Credibility assessment of CFD models for peritoneal dialysis catheter drainage resistance using the ASME V&V 40 framework

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Abstract

Purpose: We evaluated the credibility of three computational fluid dynamics (CFD) models for predicting drainage resistance of a peritoneal dialysis (PD) catheter with a multi-hole terminal segment, following the intent of the ASME V&V 40 framework. The models address two clinically relevant drainage mechanisms: lateral-hole–dominated flow with partial occlusion and end-hole–dominant drainage under gravitational alignment. Methods: Model A solves steady, laminar, incompressible, Newtonian flow in a rigid terminal segment to predict pressure–flow relationships, outflow partitioning between the end-hole and side-holes, and local wall shear. Model B augments the physics with a Carreau–Yasuda rheology and an effective roughness height to represent early biofilm or textured surfaces. Model C treats each lateral port as a porous-jump interface to emulate partial occlusion while maintaining a Newtonian bulk flow. A bench apparatus delivered controlled hydrostatic heads (20–80 cmH2O) to a commercial 62 cm, coiled Tenckhoff catheter segment submerged in 2.5% glucose dialysate at 37 °C. Occlusion states (0, 25, 50, 75% of lateral-port area) were imposed with calibrated micro-mesh wraps. For each orientation (tip-down 90°, 45°, horizontal), flow rates and pressure drops were measured, and hole-by-hole outflow was quantified by high-speed dye velocimetry at the terminal segment. Numerical spatial accuracy was examined using three successively refined, body-fitted polyhedral meshes (1.2, 3.8, and 11.7 million cells) with local refinement at ports and tip. Results: Mesh-induced changes in hydraulic resistance between medium and fine grids remained below 1.5% across models and mechanisms. Against 18 bench configurations spanning mechanism, occlusion fraction, and head, Model B reproduced pressure–flow slopes with a median absolute deviation of 7% (95th percentile 12%), and Model A achieved 6% and 10% in end-hole–dominant cases but deviated in lateral-hole occlusions (median 18%, 95th percentile 28%). Model C most closely tracked resistance escalation with progressive lateral-port blockage (median 5.3%, 95th percentile 12%) but overstated end-hole dominance when the tip was aligned with gravity (median 12%, 95th percentile 20%). Sensitivity studies indicated viscosity uncertainties of ±10% map nearly one-for-one to resistance changes for Models A and C, while effective roughness heights of 10–40 μm in Model B increased resistance by 6–18% depending on shear rate and occlusion. Conclusions: For decisions about whether an observed drain cycle is limited primarily by lateral-port occlusion versus tip alignment, Model C provides the most reliable discrimination of the first mechanism, while Models A and B are suitable for the second. All models delivered stable predictions under mesh refinement and used outputs that correspond to PD program performance criteria. The bench conditions exercised the same flow regime and orientations anticipated in the decision context, supporting their use for appraisal. Credibility scores on a 0–5 scale are reported for each factor, model, and mechanism in three tables, totaling 36 rows, to inform model selection for the intended use.

Keywords: peritoneal dialysis, computational fluid dynamics, model credibility

1. Introduction

Peritoneal dialysis (PD) provides kidney replacement therapy by exchanging dialysate through a peritoneal catheter whose terminal segment contains a distal end-hole and multiple side-holes. During drain cycles, a hydrostatic head drives effluent from the peritoneal cavity through the terminal segment into a collection bag. In routine home PD, observed drain rates and times are program-limiting performance criteria; inadequate drainage compromises ultrafiltration, increases dwell variability, and often triggers clinical workup for mechanical obstruction or malposition. Understanding how flow resistance arises within the terminal segment and how it changes with orientation and partial blockage is essential for interpreting drain failures and for refining catheter design.

Computational fluid dynamics (CFD) can characterize pressure–flow relationships and apportionment of flow between the distal tip and side ports with geometric fidelity. Yet the clinical utility of such models hinges on credibility with respect to the intended decision: namely, when a patient exhibits slow drainage, whether the limitation is attributable primarily to lateral-port occlusion by fibrin or omental contact (mechanism 1) or to posture and gravitational alignment that favors end-hole outflow while starving the ports (mechanism 2). This study applies the intent of the ASME V&V 40 framework to assess three CFD models that compute hydraulic resistance, hole-by-hole partitioning, and local wall stresses in a commercial Tenckhoff catheter terminal segment under two mechanisms that reflect early post-implant or routine-use scenarios.

We report technical evidence on numerical stability, representation of the governing physics, specification and uncertainty of key parameters, and comparison to controlled bench measurements that mimic clinical heads and orientations. The outputs examined are the same quantities used by PD programs to evaluate drain adequacy and occlusion risk: the pressure–flow slope of the terminal segment, how much of the flow exits through the end-hole versus the side-holes, and the shear levels that correlate with debris removal near ports.

Relevance of the quantities of interest — gradation.

a.
Outputs are defined but not linked to clinical interpretation.

b.
Outputs are consistent with device performance metrics but without explicit decision thresholds.

c.
Outputs map to clinical criteria or alarms, with thresholds cited and justified.

d.
Outputs are the same quantities used to drive the decision, with traceable thresholds and acceptance bands tied to program policy.

2. Question of Interest and Context of Use (COU)

The decision supported by this modeling activity is to identify, given observed drain behavior and patient posture, whether the limiting mechanism is partial occlusion of lateral ports or gravitational alignment that biases flow through the end-hole. The context of use is a quantitative analysis comparing pressure–flow relationships and partitioning for two mechanisms in the terminal segment of a standard Tenckhoff catheter under laminar flow conditions typical of PD drainage. The intended users are design engineers and clinical performance teams who seek to interpret bench tests and in-clinic drains with aligned orientation and occlusion cues.

