Credibility assessment of two CFD models for an intravascular catheter's trackability and flow resistance within the ASME V&V 40 framework

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Abstract

Computational fluid dynamics (CFD) is increasingly used to inform design trade-offs in intravascular devices whose performance depends on hydrodynamics inside the device and in the confined gap between the device and the vessel wall. We report a credibility assessment, conducted under the spirit of ASME V&V 40, of two physics-based CFD models developed for an over-the-wire intravascular catheter intended for coronary and peripheral navigation and infusion. Model-Lumen-RANS (MLR) solves steady, incompressible Reynolds-averaged Navier–Stokes (RANS) in the catheter's internal lumen and side ports to predict pressure drop versus flow, wall shear stress, and local loss coefficients. Model-Nav-NarrowGap (MNNG) applies lubrication approximations to the pericatheter thin film within tortuous geometries to estimate hydrodynamic drag during advancement, near-wall shear at contact, and pressure fields affecting trackability. The context of use is limited to supporting design selection and design verification across bench test conditions representing indicated anatomies; the models inform test-matrix reduction and acceptance rationales but are not used for clinical decisions. Model risk is medium: the models influence, but do not replace, verification testing, and consequences of incorrect predictions are mitigated by mandatory bench tests and independent safety reviews. We score six credibility dimensions on a private 0–12 scale for each combination of model and mechanism: specification of parameter ranges and sources; discretization and iteration-induced solution changes; agreement with bench measurements; mapping from predicted fields to acceptance metrics; scope alignment of validation activities to the context of use; and environmental and setup fidelity of the bench conditions. Eight mechanisms-by-model combinations are evaluated: four mechanisms—tortuous-path bending and torsion during navigation; guidewire–catheter sliding friction within the distal lumen; lumen viscous pressure drop under steady infusion; and entrance/exit losses and side-hole mixing under pulsatile delivery—assessed with each model. Validation experiments include steady and pulsatile flow loops for pressure–flow and loss-coefficient measurements across wire sizes, and tortuous-phantom navigation tests capturing push force, advancement drag, and torsional response. MLR achieves high credibility for steady lumen resistance (scores 10–11/12 across factors) and strong-to-moderate credibility for pulsatile local losses (8–9/12), with lower support for navigation-related mechanisms due to model scope limits (5–8/12). MNNG achieves high credibility for navigation drag in tortuous paths (9–10/12) and guidewire–catheter friction contributions (8–9/12), with moderate credibility where its assumptions make it less central (steady lumen and pulsatile mixing, 7–9/12). We provide two model-specific scorecard tables with 48 total graded entries—one for every assessed (factor × model × mechanism). The integrated interpretation supports targeted test-matrix reduction: MLR can bound steady-flow resistance and mean pressure budgets across sizes and wire states, while MNNG can rank geometry variants for trackability within the validated tortuosity envelope. We delineate limitations and planned future work confined to the assessed factors.

Keywords: catheter CFD, V&V 40, credibility assessment

1. 1. Background and objective

Catheter performance in the vasculature emerges from the interaction of hydrodynamic loads with geometry, materials, and operator technique. Trackability—the ability of a device to advance and steer through tortuous vessels with controlled response—and flow resistance—the pressure required to deliver a given infusion rate—are central to design verification and labeling for an over-the-wire system. These performance attributes depend both on internal lumen flow and on the thin-film flow between the device and the vessel wall as the shaft traverses curves. The balance between pressure budget, allowable infusion rate, and push force is delicate in coronary and peripheral anatomies, and engineering tools that reliably anticipate the impact of design choices can reduce the number of bench iterations and focus testing where uncertainty is maximal.

We report a credibility assessment of two complementary CFD models that we developed to support design decisions before and during design verification. The first, Model-Lumen-RANS (MLR), addresses internal hydrodynamics: it solves steady incompressible Reynolds-averaged Navier–Stokes (RANS) in the lumen and side ports, yielding pressure–flow relations, wall shear, and local loss coefficients under specified flow and wire states. The second, Model-Nav-NarrowGap (MNNG), addresses the hydrodynamics of navigation: it applies lubrication theory in the narrow annulus between the device and an enclosing tortuous conduit, estimating hydrodynamic drag opposing advancement, near-wall shear at contact, and the pressure field that modulates steering and buckling risk.

The assessment follows the principles of ASME V&V 40 for risk-informed credibility, with a context of use (CoU) constrained to preclinical design selection and design verification. Our goal is to determine, with transparent evidence and limitations, where each model provides decision-grade guidance and where experimental confirmation remains primary. The evaluation spans four mechanisms tied to the two performance categories: (1) tortuous-path bending and torsion during navigation; (2) guidewire–catheter sliding friction within the distal lumen; (3) lumen viscous pressure drop under steady infusion; and (4) entrance/exit losses and side-hole mixing under pulsatile delivery.

We quantify credibility along six dimensions scored on a 0–12 private scale defined for this study (0 indicates no credible evidence; 12 indicates compelling, decision-grade evidence): the adequacy and provenance of the parameter sets; the magnitude of solution changes under discretization and iteration refinement; the degree of agreement with bench measurements; the mapping from model outputs to acceptance metrics used in verification; the alignment of the validation program with the stated CoU; and the match between laboratory setups and the intended use environment. For each combination of model and mechanism, we present a graded entry with a short basis statement and supporting numerical evidence in the body of the article.

The overarching objective is twofold. First, we integrate physics-based simulation with bench tests in a manner that is faithful to risk-informed credibility, strengthening design rationale and focusing testing resources. Second, we delineate the limits of inference so that neither model is used beyond its validated scope. In doing so, we aim to provide a traceable record suitable for internal design control and for external review under standards that emphasize transparency, relevance, and evidence quality.

Relevance of the quantities of interest — gradation.

a.
Descriptive outputs not mapped to any acceptance criterion; qualitative rationale only.

b.
Outputs are related to acceptance metrics via proportional trends; no explicit thresholds or error budgets.

c.
Quantified mapping from model outputs to verification metrics, with justified thresholds and propagated uncertainty.

d.
Formal translation of outputs to acceptance decisions with pre-registered decision rules and bounds for Type I/II error.

2. 2. Context of Use (CoU): CFD predictions will be used to support design selection and design verification for catheter trackability and flow resistance across specified bench test conditions representative of indicated coronary and peripheral anatomies; results will inform test matrix reduction and acceptance rationales, not clinical decisions.

We define a narrow and practical application domain for both models. Predictions will inform (a) selection among design variants prior to formal verification and (b) justification for reducing the number of bench configurations tested in design verification, provided the predicted behaviors have been validated against the retained set. The intended anatomic classes correspond to labeled coronary and peripheral segments with tortuosity quantified by composite curvature and torsion measures derived from a library of centerlines. Wire sizes include 0.014–0.035 in. guidewires, with focus on 0.014–0.018 in. for coronary and 0.018–0.035 in. for peripheral indications. For infusion, the envelope includes Newtonian blood analogs spanning 3.0–4.0 mPa·s at 37 °C and volumetric flow rates 1–200 mL/min through lumens of 0.015–0.040 in. inner diameter (ID), with side-port configurations typical of infusion catheters used for drug and contrast delivery.

Model outputs are used to rank design variants and to bound expected verification results. For trackability, MNNG provides predicted advancement drag as a function of curvature sequence, shaft stiffness profile, and pericatheter film thickness, while MLR provides internal shear and pressure distributions when a wire is present in the distal lumen that may influence frictional behavior. For flow resistance, MLR provides pressure–flow relations and local loss coefficients under steady and pulsatile delivery. The models are not used to make patient-specific predictions or to substitute for safety testing; rather, they supplement experimental programs by identifying insensitive regions of design space and by providing mechanistic explanations for observed performance.

We operationalize the CoU by specifying which acceptance metrics the models can inform. For navigation, the trackability index measured in tortuous phantoms is computed as the mean push force required to achieve steady advancement at 10 mm/s through a standardized path, adjusted for rotational compliance; MNNG predicts the hydrodynamic drag and pressure field components contributing to this index. For infusion, the flow resistance threshold is defined as the maximum allowable pressure drop at the proximal luer at specified flow rates; MLR directly predicts these values and the decomposition into viscous and local losses.

This CoU implies several boundaries. The models will not be used to extrapolate beyond the input range derived from indicated anatomy, nor to assess hemocompatibility endpoints. They will not be used to qualify extreme use conditions such as hyper-viscous fluids (>5.0 mPa·s at 37 °C) or severe vasospasm equating to lumen collapse; such scenarios remain under separate testing or analysis. Within the CoU, the models will be combined with bench testing via a pre-specified decision rule: for a design variant to be advanced without additional bench

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

configurations, the model must under-predict resistance by at least a 10% margin or over-predict drag by at least a 10% margin in the validated envelope, ensuring conservatism.

The relationship between the models and the verification program is bidirectional. Bench data inform parameter selection and model updates, while simulations guide which physical tests are most informative. This interplay is carefully governed to avoid circularity: parameters that are tuned to one dataset are not validated against the same dataset for the purpose of scoring agreement; an independent holdout is maintained where feasible.
Relevance of validation activities to the CoU — gradation.

a.
Validation tests examine conditions unrelated to the intended application; no mapping to CoU.

b.
Some test scenarios overlap with the CoU but omit key regimes or device states.

c.
Validation covers the dominant regimes, device states, and boundary conditions specified in the CoU with justified gaps.

d.
Validation fully spans the CoU with documented representativeness and statistical coverage of anatomy and operating states.

3. 3. Model risk under ASME V&V 40: Medium model risk — influence is moderate (supports but does not replace bench verification), consequence of an incorrect prediction is moderate (potential suboptimal design leading to higher push force or pressure drop, mitigated by required bench testing); rationale: decisions bounded to preclinical verification with defined acceptance limits, with independent safety reviews.

The impact of the two models on design decision-making is material but bounded. Design variants are compared using the models to establish priorities for bench testing and to justify the exclusion of combinations expected to be clearly compliant or clearly noncompliant with acceptance limits. However, the models do not displace verification gates; they act as a filter and a rationale enhancer. Consequently, an incorrect prediction may influence which variants are tested first or how acceptance margins are allocated, but it cannot alone authorize a product release or labeling claim.

The potential consequences of incorrect predictions are therefore of moderate severity within the development process. An inaccurate underestimation of flow resistance could lead to selection of a less favorable internal geometry, discovered at verification with some schedule impact; a significant underestimation of navigation drag could lead to a variant being tested in a more limited tortuosity set than actually warranted, again discovered at verification. Both are mitigated by mandatory verification testing and by independent design safety reviews. Given this interplay, and consistent with V&V 40 guidance on risk-informed credibility, we classify model risk as medium and target intermediate-to-high rigor in the evidence we assemble.

This classification informed the breadth and depth of our validation plan and verification of numerical solution quality. We prioritized thorough boundary-condition specification and measurement accuracy for the regimes in which the models are expected to be informative. We also emphasized traceability: each use of a model prediction in a decision context is linked to a specific validation datum, an uncertainty estimate, and a conservatism margin.

To prevent erosion of credibility through overreach, we codified limits of extrapolation, model update policies, and a separation between parameter identification and validation testing, with independent reviews to check for consistent application across programs.
Output comparison — gradation.

a.
Qualitative or visual comparison only; no quantified discrepancies or uncertainty.

b.
Quantified differences reported at a few points or summary statistics without uncertainty.

c.
Comprehensive quantitative comparison across the CoU envelope with uncertainty bands and pre-specified error metrics.

d.
Cross-laboratory or multi-protocol corroboration with consistency checks and outlier analysis tied to decision thresholds.

4. 4. Computational models: geometry definition, physics, boundary conditions, and solution strategies (MLR and MNNG)

Model-Lumen-RANS (MLR) resolves the internal hydrodynamics of an over-the-wire catheter with straight and mildly curved sections, ports, and a distal tip region. The computational domain comprises the proximal luer segment, internal lumen of circular cross-section with IDs spanning 0.015–0.040 in. (0.38–1.02 mm), a side port array that can be configured for infusion (1–6 ports of 0.3–0.7 mm diameter at axial spacings of 0.5–3.0 mm), and the distal tip exit. For cases with a guidewire inserted, the wire is modeled as a concentric or slightly eccentric solid cylinder of diameter 0.014–0.035 in., with interference fits modeled by appropriate clearances where applicable. Fluid is an incompressible Newtonian analog with density 1050 kg/m3 and viscosity 3.0–4.0 mPa·s at 37 °C, consistent with glycerol–water mixtures calibrated by capillary viscometry. The governing equations are steady-state RANS with the k–ω SST turbulence closure; however, for Reynolds numbers below approximately 2000 in the lumen, the flow is laminar and the turbulence model reverts to low-Re behavior.

Boundary conditions for MLR are set as follows: a prescribed uniform volumetric flow rate at the luer inlet ranging from 1 to 200 mL/min; zero-gauge pressure at the distal tip outflow; at side ports, either zero flux (for closed ports) or a convective opening to zero-gauge pressure with a loss coefficient applied to approximate tissue-side resistance (for infusion through ports). No-slip conditions apply to all walls and to the guidewire surface. Meshes are unstructured poly-hex with prism layers resolving wall shear, with 20–40 prism layers yielding y+ < 1 in viscous units for turbulent cases and first-layer heights of 1–5 µm depending on local Reynolds number. Typical meshes contain 6–15 million cells for single-port configurations and 12–30 million cells for multiperforated designs. The solver uses second-order upwind schemes for convection and second-order implicit for pressure–velocity coupling with SIMPLEC. Convergence criteria are normalized residuals below 106 for all equations and integral quantities (pressure drop, flow partitioning) stabilized within 0.1% over 500 iterations.

Model-Nav-NarrowGap (MNNG) treats the pericatheter flow as a thin-film problem driven by imposed advancement and by small relative motions. The model constructs a centerline-embedded coordinate system for a specified vessel path characterized by curvature κ(s) and torsion τ(s) along arc length s. The catheter shaft centerline is represented by an inextensible, torsionally compliant beam with a known stiffness distribution, but MNNG restricts attention to hydrodynamic components of resistance: the flow in the annular gap of thickness h(s,θ) between the outer surface of the catheter and the inner boundary of the conduit. Under lubrication assumptions (h/R 1, Reynolds numbers based on h are small, inertial terms negligible in the thin dimension), the axial pressure gradient balances the viscous shear, leading to a local flow rate per circumference proportional to h3 times the pressure gradient. Cross-film pressure variations are neglected; curvilinear effects are included at leading order via curvature-induced metric terms. The model solves a one-dimensional axial pressure equation with variable conductance determined by h(s,θ) and by the local contact state (contact patches reduce gap locally to near-zero; stick–slip transitions are handled via a regularization that assigns a small but finite hydrodynamic conductance).

Inputs to MNNG include the gap profile h(s,θ) (constructed from nominal shaft outer diameter, conduit inner diameter, and manufacturing tolerances; contact is introduced where shaft–conduit interference occurs due to curvature-induced ovalization or manufacturing variability), the imposed advancement speed (1–20 mm/s in tests, default 10 mm/s), the fluid viscosity (3.0–4.0 mPa·s at 37 °C), and the boundary pressure at the distal end (set to ambient for open-tip or elevated for partial occlusion scenarios). The outputs are the axial pressure profile, the integrated hydrodynamic drag opposing advancement, and near-wall shear at contact-adjacent regions. Numerical implementation uses finite differences along s with upwinding for any convective terms introduced by axial compliance modeling, a uniform grid of Δs = 0.25–1.0 mm depending on curvature gradients, and local relaxation to converge nonlinearly coupled conductance–pressure relations. For transient scenarios where advancement rate varies, a semi-implicit time integrator is used with Δt = 0.5–2 ms and tolerance on successive updates of 106 in normalized residuals.

For both models, we generate geometry variants and boundary conditions from design databases and bench protocols. The MLR geometry builder consumes CAD representations of the luer, lumen, side ports, and distal tip; MNNG consumes centerline libraries from CT-derived and bench jig paths with documented curvature–torsion sequences. Where guidewires are inserted in MLR, wire–lumen eccentricity is generated via a Latin hypercube over a 0–30% offset relative to lumen radius to sample realistic wire biases. In all cases, temperature is set to 37 ± 0.5 °C to match bench fluids.

Verification activities for the numerical solution include canonical test problems (Poiseuille flow in concentric and eccentric annuli; orifice and sudden expansion benchmarks) to verify solver implementation. For MLR, we reproduced dimensionless pressure drops in concentric annuli to within 0.3% of analytic values at Re < 2000 and loss coefficients for orifices to within 2.5% of literature correlations for beta ratios β = 0.4–0.7. For MNNG, we compared analytic lubrication solutions in straight annuli and curved channels against numerical solutions; errors in integrated drag were below 1.0% at Δs = 0.5 mm for gap thicknesses h/R ≤ 0.05.
Numerical solver error — gradation.

a.
No quantification of discretization or iteration effects; unverified solver settings.

b.
Single-resolution runs with heuristic convergence; limited spot checks for sensitivity.

c.
Systematic mesh/time-step refinement with observed order and uncertainty estimates on key outputs.

d.
Code- and solution-verification including canonical benchmarks, observed order, and uncertainty propagation into decisions.

5. 5. Mechanisms assessed and mapping to quantities of interest

We examine four mechanisms that connect design features to trackability and flow resistance. The first mechanism, tortuous-path bending and torsion during navigation, captures how hydrodynamic drag generated in the narrow film between the shaft and the vessel wall adds to mechanical resistance from bending and friction at contact points. For this mechanism, the quantity of interest (QoI) is the integrated hydrodynamic drag opposing advancement along a specified path and the distribution of pressure along the shaft, both expressed as functions of curvature sequence and speed. Secondary QoIs include near-wall shear at contact-adjacent patches, which can inform abrasion risk qualitatively.

The second mechanism, guidewire–catheter sliding friction within the distal lumen, focuses on the contribution of internal viscous shear to the apparent friction between the wire and the polymeric lumen when both are present. In constricted distal segments, a thin axial film between wire and lumen can generate appreciable shear that modulates the mechanical friction. The QoIs are the pressure gradient and wall shear stress in the annular region of the distal lumen, and their contributions to the force balance during wire–catheter motion relative to each other.

The third mechanism, lumen viscous pressure drop under steady infusion, addresses the classical question of flow resistance. For a given internal geometry (lumen ID and length; side ports; distal exit), we require the mean pressure drop at prescribed flow rates. QoIs are the total pressure drop between the luer inlet and the exit(s), along with the decomposition into distributed viscous losses and local losses at geometric features. These directly map to verification acceptance thresholds that cap the allowable pressure at the luer for specified flows.

The fourth mechanism, entrance/exit losses and side-hole mixing under pulsatile delivery, considers unsteady delivery such as contrast injection and bolus drug delivery. Complex jet interactions and unsteady local losses contribute to mean pressure drop and influence dispersion. QoIs are mean and cycle-averaged loss coefficients for entrance and exit features under prescribed waveforms (frequency 1–2 Hz, Womersley number 3–6 in the lumen), along with spatial patterns of jets emerging from side ports and the main tip.

MLR is the principal model for the third and fourth mechanisms and an auxiliary provider of internal shear fields for the second mechanism. MNNG is the principal model for the first mechanism and contributes to the second mechanism by characterizing hydrodynamic conditions near the distal end when wire and shaft co-move or slide at different speeds. Mapping from QoIs to acceptance metrics is straightforward for steady resistance; for unsteady losses and navigation drag, the mapping is via their contributions to mean push force and pressure budgets in standardized tests.

Relevance of the quantities of interest — gradation.

a.
Outputs loosely associated with performance but not used in acceptance decisions.

b.
Outputs partially aligned to performance metrics, with qualitative translation.

c.
Outputs directly tied to acceptance metrics with calculation procedures and tolerances.

d.
Outputs drive explicit decision rules with quantified uncertainty and conservatism margins.

6. 6. Credibility plan: factors evaluated, evidence sources, and scoring method (0–12 scale)

We assess credibility along six dimensions scored on a 0–12 private scale calibrated for this study: 0 indicates no credible evidence; 4 indicates preliminary evidence; 8 indicates strong evidence suitable for supportive use; and 12 indicates compelling, decision-grade evidence suitable for bounding decisions within the CoU. The six dimensions are: (1) the adequacy and provenance of the parameter sets used for each mechanism; (2) the magnitude and characterization of changes in the computed solution under mesh and time-step refinement, including residual control; (3) the degree of agreement between computed outputs and physical measurements with quantified discrepancies; (4) the traceable linkage between computed fields and the acceptance metrics actually used in verification; (5) the degree to which the validation experiments as a whole reflect the configurations and regimes encompassed by the CoU; and (6) the fidelity of the laboratory setups, including fluids, temperature, assemblies, path geometries, and measurement systems, to the intended use environment.

Evidence sources include canonical solver verification cases, bench flow-loop measurements of pressure–flow relations across catheters and wire sizes, pulsatile injection tests for entrance/exit loss characterization and side-hole interaction effects, and tortuous-phantom navigation tests capturing push force and torsional response. For each mechanism and model, we compiled input parameter ranges and uncertainties from design databases and from the bench protocols themselves. Solution verification comprises mesh and time-step refinements tailored to each model: spatial refinement and residual tolerances for MLR, axial grid and temporal step checks for MNNG. Agreement with experiments is quantified using mean absolute percent error (MAPE), bias, and Bland–Altman limits where appropriate.

We apply a simple but conservative aggregation rule to maintain traceability: the score for each dimension in each mechanism–model combination is the minimum of (a) the strongest applicable evidence and (b) any applicable evidence gaps or caveats. For example, if agreement with experiments is high under a subset of operating points but untested elsewhere in the CoU, we cap the score accordingly. Scores are assigned by a two-member panel and reviewed by an independent engineer not otherwise involved in modeling or testing.

The resulting scorecards are presented as two tables—one per model—each with 24 rows corresponding to the six dimensions across four mechanisms. Each row names the dimension and the model and mechanism to which it applies, reports the score alone in the level column, and states a concise basis. Supporting paragraphs in Sections 7–12 detail the data, methods, and uncertainties underlying these bases. An integrated interpretation in Section 15 explains how these scores inform design verification plans and test-matrix reduction while guarding against overreach.

Relevance of validation activities to the CoU — gradation.

a.
Ad hoc tests with unclear relationship to labeled indications.

b.
Targeted tests cover some labeled anatomies or operating states; notable omissions remain.

c.
Planned tests span labeled anatomies and operating states with explicit mapping to model scenarios.

d.
Validation plan includes statistical sampling of anatomy and operating states and pre-defined acceptance for representativeness.

7. 7. Model inputs (clear): specification of flow rates, waveform shapes, fluid properties, wire–lumen friction coefficients, curvature radii, and vessel path geometries for each mechanism; provenance and ranges

Parameter sets for all simulations were derived from three sources: engineering drawings and bills of materials for geometry limits (lumen IDs, OD tolerances, side-port patterns); bench protocols for operating points (flow rates, waveform shapes, infusion durations, advancement speeds); and an anatomy library of centerlines segmented from 90 CT datasets and abstracted into bench jigs spanning left anterior descending, right coronary, and superficial femoral artery tortuosities. From the drawings, lumen IDs ranged 0.015–0.040 in. with length 60–150 cm; shaft ODs ranged 0.024–0.048 in. with 0.0005–0.0015 in. tolerances. Side-port arrays varied from 1 to 6 ports with diameters 0.3–0.7 mm and spacing 0.5–3.0 mm. Wire sizes were 0.014–0.035 in.; distal wire–lumen clearance under nominal concentricity was 0.050–0.400 mm depending on combinations.

For infusion, flow rates were drawn from verification protocols: steady 1, 5, 10, 20, 50, 100, and 200 mL/min; pulsatile 1 Hz sinusoidal about 20 and 50 mL/min with amplitudes ±50% and square-wave boluses of 100 mL over 2 s. Fluid viscosity targets were 3.0, 3.5, and 4.0 mPa·s at 37 °C with ±5% tolerance; density 1050 kg/m3 ± 1%. Waveform shapes were acquired from syringe pump logs and reproduced in simulations as volumetric inflow functions to within 1.5% RMS deviation over cycles.

For navigation, centerline-derived paths were distilled into a curvature–torsion library: 12 coronary paths with peak curvature 0.8–1.3 cm1 and torsion 0.5–0.9 cm1; 8 peripheral paths with peak curvature 0.3–0.7 cm1 and torsion 0.1–0.4 cm1. Bench jigs reproduced these paths with positional accuracy ±0.5 mm over 300 mm length and angle accuracy ±1.0°. Advancement speeds of 5, 10, and 20 mm/s were imposed in tests and simulations. Gap thickness h(s,θ) was constructed from nominal OD and jig ID with measured jig diameters (precision-bored PTFE tubes) and temperature-corrected polymer shaft diameters; the resulting mean gap in non-contact sections ranged 25–125 µm with estimated SD 8–20 µm across manufacturing lots.

Wire–lumen friction coefficients used in hybrid analyses and sensitivity studies were drawn from ring-on-rod tests at 37 °C with hydrated polymer liners and PTFE-coated wires: kinetic coefficients 0.08–0.14 for 0.014 in. wire in 0.018–0.021 in. lumen, 0.06–0.10 for 0.018 in. wire in 0.021–0.025 in. lumen, and 0.05–0.09 for 0.035 in. wire in 0.038–0.042 in. lumen. While the friction law itself is mechanical, the hydrodynamic component of the apparent friction in narrow gaps depends on viscous shear; the parameter ranges above inform composite models used in interpreting MLR and MNNG predictions against push-force data.

Model inputs — gradation.

a.
Parameters chosen arbitrarily or from informal sources; undocumented ranges.

b.
Parameters derived from a mix of documented and assumed values; partial traceability.

c.
Parameters drawn from controlled drawings, protocols, and measurements; uncertainties quantified; sensitivity explored.

d.
Parameters pre-registered with provenance, bounds, and update rules; uncertainty propagated into acceptance margins.

8. 8. Numerical solver error (clear): mesh/time-step refinement procedures, residual controls, and observed solution changes per model and mechanism

For MLR, we performed spatial refinement studies for each mechanism configuration using three systematically refined meshes (N, ~2N, ~4N cells) and monitored integral quantities: total pressure drop between luer and exit, partitioned losses at side ports, and wall shear metrics. Observed changes between the two finest meshes were 0.3–0.7% for steady lumen resistance cases (Re 200–1800) and 0.6–1.2% for pulsatile mixing cases (effective Womersley number 3–6), with apparent order of accuracy between 1.8 and 2.1. Iterative convergence criteria drove residuals below 106 and stabilized integral outputs within 0.1% over the last 500 iterations. For cases with eccentric wires, localized gradients near contact led to slightly larger grid sensitivities on peak wall shear (up to 2.5%), but the overall pressure drop remained within 0.9% of the extrapolated Richardson limit on the finest mesh.

For MNNG, axial grid refinement with Δs of 1.0, 0.5, and 0.25 mm yielded changes in integrated hydrodynamic drag of 0.8–1.3% for coronary paths and 0.5–0.9% for peripheral paths at 10 mm/s advancement. In scenarios with intermittent contact patches introduced by ovalization, the regularization length scale was halved to check stability of solutions; changes in drag remained below 1.5%. For transient injections superimposed on advancement, time-step halving (Δt from 2.0 to 1.0 to 0.5 ms) produced changes in peak pressure of 1.0–1.6% and in mean drag of 0.7–1.1%. Convergence tolerances on the nonlinear pressure–conductance iterations were tightened from 105 to 106 with negligible change (<0.1%) to integrated outputs, confirming iteration adequacy.

We verified that numerical errors are small relative to experimental uncertainty. For steady lumen resistance, the bench instrumentation and fluid-property uncertainties combine to 1.5–2.5% in pressure drop; MLR grid/time uncertainties are below this level, typically 0.4–1.0%. For navigation drag, push-force measurement uncertainty (load cell ±0.02 N over typical 0.3–1.2 N range; 1.7–6.7% of reading) dominates; MNNG axial-discretization uncertainty is typically 0.6–1.0%. For pulsatile losses, the contribution of waveform tracking uncertainty (1.5% RMS) exceeds the MLR numerical uncertainty (0.8–1.2%).

To support the score assignments later, we tied the reported uncertainties to each mechanism–model pair explicitly: steady lumen resistance (MLR) 0.4–0.9%; pulsatile mixing (MLR) 0.8–1.2%; tortuous navigation (MNNG) 0.6–1.3%; distal wire–lumen shear contributions (both models used contextually) 0.9–1.5% in the hydrodynamic component. These numbers are used in Sections 9–12 to calculate model–measurement discrepancies normalized by combined uncertainty.

Numerical solver error — gradation.

a.
Unquantified or anecdotal statements of convergence.

b.
One-dimensional sensitivity checks without formal refinement or observed order.

c.
Multi-level refinement with reported observed order and estimated discretization uncertainty on QoIs.

d.
Combined code and solution verification with uncertainty integration into validation metrics.

9. 9. Output comparison (clear): quantitative comparisons to flow-loop pressure–flow curves, pulsatile loss coefficients, and navigation push-force metrics from tortuous-phantom tests for each mechanism

Steady lumen resistance (MLR). We tested eight catheter variants covering lumen IDs 0.018, 0.021, 0.025, 0.029, 0.035, and 0.040 in., two side-port patterns (single distal tip vs three distal ports), and three wire sizes (none, 0.014, and 0.018 in.). Pressure–flow curves were measured in a constant-temperature bath (37.0 ± 0.2 °C) with a differential pressure transducer (±0.25% FS over 0–300 kPa) and a syringe pump validated for steady flow. The measured curves were linear within 2% over 1–200 mL/min except at the smallest IDs where entrance effects caused slight deviations at high flow. MLR predictions of total pressure drop achieved a mean absolute percent error (MAPE) of 3.1% across 96 operating points, with a maximum absolute error of 7.2% at 200 mL/min for the 0.018 in. lumen with 0.018 in. wire (expected near-annular flow). After subtracting estimated measurement and fluid-property uncertainties, normalized discrepancies lay within ±1.1 standard deviations for 92% of points. The predicted decomposition into viscous and entrance losses aligned with measured changes upon altering entrance geometry (adding a radiused funnel reduced drop by 10–12% experimentally; MLR predicted 11–13%).

Pulsatile entrance/exit losses and side-hole mixing (MLR). For three side-port patterns and two IDs (0.021 and 0.029 in.), we measured cycle-averaged loss coefficients at 1 Hz sinusoidal flows centered at 20 and 50 mL/min (±50% amplitude), with and without simultaneous side-port flow (ambient outlet) to capture mixing interaction. Loss coefficients were computed from measured mean pressure drop minus the distributed viscous component estimated via laminar theory. MLR predicted cycle-averaged loss coefficients with MAPE 6.5% across 24 configurations and captured the modest increase (3–5%) in mean drop associated with out-of-phase side-port jets. The spatial patterns of jets qualitatively matched dye visualization: for three evenly spaced side ports, MLR predicted symmetric radial jets with decay length 4–7 diameters; for clustered ports, jet impingement led to local recirculation near the tip, also observed. Peak wall shear near ports was within 12% of particle image velocimetry (PIV) estimates in an acrylic surrogate (n = 3 tests).

Tortuous-path navigation (MNNG). We conducted phantom tests using 12 coronary and 8 peripheral paths derived from our centerline library. A stepper actuator advanced the catheter–wire assembly at 10 mm/s with a constant rotation bias of 30°/s applied at the hub to simulate steering. Push force was recorded with a 1 N-range load cell (±0.02 N accuracy). We extracted the hydrodynamic component of resistance by conducting repeats in air and in fluid and subtracting the air-run force from the fluid-run force, assuming the mechanical contributions were similar. Across all paths and three catheter OD variants (0.028, 0.032, 0.038 in.), MNNG predicted the hydrodynamic drag with MAPE 7.9% (n = 60 path–device combinations), with higher discrepancies (up to 12%) in the most tortuous coronary path where intermittent contact patches caused variability. Bias was 1.8% (model slightly conservative). The model captured the expected scaling with viscosity (drag increased by 13–15% when viscosity was raised from 3.0 to 3.5 mPa·s, vs 12–16% measured) and gap (drag decreased by 22–26% when OD was reduced by 0.004 in., vs 20–25% measured).

Guidewire–catheter sliding friction within the distal lumen (MLR and MNNG). We performed specialized tests in a short bench setup where a 60 mm distal segment with a wire inserted was driven at relative speeds 1–10 mm/s while fluid was infused at 10–50 mL/min to create annular flow. Apparent friction force was measured as a function of relative speed and flow. Separating mechanical and hydrodynamic components by extrapolating to zero flow yielded an estimate of viscous contribution. MLR predicted distal annular shear stresses that, when integrated over the contact length, accounted for 18–35% of the measured incremental friction at 50 mL/min depending on clearance (0.05–0.20 mm), in line with the 20–33% range inferred from tests across wire sizes. MNNG, when applied to the distal segment with the same annular assumptions, produced similar estimates, with absolute differences from MLR < 8% and MAPE vs inferred hydrodynamic increment 9.6% (n = 18). Agreement degraded to 14–16% MAPE at the smallest clearances where minor eccentricity significantly affected shear.

We emphasize that the outputs compared here are precisely those used for acceptance rationale: mean pressure drop vs flow for steady infusion; cycle-averaged loss coefficients for pulsatile delivery; and hydrodynamic drag for trackability metrics. In each case, comparisons were made with independent datasets not used for parameter tuning, and uncertainty was accounted for by combining numerical and experimental sources. These quantitative agreements underpin the scores assigned in the model-specific tables.

Output comparison — gradation.

a.
Visual trend matching without statistics or uncertainty.

b.
Pointwise error metrics reported; no uncertainty or validation plan link.

c.
Structured comparison across the CoU with predefined metrics and uncertainty normalization.

d.
Multi-facility or multi-method corroboration with outlier forensics and decision impact analysis.

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

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

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

10. 10. Relevance of the quantities of interest (clear): mapping from computed fields (pressure drop, loss coefficients, hydrodynamic drag, near-wall shear) to acceptance metrics (trackability index, flow resistance thresholds) for each mechanism

For steady infusion, the verification acceptance criterion is a maximum allowable pressure at the luer for specified flow rates, based on pump capability and safety margins. MLR computes total pressure drop between the luer and the exit(s), which is directly compared to this acceptance threshold; a buffer of 10% is applied when MLR bounds are used to reduce the number of bench points. The decomposition into distributed and local losses further supports design rationale, for example demonstrating that a change in tip geometry yields an estimated 12% reduction in entrance losses at 100 mL/min that would translate to a 7% reduction in total drop for the 0.029 in. lumen design.

For pulsatile delivery, cycle-averaged loss coefficients are compared to steady-flow equivalents used in verification to justify the use of steady surrogates or to quantify additional headroom. MLR's predicted mean increase in loss coefficient under 1 Hz sinusoidal flow (3–5% above steady for the tested geometries) provides the basis for applying a correction factor in acceptance calculations when pulsatility is expected.

For navigation, the trackability index is the mean push force required to achieve 10 mm/s advancement through a given path with a standardized wire. Mechanical contributions dominate this force, but a hydrodynamic component is present when the device displaces fluid in a narrow annulus during motion. MNNG's integrated hydrodynamic drag estimates enter the force balance used to interpret push-force data and to extrapolate to untested OD variants within the validated curvature envelope. By quantifying this component to within approximately 8–10% MAPE across tested paths, we can conservatively project relative changes in total push force attributable to hydrodynamics when the mechanical design is held fixed.

For the distal wire–lumen friction mechanism, the hydrodynamic contribution estimated by MLR in the annular region provides a defensible fraction of the apparent friction under infusion, informing tolerance decisions for distal clearances. When integrated over the distal segment, increases in shear predicted by MLR due to a 20% reduction in clearance correspond to a 6–9% increase in apparent friction at 50 mL/min in our tests; this mapping underlies a design rule for clearance optimization that balances deliverability with flow resistance.

Collectively, these mappings ensure that the computed fields serve as quantitative predictors for the same metrics used to accept or reject design variants under verification, enabling targeted test-matrix reduction where confidence is high and clear conservatism margins are available.

Relevance of the quantities of interest — gradation.

a.
Outputs inform intuition only; not used in formal acceptance.

b.
Outputs translated to acceptance with expert judgment but no quantified link.

c.
Outputs converted to acceptance metrics using formulae and documented assumptions.

d.
Outputs embedded in decision rules with uncertainty budgets and pre-set margins.

11. 11. Relevance of validation activities to the CoU (clear): justification that selected bench tests span the intended anatomy classes, wire sizes, and flow regimes tied to labeling

The validation program spans the device configurations and operating regimes encompassed by the stated CoU. For infusion, the steady flow tests cover 1–200 mL/min across six lumen sizes and two side-port patterns with and without a wire, reflecting clinical infusion rates for drug and contrast in coronary and peripheral settings. The pulsatile tests at 1 Hz with ±50% amplitude bracket the typical heart rate and injection profiles used in verification; while higher-frequency components can occur in some injections, the 1–2 Hz band captures the dominant unsteady contribution to mean pressure drop within the lumen diameter range studied.

For navigation, the tortuous-phantom tests employ 12 coronary and 8 peripheral paths derived from clinical centerlines and realized in bench jigs with documented fidelity. The paths span peak curvature and torsion values representative of left anterior descending, right coronary, and superficial femoral segments. Wire sizes reflect typical usage under the labeled indications. The advancement speeds (5–20 mm/s) are within operator-typical ranges used in verification for repeatability and safety.

We considered known gaps. The most severe tortuosity observed clinically (peak curvature > 1.4 cm1 with multiple compound bends) is intentionally excluded from the CoU and from validation, as it is outside current labeling and handled by separate risk controls. Similarly, extreme viscosity cases (>5.0 mPa·s at 37 °C) are not validated here. Within the CoU, we ensured that each class of scenario that will be informed by the models has at least three independent physical exemplars tested (e.g., three different lumen sizes at high flow for steady resistance; three distinct coronary paths for navigation).

Importantly, we maintained independence between parameter identification and validation. For steady resistance, entrance loss coefficients were not tuned to match any of the measured curves used for scoring; they were derived from separate orifice tests. For navigation, the contact regularization parameter in MNNG was chosen based on analytic considerations and a separate straight-annulus calibration before being used in tortuous paths.

Given this design, we judge that the validation exercises are well-aligned with the intended application, with justified gaps documented and bounded by decision rules that preserve conservatism where needed.

Relevance of validation activities to the CoU — gradation.

a.
Validation unrelated to intended use; extrapolation required for all applications.

b.
Partial coverage of intended use; significant extrapolation in key regimes.

c.
Coverage of primary use cases with explicit documentation of small gaps and mitigations.

d.
Full coverage with statistical sampling and cross-validation across facilities.

12. 12. Test conditions (clear): matching of fluid analogs, temperature, catheter-wire assembly, curvature libraries, and flow loops to in-IFU ranges; instrumentation accuracy

All bench tests were conducted in a temperature-controlled bath at 37.0 ± 0.2 °C with blood-analog fluids formulated to 3.0, 3.5, and 4.0 mPa·s viscosity by weight-percent glycerol–water mixtures. Viscosity was measured before and after each test set using a capillary viscometer traceable to NIST (±1.5% reading), and density was measured with a vibrating-tube densitometer (±0.5 kg/m3). Flow delivery used a programmable syringe pump with factory calibration verified by gravimetric collection (±0.8% over 1–200 mL/min), and the pulsatile profile fidelity was checked against the programmed waveform with a flow sensor (±1.5% RMS deviation).

Pressure was measured with differential transducers selected for range and accuracy: 0–100 kPa (±0.25% FS) for low-flow steady runs and 0–300 kPa (±0.25% FS) for higher flows. Frequency response was adequate for 1–2 Hz waveforms (3 dB at 30 Hz). For navigation, push force was measured with a 1 N load cell (±0.02 N accuracy, linearity ±0.02 N), and actuator speeds were verified with an encoder (±0.05 mm/s). Phantom paths were machined from acrylic or assembled from PTFE tubing with measured IDs (±10 μm) and path coordinates validated to within ±0.5 mm versus the design centerlines.

Device assemblies matched those used in design verification, including the same guidewire models and sizes, hydration protocols for polymer liners (minimum 30 minutes soak), and port occlusion states. Guides were flushed of air prior to infusion to eliminate compressibility artifacts. Measurements were repeated three times per condition; for navigation, five repeats were used per path–device combination to address variability in contact patterns.

Uncertainty budgets were constructed per ISO GUM principles. Combined standard uncertainty in steady pressure drop was 1.5–2.5% across flow rates, including contributions from pressure transducer accuracy, flow delivery uncertainty, fluid property uncertainty, and temperature drift. For pulsatile loss coefficients, additional contributions from waveform tracking (1.5% RMS) and cycle averaging (0.5%) yielded combined uncertainties of 2.0–3.0%. For navigation push force, combined standard uncertainty was 0.02–0.05 N depending on path (1.7–6.7% of typical readings). These budgets inform the normalized differences reported in Section 9.

Test conditions — gradation.

a.
Laboratory conditions deviate substantially from intended use; instrumentation undocumented.

b.
Some conditions matched; notable mismatches in fluids, temperature, or assemblies.

c.
Conditions closely matched to intended use with quantified instrumentation accuracy and repeatability.

d.
Comprehensive environmental fidelity with cross-checks, calibration chains, and environmental stress coverage.

13. 13. Use error (passing mention): operator technique and setup nuances noted qualitatively alongside the validation protocols

Operator technique can influence navigation tests (e.g., the way torsion is applied at the hub or how slack is managed) and setup nuances such as incomplete de-airing in infusion loops can perturb pressure measurements; the protocols included reminders and training steps to minimize these effects and to maintain repeatability across runs.

14. 14a. Credibility scorecard for Model-Lumen-RANS (MLR)

The following entries provide graded evaluations for MLR across the four mechanisms, alongside brief bases that restate quantitative findings documented in Sections 7–12. Scores are on the private 0–12 scale defined for this study. Each basis references parameter provenance, numerical sensitivity, agreement with independent tests, mapping to acceptance metrics, alignment of validation activities with the stated CoU, and laboratory fidelity. Rows are organized by mechanism, and factors not directly supported by strong evidence for a given mechanism reflect the model's scope limitations.
Output comparison — gradation.

a.
Qualitative checks only; no metrics or uncertainty.

b.
Limited pointwise error metrics; incomplete operating envelope.

c.
Broad operating envelope with MAPE/bias and uncertainty normalization.

d.
Replicated across facilities with consistency analysis and predefined decision thresholds.

15. 14b. Credibility scorecard for Model-Nav-NarrowGap (MNNG)

The table below reports graded evaluations for MNNG across the four mechanisms. Scores reflect the model's centrality to navigation mechanics and its supporting role in distal annular flow. Bases restate quantitative findings from Sections 7–12, with attention to parameter sources and ranges, discretization and iteration sensitivity, agreement with independent pathway tests, linkage to trackability metrics, alignment of validation activities to the CoU, and the fidelity of bench setups.
Test conditions — gradation.

a.
Major mismatches between bench and intended environment.

b.
Several key elements matched; notable differences remain.

c.
High-fidelity matching of fluids, temperature, assemblies, and paths; quantified uncertainties.

d.
Extensive environmental validation including stress cases and cross-lab checks.

16. 15. Integrated interpretation across mechanisms: implications for design verification and test-matrix reduction

The combined evidence positions MLR as a primary tool for bounding steady-flow resistance across lumen sizes, wire states, and side-port configurations, and MNNG as a primary tool for ranking navigation performance across tortuosity classes and outer diameter variants. We therefore recommend the following design verification strategy adjustments. For steady infusion, use MLR to screen and reduce the number of bench flow points for each geometry: for example, for any design variant where MLR predicts total pressure drop at 100 mL/min to be at least 10% below the acceptance limit with a demonstrated MAPE of 3.1% and numerical uncertainty below 1%, drop the 50 mL/min bench point from verification as redundant and test only at 10, 100, and 200 mL/min. For pulsatile delivery, apply MLR's 3–5% mean-loss correction when comparing to steady acceptance thresholds, and restrict bench pulsatile testing to one representative waveform per side-port pattern when the model predicts similar corrections across patterns within ±1%.

For navigation, use MNNG to rank OD variants and select paths for bench testing within the validated tortuosity envelope: for instance, if MNNG predicts a 20–25% decrease in hydrodynamic drag when OD is reduced by 0.004 in. across all 12 coronary paths, prioritize testing the three coronary paths exhibiting the largest residual drag and conduct confirmatory tests on one peripheral path. Maintain conservatism by ensuring that the held-out paths are no more tortuous than those tested. Where advance speeds or viscosities differ materially from the validation set, retain bench testing until MNNG predictions are explicitly checked at those states.

The analysis also yields mechanism-specific cautions. For distal wire–lumen friction under infusion, both models can estimate the hydrodynamic contribution to apparent friction, and the evidence suggests that this contribution accounts for roughly one-fifth to one-third of the measured increment at 50 mL/min for clearances 0.05–0.20 mm. Use this to inform tolerance choices: tightening clearance by 20% to reduce backflow may increase apparent friction by 6–9% under infusion, which is acceptable if push-force margins remain; otherwise, alternative coatings or liners should be considered. However, because the mapping from shear to friction depends on contact mechanics beyond fluid effects, retain bench confirmation for any new material or surface treatment.

Across both models, the parameter sets used are anchored in controlled drawings and protocols, with ranges that cover labeled anatomies and operating conditions and with quantified uncertainties that were propagated in sensitivity studies; this supports their deployment within the specified envelope. The numerical solution changes under refinement are small compared to experimental uncertainties: for MLR, 0.3–1.2% depending on mechanism; for MNNG, 0.6–1.3%, ensuring that solver-induced variability does not drive acceptance decisions. Agreement with independent bench measurements is strong where each model is central: steady resistance (MLR) MAPE 3.1% with decomposition fidelity; navigation hydrodynamic drag (MNNG) MAPE 7.9% with conservative bias, both normalized by combined uncertainties. The predicted quantities match the verification metrics one-to-one for steady resistance and via direct contributions for navigation drag and pulsatile mean losses, enabling their use in decision rules with explicit margins. Validation experiments span the indicated anatomies and operating states with justified gaps outside labeling; independence between parameter identification and validation was preserved. Laboratory conditions—fluids, temperature, assemblies, path fidelity, and instrumentation—match the intended use environment and are quantified by uncertainty budgets that are incorporated into normalized error calculations.

These interpretive statements collectively justify the score patterns in Sections 14a and 14b: high scores for steady resistance under MLR and navigation drag under MNNG; moderate-to-strong scores for pulsatile mixing under MLR; and supportive but lower scores where a model's scope is auxiliary. The implications for design verification are to use each model as a targeted reducer of test scope within its validated domain, always retaining a conservative buffer and confirmatory tests to manage residual risks.

Model inputs — gradation.

a. Unstructured parameter choices without uncertainty bounds.

b. Partially documented parameter ranges with limited uncertainty quantification.

c. Documented parameter sources and quantified ranges with sensitivity studies.

d. Parameter governance with provenance, update rules, and uncertainty propagation into decisions.

17. 16. Limitations within the stated CoU and planned future work confined to the assessed factors

The assessed models deliberately neglect several phenomena to maintain tractability and to focus on the CoU. For MLR, blood is modeled as Newtonian and thermal effects are ignored; non-Newtonian shear-thinning at low shear may be relevant below 1 mL/min for the smallest lumens and could modestly reduce predicted resistance. Side-hole mixing is assessed for 1 Hz waveforms; injection transients with higher harmonics are not explicitly resolved in this study, though the cycle-averaged loss coefficients provide a first-order correction. Wire–lumen friction models are limited to hydrodynamic contributions; contact mechanics and surface chemistry effects were not simulated and are left to experiment.

For MNNG, the lubrication approximation assumes small gap thickness compared to radius and neglects inertia normal to the film. While appropriate for the tested gaps and speeds, this approximation may underpredict drag where transient squeezing flows occur at rapid advancement or during aggressive steering, conditions outside the CoU. Contact regularization, necessary for numerical stability, introduces a tunable small conductance in near-zero-gap regions; we chose this based on analytical considerations, but detailed contact mechanics were not modeled. The model also treats the shaft centerline kinematics as prescribed, not coupled to the hydrodynamic pressures through full structural dynamics; thus, hydrodynamic–elastic interactions are only included parametrically via stiffness distributions.

Validation scope is bounded by labeled indications. Extreme tortuosity beyond the highest path in our library, extreme viscosities, and pathologies (e.g., stenoses with significant area reduction) are not covered. Likewise, the models have not been validated for hemocompatibility endpoints or detailed dispersion of drugs downstream of side ports. Within the CoU, we maintain conservative decision rules and retain bench confirmation for new regimes.

Planned future work focuses on deepening evidence within the same factor framework. For MLR, we will add 2 Hz pulsatile injection tests and expand PIV measurements around side ports to better characterize unsteady jet interactions, aiming to reduce the uncertainty on cycle-averaged loss coefficients from 6.5% MAPE to ≤5%. For MNNG, we will incorporate a simplified coupling to a torsionally compliant beam model to capture feedback between hydrodynamic pressure and shaft bending at sharp bends, and we will test additional coronary paths (n=6) to extend the validated tortuosity envelope modestly while preserving alignment with labeling.

Crucially, in all planned activities we will continue to use independent datasets for validation, pre-register parameter update rules, and maintain uncertainty budgets, so that improvements in scores, where achieved, are supported by traceable, decision-relevant evidence.

Output comparison — gradation.

a. Initial pointwise checks; limited regimes; no uncertainty.

b. Expanded regimes with error metrics; partial uncertainty.

c. Comprehensive regimes with uncertainty normalization and independence between tuning and validation.

d. Multi-regime, multi-lab corroboration with decision-based thresholds and outlier forensics.

18. 17. Conclusions

We conducted a risk-informed credibility assessment, aligned with ASME V&V 40 principles, of two CFD models supporting design selection and verification for an over-the-wire catheter's trackability and flow resistance. The lumen-focused RANS model (MLR) achieved high credibility for steady-flow resistance and strong credibility for pulsatile entrance/exit and mixing losses within the tested waveform band, with quantitative agreements to independent measurements and numerical uncertainties well below experimental noise. The narrow-gap navigation model (MNNG) achieved high credibility for hydrodynamic drag during advancement in tortuous paths representative of labeled coronary and peripheral anatomies, with conservative bias and appropriate sensitivity to viscosity and gap thickness. Both models provided supportive insight into the hydrodynamic component of distal wire–lumen friction.

We presented two model-specific scorecards totaling 48 graded entries across six credibility dimensions and four mechanisms per model. Bases for each score rest on parameter provenance and ranges, numerical refinement behavior, agreement with bench data including uncertainty normalization, direct linkage of outputs to acceptance metrics, validation program alignment with the stated CoU, and laboratory fidelity. The integrated interpretation translates these scores into practical guidance for reducing verification test matrices while preserving safety margins and maintaining conservatism.

The models are not used for clinical decisions or for regimes outside labeling. They complement required bench verification and guide resource allocation by explaining mechanistic trade-offs and by bounding expected outcomes. Future work will deepen evidence within the same factor framework, modestly extend the validated regime where justified, and preserve the separation between tuning and validation. With these guardrails, the models provide reliable support for preclinical design control and contribute to a transparent, quantitative engineering rationale for catheter performance.

Test conditions — gradation.

a.
Unspecified or poorly controlled laboratory environments.

b.
Controlled environment for some tests; key mismatches remain.

c.
Well-controlled environment matching intended use with quantified uncertainties.

d.
Extensively validated environments with cross-checks and stress-condition coverage.

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Table 1: Credibility factors for Model-Lumen-RANS (MLR) across four mechanisms on a 0–12 scale.

Credibility factor	Level	Basis
Model inputs - MLR - Tortuous-path bending and torsion during navigation	7/12	Gap and path parameters pulled from centerline library; viscosity 3.0–4.0 mPa·s; clearances 25–125 µm (Section 7).
Numerical solver error - MLR - Tortuous-path bending and torsion during navigation	8/12	Grid/time refinements yield 0.9–1.5% changes in distal shear contributions (Section 8).
Output comparison - MLR - Tortuous-path bending and torsion during navigation	6/12	Internal shear explains 18–35% of incremental friction; MAPE 9.6–14% vs inferred hydrodynamic component (Section 9).
Relevance of the quantities of interest - MLR - Tortuous-path bending and torsion during navigation	5/12	Shear fields relate indirectly to push force via composite models; used as supportive evidence (Section 10).
Relevance of validation activities to the CoU - MLR - Tortuous-path bending and torsion during navigation	5/12	Navigation validations emphasize MNNG; MLR used only for distal shear in select setups (Sections 9 and 11).
Test conditions - MLR - Tortuous-path bending and torsion during navigation	6/12	Benchtop assemblies and fluids matched; distal segment rigs at 37 °C with instrumented friction tests (Section 12).
Model inputs - MLR - Guidewire–catheter sliding friction within the distal lumen	6/12	Wire sizes 0.014–0.018 in., clearances 0.05–0.20 mm; friction coefficients 0.08–0.14 from ring-on-rod (Section 7).
Numerical solver error - MLR - Guidewire–catheter sliding friction within the distal lumen	8/12	Eccentric-wire meshes show <0.9% change in pressure drop; peak shear varies up to 2.5% (Section 8).
Output comparison - MLR - Guidewire–catheter sliding friction within the distal lumen	6/12	Shear-based hydrodynamic increment accounts for 18–35% of measured friction; MAPE 10–12% (Section 9).
Relevance of the quantities of interest - MLR - Guidewire–catheter sliding friction within the distal lumen	6/12	Annular shear integrated over 60 mm maps to apparent friction increments used in deliverability rationale (Section 10).
Relevance of validation activities to the CoU - MLR - Guidewire–catheter sliding friction within the distal lumen	5/12	Short-segment rigs mirror distal lumen states used in verification; scope limited to select sizes (Section 11).
Test conditions - MLR - Guidewire–catheter sliding friction within the distal	6/12	37 °C fluids; calibrated pumps and pressure sensors; repeatability across three runs per point (Section 12).

Table 2: Credibility factors for Model-Nav-NarrowGap (MNNG) across four mechanisms on a 0–12 scale.

Credibility factor	Level	Basis
Model inputs - MNNG - Tortuous-path bending and torsion during navigation	10/12	Curvature–torsion library spans labeled anatomies; gaps 25–125 µm; speeds 5–20 mm/s; viscosity 3.0–4.0 mPa·s (Section 7).
Numerical solver error - MNNG - Tortuous-path bending and torsion during navigation	9/12	Axial grid Δs refinement yields 0.6–1.3% changes in drag; transient Δt changes 0.7–1.1% (Section 8).
Output comparison - MNNG - Tortuous-path bending and torsion during navigation	9/12	Hydrodynamic drag MAPE 7.9% (n=60); bias 1.8%; viscosity and gap scalings captured (Section 9).
Relevance of the quantities of interest - MNNG - Tortuous-path bending and torsion during navigation	10/12	Integrated drag directly contributes to trackability index and conservatism margins (Section 10).
Relevance of validation activities to the CoU - MNNG - Tortuous-path bending and torsion during navigation	9/12	Twelve coronary and eight peripheral paths validated within labeled tortuosity envelope (Section 11).
Test conditions - MNNG - Tortuous-path bending and torsion during navigation	9/12	37 °C fluids; calibrated load cells; jig fidelity ±0.5 mm; five repeats per path–device (Section 12).
Model inputs - MNNG - Guidewire–catheter sliding friction within the distal lumen	9/12	Distal annular profiles from drawings and metrology; clearances 0.05–0.20 mm; speeds 1–10 mm/s (Section 7).
Numerical solver error - MNNG - Guidewire–catheter sliding friction within the distal lumen	9/12	Axial refinement and contact-regularization checks change drag/shear by 0.9–1.5% (Section 8).
Output comparison - MNNG - Guidewire–catheter sliding friction within the distal lumen	8/12	Hydrodynamic increment MAPE 9.6% vs inferred; degrades to 14–16% at smallest clearances (Section 9).
Relevance of the quantities of interest - MNNG - Guidewire–catheter sliding friction within the distal lumen	9/12	Distal shear contribution used in deliverability trade-offs for clearance optimization (Section 10).
Relevance of validation activities to the CoU - MNNG - Guidewire–catheter sliding friction within the distal lumen	8/12	Short-segment annular tests reflect distal conditions; subset of sizes exercised (Section 11).
Test conditions - MNNG -	8/12	Matched fluids and temperature; instrument accuracy