion from specimen response. These steps provided a reproducible setup that supported the model–test comparisons described earlier.
Measurement traceability — gradation.

a.
0: Instruments not calibrated; no traceability.

b.
1: Instruments calibrated once; no ongoing verification.

c.
2: Instruments calibrated; routine verification checks performed; uncertainties estimated.

d.
3: Instruments calibrated and verified before each test series; uncertainties quantified and used in analysis.

e.
4: Instruments calibrated and verified before each test; uncertainties propagated to decision metrics.

15. Results: Credibility Scores by Factor for Each Model–Mechanism Pair

The evidence assembled under this program yields different strengths across factors and mechanisms, reflecting the differing sensitivities of axial centric loading and oblique lateral excursion to boundary details and material heterogeneity. Mesh-induced changes in all reported QOIs were small between the two finest meshes for both models and both mechanisms, with maximum percent changes of 2.2% for MRIM SED under oblique lateral excursion and 1.3% for SJCM stiffness under the same mechanism, indicating stable discretizations. Agreement with benchtop measurements was closer under axial centric loading than under oblique lateral excursion: for axial loading, MRIM micromotion and crest strain differed by 6.5% and 7.7%, respectively, while SJCM stiffness and abutment displacement differed by 5.8% and 6.1%. Under oblique lateral excursion, MRIM crest strain differed by 21.0% and micromotion by 5.3%, and SJCM stiffness and abutment displacement differed by 15.2% and 17.9%.

The linkage between the reported outputs and the early-loading decision thresholds is immediate: the MRIM micromotion predictions of 24–77 μm sit below the 150 μm limit, and the crest strains of 2,165–5,480 $\mu\epsilon$ remain at or below levels associated with concern in the literature; SJCM displacements under axial loading correspond to micromotions comfortably within safe limits via the transfer function, and oblique displacements, while larger, remain below the 150 μm reference. The tests emulated the COU loads and directions closely, with measured deviations in load vector direction within 0.5 degrees for axial and within 2 degrees for oblique, and fixture compliance differences relative to the model boundary treatments of approximately 8% for axial and 14% for oblique, as established by the steel-dummy calibration. The modeling toolchain was stable and tested, with automated unit and regression tests and log checks ensuring that runs matched configured settings, and the human-process controls were effective, as demonstrated by the independent replication within 2.1% for key outputs and the successful detection of a seeded oblique-load angle error.

The following sections present model-specific summary tables. Each table includes rows for each factor and mechanism scored on the 0–4 scale, with a one-line basis statement listing the relevant numbers that underlie the score. The basis lines echo numerical findings also reported in the prose so that readers can trace consistency between text and tables.

Presentation of credibility results — gradation.

a.
0: No structured presentation.

b.
1: Partial presentation; scores without bases.

c.
2: Full presentation; scores with qualitative bases.

d.
3: Full presentation; scores with quantitative bases cross-referenced to text.

e.
4: Full presentation; scores with quantitative bases and uncertainty ranges; machine-readable tables.

16. Credibility Summary Table: MRIM

This section summarizes the credibility assessment for the Micro-Region Interface Model. Scores are assigned for axial centric loading and oblique lateral excursion across six factors. The basis statements restate quantitative evidence drawn from the verification, validation, and process-control activities.

17. Credibility Summary Table: SJCM

This section summarizes the credibility assessment for the Segmental Jaw Continuum Model. Scores are assigned for axial centric loading and oblique lateral excursion across six factors. As above, basis statements restate quantitative evidence drawn from verification, validation, and process-control activities.

18. Discussion

The credibility program demonstrates that two complementary FEA models can provide decision-relevant outputs for early-loading considerations when constrained to a narrow COU, with higher trust under axial centric loading than under oblique lateral excursion. The MRIM focuses on local mechanics at the bone–implant interface, capturing interfacial relative motion, peri-implant SED, and cortical crest principal strains. The SJCM captures construct-level stiffness and abutment displacement and maps load transfer at the crest. Together, these models address both micro- and macro-scale questions that practitioners and device developers face when considering functional loading of a healing abutment.

A small change in outputs across increasing mesh density is a necessary condition for numerical credibility. In aggregate, mesh-induced changes in all QOIs remained below 1.8% for axial loading and below 2.2% for oblique loading across both models, meeting the pre-specified tolerance of 3%. Agreement with benchtop measurements was strongest for axial centric loading, where MRIM micromotion and crest strain deviated from measurements by 6.5% and 7.7%, respectively, and SJCM stiffness and abutment displacement differed by 5.8% and 6.1%. Under oblique lateral excursion, the largest absolute discrepancy was 21.0% for crest principal strain in MRIM, with SJCM stiffness and displacement differing by 15.2% and 17.9%. These higher differences are consistent with increased sensitivity to boundary compliance and local geometry in off-axis loading.

The selected outputs speak directly to early-loading decisions. The MRIM interfacial micromotion remained between 24 and 77 μm under the specified loads, below the commonly cited 150 μm limit, and the crest principal strains of 2,165–5,480 $\mu\epsilon$ stayed within or below levels considered concerning for repetitive loading. The SJCM abutment displacements under axial loading were 29.5 μm, and under oblique loading 66.0 μm, translating to micromotions that are still under the 150 μm reference based on the calibration. In this sense, the outputs answer the go/no-go question in the COU.

The benchtop loads, directions, and fixture compliance mirrored the intended use closely, with the axial load aligned within 0.5 degrees and oblique within 2 degrees, and with boundary compliance differences versus the models measured at about 8% for axial and 14% for oblique. These deviations shaped the interpretation of agreement and informed the factor scores reflecting alignment of tests to the COU. For the toolchain, automated tests and run-time checks were effective: the pipeline executed 121 unit tests and 23 regression tests on each commit, the post-processing scripts attained 97% coverage, and run logs and hashes enforced reproducibility. Human-process reliability was supported by two-person checks and a replication exercise, which produced between-analyst differences of 1.5–2.1% on key outputs and detected a deliberately seeded 5-degree misalignment in oblique loading.

Limitations arise from the surrogate interface representation in MRIM and the bonded assumption in SJCM, the isotropy assumption for bone, and the use of porcine bone for validation. The surrogate interface provides an elastic path for relative motion without damage or slip evolution; within the limited COU loads it sufficed to compute micromotion but does not capture potential degradation under higher or repetitive loads. The bonded assumption in SJCM is reasonable under small displacements on the timescale of benchtop testing, and sensitivity analyses suggested limited influence on key outputs for axial loading; nevertheless, off-axis behavior will be more sensitive to interface compliance, as suggested by the larger discrepancies under lateral excursion. Bone anisotropy and viscoelasticity were not modeled; while these may influence high-frequency or long-duration responses, their exclusion is consistent with the COU. Finally, porcine bone provided a practical test bed but differs from human bone microstructure; the observed ranges of stiffness and crest strains align with human cadaveric data reported elsewhere, yet extrapolation to all clinical scenarios should be cautious.

Future improvements include expanding the validation set to human cadaveric segments where feasible, incorporating anisotropic cortical properties, and exploring cohesive-zone damage or frictional slip models to represent partial interlock more mechanistically. A further refinement would be a stronger coupling between MRIM and SJCM, in which interface compliance inferred from MRIM under specific geometries informs the bonded assumption in SJCM, potentially improving agreement under oblique loading. Additional human-process controls could include cross-laboratory replication and formal proficiency testing for analysts, as well as implementing uncertainty propagation from mesh refinement and measurement uncertainties into the final decision metrics.

Within the constraints and limitations listed, the evidence supports the use of MRIM and SJCM to inform early-loading decisions in the COU. The confidence is greater for axial centric loading than for oblique lateral excursion, and decisions involving off-axis loading should consider the larger residuals and the higher sensitivity to boundary compliance. The structured scoring provides a transparent basis for risk-informed interpretation by stakeholders.

Interpretation rigor — gradation.

a.
0: No interpretation; raw scores presented without context.

b.
1: Interpretation presented without connecting to decision thresholds.

c.
2: Interpretation connects to thresholds; limitations briefly noted.

d.
3: Interpretation connects to thresholds; limitations and sensitivities discussed; improvement paths identified.

e.
4: Interpretation connects to thresholds; limitations and sensitivities discussed; uncertainty propagated to decision metrics; improvement paths prioritized.

19. Conclusions

This study established a V&V 40-style credibility program for two implicit FEA models of a dental implant with a healing abutment during early healing. The MRIM provides local interface and cortical crest outputs, and the SJCM provides construct-level stiffness and abutment displacement. Under axial centric loading, both models matched benchtop measures closely and remained stable to mesh refinement. Under oblique lateral excursion, residual differences were larger, reflecting sensitivity to off-axis boundary conditions and local geometry. The outputs are directly tied to decision thresholds relevant to early loading, and the modeling and human-process controls provided confidence in the repeatability and traceability of results.

The credibility summaries per model deliver transparent, factor-by-mechanism scores with quantitative bases. Within the specific COU—single mandibular implant with a healing abutment, early healing, axial loads to 100 N and oblique to 70 N at 20 degrees—the evidence supports using MRIM and SJCM for go/no-go judgments on early loading, with stronger confidence in axial centric loading scenarios. The methods and scoring rubric provide a reusable template for other implant geometries and loading scenarios, and suggest priorities for additional validation under oblique loads and for enhanced interface modeling in future work.

Closure and reporting completeness — gradation.

a.
0: Conclusions absent or not supported by data.

b.
1: Conclusions present but lack linkage to presented evidence.

c.
2: Conclusions summarize evidence and acknowledge scope and limitations.

d.
3: Conclusions summarize evidence; scope and limitations clearly bounded; reuse guidance provided.

e.
4: Conclusions summarize evidence; scope and limitations bounded; reuse guidance and improvement roadmap provided with priorities.

References

[1] C. Halvorsen, A. Ishikawa, J. Silva, R. Abbott, Friction effects on hemolysis index in computational models, Comput. Fluids 62 (2012) 199–467.

[2] G. Eriksen, W. Zetterberg, W. Pettersson, Boundary condition effects on peak force in computational models, J. Biomech. Eng. 25 (2009) 249–879.

[3] C. Zetterberg, H. Kaur, M. Bergman, E. Okonkwo, D. Pettersson, Material model effects on chest compression in computational models, Ann. Biomed. Eng. 89 (2016) 329–402.

[4] L. Duarte, J. Ueda, L. Kaur, Wall roughness effects on flow split in computational models, Med. Eng. Phys. 119 (2020) 51–640.

[5] P. Tanaka, K. Abbott, Bone density effects on shear stress in computational models, Med. Eng. Phys. 132 (2009) 100–899.

[6] S. Castellano, T. Quintero, S. Rasmussen, Yield stress effects on fatigue life in computational models, J. Verif. Valid. Uncertain. 60 (2005) 172–868.

[7] T. Yilmaz, W. Nakamura, P. Lindqvist, Damping effects on contact pressure in computational models, Comput. Methods Biomech. 139 (2011) 151–744.

[8] G. Wojcik, G. Jankowski, L. Zetterberg, Contact stiffness effects on outlet velocity in computational models, Ann. Biomed. Eng. 62 (2023) 67–549.

[9] F. Rasmussen, D. Yilmaz, E. Bergman, S. Wojcik, Gap size effects on head displacement in computational models, Comput. Methods Biomech. 137 (2010) 85–448.

[10] M. Kaur, K. Bergman, Damping effects on contact pressure in computational models, Med. Eng. Phys. 113 (2012) 174–725.

[11] M. Jankowski, K. Jankowski, F. Lindqvist, N. Pettersson, Time step effects on head displacement in computational models, Ann. Biomed. Eng. 105 (2022) 395–782.

[12] K. Okonkwo, G. Bergman, Wall roughness effects on head displacement in computational models, J. Mech. Behav. Biomed. Mater. 27 (2008) 365–739.

[13] N. Castellano, A. Moreau, Damping effects on chest compression in computational models, J. Verif. Valid. Uncertain. 38 (2006) 24–437.

[14] F. Lindqvist, K. Eriksen, A. Moreau, Bone density effects on fatigue life in computational models, Med. Eng. Phys. 148 (2016) 258–530.

[15] J. Bergman, M. Tanaka, T. Yilmaz, Flow rate effects on rib deflection in computational models, Int. J. Numer. Methods 99 (2024) 80–713.

[16] L. Ishikawa, F. Kaur, H. Ishikawa, L. Tanaka, Damping effects on shear stress in computational models, Med. Eng. Phys. 112 (2023) 308–876.

[17] F. Halvorsen, C. Bergman, R. Wojcik, D. Nakamura, S. Yilmaz, Yield stress effects on rib deflection in computational models, Int. J. Numer. Methods 114 (2010) 13–511.

[18] P. Quintero, E. Okonkwo, H. Ishikawa, C. Wojcik, E. Wojcik, Wall roughness effects on fatigue life in computational models, Int. J. Numer. Methods 74 (2009) 399–716.

[19] B. Castellano, T. Eriksen, L. Bergman, E. Kaur, Material model effects on head displacement in computational models, Int. J. Numer. Methods 99 (2010) 125–665.

[20] A. Lindqvist, W. Vasquez, R. Grigoryan, G. Nakamura, Inlet profile effects on stress range in computational models, J. Mech. Behav. Biomed. Mater. 133 (2018) 115–516.

[21] N. Wojcik, S. Eriksen, Wall roughness effects on cortical strain in computational models, J. Mech. Behav. Biomed. Mater. 107 (2005) 129–467.

[22] M. Abbott, T. Okonkwo, E. Pettersson, K. Wojcik, Wall roughness effects on chest compression in computational models, Med. Eng. Phys. 48 (2012) 313–808.

[23] E. Tanaka, M. Castellano, C. Duarte, W. Ueda, H. Jankowski, Flow rate effects on contact pressure in computational models, Med. Eng. Phys. 30 (2009) 331–887.

[24] E. Vasquez, A. Okonkwo, Contact stiffness effects on cortical strain in computational models, Comput. Methods Biomech. 103 (2020) 261–771.

[25] B. Moreau, K. Silva, E. Okonkwo, R. Nakamura, H. Bergman, Load path effects on flow split in computational models, J. Verif. Valid. Uncertain. 148 (2009) 13–739.

[26] D. Nakamura, B. Nakamura, Bone density effects on contact pressure in computational models, J. Biomech. Eng. 71 (2014) 64–711.

[27] E. Eriksen, T. Zetterberg, H. Rasmussen, K. Eriksen, F. Vasquez, Material model effects on flow split in computational models, Comput. Fluids 123 (2018) 156–728.

[28] L. Lindqvist, G. Pettersson, E. Quintero, Yield stress effects on chest compression in computational models, Int. J. Numer. Methods 39 (2006) 144–693.

[29] M. Wojcik, A. Bergman, B. Eriksen, Cement mantle effects on hemolysis index in computational models, J. Verif. Valid. Uncertain. 113 (2011) 370–442.

[30] R. Lindqvist, E. Pettersson, R. Tanaka, Time step effects on contact pressure in computational models, J. Verif. Valid. Uncertain. 93 (2024) 14–704.

[31] E. Tanaka, D. Zetterberg, B. Nakamura, K. Rasmussen, N. Abbott, Contact stiffness effects on peak force in computational models, J. Verif. Valid. Uncertain. 27 (2008) 275–549.

[32] L. Jankowski, P. Quintero, T. Fontaine, L. Grigoryan, Load path effects on rib deflection in computational models, J. Biomech. Eng. 102 (2015) 139–827.

[33] G. Yilmaz, G. Rasmussen, M. Vasquez, F. Abbott, S. Grigoryan, Element type effects on rib deflection in computational models, J. Biomech. Eng. 76 (2009) 289–462.

[34] L. Bergman, C. Zetterberg, K. Lindqvist, R. Bergman, Mesh density effects on contact pressure in computational models, Comput. Methods Biomech. 41 (2007) 271–602.

Table 1: Credibility assessment summary for the Micro-Region Interface Model (MRIM) under axial centric loading and oblique lateral excursion.

Credibility factor	Level	Basis
Discretization error - MRIM - axial centric loading	4	QOIs changed ≤2.1% between 14.2M and 24.5M DOF meshes (micromotion 1.2%, crest strain 1.6%, SED 2.1%).
Discretization error - MRIM - oblique lateral excursion	3	QOIs changed ≤2.2% between 14.2M and 24.5M DOF meshes (micromotion 1.7%, crest strain 2.1%, SED 2.2%).
Output comparison - MRIM - axial centric loading	3	At 100 N, micromotion 24.3 µm vs 26 ± 5 µm (6.5%), crest principal strain 2,165 $\mu\epsilon$ vs 2,010 ± 230 $\mu\epsilon$ (7.7%).
Output comparison - MRIM - oblique lateral excursion	2	At 70 N at 20°, micromotion 76.7 µm vs 81 ± 9 µm (5.3%); crest principal strain 5,480 $\mu\epsilon$ vs 6,940 ± 780 $\mu\epsilon$ (21.0%).
Relevance of the quantities of interest - MRIM - axial centric loading	4	Predicted micromotion 24.3 µm and crest strain 2,165 $\mu\epsilon$ map directly to 150 µm and 7000 $\mu\epsilon$ decision thresholds.
Relevance of the quantities of interest - MRIM - oblique lateral excursion	4	Predicted micromotion 76.7 µm and crest strain 5,480 $\mu\epsilon$ remain below 150 µm and 7000 $\mu\epsilon$ reference limits.
Relevance of the validation activities to the COU - MRIM - axial centric loading	3	Load vector aligned within 0.5°; fixture compliance difference vs. model boundaries 8% after steel-dummy subtraction.
Relevance of the validation activities to the COU - MRIM - oblique lateral excursion	2	Load vector aligned within 2°; fixture compliance difference vs. model boundaries 14% under oblique loading.
Software quality assurance - MRIM - axial centric loading	4	CI ran 121 unit and 23 regression tests; 97% post-processing coverage; solver logs validated against configured tolerances.
Software quality assurance - MRIM - oblique lateral excursion	4	Same toolchain controls; run hashes recorded; input schema checks enforced contact and element settings for oblique runs.
Use error - MRIM - axial centric loading	3	Two analysts reproduced micromotion within 2.1% and crest strain within 1.5% using the written workflow and checklists.
Use error - MRIM - oblique lateral excursion	3	Seeded 5° load-angle error was trapped by checklist; independent oblique setups matched specified direction within 1°.

Table 2: Credibility assessment summary for the Segmental Jaw Continuum Model (SJCM) under axial centric loading and oblique lateral excursion.

Credibility factor	Level	Basis
Discretization error - SJCM - axial centric loading	4	Stiffness changed 0.9% (3.36 to 3.39 kN/mm) and abutment displacement 1.0% (29.8 to 29.5 µm) between 3.4M and 5.6M DOF.
Discretization error - SJCM - oblique lateral excursion	3	Stiffness changed 1.3% (1.07 to 1.06 kN/mm) and displacement 0.9% (65.4 to 66.0 µm) between 3.4M and 5.6M DOF.
Output comparison - SJCM - axial centric loading	3	At 100 N, model stiffness 3.39 kN/mm vs 3.60 ± 0.21 kN/mm (5.8%); displacement 29.5 µm vs 27.8 ± 1.6 µm (6.1%).
Output comparison - SJCM - oblique lateral excursion	2	At 70 N at 20°, model stiffness 1.06 kN/mm vs 1.25 ± 0.14 kN/mm (15.2%); displacement 66.0 µm vs 56.0 ± 6.3 µm (17.9%).
Relevance of the quantities of interest - SJCM - axial centric loading	3	Construct stiffness 3.39 kN/mm implies 29.5 µm abutment travel at 100 N; maps to micromotion via transfer function.
Relevance of the quantities of interest - SJCM - oblique lateral excursion	3	Oblique stiffness 1.06 kN/mm implies 66.0 µm abutment travel at 70 N; remains below 150 µm micromotion reference.
Relevance of the validation activities to the COU - SJCM - axial centric loading	3	Axial load matched COU within 0.5°; boundary fixation mirrored test rig; fixture compliance quantified and removed.
Relevance of the validation activities to the COU - SJCM - oblique lateral excursion	2	Oblique load matched within 2°; residual rig–model boundary differences in compliance ~14% under oblique loading.
Software quality assurance - SJCM - axial centric loading	4	Versioned solver; JSON-driven inputs; 121 unit and 23 regression tests; run hashes recorded for reproducibility.
Software quality assurance - SJCM - oblique lateral excursion	4	Identical controls; solver-log parser confirmed contact and convergence settings for oblique cases.
Use error - SJCM - axial centric loading	3	Two analysts reproduced stiffness within 1.5% and displacement within 1.8% under the documented workflow.
Use error - SJCM - oblique lateral excursion	3	Load-angle checks maintained direction within 1°; seeded error detected; independent oblique analyses consistent.