In routine PD, drainage proceeds under heads between approximately 20 and 80 cmH2O as the bag is lowered below the patient. Drained volumes on the order of 1.5–2 L occur over 6–20 minutes in uncomplicated cases. For this COU, we consider the terminal segment resistance acceptable if the pressure–flow slope does not exceed 150 cmH2O per L/min in tip-down orientation and if side-hole occlusion of 50% or less does not elevate the slope above 180 cmH2O per L/min in horizontal orientation. These thresholds are informed by historical drain-cycle performance with the same catheter family and by bag-level acceptance tests that manufacturers apply to ensure adequate drainage capacity.

The analysis focuses on laminar, incompressible regimes; Reynolds numbers based on mean lumen velocity at 200 mL/min and 2.6 mm inner diameter are approximately 1300 for Newtonian dialysate at 37 °C. This is below transitional onset in smooth tubes and well within the laminar range in the presence of distributed entrance and exit effects through side ports. The COU excludes siphon interruptions, abdominal pressure modulation due to breathing, and catheter migration into the pelvis, which are clinically relevant but beyond the terminal segment physics addressed here.

Model form — gradation.

a.
Governing equations are plausible but not justified for the flow regime or device features.

b.
Governing equations match the flow regime; some device features are omitted or simplified without sensitivity analysis.

c.
Governing equations and constitutive laws are justified for the flow regime; all dominant device features are included with sensitivity analyses on simplifications.

d.
Governing equations are validated for the flow regime; device and boundary physics are represented with evidence that omitted effects do not alter the decision outcome.

3. Model Risk Analysis under ASME V&V 40

The consequence of an incorrect determination about the dominant drainage mechanism is moderate: a false attribution to posture might lead to repeated drain attempts and patient discomfort before imaging or lysis is considered; a false attribution to occlusion could trigger unnecessary interventions or device exchange. The decision is not irreversible and can be cross-checked with alternate diagnostics. The tolerance for modeling uncertainty is therefore balanced; high rigor is expected in numerical stability and in matching bench resistance trends across orientations and occlusion states, while more exploratory tolerance exists for detailed hole-by-hole flow breakdowns so long as the end-hole fraction is reasonably captured.

Evidence generation was prioritized around demonstrating stable pressure–flow slopes under mesh refinement, establishing that the chosen physics sets can reproduce orientation-specific resistance changes, and bounding how parameter choices for viscosity, roughness, and occlusion affect the decision. Because the model is not used directly for patient management but rather to interpret device-level test data and to support design refinements, the residual risk from modeling insufficiencies is acceptable if quantitative agreement remains well within the variability of bench measurements and design acceptance bands.

We thus apply a graded approach: numerical refinement studies across all three models and both mechanisms; model-to-bench comparisons for 18 configurations spanning head, orientation, and occlusion percentage; and targeted parameter sweeps that quantify effect sizes on the key slope metric and end-hole fraction. The grading translates into 0–5 scores for six credibility factors for every model–mechanism pair, with scores grounded in the observed numerical changes, deviations

Figure 1: Terminal-segment geometry and coordinate system for the Tenckhoff catheter model: inner lumen 2.6 mm ID, outer diameter 4.6 mm, distal tip with 1.8 mm end-hole and eight 1.5 mm lateral ports over a 22 mm terminal length; orientations defined by tip angle relative to gravity (0° horizontal, 45°, 90° tip-down).

from bench means and spreads, and the degree to which outputs inform the COU decision.
Output comparison — gradation.

a.
Qualitative agreement asserted with no shared metrics or test conditions.

b.
Quantitative comparison on a subset of conditions; uncertainty not characterized.

c.
Quantitative comparison across relevant conditions; measurement uncertainty and model variability reported.

d.
Quantitative comparison across all relevant conditions; error distributions and uncertainty propagated to decision thresholds.

4. Computational Models: Geometry, Physics, and Boundary Conditions

All models share a common geometry derived from metrology of a commercial coiled Tenckhoff catheter: inner lumen diameter 2.6 mm, outer diameter 4.6 mm, and a 22 mm terminal segment containing one distal end-hole of 1.8 mm diameter and eight lateral ports of 1.5 mm diameter spaced at 2.5 mm axial increments with alternating circumferential positions. The terminal tip includes a 0.5 mm chamfer consistent with manufacturing practice. The computational domain comprises the final 40 mm of the catheter lumen and the terminal ports to their outer surfaces, where discharge to the peritoneal cavity is represented. Flow is driven by an imposed pressure difference between the cavity and upstream catheter lumen consistent with hydrostatic head, and gravity is included as a body force to reflect orientation-dependent pressure distributions.

Model A solves steady-state, laminar, incompressible Navier–Stokes equations with constant properties at 37 °C for dialysate composed of a 2.5% glucose solution: dynamic viscosity 1.20 mPa·s and density 1015 kg/m3. No-slip boundary conditions are applied at rigid walls, and outlet boundaries at each hole are specified as pressure boundaries at peritoneal pressure with zero normal stress gradient. Gravity is aligned with the specified tip-down angle to introduce hydrostatic effects on pressure and streamline curvature near the tip.

Model B modifies the constitutive description to a Carreau–Yasuda shear-thinning model with mu_inf = 0.95 mPa·s, mu_0 = 2.50 mPa·s, lambda = 1.2 s, a = 2.0, and n = 0.70 to emulate protein-enriched dialysate that is commonly reported early post-implant. To represent early biofilm or conditioned-surface texture, an effective sand-grain roughness k_s is applied on the interior surfaces of the terminal segment and ports, varied between 10 and 40 μm in sensitivity runs, with equivalent Nikuradse scaling. No-slip is retained. All other boundary conditions match Model A.

Model C retains the Newtonian bulk flow of Model A but replaces each lateral port opening with a porous-jump interface located at the orifice plane, characterized by a linear resistance coefficient R_jump (Pa·s/m) and an inertial loss coefficient C2 (dimensionless), calibrated to represent 0, 25, 50, and 75% area occlusion states using thin mesh wraps in bench tests. The distal end-hole remains represented fully with a pressure outlet. The porous-jump approach captures added entrance loss from partial obstruction without resolving the detailed micro-contact geometry, reducing computational cost while providing a mechanism to vary blockage quantitatively.

Spatial discretization uses polyhedral control volumes with prism layers resolving near-wall gradients; three nested meshes are employed: coarse (1.2 million cells, minimum near-port cell size 80 μm), medium (3.8 million cells, 40 μm), and fine (11.7 million cells, 20 μm). First-layer thickness is 10 μm with 12 prism layers to achieve y+ < 1 under all conditions. Pressure–velocity coupling uses SIMPLEC with second-order schemes for all transport equations. Convergence criteria require residuals below 1e-6 and stability of integral quantities (total flow, port flows, wall shear) to within 0.1% over 500 iterations. Each run is initialized from the previous head condition to hasten convergence.

The hydrostatic head is set by prescribing a pressure difference between the upstream inlet plane (at the proximal end of the domain) and the pressure at the outlets corresponding to 20, 40, 60, and 80 cmH2O. Orientation is varied by rotating the gravity vector relative to the catheter axis: 0° (horizontal), 45°, and 90° (tip-down). For the mechanism classification, lateral-hole–dominated drainage is examined primarily in the horizontal orientation with imposed occlusion fractions; end-hole–dominant drainage is examined in the 90° tip-down state without imposed occlusion. All combinations are

Table 1: Key model geometry, physics, and boundary parameters used across all simulations.

Credibility factor	Level	Basis
Inner diameter	2.6 mm	Measured by optical metrology; tolerance ±0.05 mm
End-hole diameter	1.8 mm	Manufacturer specification; confirmed within ±0.03 mm
Lateral-port diameter and count	1.5 mm, 8 ports	Spacing 2.5 mm over a 22 mm terminal segment
Dialysate properties (Model A, C)	mu=1.20 mPa·s, rho=1015 kg/m3	2.5% glucose at 37 °C; variability ±10% for sensitivity
Shear-thinning parameters (Model B)	mu_inf=0.95, mu_0=2.50 mPa·s, lambda=1.2 s, a=2.0, n=0.70	Carreau–Yasuda fit to protein-enriched dialysate
Effective roughness (Model B)	k_s=10–40 µm	Represents early biofilm; applied to lumen and ports
Porous-jump coefficients (Model C)	R_jump calibrated; C2 fixed at 1.2	R_jump set per occlusion fraction via bench wrap characterization
Hydrostatic heads	20, 40, 60, 80 cmH2O	Set by pressure boundary difference
Orientations	0°, 45°, 90° tip-down	Implemented by rotating gravity vector
Mesh sizes	1.2M, 3.8M, 11.7M cells	Near-port min size 80, 40, 20 µm; y+<1

also run at intermediate heads to support sensitivity analyses.

Discretization error — gradation.

a.
Single mesh used with no numerical sensitivity evidence.

b.
Two meshes compared; integral quantities show modest change.

c.
Three or more systematically refined meshes; integral quantities demonstrate asymptotic convergence.

d.
Three or more meshes with formal error estimation and observed order reported; refinement applied until error is small relative to experimental uncertainty.

5. Mechanisms of Drainage Resistance Considered

Mechanism 1: Lateral-hole–dominated drainage with partial occlusion. When the catheter lies nearly horizontal within the pelvis, gravitational alignment contributes little to a tip bias, and outflow distributes among the lateral ports. Early fibrin deposition or contact with omentum can reduce the effective entrance area at some ports. The increased entrance losses at affected holes shift the overall hydraulic resistance, throttling aggregate flow even if the distal tip remains open. This mechanism is characterized by increased pressure–flow slope and a redistribution of outflow among lateral holes, typically away from the most occluded positions.

Mechanism 2: End-hole–dominant drainage under gravitational alignment. When a patient sits up or when the catheter tip is oriented downward, the hydrostatic column within the lumen favors a pressure gradient that accelerates towards the tip; streamlines align towards the end-hole such that a higher fraction of the total flow exits distally. The lateral ports contribute less, raising the effective resistance of the terminal segment by concentrating losses through the tip contraction region. This mechanism is not a pathological occlusion but a posture-induced flow bias that can still diminish usable drain rates during short cycles.

Both mechanisms can be observed in practice, sometimes within a single drain cycle as posture or intra-abdominal content shifts. The modeling objective is to predict how the pressure–flow slope and outflow partition respond under the two mechanisms and to quantify how partial area reductions at lateral ports amplify the slope in the first mechanism while how tip alignment enhances the distal fraction in the second.

Model inputs — gradation.

a.
Inputs selected from literature or defaults; no ranges or sources documented.

b.
Inputs measured or sourced with citations; broad ranges specified without prioritization.

c.
Inputs measured or sourced with traceable ranges; key inputs prioritized and varied in sensitivity studies.

d.
Inputs measured or sourced with traceable ranges; uncertainties quantified and propagated to outputs relevant for the decision.

6. Quantities of Interest (QoIs) for Drainage Performance

The primary quantity of interest is the terminal segment hydraulic resistance defined as the ratio of pressure drop across the terminal segment to the volumetric flow rate, expressed in cmH2O per L/min. This slope is evaluated over the head range 20–80 cmH2O to characterize how the terminal segment throttles the drain. Secondary quantities are the fraction of total outflow exiting the distal end-hole and, complementarily, the distribution among the lateral ports; and the local wall shear stress along the terminal segment and near port entrances, as a surrogate for debris clearance potential.

For interpretation of bench and clinical drain performance, the pressure–flow slope directly ranks the ease of drainage, while the end-hole fraction discriminates between posture-driven bias and true port blockage. Local shear maps support inferences about whether flow conditions can self-clear early fibrin strands at openings. These QoIs are extracted from CFD by integrating outlet fluxes by port and by computing surface-averaged and peak wall shear values over patches around each port and the distal contraction.

QoIs were recorded for each head, orientation, and occlusion combination and summarized as means and standard deviations over the three mesh levels for the refined states to ensure numerical stability of the reported values. Where relevant, QoIs were normalized by their clean, tip-down baseline to isolate the effect of occlusion or orientation alone.

Relevance of the quantities of interest — gradation.

a.
Outputs partially overlap with decision needs; mapping is indirect.

b.
Outputs align with decision needs; mapping described qualitatively.

c.
Outputs align with decision needs; mapping includes quantitative bounds and thresholds.

d.
Outputs are identical to decision metrics; mapping includes quantitative thresholds with traceability to acceptance criteria.

7. Experimental Bench Methods for Output Comparison

A bench apparatus replicated controlled hydrostatic drainage through a Tenckhoff catheter terminal segment submerged in a 37 °C bath of 2.5% glucose dialysate. A constant-head tank adjustable between 20 and 80 cmH2O provided pressure, while a precision electronic manometer measured proximal lumen pressure and a coriolis mass flow meter recorded volumetric flow rate at 1 kHz. The terminal segment was mounted in a clear acrylic chamber with rotational control to set the tip angle at 0°, 45°, or 90° tip-down relative to gravity. Lateral-port occlusions were imposed by wrapping the terminal segment in a nylon micro-mesh with calibrated open area fractions yielding approximate 25%, 50%, and 75% area blockage when indexed to port positions; end-hole patency was maintained for mechanism-1 tests.

Eighteen configurations were tested in triplicate: clean (0% occlusion) at each of three orientations and each of three heads (20, 40, 80 cmH2O), and for mechanism-1 tests, 25%, 50%, and 75% occlusions at horizontal orientation for the same heads. Each run began with a 2-minute stabilization and proceeded for 3 minutes of steady acquisition; temperature held at 37.0 ± 0.2 °C. Measurement uncertainties (expanded k=2) were ±0.6 cmH2O for pressure and ±1.5 mL/min for flow, leading to an uncertainty in the slope of approximately ±5–8% across the head range. Repeatability across triplicates produced a coefficient of variation of 3–6% in the computed slope.

Hole-by-hole outflow fractions were estimated by introducing a neutrally buoyant dye pulse upstream and capturing high-speed video at 2000 fps focused on the terminal ports and tip; pixel-wise velocimetry provided relative jet velocities, which were scaled by the time-averaged total flow and outlet areas to yield port fluxes. End-hole fraction estimates by dye velocimetry agreed with integral balances within 5% absolute in clean cases and 8% absolute in occlusion cases, well within the needs of the comparison.

For each configuration, the bench pressure–flow slope in cmH2O per L/min was computed by linear regression through the measured pressure and flow data across the heads, constrained to pass through the origin for clean cases and with an intercept allowed for occlusion cases to capture static head offsets from mesh wraps. These slopes provide the reference for comparing model predictions of the terminal segment resistance.

Relevance of the validation activities to the COU — gradation.

a.
Tests are not representative of the use environment or decision conditions.

b.
Tests partially represent the use environment or exercise a subset of decision conditions.

c.
Tests represent the use environment and exercise the decision conditions; some simplifications remain.

d.
Tests mirror the use environment and exercise all decision conditions with the marketed device and clinically relevant fluids.

8. Discretization Error Assessment

We assessed numerical stability of the pressure–flow slope, end-hole fraction, and local wall shear with systematic mesh refinement across the three meshes. For Model A in mechanism-1 configurations (horizontal with occlusions), the change in terminal-segment slope between the medium and fine mesh was 0.9% on average across heads and occlusion fractions, with a maximum of 1.1% at 75% occlusion and 80 cmH2O. In mechanism-2 configurations (tip-down, clean), the change was 0.8% on average, peaking at 0.9% at 80 cmH2O. End-hole fraction varied by less than 0.6 percentage points between medium and fine grids in all cases.

Model B exhibited slightly larger changes attributable to increased near-wall gradient sensitivity under shear-thinning: the difference in slope between medium and fine meshes was 1.3% on average across mechanism-1 cases and 1.4% in mechanism-2, with maxima of 1.5% at 75% occlusion and 80 cmH2O. End-hole fraction differences remained under 0.8 percentage points. Local peak wall shear estimates within 2 mm of lateral-port entrances changed by up to 2.1% between medium and fine meshes.

Model C, whose porous-jump representation collapses thin port entrance layers into interface conditions, showed the smallest sensitivity: slope differences between medium and fine meshes were 0.7% (mechanism 1) and 0.9% (mechanism 2), with end-hole fraction shifts less than 0.4 percentage points. Across all models and mechanisms, formal order-of-accuracy estimation using the three grids yielded observed orders between 1.8 and 2.2 for the slope, consistent with the second-order spatial schemes used, and extrapolated zero-mesh-limit slopes differed from fine-grid values by less than 1.2% in every case.

These results demonstrate that the integral outputs supporting the decision are numerically robust under mesh refinement. The remaining discretization-induced variations are small relative to the bench slope uncertainty of ±5–8% and do not

change the classification of mechanism or the exceedance of the thresholds defined in the COU.
Discretization error — gradation.

a.
No refinement study; single-grid results reported.

b.
Two-grid check with qualitative stability discussion.

c.
Three-grid study with observed order and grid convergence index estimation.

d.
Three-grid study with observed order, error band quantified, and demonstration that numerical error is small relative to experimental uncertainty.

9. Model Form Adequacy

The physics choices in each model target distinct aspects of terminal-segment drainage. Model A assumes Newtonian dialysate and rigid walls, appropriate for 2.5% glucose solutions at 37 °C and for the stiff terminal segment molded from silicone or polyurethane. The laminar, steady treatment is reasonable given Reynolds numbers near 1300 and the absence of unsteady forcing in the bench. Under mechanism 2, where the end-hole contraction dominates losses, these assumptions capture the bulk flow behavior and yield slopes consistent with bench values. Under mechanism 1 with partial occlusions, Model A lacks explicit representation of added entrance losses at obstructed ports beyond geometric constriction, which limits its ability to replicate the observed acceleration of the slope.

Model B introduces shear-thinning, recognizing that dialysate can be enriched with proteins and cellular content early post-implant, lowering the apparent viscosity near high-shear regions such as port entrances and the tip. The Carreau–Yasuda model accommodates shear-rate dependent viscosity reductions, thereby adjusting entrance and contraction losses dynamically. The addition of an effective roughness height emulates early biofilm or textured surfaces that can elevate wall friction. These augmentations improve agreement with bench slopes in both mechanisms, particularly when occlusion-induced shear intensification near the functional entrances raises the sensitivity to rheology.

Model C employs porous-jump interfaces at lateral ports to represent partial blockage. This form permits explicit control of added resistance at each lateral opening without resolving the microgeometry of omental contact or fibrin strands. By calibrating the linear resistance coefficient to bench wraps, the model can emulate how area loss and entrance resistance combine to elevate the terminal slope. However, the porous-jump treatment cannot adjust end-hole contraction losses; as a result, when the tip is aligned with gravity and dominates the discharge, the model tends to misallocate losses to lateral ports, overstating the slope increase when they are in fact bypassed.
Model form — gradation.

a.
Assumptions and simplifications are stated but not justified for the scenario.

b.
Assumptions are justified for parts of the scenario; missing physics acknowledged.

c.
Assumptions are justified for the scenario; sensitivity to missing physics explored.

d.
Assumptions are validated for the scenario; residual form error is bounded against decision impact.

10. Model Inputs: Sources, Ranges, and Justification

Geometric inputs were obtained from optical metrology of three catheters from the same SKU: inner diameter 2.60 ± 0.03 mm, end-hole diameter 1.80 ± 0.02 mm, and lateral-port diameters 1.50 ± 0.02 mm. The terminal tip chamfer length measured 0.50 ± 0.05 mm. These dimensions informed the computational geometry and were held fixed across mesh levels. Dialysate density at 37 °C was measured with a vibrating-tube densitometer as 1015 ± 3 kg/m3. For Models A and C, dynamic viscosity was measured with a cone-and-plate rheometer as 1.20 ± 0.12 mPa·s (±10%). For Model B, Carreau–Yasuda parameters were fit to shear-rate–dependent measurements on dialysate spiked with bovine serum albumin (5–15 g/L) to emulate early peritoneal effluent, producing mu_0 = 2.50 mPa·s, mu_inf = 0.95 mPa·s, lambda = 1.2 s, a = 2.0, n = 0.70 with fit residuals under 5%.

Effective roughness heights for Model B were inferred from scanning electron micrographs of conditioned catheter segments after 7 and 14 days of in vitro exposure to albumin-rich dialysate. Surface height distributions suggested equivalent sand-grain roughness between 10 and 40 µm; we used 10, 25, and 40 µm in sensitivity runs. For Model C, porous-jump linear resistance coefficients R_jump were calibrated by matching clean and wrapped port discharge coefficients in an orifice rig: R_jump values corresponding to 0, 25, 50, and 75% area loss were 0.0, 2.5×10^8, 6.7×10^8, and 1.6×10^9 Pa·s/m, respectively, with an inertial coefficient C2 fixed at 1.2. The calibration dataset yielded a coefficient of determination R^2 of 0.97 between wrap open area and the inferred port resistance.

We conducted one-at-a-time parameter variations to assess output sensitivity. In Models A and C, viscosity variations of ±10% led to slope changes of ±9.2% on average across configurations; in Model B the influence was attenuated in high-shear regions, yielding ±7.5% slope shifts for the same viscosity bounds. Roughness variations between 10 and 40 µm in Model B raised the slope by 6–18% depending on occlusion level and orientation (largest under mechanism 1 with 75% occlusion). For Model C, a ±20% adjustment in R_jump produced ±9% changes in the terminal slope in mechanism-1 configurations, consistent with the linearized entrance resistance model. End-hole fraction was less sensitive to these parameters, shifting by 1–4 percentage points across the explored ranges.
Model inputs — gradation.

Table 2: Summary of input sources and ranges used in sensitivity analyses.

Credibility factor	Level	Basis
Inner diameter	2.60 ± 0.03 mm	Optical metrology, n=3
End-hole diameter	1.80 ± 0.02 mm	Optical metrology, n=3
Lateral-port diameter	1.50 ± 0.02 mm	Optical metrology, n=24 (across 3 catheters)
Density	1015 ± 3 kg/m3	Vibrating-tube densitometer
Viscosity (Newtonian)	1.20 ± 0.12 mPa·s	Cone-and-plate rheometry
Carreau–Yasuda mu_0	2.50 mPa·s	Rheometry fit (BSA-spiked)
Carreau–Yasuda mu_inf	0.95 mPa·s	Rheometry fit (BSA-spiked)
lambda, a, n	1.2 s, 2.0, 0.70	Rheometry fit residuals <5%
Effective roughness	10–40 µm	SEM-based inference
R_jump (Model C)	0.0; 2.5e8; 6.7e8; 1.6e9 Pa·s/m	Orifice-rig calibration vs wrap area

a.
Inputs unmeasured; no ranges provided.

b.
Inputs measured or cited; ranges broad and unranked.

c.
Inputs measured or cited with prioritized ranges; sensitivity on key inputs performed.

d.
Inputs measured with quantified uncertainty; uncertainty propagated to outputs with respect to decision.

11. Equivalency of Input Parameters

We note that matching bench wraps to porous-jump coefficients and translating scanning electron micrographs to a single effective roughness rely on establishing correspondences between physical constructs and model parameters. While cross-walks were drawn to map open area fractions to R_jump and microtexture to k_s, we did not attempt to define a universal one-to-one mapping across all occlusion geometries or surface chemistries.

Similarly, the Carreau–Yasuda parameters for protein-enriched dialysate capture a representative rheological envelope but do not aim to be equivalent to any single patient's effluent properties. The intent is to represent plausible ranges rather than to assert parameter identity across bench and clinical conditions.

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

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

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

Model inputs — gradation.

a.
Parameter correspondences to physical surrogates are not discussed.

b.
Parameter correspondences are proposed with qualitative rationale.

c.
Parameter correspondences are supported by targeted calibration data.

d.
Parameter correspondences are supported by multi-condition calibration and cross-validation.

12. Output Comparison to Bench Data

We compared model-predicted terminal-segment slopes against bench-derived slopes for 18 configurations, computing absolute and relative deviations. For mechanism 2 (tip-down, clean), Model A produced a median absolute deviation of 6% with a 95th percentile of 10% across heads, and the end-hole fraction was within 5 percentage points of dye-velocimetry estimates (model 58–66% vs bench 61–68% depending on head). Model B slightly improved the slope match in these clean, tip-down cases, with 5% median and 9% 95th percentile deviations, and end-hole fractions within 4 percentage points (model 60–67%). Model C overstated the slope modestly in tip-down alignment, yielding a median deviation of 12% and 95th percentile of 20% across heads; end-hole fractions lagged bench values by 6–9 percentage points, reflecting residual allocation of loss to lateral interfaces.

For mechanism 1 (horizontal orientation with occlusions), the bench evidenced slope escalation from a clean baseline of 85 ± 6 cmH2O per L/min at 40 cmH2O head to 130 ± 9 cmH2O at 50% occlusion and 210 ± 14 cmH2O at 75% occlusion. Model A underpredicted these escalations: median deviation 18% with a 95th percentile of 28% across occlusion fractions and heads; end-hole fraction remained near 25–32% in the model while dye-velocimetry indicated 18–26%, implying insufficient entrance loss at occluded ports. Model B matched the trends better, with slope deviations of 8% median and 15% 95th percentile, aided by shear-thinning effects at constricted entrances and elevated effective roughness; end-hole fractions were within 5 percentage points. Model C most faithfully captured the slope increases with occlusion, delivering 5.3% median and 12% 95th percentile deviations; it also reproduced the reduced contribution from the most occluded ports detected by velocimetry, though it could not localize blockage spatially without port-specific coefficients.

Local wall shear stress along the terminal segment and near port entrances was not directly measurable on the bench; however, indirect evidence from dye clearing and particle adhesion suggests that the model-predicted ranges are plausible. Model A and C reported peak wall shear near lateral entries between 1.0 and 1.8 Pa under clean conditions at 40 cmH2O head, rising to 2.1–2.8 Pa with 75% occlusion. Model B, with shear-thinning and roughness, predicted slightly lower wall shear near occluded entrances due to locally reduced viscosity at high

shear rate and higher frictional losses along the lumen; peaks ranged from 0.9 to 2.4 Pa depending on occlusion and head.
Output comparison — gradation.

a.
Comparisons are limited to single points with no uncertainty.

b.
Comparisons include multiple points; uncertainty referenced but not quantified.

c.
Comparisons span the relevant space; uncertainties for both model and experiment are reported.

d.
Comparisons include error distributions and the implications for decision thresholds are quantified.

13. Relevance of the QoIs to the COU

The computed pressure–flow slope, end-hole fraction, and wall shear maps bear directly on the decision defined in the COU. The slope quantifies drain capacity across heads and occlusions and can be compared to acceptance bands of 150–180 cmH2O per L/min. The end-hole fraction discriminates between posture-induced bias and lateral-port blockage, which informs whether a posture change or mechanical clearing attempt is likely to improve the drain. Wall shear near ports provides context on the likelihood that moderate increases in head or slight reorientation can self-clear obstructions.

We therefore treat these outputs as the primary evidence supporting the decision. Their extraction from the models is robust, relies on integral balances and well-resolved surfaces, and is not an extrapolation from surrogate quantities. The bench apparatus also reports these quantities (or proxies) directly enough to support a meaningful quantitative comparison.
Relevance of the quantities of interest — gradation.

a.
Outputs are only loosely associated with the decision and require interpretive leaps.

b.
Outputs are related to the decision with a clear but indirect mapping.

c.
Outputs are directly mapped to decision metrics with tolerances defined.

d.
Outputs are identical to the decision metrics and are reported with the same units and thresholds used in practice.

14. Relevance of Validation Activities to the COU

The bench conditions mimic drainage through the marketed catheter under hydrostatic heads and orientations seen in routine PD. The fluid properties, temperatures, and device geometry align with clinical practice. The occlusion surrogates change lateral-port availability in a controlled and quantifiable way, exercising the same mechanism that fibrin and omental contact introduce in early use. The measurement system resolves pressure–flow slopes and outflow partitioning at the same scales used to judge drain adequacy. While the bench does not reproduce abdominal wall compliance or peristaltic motions, those phenomena are outside the terminal-segment physics targeted by this modeling activity.

Between the heads, orientations, and occlusion levels tested, the validation space spans the decision conditions such that model-to-bench comparisons can inform whether a given physics representation suffices for this COU. The absence of peritoneal compliance and patient motion is unlikely to confound the interpretation of terminal-segment resistance and outlet partitioning.
Relevance of the validation activities to the COU — gradation.

a.
Validation tests do not reflect the use case.

b.
Validation tests partially reflect the use case.

c.
Validation tests reflect the use case with some simplifications that are shown not to bias the decision.

d.
Validation tests mirror the use case and exercise the full decision envelope with the marketed device and relevant fluids.

15. Credibility Factor Scoring (0–5) by Model and Mechanism

We graded six credibility factors on a 0–5 confidence scale for each combination of model and mechanism. Scores reflect the strength of evidence in numerical stability, adequacy of the chosen physics relative to the mechanism, specification and sensitivity of inputs, agreement with bench slopes and outflow partitioning, the decision-value of the outputs, and the representativeness of tests to the decision context. The three summary tables that follow provide one row for each factor–model–mechanism combination, totaling 36 rows across the paper. The LEVEL column contains the score only. The basis column provides a one-line statement anchored in the quantitative findings reported in the corresponding prose.

The numerical evidence used to assign levels includes mesh-change percentages for the slope and end-hole fraction, measured deviations from bench slopes and outflow fractions, and sensitivity magnitudes under input parameter variations. For interpretability and audit, the wording in the tables mirrors the values presented in the sections on discretization, output comparison, and input sensitivity.

Beyond the tabulated grades, the narrative in the Synthesis and Discussion sections indicates when a model is preferred for distinguishing a specific mechanism under the COU. The scoring does not merge factors across models or mechanisms; each appears explicitly.
Output comparison — gradation.

a.
Scores assigned without quantitative support.

b.
Scores supported by selected data points.

c.
Scores supported by aggregate metrics across the relevant space.

d.
Scores supported by aggregate metrics with uncertainty quantified against decision thresholds.

16. Credibility assessment summary for Model A: Steady Newtonian CFD

Model A employs steady, laminar, incompressible, Newtonian flow with rigid walls and no-slip, representing clean 2.5% glucose dialysate. It is computationally efficient and numerically robust under mesh refinement. It captures end-hole–dominant drainage well when the tip aligns with gravity, matching bench slopes within 10% at the 95th percentile in those conditions. Under lateral-port occlusion, it underestimates the added entrance loss at constrained openings, leading to larger deviations. Input sensitivity is dominated by viscosity, which maps nearly linearly to the terminal slope.

The table below reports scores for each factor under both mechanisms. Evidence statements are limited to a single line and restate values argued in the body text.
Model form — gradation.

a.
Simplified equations not tied to mechanism details.

b.
Equations tied to flow regime; key entrance/exit losses partially represented.

c.
Equations tied to flow regime with evidence on missing entrance effects.

d.
Equations comprehensively represent entrance and contraction losses for both mechanisms.

17. Credibility assessment summary for Model B: Shear-thinning CFD with surface roughness

Model B augments the Newtonian formulation with a Carreau–Yasuda rheology and an effective roughness height applied to lumen and port surfaces. This framework captures shear-rate–dependent viscosity reductions near entrances and contraction and accounts for elevated wall friction from early surface conditioning. Under both mechanisms, these additions improve pressure–flow slope agreement with the bench compared to Model A, particularly when lateral-port occlusion intensifies shear near functional entrances. Numerical stability remains strong, though gradients near rough walls demand finer near-wall resolution.

Input sensitivities include both rheological parameters and roughness; the latter increases the slope by 6–18% across the 10–40 μm range, an effect that must be bounded for confident use. The table below lists factor grades and concise bases.
Model inputs — gradation.

a.
Augmented physics parameters are assigned without measurement.

b.
Augmented physics parameters are measured on surrogates with broad ranges.

c.
Augmented physics parameters are measured and bounded; sensitivity on key ones performed.

d.
Augmented physics parameters are measured, bounded, and propagated to decision metrics.

18. Credibility assessment summary for Model C: Porous-jump hole occlusion CFD

Model C retains the Newtonian bulk formulation but introduces porous-jump interfaces at lateral ports to emulate added entrance resistance and area loss under partial occlusion. This representation yields excellent agreement with bench slopes as occlusion progresses, because the added loss is directly parameterized and calibrated to wrap open area. In clean, tip-down conditions where the distal contraction dominates, the porous interfaces can misattribute losses, leading to a modest overstatement of slope and an underprediction of end-hole fraction.

Inputs include the porous-jump resistance coefficients calibrated against an orifice rig; sensitivity of the terminal slope to ±20% variations in these coefficients is ±9% under mechanism 1. Numerical stability is strong due to reduced near-entrance layer resolution needs. The table that follows provides factor grades and bases.
Output comparison — gradation.

a.
Agreement not demonstrated for the conditions where the model is strongest.

b.
Agreement demonstrated for a subset of conditions where the model is strongest.

c.
Agreement demonstrated across the relevant conditions where the model is strongest.

d.
Agreement demonstrated across relevant and challenging conditions; residual error quantified.

19. Synthesis for Decision-Making within the COU

For the decision of whether slow drainage is limited primarily by lateral-port blockage or by posture-induced tip dominance, the combined evidence indicates a division of strength among the models. When occlusion of side-holes is suspected or imposed, the porous-jump representation in Model C most faithfully captures the escalation of the pressure–flow slope and the reallocation of outflow away from affected ports; when the tip is aligned with gravity in the absence of imposed occlusion, the simpler Newtonian Model A and the shear-thinning Model B both produce slopes and end-hole fractions that align closely with bench values.

The variability attributable to mesh resolution remains small: across all model–mechanism pairs, changes in the terminal slope from the medium to the fine grid did not exceed 1.5%, and the residuals from formal order-of-accuracy estimates were similarly low relative to the 5–8% experimental slope uncertainty, ensuring numerical stability does not confound the classification.

Parameter uncertainty propagates to the slope at magnitudes that are material but bounded. Viscosity varied by ±10% shifts the slope by approximately ±9% in Models A and C and moderately less in Model B; effective roughness heights between 10 and 40 μm increase slopes by 6–18% in Model B; and ±20% adjustments in porous-jump coefficients change slopes by about ±9% in Model C. These shifts, interpreted against the acceptance bands and the observed bench spreads, do not overturn the mechanism classification in the tested scenarios.

The bench apparatus exercised the same heads, orientations, and device geometry used in practice, and reported the pressure–flow slope and outlet partitioning directly. Therefore, the tests probe the same flow modes that determine whether a drain is acceptable or mechanism-limited under the COU. Taken together, the scoring tables reflect high confidence in numerical stability and in the decision-value of the outputs, with mechanism-dependent confidence in the physics representation and agreement to bench.

Relevance of the validation activities to the COU — gradation.

a.
Bench conditions unrelated to decision conditions.

b.
Bench conditions related but incomplete with respect to decision.

c.
Bench conditions cover decision space; gaps shown to be immaterial.

d.
Bench conditions mirror decision space with the marketed device and clinical fluids and temperatures.

20. Discussion

Our evaluation shows that physics choices should be tuned to the mechanism under investigation. In lateral-port–dominated drainage with partial occlusion, the capacity to emulate increased entrance losses at the side-holes is paramount; treating the openings as porous interfaces in Model C proved effective and computationally economical. In end-hole–dominant drainage under gravitational alignment, accurate representation of the distal contraction and the laminar, steady flow suffices; the Newtonian Model A matched bench slopes closely, and Model B provided similar or slightly improved agreement via rheology and roughness adjustments. The inability of Model C to reduce emphasis on lateral interfaces in tip-dominated flow produced a consistent overstatement of the slope but not one that would lead to a misclassification of mechanism under the acceptance thresholds considered.

Several limitations temper the generality of these findings. First, we focused on a single catheter SKU with a specific terminal segment geometry; while the physics should translate across multi-hole tip designs, absolute resistance values and port-placement–dependent partitioning will vary. Second, the bench occlusion surrogates implement area reductions uniformly across ports; in vivo occlusions are often asymmetric, sometimes local to a subset of holes. Model C can mirror asymmetry by assigning port-specific porous coefficients, while Models A and B require explicit geometric changes to individual holes to capture asymmetry. Third, the rheological envelope used in Model B captures early, protein-enriched dialysate; later-stage effluents with cellular debris or fibrin networks may exhibit more complex viscoelastic behaviors not represented here.

Despite these limitations, the harmony between model predictions and bench observations across heads and orientations, and the bounded impact of parameter variations on the slope relative to the acceptance bands, provide confidence that the models can assist in parsing mechanism contributions to drain performance within this COU. For design iterations, Model C could support rapid screening of port layouts against occlusion-driven resistance increases, while Model A or B can be used to ensure acceptable performance in posture-biased drainage. For clinical interpretation, outputs such as the end-hole fraction and sensitivity of the slope to head changes inform whether a posture adjustment is likely to help.

The chosen governing equations and constitutive choices were adequate to represent the observed pressure–flow slope when the tip was favorably aligned, while they understated maldistribution and resistance growth when side-hole entrances were burdened by added losses. The input set was well bounded with metrology, rheometry, and orifice-rig calibrations; changing these within their justified ranges resulted in output shifts that, though measurable, did not eclipse the experimental variability or alter the mechanism classification in the tested conditions.

Model form — gradation.

a.
Assumptions are plausible but untested.

b.
Assumptions tested in limited regimes.

c.
Assumptions tested in regimes aligning with COU, with quantified deviations.

d.

Assumptions tested and shown to preserve decision outcome across regimes.

21. Conclusions

We applied the intent of the ASME V&V 40 framework to assess the credibility of three CFD models for predicting drainage resistance in a PD catheter terminal segment under two mechanisms: lateral-hole–dominated drainage with partial occlusion and end-hole–dominant drainage under gravitational alignment. Numerical stability under mesh refinement was demonstrated across all models, with slope changes below 1.5% between medium and fine meshes. Agreement with bench pressure–flow slopes and outlet partitioning varied by mechanism and physics set: the porous-jump Model C excelled in occlusion scenarios, while Newtonian Model A and shear-thinning Model B were most accurate in tip-dominated drainage. Input parameters were measured or calibrated, and sensitivity magnitudes were reported and interpreted against acceptance thresholds.

Across the 18 bench configurations, the model-to-measurement deviations for the pressure–flow slope were 5.3% median (12% 95th percentile) for Model C in occlusion-driven cases, 6% median (10% 95th) for Model A in tip-dominated cases, and 7% median (12% 95th) for Model B across both mechanisms. These residuals sit within or below the experimental uncertainty and do not alter the mechanism classification under the thresholds considered.

The outputs computed are identical to the decision metrics used in PD programs, and the tests exercised the same heads, orientations, and device geometry used in practice. The three tables provide explicit confidence scores for each factor, model, and mechanism. For this COU, we recommend Model C when lateral-port occlusion is the suspected limiter and Model A or B when posture-induced tip dominance is expected. Future work will extend these assessments to asymmetric occlusions, viscoelastic effluents, and time-resolved drain cycles with abdominal pressure variations.

Output comparison — gradation.

a.
Conclusions stated without quantitative tie-back.

b.
Conclusions tie back to selected quantitative results.

c.
Conclusions tie back to aggregate quantitative results and uncertainties.

d.
Conclusions quantify residual error relative to acceptance bands and decision tolerance.

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Table 3: Model A credibility factors scored on a 0–5 scale by drainage mechanism.

Credibility factor	Level	Basis
Discretization error - Model A - Mechanism 1	5	Slope changed 0.9% (max 1.1%) between medium and fine meshes; end-hole fraction shift <0.6 percentage points.
Discretization error - Model A - Mechanism 2	5	Slope changed 0.8% (max 0.9%) between medium and fine meshes; end-hole fraction shift <0.6 percentage points.
Model form - Model A - Mechanism 1	2	Newtonian, rigid-wall form underestimates entrance losses with occlusions; median slope deviation 18%, 95th percentile 28%.
Model form - Model A - Mechanism 2	4	Captures tip contraction and laminar regime; median slope deviation 6%, 95th percentile 10% in tip-down, clean cases.
Model inputs - Model A - Mechanism 1	3	Viscosity 1.20 ± 0.12 mPa·s; ±10% maps to ±9.2% slope change; geometry tightly measured.
Model inputs - Model A - Mechanism 2	4	Key inputs bounded; ±10% viscosity gives ±9.2% slope change yet classification unaffected relative to 150–180 cmH2O/L/min bands.
Output comparison - Model A - Mechanism 1	2	Against 0–75% port occlusions, slope deviations median 18%, 95th percentile 28%; end-hole fraction 6–10 points high.
Output comparison - Model A - Mechanism 2	4	Tip-down clean cases matched with median 6% and 95th percentile 10% slope deviations; end-hole fraction within 5 points.
Relevance of the quantities of interest - Model A - Mechanism 1	5	Predicts slope (cmH2O/L/min) and end-hole fraction directly used to judge drain adequacy and mechanism discrimination.
Relevance of the quantities of interest - Model A - Mechanism 2	5	Same decision metrics computed without surrogate transformations; thresholds 150–180 cmH2O/L/min apply directly.
Relevance of the validation activities to the COU - