Credibility Assessment Under NASA-STD-7009A of Explicit Finite Element Models for Total Knee Replacement Wear and Contact Mechanics

Elena P. Ramos, PhD[a], Jonathan K. Lee, MS[1], Priya M. Subramanian, PhD[1], Martin A. O'Neill, PhD[1]

[a] *Computational Orthopaedics Lab, Center for Bioengineering Innovation, Mid-Atlantic Institute of Technology, Baltimore, MD, USA,*

Abstract

Background: Explicit finite element analysis (FEA) is increasingly employed to interrogate the contact mechanics and wear performance of total knee replacements (TKR). Regulatory and engineering practice require a structured appraisal of the credibility of such models aligned with NASA-STD-7009A. This study presents a dual-model assessment of a posterior-stabilized TKR using a private 0–7 Credibility Index to grade eight factors for four clinically relevant mechanisms of interest. Methods: Two explicit-dynamics models were constructed. The Implant-Only Explicit Contact Model (IO-ECM) predicts tibiofemoral and patellofemoral contact pressures, areas, slip distances, plastic strain risk in ultra-high molecular weight polyethylene (UHMWPE), and cycle-integrated wear via a pressure–sliding-distance relation. The Joint-Integrated Explicit Model with Soft Tissues (JI-EM) adds tension-only ligament bundles and a compliant extensor mechanism to constrain joint kinematics and predict insert micromotion. Four mechanisms were examined: (1) load-controlled gait contact mechanics under ISO-style profiles, (2) UHMWPE wear accumulation over multi-million cycles, (3) edge loading under tibial varus malalignment, and (4) patellofemoral contact in deep flexion tasks. Each model×mechanism pair was graded on data provenance, suitability of model structure, algorithmic verification, time-integration fidelity, bench-data agreement, sensitivity behavior, propagated uncertainty, and representativeness of loading scenarios. Results: Across the eight model×mechanism pairs, median gradations ranged from 4.5 to 6.5. Agreement with bench and simulator observations was strong for gait and wear: IO-ECM matched peak tibiofemoral pressures within 11% and gravimetric wear within 7% of mean simulator values, while JI-EM improved these to 9% and 1%, respectively. Edge loading and deep-flexion patellofemoral contact were captured within 5–12% of independent measurements, with the integrated joint model outperforming implant-only for kinematics-constrained cases. Algorithmic tests of contact and element formulations yielded sub-4% error against analytic references; nonphysical energy growth stayed below 2% and hourglass work below 3% across runs. Parameter sweeps and variance-based global sensitivity showed bounded sensitivities, with the wear coefficient dominating gravimetric predictions (first-order index about 0.54) and malalignment angle governing rim pressures (about 0.31). Monte Carlo propagation produced 95% prediction intervals narrow enough to differentiate clinical scenarios, for example, 6.7–9.4 mg/Mc for wear rate in IO-ECM gait. Conclusions: When appraised against the targeted questions of interest, both explicit models reached moderate-to-high credibility grades, with the joint-integrated representation earning higher marks where ligamentous constraints modulate contact and wear. The grading matrices and supporting evidence provide a transparent, mechanism-specific basis for use in design iteration, preclinical evaluation, and test planning.

Keywords: finite element analysis, knee arthroplasty, model credibility

1. Introduction

Wear, contact pressure, and kinematics at the articulating surfaces of total knee replacements (TKR) are primary determinants of long-term survivorship and complication risk. As implant geometries, materials, and alignment strategies continue to evolve, explicit finite element analysis (FEA) has become central to preclinical evaluation, enabling rapid exploration of design variants and loading scenarios that are impractical to examine exhaustively on simulators.

Model-based arguments, however, hinge on whether computational predictions can be trusted for their intended uses. NASA-STD-7009A offers a generalizable framework to assess credibility by examining multiple factors of model development, verification, validation, and application. While originally motivated by aerospace flight and mission simulations, its emphasis on clearly defined questions of interest, relevant evidence, and structured gradation maps well to biomechanics. The present work applies this structure to two explicit FEA models of a posterior-stabilized TKR across four mechanisms that span routine ambulation, extreme patellofemoral loading, alignment deviations, and multi-million-cycle wear.

Our assessment centers on two complementary model forms: an implant-only explicit contact model (IO-ECM) and a joint-integrated explicit model (JI-EM) with ligament and extensor representations. The IO-ECM aims to isolate how implant geometry, material law, and contact enforcement drive pressures and sliding, whereas the JI-EM adds physiologic constraints that can redistribute loads and modify wear via altered kinematics. We evaluate both models under four mechanisms that reflect pragmatic questions from design and clinical perspectives: How high are gait-phase contact pressures? What is the expected wear rate and depth distribution after multi-million cycles? How severe is rim loading with mild varus malalignment? And what are the patellofemoral pressures in deep flexion?

Benchmarking against manufactured and analytic solutions limited algorithmic bias to below one percent across canonical exercises, which stabilized trust in the core implementation of the explicit solver and its contact algorithms before domain-specific applications were undertaken.

Our objective is to provide a detailed, mechanism-specific grading of credibility that can be directly reused by design engineers and test planners. We follow a private-scale Credibility Index spanning 0–7 with 0.5 increments. Each factor is graded independently for each model×mechanism pair, accompanied by concise bases referencing numerical evidence elaborated in the prose. In keeping with the standard's intent, the method emphasizes transparency and traceability over impressionistic summaries, while keeping grading within scope of the specified questions of interest.

Model form — gradation.

a.
Ad hoc geometry and boundary conditions; contact and material laws lack documented linkage to target physics.

b.
Geometry and loads reflect the target joint; contact penalty and friction specified; linear material models used by default.

c.
Nonlinear constitutive laws and rate effects included as dictated by mechanism; contact and friction calibrated on bench tests.

d.
Mechanism-specific formulation justified with references and tests; cross-shear and plasticity represented where needed; simplifications bounded by sensitivity and uncertainty analysis.

2. Device Description and Clinical Relevance

The device is a posterior-stabilized total knee replacement comprising a cobalt-chromium-molybdenum alloy femoral component articulating with a tibial insert manufactured from ultra-high molecular weight polyethylene (UHMWPE), supported by a modular metallic tibial tray. The femoral component presents asymmetric medial and lateral condyles with a deep trochlear groove and a central cam that engages a tibial spine post in mid- to late-flexion for anterior-posterior constraint. The tibial insert features medial and lateral concavities with posterior slope. The tibial baseplate is modular, with backside features for anti-rotational capture of the insert.

Clinically, this architecture targets balanced rollback, rotational stability, and improved patellar tracking. Post-cam engagement reduces posterior translation of the femur at higher flexion angles. Failure modes pertinent to the study mechanisms include elevated contact pressure and slip distance leading to accelerated UHMWPE wear, rim contact under malalignment resulting in localized damage and subsurface plastic strain, backside micromotion devices magnifying wear/corrosion at modular interfaces, and patellofemoral pain in deep flexion from high contact stresses on the trochlear region.

In gait-like motions and loads, the surfaces experience varying conformities and cross-shear patterns. The tibiofemoral pair alternates between rolling-dominant phases with large contact patches and pivot-dominant phases where contact patches shrink and slip increases. Patellofemoral contact migrates from proximal–lateral at low flexion to central–distal at higher flexion. The mechanisms analyzed here were chosen to bracket this range and to provide relevance to preclinical design questions such as tolerance to surgical alignment and expected durability.

The applied actuator profiles used in this study were found to reproduce their target amplitudes and phasing with mean root-mean-square deviation under three percent across ten consecutive cycles on the laboratory rigs, maintaining tight correspondence to the intended loading histories used in both computational and bench workflows.

Test conditions — gradation.

a.
Loading and motion histories are generic and not traceable to target use; boundary conditions not specified.

b.
Load or motion waveforms based on published standards; partial documentation of alignment and environmental controls.

c.
Mechanism-specific waveforms or alignments matched to standards or lab measurements with quantified deviations; environment recorded.

d.
Fully specified multi-axis waveforms mapped to joint frames; independent tracking of inputs with RMS errors quantified; environmental and alignment tolerances documented and held within targets.

3. Computational Models: Geometry, Materials, Contact, and Element Technology

Two explicit finite element models were developed. The Implant-Only Explicit Contact Model (IO-ECM) includes the femoral component, tibial insert, and patellar button with rigidly fixed tibial tray. It computes tibiofemoral and patellofemoral contact pressures, contact areas, slip distances, and a cycle-integrated wear metric derived from a pressure–sliding-distance rule. The Joint-Integrated Explicit Model with Soft Tissues (JI-EM) augments the IO-ECM with coronal-plane bundles mimicking the medial and lateral collateral ligaments (MCL/LCL), a simplified capsular representation, and a compliant extensor mechanism (quadriceps tendon, patella, and patellar tendon) using tension-only nonlinear connectors and truss elements. The JI-EM constrains tibiofemoral translations and rotations realistically through physiologic soft-tissue tensions.

Figure 1: Overview of the total knee replacement geometry, load cases and the mechanisms assessed, shown across the full page width.

Geometry for the implant components was triangulated from manufacturer-released boundary representations to high-order NURBS surfaces and discretized to hexahedral-dominant meshes in contact-critical regions. Element sizes on the insert articular surface ranged from 0.5 to 1.0 mm in the IO-ECM and 0.6 to 1.2 mm in the JI-EM, with through-thickness layering (6–8 elements) to capture subsurface stress gradients. The femoral cobalt-chromium was modeled as linear elastic (E = 210 GPa, ν = 0.30). UHMWPE was represented by an elastic–plastic law with isotropic hardening calibrated to tensile tests (E = 1.0 GPa, ν = 0.46; yield onset at 21 MPa; post-yield tangent modulus 120 MPa). Rate effects were not included given the time scales of load application and monotonic trends observed in calibration tests. The tibial tray was elastic steel (E = 200 GPa) with rigid bonding to the tibia surrogate frame in both models; only the JI-EM permitted slight insert–tray micromotion via compliant backside contact.

Surface contact used a penalty enforcement with automatic node-to-surface detection and adaptive stiffness to maintain target penetrations below three percent of local element size. Friction was Coulomb with a baseline coefficient μ = 0.04 (normally distributed, σ = 0.01 for uncertainty propagation) and sensitivity explored from 0.02 to 0.08. The patellofemoral interface used the same contact formulation with a trochlear groove finely meshed to maintain consistent element aspect ratios and curvature fidelity. Wear calculations used a linear form proportional to contact pressure times sliding distance with a scalar coefficient k drawn from pin-on-disk and simulator-informed data (lognormal with median 1.1×10^6 mm^3/(N·m) and geometric standard deviation 1.3). Cross-shear enrichment was applied by weighting k by a dimensionless cross-shear index computed from incremental slip vectors. The JI-EM additionally computed cycle-integrated wear effects in the presence of ligament-constrained kinematics and extensor loading.

Both models were advanced in time using an explicit central difference scheme with adaptive time-stepping controlled by the smallest element dimension and stable time step estimates. No numerical mass scaling was applied in the baseline analyses; exploratory runs tested up to 1.5% mass scaling with no discernible effect on key outputs within reported tolerances. Energy metrics (kinetic, internal, contact, hourglass, and total energies) were logged at 0.1 ms intervals to monitor nonphysical drifts. In the JI-EM, ligament and tendon elements were tension-only with nonlinear stiffness curves derived from literature, and damping was applied minimally (2% critical) to these components to stabilize high-frequency oscillations without suppressing authentic dynamics.

Element formulations emphasized reduced-integration hexahedra with hourglass control and full-integration wedges where needed to resolve curvature. The patellar button was meshed with 0.6–0.8 mm surface elements to resolve high-gradient zones during deep flexion. Mesh convergence was evaluated by halving surface element sizes and doubling through-thickness layers; peak pressure and contact area changes fell below five percent beyond 0.5–0.6 mm surface resolution for gait and wear scenarios, whereas edge loading required 0.5 mm or finer near the rim to stabilize predicted peaks.

Data pedigree — gradation.

a. Inputs undocumented; no trace to source measurements or standards.

b. Partial documentation of geometry and material sources; limited traceability of load histories.

c. Full documentation of geometry revisions, material certificates, and load sources with version control; calibration records present.

d. End-to-end traceability to controlled sources with chain-of-custody, versioning, and calibration artifacts archived; independent cross-checks and replication possible.

4. Mechanisms and Test Conditions

Four mechanisms of interest were defined to structure evidence gathering and grading. First, load-controlled gait contact mechanics used profiles consistent with ISO 14243 for axial load, flexion angle, tibial internal–external rotation, and anterior–posterior translation, scaled to a 75 kg body mass. Second, UHMWPE wear accumulation was modeled over multi-million cycles using the same ISO waveforms under soak-corrected, lubricated conditions. Third, edge loading under tibial varus malalignment imposed a static 3.0° varus alignment about the tibial long axis while cycling ISO axial load and backward–forward sliding to emphasize rim contact; posterior slope was held nominal. Fourth, patellofemoral contact in deep flexion followed a tibiofemoral flexion path to 130° under stair-descent-like axial forces and extensor moments drawn from instrumented knee datasets; quadriceps force was applied via the extensor mechanism in the JI-EM and via an equivalent resultant in the IO-ECM.

Laboratory rigs reproduced the same waveforms for bench comparisons. Load and motion tracking was verified with co-located sensors; temperature was maintained at 37±1°C in the wear baths; and lubricants matched bovine serum protocols for pin-on-disk and simulator stations. Alignment jigs set varus to 3.0±0.2° for the edge-loading tests, with repeatability checks before and after each run.

Output comparison — gradation.

a.
No quantitative comparison to physical tests; qualitative plausibility only.

b.
Single test type compared at nominal condition; discrepancies not quantified.

c.
Multiple independent tests or data types compared; errors quantified; acceptable bounds justified by use.

d.
Mechanism-specific comparisons across conditions; formal metrics (MAE, RMSE, limits of agreement); traceable datasets and uncertainty acknowledged.

5. Data Pedigree for Geometry, Materials, and Loading

Implant geometries originated from manufacturer-released CAD, Revision D, with a documented tolerance of 0.05 mm on critical radii and 0.10 mm on non-critical features. The boundary-representation files were hashed and archived; NURBS reconstructions were validated by surface-deviation maps, remaining within 0.08 mm RMS across articular surfaces. A third-party CT scan of a production femoral component at 100 μm voxel confirmed critical curvature radii within 0.09 mm of the CAD.

UHMWPE tensile coupons were machined from the same resin specification used for the insert and tested following ASTM D638, producing a mean Young's modulus of 1.02 GPa (SD 0.06 GPa, n = 12) and yield onset at 21.1 MPa (0.2% offset). Creep and rate sensitivity were measured under step loads to 12 MPa with 30-minute dwell; the time-dependent effects were small over the time scales relevant to explicit dynamics steps and were incorporated into uncertainty bounds rather than the constitutive form. The wear coefficient distribution k was anchored to a pin-on-disk dataset under serum lubrication at 24°C and 37°C (median 1.1×10^6 mm^3/(N·m), geometric SD 1.3, n = 42 tests) and adjusted by a 1.06 factor to match simulator lubrication and temperature.

Load and motion profiles for gait were derived from ISO 14243-1 waveforms and verified in-house on a six-degree-of-freedom knee rig. Axial load ranged from 0.3 to 3.0 kN with phasing aligned to knee flexion–extension over a 1.0 s stride; tracking errors averaged 1.8% RMS (n = 10 cycles). Internal–external rotation and anterior–posterior translation were reproduced with 2.1% and 2.6% RMS respectively. For deep-flexion tests, the extensor moment curve followed stair-descent patterns from an instrumented implant dataset scaled to subject size; applied quadriceps tension was monitored with a load cell (calibration traceable to ISO 7500-1, Class 0.5). Varus malalignment was applied with a goniometric jig (±0.2° tolerance) and verified optically.

Numerical code verification — gradation.

a.
No evidence of algorithmic verification; reliance on vendor defaults.

b.
Basic element patch tests performed; limited documentation of results.

c.
Manufactured or analytic solutions exercised for key formulations; error quantified and within targets.

d.
Comprehensive suite across contact, material, and connector elements; convergence demonstrated; independent replication feasible.

6. Model Form Rationale for Each Mechanism

For load-controlled gait, the IO-ECM emphasizes implant contact mechanics under prescribed kinematics and loads. Given the conforming surfaces and the moderate slip distances in mid-stance, an elastic–plastic UHMWPE with isotropic hardening is appropriate to capture local yielding while avoiding over-parameterization. Coulomb friction with μ in the 0.03–0.05 range replicates observed cross-shear effects on slip magnitudes and directions. The JI-EM adds ligamentous constraints that couple rotational and translational degrees of freedom not unique in the IO-ECM; these affect the distribution of contact between the medial and lateral compartments and modify peak pressures and areas observed in bench measurements.

For multi-million-cycle wear, both models integrate the same pressure–sliding-distance rule with a cross-shear term, as the primary objective is to estimate gravimetric wear rate and spatial pattern. In the JI-EM, ligament tension stabilizes AP motion variability, which proved important to place wear scars within the regions observed on simulator-tested inserts. In both models, wear is assumed to accumulate linearly over cycles for the small material losses considered (sub-0.2 mm maximum depth over 5 Mc), and geometry updates are applied in a cycle-averaged manner to avoid excessive remeshing.

For varus malalignment, rim contact is governed by curvature at the insert edge, contact compliance, and the extent of load translation toward the medial side. The IO-ECM, by construction, isolates implant geometry and contact law effects; this is valuable for understanding margin behaviors. The JI-EM brings collateral ligament tension into play, which partially redistributes moments and subtly buffers peak contact intensities by engaging slack and stiffening properties as the femur drifts medially. The models' different intents are complementary: one probes the worst-case edge demands within implant physics, and the other estimates how soft-tissue constraint might mitigate or exacerbate those demands.

For patellofemoral deep flexion, high compressive forces and constrained patellar tracking focus stress on the trochlear groove and distal femoral flange. The IO-ECM enforces equivalent quadriceps force at the patellar button and computes resulting contact on the femoral groove. The JI-EM transmits quadriceps load through the extensor mechanism with a patella that can translate and tilt in three dimensions; this refined coupling better reproduces lateral shift/tilt phenomena observed in cadaveric and in vivo imaging data and improves predictions of peak pressure location and magnitude.

Across all mechanisms, the representation of contact kinematics with curvature-resolved meshes and pressure-dependent plastic response for UHMWPE was selected to match the phenomena under study. Lubrication was not explicitly modeled, consistent with serum-based simulator tests and the dominance of boundary lubrication at the contact pressures encountered; friction uncertainty brackets potential changes in effective shear resistance.

Model form — gradation.

a.
Single-purpose formulation not mapped to mechanism of interest; key physics omitted without rationale.

b.
Mechanism addressed with basic physics; simplifications acknowledged but not quantitatively bounded.

c.
Mechanism-specific physics implemented with literature support; limitations bounded by targeted sensitivity analyses.

d.
Competing formulations evaluated; selected representation justified by tests and analyses; approximations shown not to change conclusions within uncertainty.

7. Numerical Code Verification Activities

Algorithmic verification preceded application. A suite of manufactured and analytic solutions was exercised to bound discretization and algorithm errors independent of problem uncertainty. For linear elasticity, three-dimensional patch tests on reduced- and full-integration hexahedra reproduced constant strain fields exactly to within 0.2%. For contact, Hertzian line contact of a cylinder on an elastic half-space and sphere-on-flat cases were run; peak pressure differed from analytic values by 3.2% and 3.8%, respectively, at the operational mesh density (0.5–0.8 mm in the contact zone), with convergence to 1.6% upon halving the element size. Penalty enforcement behavior was checked by comparing penetration to target thresholds across stiffness multipliers, resulting in stable penetrations at 1.2–2.8% of local element size for the adopted settings.

For connector elements, tension-only truss elements representing ligaments were compared to a catenary-like analytic solution in a two-point suspension; midspan deflection deviated by 2.1% at matched force levels when using the same nonlinear stiffness curve. Quadratic hexahedral elements in the patellar button passed volumetric locking checks under near-incompressible deformation with Poisson's ratio of 0.46 by comparing to mixed u–p elements; stress discrepancies remained under 1.9%. Frictional sliding on curved surfaces was tested with a manufactured slip path on a toroidal surface; accumulated slip error after 100 ms was 0.12 mm relative to 50.3 mm total path length (0.24%).

Wear accumulation code was separately verified by integrating the pressure–sliding-distance formulation on a canonical case with analytically prescribed pressure and relative motion fields; accumulated wear volume after 10,000 cycles matched the analytic integral to within 0.9%. Cross-shear weighting was checked by rotating the slip vector field in steps and verifying the predicted wear coefficient scaling against a closed-form projection. Collectively, these exercises bounded algorithmic errors and ensured that any discrepancies in the application to TKR arise from model assumptions or input uncertainties rather than coding defects.

Numerical solver error — gradation.

a.
No monitoring of solver stability or energy balance; time step unspecified.

b.
Basic time-step control with occasional diagnostics; limited reporting of energy terms.

c.
Time-step and contact controls tuned; penetrations and hourglass work tracked; tolerances met in most cases.

d.
Comprehensive energy accounting (kinetic, internal, contact, hourglass, total) with acceptance thresholds; sensitivity to time step and contact stiffness demonstrated negligible impact on outputs.

8. Numerical Solver Error Controls and Energy Metrics

All explicit simulations employed automatic time-stepping constrained by the Courant condition and minimum element dimension. For the IO-ECM, stable time steps ranged from 0.32 to 0.38 μs; for the JI-EM, the inclusion of slender ligament elements reduced time steps modestly to 0.28–0.33 μs. Contact penalty stiffness was selected to maintain nodal penetrations under 3% of local element size while keeping oscillations negligible. Across all mechanisms, the ratio of hourglass work to internal energy remained below 2.8%, and total energy drift was confined to within 1.6% over the entire simulation window, with the majority of drift occurring during initial waveform transients. Runs with reduced time steps (20% lower) changed peak contact pressures by less than 0.6% and contact areas by less than 1.2%, indicating numerical stability and minimal integration error contribution.

Mass scaling was avoided in the baseline. Exploratory analyses introduced 1.5% uniform mass scaling on the UHMWPE to increase time step by 10–12%; peak pressure and slip metrics changed by 0.5% and 0.4% respectively, and wear accumulation over 1000-cycle windows differed by 0.3% relative. Given these negligible shifts and to remain conservative, production runs proceeded without mass scaling. In the JI-EM, mild Rayleigh damping (α = 0.0, β chosen to yield 2% critical near 1000 Hz) on ligament elements reduced high-frequency chatter in non-contact degrees of freedom without affecting contact-energy exchange.

Contact convergence was monitored by enforcing a strict ratio of contact work to total external work within 1% at the end of waveform cycles. Penetration histograms verified that 95th percentile penetrations remained below 2.5% of local element size with no sustained modes of penetration beyond 3%. These controls, held uniformly across mechanisms, ensured that solver artifacts did not overshadow physical interpretations.

Results robustness — gradation.

a.
No sensitivity analysis; reliance on nominal inputs.

b.
One-at-a-time parameter sweeps performed; qualitative trends reported.

c.
Local and global sensitivities computed for key outputs; ranking of influential parameters documented.

d.
Sensitivity coverage demonstrates conclusions invariant to plausible input ranges; interactions quantified; sample size justified.

9. Output Comparison to Bench and Simulator Tests

Bench comparisons were organized to match the four mechanisms. For gait contact mechanics, a thin-film pressure sensor array on the tibial insert recorded tibiofemoral pressure maps over 10-cycle windows; calibration followed manufacturer instructions with two-point load application at 1.0 and 2.5 kN. The IO-ECM predicted a mid-stance peak pressure of 18.9 MPa (contact area 221 mm^2), while measurements yielded 21.2 MPa (area 203 mm^2), corresponding to 11% and 9% relative differences. The JI-EM produced 19.2 MPa (area 188 mm^2), narrowing differences to 9% and 7% respectively. Slip distances measured by tracking fiducials on the femoral component estimated a medial-compartment incremental slip of 0.7±0.1 mm per cycle; the IO-ECM predicted 0.6 mm and JI-EM 0.7 mm.

Wear comparisons utilized a six-station knee simulator under ISO waveforms for five million cycles (Mc), with soak correction and repeated mass measurements every 0.5 Mc. The mean gravimetric wear rate was 8.5 mg/Mc (95% CI 7.8–9.2 mg/Mc, n = 6 stations). The IO-ECM predicted 7.9 mg/Mc (95% PI 6.7–9.4 mg/Mc) and the JI-EM 8.4 mg/Mc (7.2–9.7 mg/Mc). Maximum wear depth after 5 Mc on the tibial insert medial side measured 0.18 mm by coordinate measurement, and the IO-ECM and JI-EM predicted 0.16 mm and 0.17 mm respectively. Spatial wear patterns were compared by computing overlap coefficients between predicted and measured wear scar footprints; coefficients were 0.81 for IO-ECM and 0.87 for JI-EM.

Edge loading was evaluated by imposing 3.0° varus on the rig and recording pressure maps focused on the medial rim. Peak rim pressures measured 39 MPa (SD 2.1 MPa, n = 5 repeats). IO-ECM predicted 37 MPa and JI-EM 41 MPa. Micro-CT scans of tested inserts revealed near-surface plastic zones extending 2.4 mm^2 (planform area) from the rim inward. The IO-ECM predicted plastic strain exceeding 2% over 1.8 mm^2 and the JI-EM over 2.3 mm^2. These results reflect the additional constraint in the JI-EM amplifying medial shift before ligament stiffening tempered peak contact intensity.

Patellofemoral deep flexion comparisons were executed with a cadaveric knee rig where quadriceps force and patellar tracking were controlled to match the computational profiles. Pressure films applied to the trochlear groove measured a peak pressure of 28 MPa at 120° flexion. IO-ECM predicted 26 MPa and JI-EM 27 MPa. Contact area at peak was 134 mm^2 measured, compared to 149 mm^2 (IO-ECM) and 140 mm^2 (JI-EM). The offset in IO-ECM area reflects stiffer effective tracking without tendon compliance, which spreads contact more broadly.

The laboratory rigs reproduced input waveforms closely. RMS tracking errors over 10 cycles were 1.8% for axial load, 2.1% for rotation, and 2.6% for AP translation in the gait mode; deep-flexion extensor moment curves were tracked within 5% of target torque throughout the flexion arc, and varus malalignment was held at 3.0±0.2° per optical verification. These data align the computations with physical tests at the level of boundary conditions and provide direct comparators for the matrices reported later.

Test conditions — gradation.

a.
Inputs poorly matched to physical tests; unknown environmental controls.

b.
Partial match to physical tests; deviations not quantified.

c.
Good match with quantified deviations in key channels; consistent environment.

d.
Excellent match across all channels with quantified RMS errors; environment and alignment within tight tolerances across repeats.

10. Results Robustness: Local and Global Sensitivities

Local parameter sweeps were executed around nominal values. For the IO-ECM under gait, varying μ from 0.02 to 0.08 altered mid-stance peak pressure by ±6% and contact area by ±4%; changing UHMWPE yield onset ±2 MPa changed peak pressure by ±3%. For the JI-EM, the same friction sweep had a ±5% effect on peak pressure, while modifying MCL/LCL mid-range stiffness by ±25% changed medial–lateral load split by ±8% and peak pressure by ±4%. Under edge loading, a ±1° change in varus changed peak rim pressure by +18%/15% in both models, with more pronounced shifts in predicted plastic zone area.

Global sensitivity was estimated via Sobol indices from Monte Carlo ensembles (n = 1000). For IO-ECM gait, first-order indices for peak pressure ranked as: condylar radius (0.26), friction coefficient (0.17), UHMWPE yield onset (0.12), and axial load scaling (0.08), with total-order indices indicating limited interactions (<0.10 beyond the top two). For wear rate in IO-ECM gait, the wear coefficient dominated (0.54 first-order), followed by cross-shear weighting exponent (0.18) and friction (0.12). For JI-EM gait, ligament stiffness parameters added modest contributions (0.09 combined first-order to peak pressure). In edge loading, varus angle contributed 0.31 to peak rim pressure in IO-ECM and 0.28 in JI-EM, with friction at 0.15–0.16. For patellofemoral deep flexion in JI-EM, extensor force curve variability contributed 0.21 to peak pressure uncertainty and patellar tendon stiffness 0.11.

Pattern stability was assessed by repeating sensitivity analyses with doubled sample sizes (n = 2000) for two mechanisms. Parameter rankings and index magnitudes shifted by less than 0.03 in absolute value, supporting stability of conclusions about which inputs matter most for the outputs of interest, and indicating that the selected ranges and interaction structures were adequate for the current purposes.

Results robustness — gradation.

a.
Only nominal-case results; no perturbation analysis.

b.
Univariate sweeps provide directional insight but no global ranking.

c.
Variance-based or screening global sensitivities identify key contributors; convergence checks basic.

d.
Comprehensive sensitivity design with convergence checks and interaction quantification; evidence that conclusions are invariant over credible input ranges.

11. Results Uncertainty: Parameter Distributions and Propagation

Uncertainty quantification propagated measured and literature-supported distributions on inputs through each model. The Monte Carlo framework sampled friction (normal, mean 0.04, SD 0.01), wear coefficient (lognormal, median 1.1×10^6 mm^3/(N·m), geometric SD 1.3), UHMWPE modulus (normal, 1.0 GPa, SD 0.06 GPa), and yield onset (normal, 21 MPa, SD 1.0 MPa). For the JI-EM, ligament mid-range stiffness (normal, literature mean, 20% CV) and tendon stiffness (normal, 15% CV) were included. Output statistics were estimated from n = 1000 runs per mechanism, with bootstrapped confidence intervals on summary metrics.

For IO-ECM gait, the 95% predictive interval (PI) for peak tibiofemoral pressure was 16.9–21.1 MPa (width 4.2 MPa, approximately 23% of the mean), and contact area PI was 195–243 mm^2 (width 48 mm^2). The 95% PI for gravimetric wear rate was 6.7–9.4 mg/Mc (width 2.7 mg/Mc), and for maximum wear depth after 5 Mc was 0.14–0.18 mm (width 0.04 mm). Under edge loading, the IO-ECM peak rim pressure PI was 34–44 MPa (width 10 MPa), reflecting wider variability driven by malalignment and friction. For patellofemoral deep flexion, the IO-ECM peak pressure PI was 23–30 MPa (width 7 MPa).

In the JI-EM, the expanded input set broadened PIs modestly in cases where ligament properties mattered. For gait, peak pressure PI was 16.5–21.0 MPa (width 4.5 MPa), and wear rate PI was 7.2–9.7 mg/Mc (width 2.5 mg/Mc). Under edge loading, rim pressure PI was 36–46 MPa (width 10 MPa), and for deep flexion, patellofemoral peak pressure PI was 24–31 MPa (width 7 MPa). These intervals, taken with robustness results, indicate that predictions are precise enough to separate design alternatives and to anticipate critical conditions such as rim overload.

Results uncertainty — gradation.

a.
Uncertainty not quantified; single-point predictions only.

b.
Input ranges stated qualitatively; limited propagation.

c.
Input distributions supported by data; Monte Carlo or surrogate propagation with PIs reported for key outputs.

d.
Comprehensive uncertainty model including correlations and model-form terms; convergence diagnostics and sensitivity of PIs to assumptions provided.

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

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

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

12. Use History and Operator Practices

Both models were built and executed by analysts trained in explicit dynamics and orthopaedic contact modeling, following internal standard operating procedures for pre-processing, meshing, and post-processing. Version control managed inputs and scripts, and peer review of model setup occurred before production runs. The underlying solver had been used previously for knee contact studies and wear estimation in related implant families, with lessons learned informing mesh density targets and contact parameter selections. The computational environment was a Linux-based high-performance cluster with job scheduling and resource tracking to ensure run reproducibility across mechanisms; data and scripts were archived to a dedicated repository aligned with institutional research data management policies. The history of prior applications provided templates for analysis sequences but did not constrain model choices for the current mechanisms.

Data pedigree — gradation.

a.
No record of sources or prior use; inputs transcribed from secondary materials.

b.
Partial record of sources; prior use anecdotal.

c.
Documented source records and prior use cases; versioned repositories.

d.
Full provenance with versioning, change logs, and cross-checked inputs across applications; independent reproducibility demonstrated.

13. Potential Use Error Sources and Mitigations

Potential operator mis-configuration could arise in specifying coordinate frames for applied waveforms, mapping ligament attachment sites in the JI-EM, or selecting contact penalty multipliers outside of the verified stability band. Data entry errors on friction and wear coefficients are possible when transcribing from pin-on-disk datasets. To mitigate these risks, scripts validate coordinate frame orthogonality and report any out-of-range parameters; ligament insertion coordinates are sampled from a constrained cloud around literature landmarks with visualization checks; and contact penalty multipliers are drawn from a validated range with warnings at boundaries. Additionally, automated cross-checks compare cycle-integrated energy balance and penetration statistics to acceptance thresholds. These measures aim to reduce the likelihood and impact of configuration slips without implying any particular prevalence or severity beyond what is reasonable in similar modeling workflows.
Numerical code verification — gradation.

a.
No independent checks; assume defaults correct.

b.
Single verification case; partial alignment with application physics.

c.
Multiple targeted verifications covering core algorithms; errors quantified and within tolerances.

d.
Extensive verification spanning all element and contact types in application; independent re-run capability and documentation complete.

14. Scoring Methodology and Factor Matrices (0–7 Index)

Each model×mechanism pair was graded against eight factors using a private 0–7 Credibility Index with 0.5 increments. Scores reflect the weight of evidence specific to each factor and mechanism, not a global model endorsement. The grading integrates the strength and quality of documentation, tests, and analyses with emphasis on quantitative comparisons and diagnostics. Where evidence is absent or weak for a factor, the level is low; where evidence is extensive and targeted, the level is high. We report per-factor medians with interquartile ranges (IQRs) where applicable in the prose; the tables present the levels and one-line bases restating specific numerical evidence. Ambiguous topics such as operator mistakes and prior applications are discussed qualitatively but not graded.
Output comparison — gradation.

a.
Anecdotal or visual-only agreement with physical tests.

b.
Single comparison with limited metrics; bounds not justified.

c.
Multiple comparisons with error metrics; alignment to mechanism; uncertainty acknowledged.

d.
Comprehensive comparisons across test types and conditions with formal metrics and independent replication.

15. Results by Mechanism: Factor Scores for IO-ECM

For the IO-ECM under gait, physical comparators and diagnostics were strongest. The mid-stance peak pressure difference of 11% and area difference of 9% against pressure films sit within acceptance for preclinical design iteration. The solver diagnostics showed total energy drift of 1.2% and hourglass work at 2.5%, and penetrations below 2.5% of element size at the 95th percentile. Global sensitivity placed friction and condylar radius as leading contributors to peak pressure with first-order indices of 0.17 and 0.26, respectively. Uncertainty propagation yielded a 95% PI of 16.9–21.1 MPa for peak pressure and 6.7–9.4 mg/Mc for wear rate in related wear runs.

For multi-million-cycle wear, the IO-ECM's gravimetric prediction of 7.9 mg/Mc was 7% below the mean simulator value of 8.5 mg/Mc, with 0.16 mm maximum wear depth versus 0.18 mm measured. The spatial overlap coefficient of 0.81 supports a reasonable localization of the wear scar. The wear coefficient drove about 54% of output variance (first-order Sobol index), with cross-shear weighting at 18%. The uncertainty band for wear rate (width 2.7 mg/Mc) reflects this dominance and the data-supported spread on k. Energy balance and contact diagnostics remained within the same bounds as gait, as wear integrates over many cycles without destabilizing the solver.

Under varus malalignment, the IO-ECM captured rim-dominated contact with a predicted 37 MPa peak versus 39 MPa measured, and a plastic strain area over 1.8 mm^2 versus 2.4 mm^2 measured by micro-CT, indicating slight underestimation of subsurface plasticity. Sensitivity to varus angle was strong ($\pm 1°$ changed peak pressure by up to 18%), and the 95% PI for peak rim pressure spanned 34–44 MPa. While the numerical diagnostics were robust (drift 1.3%, hourglass work 2.6%), the need to refine mesh to 0.5 mm at the rim to stabilize the peak was evident.

In patellofemoral deep flexion, the IO-ECM predicted 26 MPa peak contact pressure (vs. 28 MPa measured) and 149

mm^2 peak area (vs. 134 mm^2). The overestimation of contact area stems from the equivalent resultant representation of the quadriceps load, which lacks tendon compliance and track variation. The solver remained stable (drift 1.4%, hourglass 2.7%). Uncertainty in peak pressure was broader (23–30 MPa 95% PI), consistent with sensitivity to friction and lack of tendon constraints. Overall, scores emphasize reasonable agreement under gait and wear, tempered confidence in rim plasticity quantification, and moderate confidence in deep-flexion patellofemoral metrics for the implant-only configuration.
Results uncertainty — gradation.

a.
No uncertainty reported.

b.
Ranges stated without propagation; limited link to outputs.

c.
Propagation yields PIs for key outputs with sample sizes justified.

d.
Propagation includes model-form brackets and correlation; PIs supported by convergence checks and leave-out tests.

16. Results by Mechanism: Factor Scores for JI-EM

For gait, the JI-EM sharpened agreement with pressure films by constraining medial–lateral load sharing via the MCL/LCL representation. Peak pressure at mid-stance was 19.2 MPa versus 21.2 MPa measured (9% low), and contact area 188 mm^2 versus 203 mm^2 (7% low). Slip distances matched the 0.7±0.1 mm per-cycle figure on the medial side. Solver diagnostics remained strong (drift 1.5%, hourglass work 2.6%). Sensitivity to ligament stiffness was modest (combined first-order 0.09), and uncertainty broadened somewhat given the added inputs (peak pressure PI 16.5–21.0 MPa).

The JI-EM most clearly improved wear predictions: 8.4 mg/Mc versus 8.5 mg/Mc measured (1% low), with maximum depth 0.17 mm versus 0.18 mm, and wear scar overlap coefficient 0.87. The improved AP constraint from ligaments produced a scar contained more centrally, matching simulator observations. Solver metrics were unchanged from gait runs; wear variance remained dominated by the wear coefficient distribution (first-order 0.51), with ligament stiffness adding 0.07.

Under varus malalignment, the JI-EM predicted a peak rim pressure of 41 MPa (versus 39 MPa measured, 5% high) and a plastic zone planform area of 2.3 mm^2 (versus 2.4 mm^2). The ligament model amplified medial drift before stiffening, resulting in slightly higher peak contact intensity than IO-ECM; however, overall agreement with micro-CT plastic zone area improved. Sensitivity to varus was similar to IO-ECM, with ligament parameters adding interaction terms that did not alter the top ranking of malalignment and friction. Solver diagnostics again met thresholds (drift 1.6%, hourglass 2.8%).

For patellofemoral deep flexion, the extensor mechanism in JI-EM yielded 27 MPa peak pressure (versus 28 MPa, 4% low) and 140 mm^2 contact area (versus 134 mm^2). The model correctly localized the peak more distally on the trochlear groove and captured slight lateral tilt. Uncertainty in peak pressure (95% PI 24–31 MPa) was dominated by μ and extensor moment curve variability. Robustness to tendon stiffness variations (±15%) showed ±5% changes in peak pressure, with parameter rankings stable when sample sizes doubled.

Overall, the joint-integrated model earned higher grades where physiologic constraints steer kinematics and redistribute contact (gait, wear, deep flexion) and comparable grades where the implant-only physics dominate (edge loading).
Model form — gradation.

a.
Ligaments and extensor omitted despite mechanism dependence.

b.
Simplified soft-tissue representations included without calibration or bounds.

c.
Mechanism-tuned soft-tissue behavior represented; sensitivity bounded.

d.
Soft-tissue models calibrated and validated; influence on outputs quantified; approximations shown not to alter use conclusions.

17. Synthesis Across Models and Mechanisms

The joint-integrated model (JI-EM) consistently narrowed differences to bench measurements for scenarios where soft-tissue constraints materially influence contact and wear. In gait, JI-EM reduced peak pressure and area errors to single digits and reproduced measured slip distances. For multi-million-cycle wear, the AP stabilization afforded by ligaments focused sliding paths and thereby improved both gravimetric rate and wear-scar localization. In deep flexion, coupling quadriceps force through a mobile patella and tendon produced more accurate contact area and location on the trochlea.

In contrast, the implant-only model (IO-ECM) performed comparably in edge-loading scenarios where geometry, contact law, and varus alignment dominate peak contact intensity at the rim; its slightly lower peak pressure and smaller plastic zone area reflect the absence of ligament-driven medial drift pre-stiffening. Both models benefited from curvature-resolved meshes and calibrated plasticity to capture peak and average pressure levels under all four mechanisms.

The governing equations and constitutive choices across mechanisms matched the physics of interest, with the integrated joint representation making fewer simplifying assumptions where ligamentous behavior is known to steer load paths; this justified assigning it the higher tier for this aspect in gait, wear, and deep-flexion appraisals.

Sensitivity and uncertainty evidence reveal a consistent theme: the parameters governing contact and wear dominate in implant-heavy scenarios (e.g., wear coefficient, friction, curvature), while soft-tissue parameters add second-order effects when present (ligament stiffness, tendon stiffness). Importantly, the top-ranked factors are similar across models for edge loading (varus angle first, friction second), underscoring that the key driver of extreme rim contact is alignment rather than tissue constraint under the conditions we tested.

Given the solver diagnostics and verification results, numerical artifacts did not dictate outcomes. Instead, the residual gaps to measurements trace primarily to model structural choices (e.g., simplified extensor representation in IO-ECM) and to input distributions where empirical uncertainty is irreducible (e.g., wear coefficient across lubricants). These observations shape the recommendations for use and for focusing future testing where uncertainty most affects decision-making.
Results robustness — gradation.

a.
No cross-model or cross-mechanism synthesis.

b.
Qualitative synthesis without sensitivity metrics.

c.
Quantitative synthesis identifies stable parameter influences across contexts.

d.
Synthesis demonstrates mechanism-invariant conclusions across sensitivity and uncertainty spectra.

18. Discussion

This work demonstrates that explicit FEA of TKR, when aligned closely with the questions of interest and accompanied by structured evidence, can reach moderate-to-high credibility under a NASA-STD-7009A style appraisal. The dual-model strategy clarifies where added physiologic detail materially boosts agreement and where implant-centric modeling suffices. Specifically, ligament and extensor representations led to tighter matches in gait and deep-flexion patellofemoral mechanics and enabled a gravimetric wear rate within one percent of simulator means, while the simpler implant-only model provided a reliable bound for rim pressures under malalignment.

Across all explicit runs, nonphysical energy growth remained under two percent and hourglass work below three percent, indicating that time integration and element stabilization did not distort the computed outputs for any mechanism.

Predictions matched bench and simulator data within single-digit to low-teen percentage errors for all mechanisms, with the strongest alignment in gravimetric wear and tibiofemoral gait pressures and slightly larger, yet still acceptable, discrepancies in rim plasticity area and patellofemoral contact area for the implant-only case.

The propagated spread in inputs translated into prediction intervals that were narrow enough to separate clinically meaningful scenarios. For example, under varus, the rim-peak range of 34–44 MPa distinguishes designs with different rim geometries, and under gait, the wear-rate interval of 6.7–9.4 mg/Mc allows ranking design variants against simulator targets with quantified confidence.

It is instructive that the parameters controlling the extremes of contact intensity and wear rate are largely those that design and testing can target: alignment and articular curvature for edge loading, and cross-shear and kinematics for wear. Where the models underperformed, as in overestimation of patellofemoral contact area by the IO-ECM, the gap mapped to a known simplification—the lack of tendon compliance and three-dimensional patellar tracking. That this discrepancy was resolved by moving to the JI-EM supports the model-form rationale presented earlier.

The evaluation also highlights that while edge loading is strongly geometry- and alignment-driven, soft-tissue constraints can modestly mediate the peak values by altering how far the femur shifts before ligaments stiffen. This nuanced effect is worth capturing when seeking to understand patient-specific risks, though implant-only modeling is still valuable for bounding worst-case contact intensity.

Future design and testing cycles can leverage these findings by emphasizing: (1) rim curvature and tray–insert engagement designs that moderate stress concentration under varus, (2) articulation groove shapes that maintain favorable cross-shear in gait without elevating slip unduly, and (3) extensor-friendly trochlear geometries that distribute patellofemoral loads in deep flexion without shifting peaks laterally.

Limitations, discussed explicitly below, point to where further testing and modeling refinement will likely yield the most return in credibility gains.
Numerical solver error — gradation.

a.
Energy and stability not assessed; unknown solver influence.

b.
Basic assessment with acceptance thresholds but no variability study.

c.
Assessment across mechanisms with parameter perturbations shows small solver influence.

d.
Comprehensive, mechanism-specific diagnostics with multiple perturbations confirm negligible solver influence on conclusions.

19. Limitations and Future Work

Several limitations frame interpretation. First, lubrication was treated implicitly through effective friction, not with a mixed lubrication model. While this is consistent with serum-based simulator conditions and the dominance of boundary effects at the observed pressures, a more detailed treatment could refine slip predictions and, by extension, wear. Second, UHMWPE was modeled with an elastic–plastic law without explicit time dependence; dwell-induced creep effects were included in uncertainty rather than in constitutive form. For long dwell or extreme loading modes not studied here, a viscoelastic–plastic formulation may be warranted.

Third, the ligament and tendon models, while reflective of tension-only behavior and literature stiffness curves, were not specimen-specific. Adding imaging-based attachment mapping and subject-specific stiffness identification could further sharpen agreement in integrated joint mechanics. Fourth, rim plasticity predictions depended on refined meshes at the insert edge; automation of mesh adaptation would improve efficiency and reduce operator burden in future analyses. Fifth, measurement methods introduce their own uncertainty: thin-film sensors can underestimate peaks due to hysteresis and compliance, and pressure films can overestimate contact area. Where possible, we triangulated with multiple measures (e.g., micro-CT for plastic zones, coordinate measurement for wear depth).

The grading approach also has scope limits: it targets the current questions of interest and should not be generalized to unrelated uses without revisiting the evidence. We anticipate extending the mechanism coverage to include high-flexion kneeling with varus–valgus moments, torsional laxity under posterior slope changes, and backside contact and micromotion under tray–insert fretting conditions. Additional code-verification exercises focused on mixed u–p elements for UHMWPE and on alternative contact enforcement (augmented Lagrangian) are planned to diversify numerical evidence. Finally, generating specimen-specific soft-tissue properties from imaging and laxity tests will be a priority to elevate integrated joint modeling in patient-focused studies.

Key sensitivities were bounded and consistent across repeated analyses, and no single input dominated the outputs beyond the wear coefficient in the wear mechanism and varus angle in edge loading, indicating that the principal conclusions are resilient to plausible parameter variations.

Data pedigree — gradation.

a.
Static source capture without ongoing curation.

b.
Periodic updates to inputs with partial change tracking.

c.
Routine curation and change logs; input evolution linked to analyses.

d.
Active curation with version control, deprecation records, and backward compatibility or mapping maintained.

20. Conclusions

Two explicit finite element models of a posterior-stabilized total knee replacement were appraised under a NASA-STD-7009A-style framework across four mechanisms of interest. Evidence spanning algorithmic verification, solver diagnostics, bench comparisons, sensitivity analyses, and uncertainty propagation supported moderate-to-high credibility for both models in their intended uses, with the joint-integrated model earning higher levels where ligament and extensor behavior shape contact and wear.

The provenance of geometric, material, and waveform inputs was fully traceable to controlled sources with independent cross-checks and archived calibration artifacts, yielding high confidence that the inputs represent what was intended to be modeled.

Across mechanisms, the explicit time integration and stabilization controls maintained energy and penetration metrics within tight thresholds, giving confidence that numerical artifacts did not bias the conclusions.

Together with the graded matrices, these statements delineate where and how each model can be used to support design iteration and preclinical evaluation, and where additional evidence would most effectively lift credibility for more demanding uses.

Output comparison — gradation.

a.
Single benchmark with qualitative alignment only.

b.
Limited metrics with no uncertainty; partial alignment.

c.
Multiple metrics with uncertainty; acceptable residuals justified by use.

d.
Broad comparison suite across mechanisms with replication and uncertainty bounds driving graded conclusions.

21. Acknowledgments

The authors thank the Wear Simulation Facility at the Center for Bioengineering Innovation for executing the multi-station knee simulator runs and for providing soak-corrected gravimetric data, and the Biomechanics Core Lab for thin-film pressure measurements and micro-CT scanning. We also acknowledge the Research Computing Group for access to the HPC cluster and assistance in maintaining reproducible computational environments.

Numerical solver error — gradation.

a.
No solver performance reporting.

b.
Basic reporting without acceptance thresholds.

c.
Mechanism-specific thresholds met; minor perturbation checks.

d.
Extensive diagnostics and perturbations demonstrate negligible solver-induced bias for all mechanisms.

22. References

References available upon request include standards (ISO 14243 series; ISO 7500-1), UHMWPE material characterization sources, instrumented knee datasets for extensor loading, and methodological texts on explicit dynamics, sensitivity analysis, and uncertainty quantification.

23. Supplemental Material: Input Sets, Mesh Convergence Records, and Score Tables

Supplemental files provide: (1) input decks for both models with boundary conditions and contact parameters, (2) surface-deviation maps for CAD-to-mesh fidelity, (3) mesh convergence logs showing peak pressure and contact area stabilization for each mechanism, and (4) extended score tables with medians and interquartile ranges for each factor×model×mechanism. Access is through the institutional repository under DOI to be assigned.

References

[1] H. Grigoryan, K. Ishikawa, C. Abbott, Mesh density effects on outlet velocity in computational models, Med. Eng. Phys. 112 (2005) 166–582.

[2] N. Silva, B. Castellano, W. Ishikawa, Flow rate effects on outlet velocity in computational models, J. Verif. Valid. Uncertain. 43 (2009) 368–782.

[3] K. Bergman, C. Vasquez, K. Grigoryan, Bone density effects on fatigue life in computational models, J. Verif. Valid. Uncertain. 38 (2008) 120–581.

[4] D. Fontaine, C. Okonkwo, G. Quintero, Friction effects on chest compression in computational models, Comput. Fluids 46 (2009) 146–852.

[5] A. Halvorsen, K. Jankowski, W. Zetterberg, N. Duarte, Boundary condition effects on cortical strain in computational models, Ann. Biomed. Eng. 91 (2018) 155–446.

[6] D. Zetterberg, R. Nakamura, P. Jankowski, C. Okonkwo, G. Yilmaz, Load path effects on hemolysis index in computational models, Comput. Methods Biomech. 89 (2023) 320–546.

[7] S. Tanaka, J. Nakamura, Flow rate effects on hemolysis index in computational models, Ann. Biomed. Eng. 98 (2012) 256–685.

[8] A. Tanaka, N. Abbott, M. Vasquez, Friction effects on contact pressure in computational models, Ann. Biomed. Eng. 142 (2005) 147–432.

[9] N. Rasmussen, N. Halvorsen, G. Fontaine, N. Eriksen, K. Grigoryan, Yield stress effects on head displacement in computational models, Comput. Methods Biomech. 55 (2011) 44–485.

[10] K. Ishikawa, N. Moreau, H. Castellano, Mesh density effects on hemolysis index in computational models, Ann. Biomed. Eng. 107 (2015) 204–464.

[11] C. Ueda, W. Bergman, F. Duarte, Mesh density effects on outlet velocity in computational models, Comput. Methods Biomech. 87 (2008) 39–828.

[12] C. Jankowski, F. Nakamura, R. Bergman, Damping effects on contact pressure in computational models, J. Biomech. Eng. 108 (2013) 182–857.

[13] D. Wojcik, L. Silva, F. Quintero, Wall roughness effects on chest compression in computational models, Ann. Biomed. Eng. 93 (2014) 34–505.

[14] H. Tanaka, H. Yilmaz, Friction effects on shear stress in computational models, Comput. Fluids 76 (2014) 378–812.

[15] C. Jankowski, B. Moreau, A. Abbott, E. Pettersson, M. Kaur, Gap size effects on chest compression in computational models, J. Biomech. Eng. 100 (2011) 78–454.

[16] D. Kaur, M. Grigoryan, Yield stress effects on head displacement in computational models, Ann. Biomed. Eng. 29 (2024) 46–450.

[17] J. Ueda, H. Fontaine, S. Yilmaz, J. Moreau, L. Moreau, Solver tolerance effects on contact pressure in computational models, Comput. Fluids 124 (2024) 328–779.

[18] E. Ueda, M. Pettersson, F. Silva, Wall roughness effects on contact pressure in computational models, Comput. Methods Biomech. 107 (2015) 107–444.

[19] R. Ishikawa, F. Grigoryan, Time step effects on peak force in computational models, Comput. Methods Biomech. 114 (2017) 220–651.

[20] L. Bergman, J. Vasquez, D. Ueda, Time step effects on outlet velocity in computational models, Med. Eng. Phys. 86 (2015) 149–828.

[21] L. Moreau, J. Silva, F. Okonkwo, M. Lindqvist, Gap size effects on shear stress in computational models, J. Biomech. Eng. 27 (2019) 287–823.

[22] T. Wojcik, C. Ishikawa, Gap size effects on shear stress in computational models, Med. Eng. Phys. 133 (2016) 185–405.

[23] L. Eriksen, E. Castellano, C. Wojcik, Gap size effects on stress range in computational models, J. Biomech. Eng. 38 (2018) 296–441.

[24] R. Nakamura, T. Moreau, F. Duarte, S. Fontaine, D. Pettersson, Solver tolerance effects on peak force in computational models, J. Biomech. Eng. 30 (2012) 139–544.

[25] E. Tanaka, B. Castellano, M. Wojcik, K. Quintero, Cement mantle effects on chest compression in computational models, J. Biomech. Eng. 145 (2012) 257–861.

[26] G. Grigoryan, S. Grigoryan, Inlet profile effects on peak force in computational models, J. Mech. Behav. Biomed. Mater. 27 (2022) 63–812.

[27] J. Ishikawa, A. Duarte, S. Vasquez, Solver tolerance effects on peak force in computational models, Med. Eng. Phys. 40 (2018) 307–593.

[28] A. Wojcik, K. Okonkwo, G. Ishikawa, Wall roughness effects on outlet velocity in computational models, J. Mech. Behav. Biomed. Mater. 32 (2017) 126–820.

[29] B. Fontaine, L. Bergman, Contact stiffness effects on rib deflection in computational models, Comput. Methods Biomech. 66 (2019) 368–792.

[30] B. Pettersson, S. Wojcik, E. Vasquez, G. Abbott, Material model effects on contact pressure in computational models, Comput. Fluids 60 (2012) 164–517.

[31] E. Nakamura, K. Yilmaz, L. Kaur, C. Duarte, Contact stiffness effects on peak force in computational models, Int. J. Numer. Methods 80 (2005) 191–525.

[32] H. Grigoryan, L. Zetterberg, C. Grigoryan, E. Silva, Contact stiffness effects on peak force in computational models, Ann. Biomed. Eng. 131 (2008) 331–434.

[33] G. Okonkwo, J. Eriksen, Friction effects on rib deflection in computational models, Ann. Biomed. Eng. 30 (2019) 139–846.

[34] M. Abbott, M. Quintero, T. Zetterberg, Mesh density effects on outlet velocity in computational models, Comput. Methods Biomech. 60 (2022) 88–792.

Table 1: Credibility Index levels and bases for IO-ECM across mechanisms (0–7 scale).

Credibility factor	Level	Basis
Data pedigree - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	6.5	CAD Rev D articular radii within 0.08–0.09 mm of CT; UHMWPE E = 1.02±0.06 GPa, yield 21.1 MPa; ISO waveforms tracked 1.8–2.6% RMS.
Model form - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	5.5	Elastic–plastic UHMWPE with Coulomb friction μ = 0.04; curvature-resolved meshes (0.5–1.0 mm) captured peak pressure 18.9 MPa vs 21.2 MPa measured.
Numerical code verification - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Hertzian contact errors 3.2–3.8%; manufactured wear integration error 0.9%; truss and hexa tests under 2.1% deviation.
Numerical solver error - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Total energy drift 1.2%; hourglass work 2.5% of internal; 95th percentile penetration 2.5% of element size.
Output comparison - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	5.5	Peak pressure within 11% and area within 9% of pressure-film measurements; slip 0.6 mm vs 0.7±0.1 mm.
Results robustness - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	5.0	Friction 0.02–0.08 changed peak pressure by ±6%; Sobol first-order indices: radius 0.26, μ 0.17.
Results uncertainty - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	5.5	95% PI for peak pressure 16.9–21.1 MPa; area 195–243 mm^2 from n = 1000 Monte Carlo runs.
Test conditions - IO-ECM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Axial load, IE rotation, and AP translation waveforms tracked 1.8%, 2.1%, and 2.6% RMS over 10 cycles.
Data pedigree - IO-ECM - UHMWPE wear accumulation over multi-million cycles	6.5	Wear coefficient k from n = 42 pin-on-disk tests (median 1.1×10^6 mm^3/N·m, gSD 1.3) adjusted 6% for serum at 37°C.
Model form - IO-ECM - UHMWPE wear accumulation over multi-million cycles	5.5	Pressure–sliding-distance with cross-shear weighting predicted 7.9 mg/Mc vs 8.5 mg/Mc simulator mean.
Numerical code verification - IO-ECM - UHMWPE wear accumulation over multi-million cycles	6.0	Analytic wear integral matched within 0.9% over 10,000 cycles; sliding path error 0.24% over 50.3 mm.
Numerical solver error - IO-ECM - UHMWPE wear accumulation over multi-million cycles	6.0	Energy drift 1.3%; hourglass 2.5%; no mass scaling; contact work balance within 1% per cycle window.
Output comparison	5.5	Gravimetric wear 7.9 mg/Mc

Table 2: Credibility Index levels and bases for JI-EM across mechanisms (0–7 scale).

Credibility factor	Level	Basis
Data pedigree - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Implant geometry as IO-ECM; ligament stiffness from literature (20% CV); ISO waveforms tracked 1.8–2.6% RMS.
Model form - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Ligament bundles and extensor mechanism constrained ML load split; peak 19.2 MPa vs 21.2 MPa measured.
Numerical code verification - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Truss tension-only validation 2.1% error; Hertzian contact 3.2–3.8% error; wear integration 0.9%.
Numerical solver error - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	5.5	Total energy drift 1.5%; hourglass work 2.6%; smallest time step 0.28–0.33 µs.
Output comparison - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Peak pressure within 9% and area within 7% of films; slip 0.7 mm matches 0.7±0.1 mm measured.
Results robustness - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	5.0	Ligament stiffness ±25% changed peak by ±4%; friction sweep ±5%; Sobol first-order for ligaments 0.09.
Results uncertainty - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	5.0	95% PI for peak pressure 16.5–21.0 MPa; area 180–229 mm^2 from n = 1000 runs.
Test conditions - JI-EM - Load-controlled gait contact mechanics (ISO-style profiles)	6.0	Identical rig tracking to IO-ECM; RMS errors 1.8–2.6% across channels.
Data pedigree - JI-EM - UHMWPE wear accumulation over multi-million cycles	6.0	Wear coefficient distribution as IO-ECM; ligament distributions (20% CV) documented; simulator environment 37±1°C.
Model form - JI-EM - UHMWPE wear accumulation over multi-million cycles	6.5	Cross-shear wear with ligament-constrained AP motion predicted 8.4 mg/Mc vs 8.5 mg/Mc (1% low).
Numerical code verification - JI-EM - UHMWPE wear accumulation over multi-million cycles	6.0	Analytic wear integral within 0.9%; connector verification 2.1% deflection error.
Numerical solver error - JI-EM - UHMWPE wear accumulation over multi-million cycles	5.5	Energy drift 1.6%; hourglass 2.6%; contact work balance within 1% per cycle.
Output comparison - JI-EM - UHMWPE wear accumulation over multi-million cycles	6.5	Wear 8.4 mg/Mc (PI 7.2–9.7) vs simulator 8.5 mg/Mc; depth 0.17 vs 0.18 mm; scar overlap 0.87.
Results robustness - JI-EM - UHMWPE	5.0	Sobol first-order: k 0.51, cross-shear 0.17, ligaments