Establishing credibility for implicit FEA of intraocular lens haptics under capsular contraction: dual-model, tri-mechanism assessment under ASME V&V 40

Alexandra M. Levin, PhD[a], Jungho Park, PhD[b], Rafael Ortega, MS[c], Priya Raman, PhD[1], Elena Novak, MS[1], Michael T. Wright, MD[1]

[a]*Computational Biomechanics Group, Vision Devices R&D, ClearSight Medical, Inc., San Jose, CA, USA,*
[b]*Mechanical Engineering Department, Western Institute of Technology, Seattle, WA, USA,*
[c]*Department of Ophthalmology, Bayview Medical Center, Tampa, FL, USA,*

Abstract

Postoperative capsular bag contraction can impose substantial loads on foldable intraocular lens (IOL) haptics, altering optic position and risking haptic overstress. We present a dual-model, tri-mechanism computational assessment tailored to a design-selection context-of-use (COU) under ASME V&V 40. The detailed model (Model D3) is a 3D implicit finite element (FE) simulation of the optic–haptic assembly in contact with a deforming capsular bag that computes haptic von Mises stress, capsule–haptic contact pressure, and optic tilt and decentration under prescribed capsular contraction. The reduced model (Model RB) is an implicit FE ring–beam representation with a rigid optic and curved beam haptics that compute global stiffness, peak beam stress, and kinematics. Three clinically motivated contraction mechanisms are represented: circumferential equatorial shrinkage, sectoral fibrosis with directional shrinkage, and anterior capsulorhexis phimosis. We characterize geometry, contact, material models, and boundary conditions for each model and mechanism; establish correctness of implementation using benchmark and patch-style verifications; quantify discretization and step-size effects; compare predictions to independent physical and literature data; and align the outputs to the COU's decision needs. Model risk is rated 3/4, reflecting high influence and moderate decision consequence. Under uniform equatorial contracture (8% circumferential shrinkage), Model D3 predicts peak haptic stress of 41 MPa, equatorial contact pressure of 38 kPa, optic tilt of 0.47°, and decentration of 0.08 mm; Model RB predicts 39 MPa, 36 kPa, 0.42°, and 0.09 mm, respectively. Under sectoral fibrosis (90° sector at 12% shrinkage), Model D3 yields 62 MPa peak stress, 1.4° tilt, and 0.29 mm decentration, while Model RB yields 54 MPa, 1.2°, and 0.24 mm. Under capsulorhexis phimosis (25% anterior rim reduction), Model D3 yields 52 MPa peak stress, 0.9° tilt, and 0.19 mm decentration; Model RB yields 46 MPa, 0.8°, and 0.17 mm. Grid and step-size convergence studies for Model D3 reduced peak-stress changes to 2.8% for uniform contraction, 5.9% for sectoral fibrosis, and 6.3% for phimosis; Model RB changes were below 2% for all mechanisms. Bench and literature comparisons support the predicted trends and magnitudes for uniform contraction and provide partial support for the other mechanisms. For the COU of design down-selection and omission of additional benchtop capsular simulant tests for the screened mechanisms, the selected quantities of interest (QOIs) are directly aligned with the decision thresholds for haptic stress and optic kinematics. Across mechanisms, sectoral fibrosis is worst-case for tilt and decentration and approaches the haptic stress design limit in both models. The assembled evidence supports use of these models to discriminate candidate haptic designs under the specified COU and guides targeted physical testing where the simulations indicate minimal margin.

Keywords: ASME V&V 40, intraocular lens, finite element analysis

1. Introduction

Intraocular lenses (IOLs) are implanted to restore visual acuity following removal of the cataractous crystalline lens. The device studied here is a foldable optic intended for in-the-bag fixation with two open-loop haptics that engage the capsular equator. While the intended initial fixation is stable, postoperative capsular fibrosis and contraction can substantially change the mechanical environment over weeks to months, applying compressive and shear forces to the haptics and, through the haptics, to the optic. These changes can induce optic tilt or decentration, degrade visual performance, and in rare cases drive haptic fracture. Because the capsular bag is a thin, hydrated, living tissue that remodels over time, direct in vivo measurement of contact forces and local haptic stresses is not currently feasible. As a result, simulation can provide critical evidence to complement bench testing and clinical observation during design selection.

ASME V&V 40 provides a risk-informed framework to establish the credibility of computational models used to support medical device decisions. It emphasizes clearly defining the context of use (COU), assessing model risk as a function of model influence and decision consequence, and then tailoring credibility activities accordingly. We apply this framework to two implicit finite element analysis (FEA) models—a detailed three-dimensional (3D) model (Model D3) and a reduced-order ring–beam model (Model RB)—over three clinically motivated capsular contraction mechanisms. For each model–mechanism pair, we report structured evidence on the mathematical description and contact representation; the realism and uncertainty of inputs; implementation checks against benchmarks; discretization and solver stability; alignment of simulations with independent data; and the appropriateness of the outputs to the COU's decision needs.

This paper is not intended to predict exact clinical outcomes. Rather, it provides decision-focused evidence that the two implicit FEA models, used together, can rank haptic design variants and identify worst cases under capsular contraction to support down-selection and scope physical testing efficiently. The analysis includes explicit numerical targets, such as peak haptic von Mises stress relative to a material-specific design limit, equatorial capsule–haptic contact pressure, and optic position metrics, to determine whether design margins exist under each contraction scenario.

Model risk tailoring under V&V 40 — gradation.

a.
General awareness of V&V 40 with ad hoc activities and no explicit mapping to influence or consequence.

b.
COU stated and qualitative risk described; partial allocation of activities without traceability to risk elements.

c.
Quantified influence and consequence feeding a documented activity plan that covers each credibility topic.

d.
Risk-based allocation of evidence with predefined quantitative acceptability targets and closure criteria per model–mechanism pair.

2. Question of interest: Does the proposed haptic geometry maintain mechanical performance under postoperative capsular contraction without increasing risk of optic tilt, decentration, or haptic overstress?

The primary question of interest is whether the proposed open-loop haptic geometry maintains acceptable stress and kinematic performance across plausible postoperative capsular contraction patterns. The decision supported by the models is down-selection among candidate haptic design variants and the decision to omit additional benchtop capsular bag simulant tests for mechanisms where model-predicted margins are ample. Mechanical acceptability is defined by three quantities of interest (QOIs): peak haptic von Mises stress, capsule–haptic contact pressure at the equator (as a proxy for tissue loading), and optic position changes (tilt and decentration) relative to the capsular bag center and reference axis.

To operationalize this question, we apply target ranges derived from material characterization and clinical optics requirements. For the current foldable acrylic haptic material, tensile failure occurs above 90 MPa in hydrated, physiologic-temperature conditions and cyclic endurance is expected up to 70 MPa; we therefore adopt a design limit of 70 MPa for peak haptic stress in static contraction scenarios. For optic position, clinically acceptable defocus and coma are maintained for tilt below approximately 2–3° and decentration below 0.4–0.5 mm for typical IOL powers; we use more stringent design gates of 1.5° tilt and 0.3 mm decentration to ensure margin. Contact pressure does not have a single clinical threshold, but reports of equatorial pressure with capsular tension rings and in simulated capsular bag testers range from 20 to 60 kPa; we interpret pressures above 80–100 kPa as potentially problematic if sustained.

Correctness of the software implementation is a precondition for using simulation results to adjudicate design choices. To that end, we verified our finite element workflows against tractable reference cases—curved-beam bending, axisymmetric contact pressure distributions, and linear-elastic patch states—and found numerical discrepancies below 1.2% for displacement and force metrics across all benchmarks described later in this manuscript, lending confidence that subsequent results reflect the modeling assumptions rather than coding or input errors.

Decision criteria completeness — gradation.

a.
Qualitative acceptance concepts without quantitative performance gates.

b.
Partial thresholds defined for one or two outputs; no link to material or clinical constraints.

c.
Quantitative limits for all primary outputs with rationale; secondary outputs qualitative.

d.
Quantitative limits for all outputs with traceability to material data and clinical optics literature, plus allowance for uncertainty.

3. Context of use (COU): computational evidence for design down-selection and scope of omitted benchtop tests

The two implicit FEA models are used to predict three outputs—peak haptic von Mises stress, equatorial capsule–haptic contact pressure, and optic tilt and decentration—under three capsular contraction mechanisms: uniform equatorial shrinkage, sectoral fibrosis with directional shrinkage, and anterior capsulorhexis phimosis. The purpose of these predictions is to provide the primary evidence to select among haptic design variants and to justify omission of additional benchtop capsular bag simulant tests for those scenarios where the simulations show unambiguous margin. The COU is restricted to foldable IOLs implanted within an intact capsular bag, with contraction magnitudes corresponding to the postoperative range observed clinically within the first year after surgery. Lens subluxation, zonular dialysis, posterior capsule tears, and complications requiring capsular tension rings are out of scope.

The models are not used to predict long-term biological remodeling or posterior capsular opacification rates; rather, they address the mechanical state under imposed degrees of contraction that represent worst-case snapshots for loading. As will be shown, the selected outputs read directly on the COU because they are the same metrics used in device design reviews

[redacted]

Figure 1: Schematic overview of the two-model strategy and three contraction mechanisms: (a) Model D3 simulating optic–haptic–capsule contact in 3D; (b) Model RB representing the capsule as a contracting ring and haptics as curved beams; (c) uniform equatorial contracture; (d) sectoral fibrosis with directional shrinkage; (e) anterior capsulorhexis phimosis.

to gate progression: they bound haptic material utilization and optic alignment. Because the models compute these outputs without requiring intermediate surrogate measures, they support decision-making without additional translation steps that could compound uncertainty.

COU specificity and boundary clarity — gradation.

a. Device and population vaguely stated; mechanisms of interest not delimited.

b. Device specified; vague user population and environmental constraints; mechanisms listed without quantitative bounds.

c. Device, population, and operating conditions quantitatively bounded; mechanisms scoped with parameter ranges.

d. COU explicitly ties outputs to decision gates, specifies excluded scenarios, and defines parameter ranges for each mechanism.

4. Model risk under ASME V&V 40: Credibility Index 3/4

We classify model risk as the product of model influence and decision consequence for the COU. Influence is high because the simulation outputs are the decisive evidence for design selection among candidate haptic geometries and for choosing to omit additional benchtop capsular bag simulant testing for the screened mechanisms. Decision consequence is moderate because an incorrect conclusion could lead to postoperative malposition that, while clinically undesirable, is typically manageable by noninvasive or minimally invasive intervention such as Nd:YAG anterior capsulotomy or device exchange, with low probability of permanent serious harm in the indicated population.

Accordingly, we adopt a Credibility Index of 3/4 and tailor our evidence plan to provide strong support for the intended use without attempting to eliminate all uncertainty. This plan includes: detailed description and justification of the mathematical representations and contact interactions; quantitative characterization of geometric and material inputs, with sensitivity bounds; formal checks of implementation accuracy against analytical and numerical benchmarks; mesh and step-size studies with pre-specified convergence targets for each mechanism and model; multiple independent comparisons of predicted kinematics and stress trends to bench and literature data; and explicit mapping of outputs to the COU decision gates. The assembled evidence is summarized in model-wise tables later in the paper.

Risk-to-evidence allocation — gradation.

a. No linkage between identified risks and selected credibility activities.

b. Qualitative mapping of risks to activities without closure criteria.

c. Quantified risks and activity plan with mechanism-by-mechanism closure targets.

d. Quantified risks, closure targets, and predefined escalation triggers if activities fail to meet targets.

5. Device and mechanisms of capsular contraction

The device is a foldable IOL with a 6.0 mm biconvex optic and two open-loop haptics, designed for in-the-bag implantation. The haptic geometry under evaluation has a nominal overall diameter of 13.0 mm at room temperature, with a 10° out-of-plane haptic angulation to position the optic appropriately. The haptics are of rectangular cross-section 0.25 mm by 0.20 mm, with a nominal arc length of 100° each and a trailing crown that engages the capsule equator. The material is a hydrophobic acrylic with elastic modulus 0.85 GPa at 35 °C and yield strength above 85 MPa; Poisson's ratio is 0.38. The optic is of the same material but is treated as either deformable (Model D3) or rigid (Model RB) depending on the model formulation to limit degrees of freedom. The capsular bag is represented as a thin elastic shell with average thickness of 12 μm, regional thickness variation captured in the detailed model (anterior rim 14–18 μm, equator 15–20 μm, posterior 4–8 μm), and effective elastic modulus between 0.5 and 1.2 MPa consistent with hydrated ex vivo inflation tests; Poisson's ratio is 0.45.

We examine three contraction mechanisms that bracket clinically observed patterns. First, uniform equatorial contracture is represented as a circumferential shrinkage of the equator by 6–10% imposed as an azimuthal prestrain in the capsular band centered on the equator. Second, sectoral fibrosis with directional shrinkage is represented by applying a larger prestrain (10–14%) over a 60–120° sector of the equator, producing asymmetric loads that can tilt and decenter the optic. Third, anterior capsulorhexis phimosis is represented by reducing the diameter of the anterior capsular rim by 20–30% through shrinkage of the anterior rim shell elements and activating contact with the haptic crowns and optic edge. In all scenarios, the posterior capsule remains intact, and zonular attachments are represented as distributed radial springs that maintain overall bag centering and provide baseline stiffness.

Among the uncertain characteristics, the modulus of the capsular bag and the spatial extent of fibrotic sectors are the dominant drivers of model variability. Variation across the ranges reported above changes the computed peak haptic stress by less than 10% under uniform contraction and by 10–18% under sectoral and phimosis scenarios, while optic tilt and decentration shift by less than 0.1° and 0.05 mm under uniform contraction and up to 0.3° and 0.06 mm in asymmetric cases. These bounds indicate that, for the design-screening purpose, the parameterization captures the essential spread of outcomes without eroding the ability to discriminate among haptic geometries.

Mechanism representation granularity — gradation.

a.
Mechanisms listed only qualitatively without spatial or temporal quantification.

b.
Mechanisms parameterized with scalar shrinkage magnitudes but no regional definition.

c.
Mechanisms parameterized with regional shrinkage magnitudes and extents, mapped to model geometry.

d.
Mechanisms parameterized with spatial and temporal fields validated against imaging or ex vivo inflation data.

6. Computational models: geometry, contact, materials, and boundary conditions (implicit FEA)

We implemented two implicit finite element models using a commercial nonlinear solver with double-precision arithmetic and static general analysis. Model D3 is a 3D deformable model that includes the optic and both haptics as solid continua and the capsular bag as a thin shell. The optic and haptics are meshed with 8-node hexahedral and 10-node tetrahedral elements as needed to conform to fillets and curvature; typical mesh counts are 80,000–120,000 elements for the device, with refined grading at haptic crowns and root fillets where stress concentrations arise. The capsular bag is meshed with 4-node shell elements spanning the anterior rim, equator, and posterior leaflet; the equatorial band is refined to element lengths of approximately 0.2–0.3 mm to support smooth contact patch resolution. Contact between the device and bag is enforced with a penalty-based, augmented Lagrange formulation with segment-to-segment detection and a friction coefficient of 0.05, consistent with lubricated ocular tissues. Normal contact stiffness is selected to limit overclosure below 0.5% of local thickness in the highest-pressure regions, and a small amount of viscous regularization (damping ratio less than 1%) stabilizes contact transitions without materially affecting quasi-static results.

Model RB represents the capsular bag as a closed circular ring with distributed radial springs to emulate zonular coupling and overall stiffness. The haptics are curved beam elements (Timoshenko kinematics) attached to a rigid optic. Two beams per haptic arc, with a hinge at the mid-crown to reflect local compliance, provide a balance of fidelity and parsimony. Contact is represented by nonlinear springs coupling beam nodes to the ring with gap activation and a small tangential penalty to emulate friction. Typical discretizations use 120 beam elements for both haptics combined and 180 ring elements, which provide smooth curvature and accurate reaction forces. Both models apply contraction by imposing prestrain (Model D3) or equivalent thermal-like shrinkage (Model RB) to the capsular bag or ring in the prescribed regions and magnitudes for each mechanism, then solve to equilibrium using full Newton iterations with automatic load stepping governed by displacement and force norms.

Boundary conditions reflect in-the-bag fixation. The posterior capsule is constrained against translation normal to the posterior leaflet, preserving overall bag curvature, while allowing circumferential and radial motions under contraction loads. The optic is initially centered with the optical axis aligned to the bag's geometric axis. A tie constraint links the optic and haptics at the junctions in Model D3; in Model RB, the optic is rigid, and the beams are rigidly attached to the optic at their roots. Outputs include peak haptic von Mises stress (averaged across an element patch to reduce discretization noise), equatorial contact pressure (integrated force per unit length along the contact patch in Model D3 and equivalent reaction per unit arc in Model RB), and optic tilt and decentration measured relative to the initial bag axis and center. We report results at nominal contraction magnitudes of 8% uniform equatorial shrinkage, 12% over a 90° sector for fibrosis, and 25% anterior rim reduction for phimosis, while also exploring nearby values to assess sensitivity.

Contact modeling rigor — gradation.

a.
Node-to-surface with default penalties; no convergence or overclosure checks.

b.
Surface-to-surface with tuned penalties; overclosure monitored qualitatively.

c.
Segment-to-segment with augmented Lagrange update; overclosure and contact patch topology checked quantitatively.

d.

Segment-to-segment with augmented Lagrange and regularization sensitivity; validated against Hertzian and ring–beam references.

7. Credibility factor: Model form — governing equations, contact formulations, and representation of capsule–haptic interaction

The mathematical representation of the device–bag system balances geometric fidelity with computational tractability. In Model D3, the optic and haptics are modeled as linear elastic continua with large-deformation kinematics to capture bending and contact-driven curvature changes. The capsular bag is a thin, nearly incompressible shell; we use reduced-integration shell elements with hourglass control and include a small transverse shear stiffness to represent through-thickness constraint. The interaction between the device and bag is mediated by surface contact with friction. The combination allows for sliding and separation and develops distributed contact patches whose azimuthal extent responds to contraction magnitudes and local curvatures.

In Model RB, the haptics are represented as planar curved beams with Timoshenko kinematics and the bag as a circumferential ring. The optic is rigid to remove deformation degrees of freedom that are small relative to those of the haptics and bag in the loading regimes of interest. The directional shrinkage of the bag (uniform or sectoral) is applied as equivalent strain and induces reactions in the beams through nonlinear gap springs. This representation captures global stiffness, approximate beam stresses, and optic kinematics efficiently but cannot develop fully resolved contact pressure fields or localized geometry details such as crown fillets or shell-edge contact at the anterior rim.

The three contraction mechanisms are mapped into both models by enforcing spatially varying shrinkage fields on the capsular shell (Model D3) and ring (Model RB). For uniform equatorial contracture, we apply an 8% azimuthal prestrain over a 3-mm-wide equatorial band (Model D3) or the full ring (Model RB). For sectoral fibrosis, we apply a 12% prestrain over a 90° sector while leaving the remaining 270° unstrained; transitions are smoothed over 10° to avoid numerical discontinuities. For anterior capsulorhexis phimosis, we impose a 25% circumferential prestrain on the anterior rim shell elements (Model D3) and on an inner ring connected to the beams by short radial elements (Model RB). The sectoral and rim mechanisms create asymmetric contact and out-of-plane loads that challenge simplified kinematics, particularly in Model RB.

Idealization adequacy — gradation.

a.
Simplified kinematics without justification; important interactions omitted.

b.
Simplifications justified qualitatively; interactions approximated with springs.

c.
Simplifications justified quantitatively against detailed models or benchmarks for each mechanism.

d.
Model form demonstrated to capture essential physics of each mechanism with quantitative agreement across multiple outputs.

8. Credibility factor: Model inputs — geometry, materials, and boundary conditions for each mechanism and model

Geometric inputs for the modeled device were obtained from engineering drawings and vendor metrology on production-like samples. Optic diameter is 6.0 ± 0.05 mm; haptic arc length is 100 ± 2° with cross-section of 0.25 ± 0.02 mm by 0.20 ± 0.02 mm; angulation is 10 ± 1°. Fillet radii at the haptic root and crown are 0.08 ± 0.02 mm and 0.06 ± 0.02 mm, respectively. These tolerances are represented in Model D3 by direct geometry modification and in Model RB by corresponding beam stiffness variations. Materials for the foldable acrylic were characterized in uniaxial tension at 35 °C and 0.9% saline: elastic modulus 0.85 ± 0.10 GPa, 0.2% offset yield 85 ± 7 MPa, ultimate tensile strength 98 ± 10 MPa. Rate effects over quasi-static conditions relevant to slow capsular contraction were negligible in tests and are not included. The capsular bag's elastic properties are less certain; we adopt a nominal modulus of 0.8 MPa with a range of 0.5–1.2 MPa based on ex vivo inflation and ring-cut tests on human and porcine tissue, and we assume near-incompressibility with Poisson's ratio 0.45. The capsule thickness field is from morphometric data: anterior 14–18 μm, equator 15–20 μm, posterior 4–8 μm.

Boundary condition magnitudes are specified per mechanism. For uniform equatorial contracture, 8% circumferential shrinkage is applied with sensitivity runs at 6% and 10%. Sectoral fibrosis is represented by 12% shrinkage over a 90° sector, with sensitivity runs at 10% and 14% and sector extent 60–120°. Anterior capsulorhexis phimosis is represented by 25% rim shrinkage, with sensitivity at 20% and 30%. Zonular support is represented as radial springs with stiffness calibrated to reproduce bag compliance observed in ex vivo lens stretching tests: 0.1 N/mm total radial stiffness distributed uniformly around the equator. The friction coefficient between the device and bag is set to 0.05; sensitivity analysis at 0.02 and 0.10 had negligible effect on predicted kinematics and less than 5% effect on peak contact pressure. These inputs and their uncertainties drive variability in outputs that we quantify by local parameter sweeps for each mechanism.

Parameter characterization depth — gradation.

a.
Nominal values assumed without source or range.

b.
Nominal values sourced; limited ranges based on engineering judgment.

c.
Nominal values with ranges from test or literature; sensitivity explored for key parameters.

d.
Comprehensive test-based distributions with propagation to outputs and uncertainty bands reported.

9. Credibility factor: Numerical code verification — benchmark and patch-style checks

We conducted implementation checks to establish that the models and workflows solve the governing equations as intended. Three benchmark families were used. First, curved-beam bending: a single haptic, modeled as a curved beam of the same arc and cross-section, was subjected to end rotations and radial displacements, and beam-tip reactions were compared between the explicit beam formulation, the solid Model D3 haptic, and closed-form Euler–Bernoulli predictions. Across four span angles (60°, 80°, 100°, 120°) and small rotations up to 5°, relative errors in end reactions were below 0.7% for Model RB and below 1.1% for Model D3, demonstrating consistent stiffness representation.

Second, contact pressure distribution: an axisymmetric surrogate of a rigid torus indenting a thin elastic shell was used to assess contact algorithms. The predicted integrated contact force and peak pressure from Model D3's segment-to-segment augmented Lagrange contact were compared to analytical Hertzian approximations in the small-deformation limit. Over indentation depths up to 0.2 mm and shell thicknesses 10–20 μm, force errors were below 1.1% and peak pressure errors below 1.8%. Third, a volumetric patch test: a small Model D3 submodel with mixed solid and shell elements under uniform strain states showed stress equilibrium to machine precision with residual force norms below 1e9 N and displacement errors below 1e7 mm, indicating correct element formulations and coupling.

Solver log files and postprocessing scripts were also exercised on synthetic datasets with known outcomes to check data handling. In all cases, the reported outputs matched expectations within floating-point rounding. These benchmarks, while idealized relative to the full device–bag problem, provide quantitative assurance that the software implementation and modeling workflow are functioning as intended before confronting the more complex contact and geometry of the three mechanisms.

Implementation verification strength — gradation.

a.
No benchmarks; reliance on software vendor assurances.

b.
Single benchmark demonstrating general correctness.

c.
Multiple benchmarks covering core physics (bending, contact, equilibrium) with quantitative error bounds.

d.
Benchmarks spanning each physics and geometry class in the COU with cross-model comparisons and closure below preset tolerances.

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

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

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

10. Credibility factor: Numerical solver error — mesh and step-size convergence, contact stabilization assessment

We quantified discretization and load-step sensitivity for both models and all mechanisms. For Model D3 under uniform equatorial contracture at 8% shrinkage, increasing the device mesh from approximately 80,000 to 320,000 elements and refining the equatorial shell elements from 0.4 mm to 0.2 mm reduced changes in peak haptic von Mises stress to 2.8%, optic tilt to 0.05°, and equatorial contact pressure to 1.6 kPa. Further refinement to 480,000 elements yielded diminishing returns (stress change 1.2%) at substantially increased computation time, and we adopted the intermediate mesh as standard. Reducing automatic load-step sizes by half (minimum increment from 0.1% to 0.05% contraction) changed peak stress by 1.9% and tilt by 0.03°. Contact stabilization energy remained below 0.4% of total strain energy throughout the solution, indicating limited regularization influence.

For Model D3 under sectoral fibrosis at 12% shrinkage over a 90° sector, the same mesh refinement reduced peak stress changes from 9.1% to 5.9% and tilt changes from 0.31° to 0.18°, with decentration stabilizing within 0.03 mm. Contact stabilization energy peaked at 1.2% during transitions of the active contact patch near sector edges. Tightening normal contact stiffness by 50% and halving step sizes further reduced stress changes to 4.6% but at the cost of convergence difficulties in two load steps; we therefore retained the primary settings and accepted the modestly higher numerical sensitivity in this asymmetric case. For anterior capsulorhexis phimosis at 25% rim reduction, mesh refinement reduced peak stress changes to 6.3% and tilt changes to 0.21°, with contact stabilization energy below 0.8%. The elevated sensitivity relative to uniform contraction arises from sharp contact transitions at the anterior rim and the high curvature of the crown fillet.

Model RB exhibits much lower discretization sensitivity due to its reduced degrees of freedom. Increasing beam elements from 60 to 240 per haptic and ring elements from 90 to 240 reduced changes in peak beam stress to below 1.8%, tilt to below 0.03°, and decentration to below 0.01 mm across all mechanisms. Halving step sizes produced changes below 0.5% for stress and 0.01° for tilt. Contact regularization in the nonlinear springs was tuned to keep artificial energy below 0.2% of the total across all runs.

Discretization and solver control maturity — gradation.

a.
Single-mesh results; no step-size or regularization sensitivity.

b.
Mesh refinement attempted; qualitative statements on stability.

c.
Mesh and step-size studies with quantitative targets; regularization energy monitored.

d.
Mesh, step-size, and contact regularization systematically tuned with convergence metrics meeting predefined tolerances per mechanism.

11. Credibility factor: Output comparison — alignment with independent physical or literature data

We compared predicted optic kinematics and stress trends to independent data where available. For uniform equatorial contraction, benchtop simulators that compress IOLs within an elastic ring provide direct analogs. In a ring-squeeze test at 8% diameter reduction using a silicone ring with stiffness matched to capsular compliance, the measured optic tilt was 0.5 ± 0.2° and decentration 0.10 ± 0.05 mm for a design-matched IOL; contact force per unit arc back-calculated from ring strain corresponded to equatorial contact pressures of approximately 30–50 kPa. Model D3 predicted 0.47° tilt, 0.08 mm decentration, and 38 kPa equatorial pressure; Model RB predicted 0.42°, 0.09 mm, and 36 kPa, all within the bench variability bands. Peak haptic stress is not directly measured in such tests, but the ratio of global stiffness (force vs. ring diameter change) between the models and the bench test differed by less than 8%, suggesting reasonable stress scaling.

For sectoral fibrosis, direct benchtop analogs are scarce. We identified an ex vivo porcine capsular bag preparation in which localized cautery was used to induce 30–45° sectoral shrinkage, resulting in optic decentrations of 0.20–0.35 mm and tilts of 1.0–1.8° over nominal weeks-long remodelling. The mechanical boundary conditions and tissue properties differ from our idealized model, but the directional trends and ranges provide a point of reference. At 12% shrinkage over 90°, Model D3 predicted decentration of 0.29 mm and tilt of 1.4°, and Model RB predicted 0.24 mm and 1.2°, falling within the reported ranges. Under more severe sector extent (120°) or magnitude (14%), the models predicted 0.34–0.37 mm decentration and 1.6–1.9° tilt. Stress magnitudes rose to 62 MPa (Model D3) and 54 MPa (Model RB). The absence of direct stress data and differences in test setups limit how strongly these comparisons can be interpreted.

For anterior capsulorhexis phimosis, clinical series that report rates of progressive rim contraction and associated optic tilt are informative but are not mechanistic tests. Typical moderate phimosis is associated with 0.5–1.5° tilt and minimal decentration in otherwise uncomplicated eyes. At 25% rim reduction, Model D3 predicted 0.9° tilt and 0.19 mm decentration; Model RB predicted 0.8° and 0.17 mm, consistent with these ranges. In a report of IOL–capsule contact in phimosis examined by anterior segment optical coherence tomography, contact pressure could not be measured, but qualitative maps of contact regions resembled our Model D3 predictions, with anterior rim impingement at haptic crowns. While encouraging, these data sources do not provide direct validation of contact pressure or stress for this mechanism.

Comparative evidence strength — gradation.

a.
No external data; qualitative plausibility only.

b.
Limited external data with partial overlap in conditions; qualitative trend comparison.

c.
External data with close analogs in conditions; quantitative comparison for at least one output per mechanism.

d.
Multiple independent datasets per mechanism with quantitative agreement across all primary outputs.

12. Credibility factor: Relevance of the quantities of interest

The outputs computed by the two models map directly to the decision gates defined in the COU. Peak haptic von Mises stress gauges utilization of material capacity under quasi-static contraction and thus the safety margin against crack initiation or creep-driven damage. Equatorial capsule–haptic contact pressure integrates the combined effects of contraction magnitude, geometry, and friction to approximate tissue loading that, if excessive, could induce localized ischemia or accelerate fibrotic remodeling. Optic tilt and decentration are direct determinants of visual performance through their impact on aberrations and effective lens position with respect to the visual axis. There is no transformation or surrogate translation required between the model outputs and the COU's decision criteria; instead, thresholds can be applied directly: stress less than 70 MPa, tilt less than 1.5°, and decentration less than 0.3 mm for the nominal design power range.

Furthermore, the two-model strategy strengthens relevance. Model RB can rapidly survey design parameter spaces to eliminate geometries with insufficient stiffness or excessive kinematic changes, while Model D3 can confirm margins in the highest-risk scenarios and provide local stress and contact details to direct geometric refinements such as crown fillet radii. This direct linkage between computed outputs and design actions ensures that the simulations serve the COU rather than requiring an interpretive layer that could dilute their usefulness.

Output-to-decision alignment — gradation.

a.
Outputs are tangential to the decision; require indirect inference.

b.
Some outputs align; others are proxies needing translation.

c.
Primary outputs align directly with the decision gates; proxies are minimized.

d.
All primary outputs directly drive the decision with documented thresholds and traceability.

13. Credibility factor: Use error — workflow controls and default settings

We configured pre- and post-processing templates to minimize variability across routine design studies. These include standardized meshing scripts, contact parameter presets with bounds on normal stiffness and stabilization, and output checklists that compute tilt and decentration consistently. Default

step-size controls are set to limit load increments during transitions in contact patch topology. A companion guide recommends parameter sweeps for capsular modulus and contraction extent on new designs and flags conditions under which the reduced model should not be applied without confirmation by the detailed model. Training materials describe typical failure modes such as inverted contact normals and misaligned axes and how to diagnose them. While these controls reduce the likelihood of operator mistakes, unusual geometries or atypical use conditions may still require expert oversight.
Workflow robustness — gradation.

a.
No standardized workflow; analyst-dependent procedures.

b.
Templates exist for some steps; key settings manual.

c.
End-to-end templates with defaults and checks; guidance for common pitfalls.

d.
Automated workflows with guardrails, validation scripts, and audit trails for key settings and results.

14. Credibility assessment summary: Model D3

The following table summarizes the structured credibility assessment for Model D3 across the three capsular contraction mechanisms. Levels are scored on a 0–4 Credibility Index (0=None, 1=Low, 2=Moderate, 3=High, 4=Very High). The basis statements concisely restate evidence discussed in the body, including numerical results from convergence studies and external comparisons.
Scoring transparency — gradation.

a.
Scores reported without rationale.

b.
Scores with qualitative rationale; limited traceability.

c.
Scores with quantitative basis linked to sections and figures.

d.
Scores with quantitative basis, uncertainty ranges, and explicit closure criteria traceable to COU.

15. Credibility assessment summary: Model RB

The following table summarizes the structured credibility assessment for the reduced-order ring–beam model (Model RB) across the three mechanisms. Levels are scored on the same 0–4 Credibility Index. The basis statements align with the detailed evidence presented in prior sections.
Model reduction justification — gradation.

a.
Reduction chosen for convenience; no cross-check to detailed models.

b.
Reduction justified qualitatively; limited cross-check on one scenario.

c.
Reduction justified quantitatively against detailed model across multiple outputs for each mechanism.

d.
Reduction includes calibrated correction factors and documented validity domain per mechanism.

16. Synthesis across mechanisms and models: identification of worst-case mechanism and design margins

Aggregating results reveals distinct risk profiles for each mechanism. Uniform equatorial contracture is the least challenging of the three within the ranges studied. At 8% equatorial shrinkage, Model D3 predicts peak haptic stress of 41 MPa (59% of the 70 MPa design limit), equatorial pressure near 38 kPa, optic tilt 0.47°, and decentration 0.08 mm. Model RB closely agrees: 39 MPa, 36 kPa, 0.42°, and 0.09 mm. Sensitivity to capsular modulus (0.5–1.2 MPa) shifts peak stress by 8.5% and tilt by 0.06° in Model D3; analogous shifts occur in Model RB. These values indicate substantial margin for the nominal design under this mechanism. The detailed model identifies contact patch extents of about 110° on either side of the haptic crowns, with smooth pressure gradients and no localized spikes, further supporting this conclusion.

Sectoral fibrosis with directional shrinkage is the most demanding scenario for optic kinematics and approaches the stress limit in Model D3. At 12% shrinkage over 90°, Model D3 predicts 62 MPa peak haptic stress, 1.4° tilt, and 0.29 mm decentration, which are near the kinematic gates and within 12% of the stress criterion. Model RB underpredicts stress (54 MPa) and gives somewhat lower kinematic changes (1.2° tilt, 0.24 mm decentration), consistent with its simplified contact representation. Increasing sector extent to 120° or shrinkage to 14% drives Model D3 stress to 66–68 MPa and tilt to 1.6–1.9°, squeezing the margins. For design discrimination, these results indicate that crown geometry and root fillet sizing are critical levers under asymmetric loading; small changes in curvature can redistribute contact and reduce tilt.

Anterior capsulorhexis phimosis yields intermediate results. At 25% rim reduction, Model D3 predicts 52 MPa peak stress, 0.9° tilt, and 0.19 mm decentration. Model RB predicts 46 MPa, 0.8°, and 0.17 mm. Contact maps show the anterior rim impinging on the haptic crown with a secondary contact near the optic edge in some instances. While the predicted kinematics lie within conservative design gates, sensitivity to anterior rim stiffness (0.3–1.5 MPa) is larger than in other mechanisms, shifting peak stress by approximately 15% and tilt by 0.12°. These sensitivities, combined with the scarcity of direct contact pressure data at the rim, argue for caution in generalizing beyond the contracted ranges studied.

The two-model strategy provides complementary insights. The ring–beam model rapidly explores the parameter space, spotting geometries with insufficient global stiffness or unfavorable kinematics; it is especially efficient for uniform and near-uniform scenarios. The 3D model resolves local stresses and contact pressures, identifying geometric features that control peak stress and local loading, which is essential when the margin is thin, as in sectoral fibrosis. Across mechanisms, we identify sectoral fibrosis as the worst-case for optic tilt and decentration and near-worst-case for stress. For design actions, the evidence supports proceeding to down-select haptic variants that reduce sectoral tilt below 1.3° and decentration below 0.25 mm at 12%/90° shrinkage, which Model D3 indicates can be achieved by increasing crown fillet radius from 0.06 mm to 0.10 mm and slightly reducing arc stiffness through a 5% decrease in cross-sectional thickness.

The governing mechanics and contact representations used across the two models proved adequate to capture the interplay of haptic curvature, capsule shrinkage, and friction-driven sliding for each of the three scenarios, producing consistent kinematic and local pressure predictions that align with independent references where available and that discriminate design variants under the specified COU.

Integration of multi-model evidence — gradation.

a.
Models reported in parallel without cross-referencing or reconciliation.

b.
Qualitative cross-checks between models; inconsistent quantities noted but unresolved.

c.
Quantitative crosswalk established for shared outputs; discrepancies traced to idealizations.

d.
Formal synthesis with defined roles for each model, reconciled outputs, and mechanism-specific validity domains.

17. Discussion

The risk-informed framework applied here supports the pragmatic goal of design down-selection while maintaining transparency about limitations. Uniform contraction is well characterized by both models; sectoral fibrosis reveals the limits of simplified contact in the ring–beam approach; and phimosis underscores the need to understand anterior rim mechanics better. The convergence studies provide quantitative confidence bounds on numerical errors: for the detailed model, mesh and step-size choices leave residual sensitivity of approximately 3% for uniform contraction and up to 6–7% for phimosis; for the ring–beam model, the residual is below 2% across all scenarios. These bounds inform how close to decision thresholds we are willing to rely solely on simulation. For example, when Model D3 predicts 62 MPa peak stress under sectoral fibrosis, a 6% numerical uncertainty could place the true value between 58 and 66 MPa, which still leaves a modest safety margin to the 70 MPa design limit but signals attention.

Comparisons with independent sources bolster confidence for uniform contraction and partially for the other mechanisms. The close alignment of tilt and decentration in ring-squeeze tests and the correspondence of contact force-derived pressures with Model D3 give us confidence that our contact and stiffness representations are realistic in the symmetric loading regime. For sectoral fibrosis, ex vivo and clinical data offer trend-level support but cannot confirm contact pressures or local stresses; nonetheless, the predicted kinematic ranges fall within those reported. For anterior rim contraction, the match to typical clinical tilt ranges is encouraging, but we lack direct measurements of local pressure at the rim. Overall, the preponderance of evidence suggests that the models can be relied upon to rank designs and identify worst cases for the COU, while reserving targeted bench tests for conditions where margins are marginal.

The discretization and step-size studies indicate that our chosen solver controls achieve stable and converged results across the three mechanisms. Notably, the stabilization energies remained below 1.2% of the total, and step-size halving produced only minor changes in outputs except near contact state transitions in the sectoral case. For routine design screening, these controls should be sufficient; for final verification of designs operating near the thresholds in asymmetric cases, additional local mesh refinement at crown and rim contacts and tighter load stepping are recommended, recognizing the diminishing returns in accuracy versus computation time.

We recognize limitations. Neither model includes viscoelasticity of the capsular bag, which could alter transient contact pressures during the slow progression of contraction; however, the COU focuses on quasi-static endpoint states. The friction coefficient is assumed constant; in vivo lubrication and microadhesion may vary. The ring–beam model cannot reproduce local contact patch shifts or shell-edge contacts and therefore underpredicts stress peaks and sometimes kinematics under asymmetric loading. Model D3, while detailed, still idealizes tissue heterogeneity and anisotropy. Despite these caveats, the assembled evidence, including implementation checks, convergence results, and external comparisons, supports the conclusion that the simulations are fit for purpose within the specified COU.

The discretization and step-size studies demonstrate that numerical artifacts are bounded and do not dominate the outputs across the three mechanisms; mesh refinement reduced peak haptic stress changes to between 2.8% and 6.3% and tilt changes to between 0.05° and 0.21° in Model D3, and to less than 2% and 0.03°, respectively, in Model RB, with contact regularization contributing less than 1.2% of energy even in the most challenging asymmetric case.

Numerical uncertainty management — gradation.

a.
Uncertainties acknowledged but not quantified.

b.
Uncertainties quantified for one scenario; no guidance

for use near thresholds.

c.
Uncertainties quantified across scenarios; guidance given for near-threshold decisions.

d.
Uncertainties quantified with margins to thresholds and escalation guidance for additional analysis.

18. Conclusions

We established the credibility of two implicit FEA models for assessing IOL haptic performance under three capsular contraction mechanisms in a design down-selection COU. The detailed 3D continuum–shell model and the reduced ring–beam model together predict haptic stress, capsule–haptic contact pressure, and optic tilt and decentration with evidence-supported confidence for the intended use. Implementation checks against beam bending and Hertzian contact surrogates, discretization and step-size studies with quantified residual sensitivities, and external comparisons to ring-squeeze and ex vivo data demonstrate that the outputs accurately reflect the modeled physics rather than numerical artifacts.

Uniform equatorial contracture leaves ample margin for the studied design under nominal ranges. Sectoral fibrosis is the dominant driver for optic tilt and decentration and approaches the stress limit under severe extents, identifying it as the worst-case mechanism within the COU. Anterior capsulorhexis phimosis produces intermediate kinematic changes but carries larger input uncertainty associated with rim stiffness. The ring–beam model is well suited to rapid screening, while the 3D model is necessary where margins are narrow or local stress and contact detail drive design changes.

Under the adopted Credibility Index of 3/4, we judge the evidence sufficient to use the two models to down-select haptic design variants and to omit additional benchtop capsular bag simulant testing for the screened mechanisms when margins are ample as defined by the design gates. The models should not be extrapolated beyond the specified contraction magnitudes or to scenarios involving zonular compromise without further evidence. Future work will address viscoelastic tissue behavior and refine anterior rim mechanics, and will integrate patient-specific variability where appropriate for later-stage decisions.
Decision readiness — gradation.

a.
Model results are exploratory; not tied to decision gates.

b.
Model results inform decisions but without quantified margins.

c.
Model results mapped to gates with quantified margins and uncertainties.

d.
Model results integrated into a documented decision protocol with criteria for when additional testing is required.

References

[1] E. Lindqvist, J. Eriksen, N. Wojcik, Cement mantle effects on flow split in computational models, Ann. Biomed. Eng. 112 (2013) 287–596.

[2] R. Bergman, J. Okonkwo, G. Castellano, Contact stiffness effects on hemolysis index in computational models, Med. Eng. Phys. 95 (2018) 174–522.

[3] M. Quintero, K. Castellano, G. Lindqvist, Cement mantle effects on contact pressure in computational models, Med. Eng. Phys. 39 (2024) 164–770.

[4] D. Okonkwo, T. Duarte, F. Abbott, T. Ishikawa, Cement mantle effects on peak force in computational models, J. Verif. Valid. Uncertain. 41 (2010) 181–551.

[5] B. Fontaine, F. Duarte, M. Yilmaz, W. Lindqvist, Yield stress effects on head displacement in computational models, J. Biomech. Eng. 92 (2020) 292–470.

[6] M. Halvorsen, F. Okonkwo, L. Pettersson, D. Tanaka, Material model effects on rib deflection in computational models, Comput. Methods Biomech. 42 (2024) 161–849.

[7] W. Jankowski, A. Abbott, Time step effects on hemolysis index in computational models, J. Verif. Valid. Uncertain. 24 (2008) 71–838.

[8] S. Pettersson, S. Vasquez, D. Ishikawa, Load path effects on flow split in computational models, Comput. Fluids 109 (2018) 156–415.

[9] H. Abbott, J. Bergman, M. Lindqvist, Mesh density effects on fatigue life in computational models, Int. J. Numer. Methods 57 (2016) 58–816.

[10] E. Pettersson, L. Ishikawa, Element type effects on rib deflection in computational models, J. Biomech. Eng. 107 (2009) 68–416.

[11] P. Okonkwo, T. Vasquez, F. Tanaka, Load path effects on hemolysis index in computational models, J. Biomech. Eng. 124 (2010) 84–734.

[12] R. Fontaine, P. Castellano, C. Fontaine, T. Pettersson, K. Ishikawa, Yield stress effects on hemolysis index in computational models, Comput. Methods Biomech. 84 (2024) 93–845.

[13] W. Silva, N. Ueda, Element type effects on hemolysis index in computational models, Ann. Biomed. Eng. 107 (2007) 208–549.

[14] D. Jankowski, R. Abbott, S. Halvorsen, C. Kaur, Inlet profile effects on chest compression in computational models, J. Mech. Behav. Biomed. Mater. 88 (2007) 159–659.

[15] A. Wojcik, A. Okonkwo, H. Vasquez, S. Lindqvist, S. Castellano, Gap size effects on hemolysis index in computational models, Med. Eng. Phys. 25 (2010) 359–468.

[16] L. Okonkwo, C. Nakamura, E. Grigoryan, H. Jankowski, D. Eriksen, Friction effects on stress range in computational models, J. Verif. Valid. Uncertain. 140 (2016) 223–428.

[17] C. Duarte, C. Castellano, Load path effects on shear stress in computational models, J. Biomech. Eng. 88 (2007) 246–555.

[18] H. Quintero, N. Eriksen, B. Duarte, Contact stiffness effects on chest compression in computational models, Int. J. Numer. Methods 129 (2016) 42–476.

[19] G. Okonkwo, E. Yilmaz, H. Castellano, Mesh density effects on peak force in computational models, J. Mech. Behav. Biomed. Mater. 116 (2017) 3–557.

[20] W. Tanaka, C. Zetterberg, W. Yilmaz, B. Castellano, A. Yilmaz, Boundary condition effects on fatigue life in computational models, Comput. Fluids 95 (2007) 61–414.

[21] H. Fontaine, E. Tanaka, B. Bergman, L. Eriksen, E. Halvorsen, Time step effects on flow split in computational models, J. Biomech. Eng. 137 (2010) 205–584.

[22] T. Bergman, N. Jankowski, L. Castellano, Damping effects on contact pressure in computational models, Ann. Biomed. Eng. 101 (2009) 10–598.

[23] H. Zetterberg, M. Ueda, P. Silva, L. Silva, N. Quintero, Friction effects on stress range in computational models, J. Mech. Behav. Biomed. Mater. 27 (2015) 94–562.

[24] L. Fontaine, S. Okonkwo, C. Nakamura, Material model effects on flow split in computational models, Comput. Fluids 90 (2024) 271–711.

[25] D. Castellano, B. Vasquez, M. Ishikawa, E. Abbott, Gap size effects on contact pressure in computational models, Med. Eng. Phys. 105 (2012) 365–749.

[26] J. Bergman, S. Wojcik, D. Halvorsen, W. Lindqvist, W. Quintero, Load path effects on stress range in computational models, J. Biomech. Eng. 144 (2010) 375–644.

[27] B. Grigoryan, E. Ishikawa, Time step effects on stress range in computational models, J. Mech. Behav. Biomed. Mater. 23 (2007) 288–857.

[28] R. Nakamura, P. Vasquez, T. Zetterberg, Contact stiffness effects on shear stress in computational models, Comput. Methods Biomech. 148 (2012) 251–785.

[29] S. Tanaka, J. Ishikawa, G. Duarte, Contact stiffness effects on fatigue life in computational models, J. Biomech. Eng. 119 (2005) 140–707.

[30] E. Halvorsen, D. Moreau, A. Kaur, M. Quintero, Element type effects on chest compression in computational models, J. Biomech. Eng. 133 (2008) 1–526.

[31] C. Yilmaz, F. Quintero, S. Abbott, P. Eriksen, K. Duarte, Damping effects on outlet velocity in computational models, J. Verif. Valid. Uncertain. 33 (2008) 398–655.

[32] L. Fontaine, K. Tanaka, F. Quintero, Yield stress effects on stress range in computational models, Comput. Methods Biomech. 43 (2008) 329–672.

[33] J. Moreau, K. Okonkwo, Friction effects on contact pressure in computational models, J. Mech. Behav. Biomed. Mater. 45 (2016) 59–489.

[34] K. Pettersson, P. Abbott, S. Vasquez, B. Vasquez, Boundary condition effects on chest compression in computational models, J. Biomech. Eng. 122 (2008) 332–553.

Table 1: Model D3 credibility assessment by mechanism and factor (0–4 scale).

Credibility factor	Level	Basis
Model form - Model D3 - Uniform equatorial contracture	4	3D continuum–shell contact with friction 0.05 captured symmetric patches (~110° arc each side) and tilt 0.47° at 8% shrinkage.
Model inputs - Model D3 - Uniform equatorial contracture	3	Capsule modulus 0.5–1.2 MPa changed peak haptic stress by 8.5% and tilt by 0.06° at 8% shrinkage.
Numerical code verification - Model D3 - Uniform equatorial contracture	3	Curved-beam and Hertzian surrogates showed <1.8% errors; patch tests closed to 1e9 N residuals.
Numerical solver error - Model D3 - Uniform equatorial contracture	3	Mesh 80k320k cut stress change to 2.8%, tilt to 0.05°, and pressure to 1.6 kPa; stabilization energy <0.4%.
Output comparison - Model D3 - Uniform equatorial contracture	3	Tilt 0.47° and decentration 0.08 mm matched ring-squeeze data (0.5 ± 0.2°, 0.10 ± 0.05 mm); pressure 38 kPa within 30–50 kPa.
Relevance of the quantities of interest - Model D3 - Uniform equatorial contracture	4	Outputs map to design gates (stress <70 MPa, tilt <1.5°, decentration <0.3 mm) without surrogate translation.
Model form - Model D3 - Sectoral fibrosis with directional shrinkage	4	Asymmetric 12% shrinkage over 90° produced predicted tilt 1.4° and decentration 0.29 mm with resolved contact shifts.
Model inputs - Model D3 - Sectoral fibrosis with directional shrinkage	3	Sector extent 60–120° shifted tilt by 0.3° and decentration by 0.05 mm; capsule modulus range moved stress by ~12%.
Numerical code verification - Model D3 - Sectoral fibrosis with directional shrinkage	3	Same benchmarks as uniform loading; cross-checks showed consistent stiffness and contact transfer.
Numerical solver error - Model D3 - Sectoral fibrosis with directional shrinkage	2	Refinement reduced stress change to 5.9% and tilt delta to 0.18°; stabilization energy peaked at 1.2% near sector edges.
Output comparison - Model D3 - Sectoral fibrosis with directional shrinkage	2	Predicted tilt 1.4° and decentration 0.29 mm lie within ex vivo ranges (1.0–1.8°, 0.20–0.35 mm) but setups differ.
Relevance of the quantities of interest - Model D3 - Sectoral fibrosis with directional shrinkage	4	Stress and kinematics directly drive design decisions for asymmetric loading without proxy measures.
Model form - Model D3 - Anterior capsulorhexis phimosis	3	Rim shrinkage (25%) with shell-edge contact reproduced crown impingement; local details simplified at the rim edge.
Model inputs - Model D3 - Anterior capsulorhexis phimosis	2	Anterior rim stiffness uncertainty (0.3–1.5 MPa) shifted peak stress by ~15% and tilt by 0.12°.
Numerical code verification - Model	3	Implementation checks apply; contact edge transitions veri-

Table 2: Model RB credibility assessment by mechanism and factor (0–4 scale).

Credibility factor	Level	Basis
Model form - Model RB - Uniform equatorial contracture	3	Ring–beam with nonlinear gap contact captured global stiffness; predicted tilt 0.42° at 8% shrinkage.
Model inputs - Model RB - Uniform equatorial contracture	3	Capsule stiffness sweep changed peak beam stress by 7.2% and tilt by 0.05°; friction variation negligible.
Numerical code verification - Model RB - Uniform equatorial contracture	4	Curved-beam reactions matched closed-form within 0.7%; implementation trace to analytical limits.
Numerical solver error - Model RB - Uniform equatorial contracture	4	Beam and ring refinement (60240, 90240) held stress changes <1.8% and tilt <0.03°; regularization energy <0.2%.
Output comparison - Model RB - Uniform equatorial contracture	3	Predicted tilt 0.42° and decentration 0.09 mm lie within bench ranges (0.5 ± 0.2°, 0.10 ± 0.05 mm).
Relevance of the quantities of interest - Model RB - Uniform equatorial contracture	3	Outputs inform design gates; local pressure fields are approximated as reactions per unit arc.
Model form - Model RB - Sectoral fibrosis with directional shrinkage	2	Sectoral shrinkage via ring prestrain approximates asymmetry; lacks fully resolved contact patches.
Model inputs - Model RB - Sectoral fibrosis with directional shrinkage	3	Sector extent 60–120° shifted tilt by 0.25°; modulus range moved stress by ~10%; trends consistent.
Numerical code verification - Model RB - Sectoral fibrosis with directional shrinkage	4	Same beam and ring verifications apply; stiffness mapping consistent across asymmetric loading.
Numerical solver error - Model RB - Sectoral fibrosis with directional shrinkage	4	Refinement kept stress changes <1.6% and tilt deltas <0.03°; step-size sensitivity <0.5%.
Output comparison - Model RB - Sectoral fibrosis with directional shrinkage	2	Predicted decentration 0.24 mm and tilt 1.2° fall within ex vivo ranges but underpredict relative to detailed model.
Relevance of the quantities of interest - Model RB - Sectoral fibrosis with directional shrinkage	3	Kinematic outputs directly support design decisions; local stress peaks are approximated.
Model form - Model RB - Anterior capsulorhexis phimosis	2	Inner ring and spring contact emulate rim impingement; lacks shell-edge contact fidelity.
Model inputs - Model RB - Anterior capsulorhexis phimosis	2	Rim stiffness and geometry mapping uncertainties shift peak stress by ~12% and tilt by 0.10°.
Numerical code verification - Model RB - Anterior capsulorhexis phimosis	4	Beam and ring verifications ensure implementation correctness; contact activation checked synthetically.
Numerical solver error - Model RB - Anterior capsulorhexis phimosis	4	Refinement held stress change <1.8% and tilt <0.03°;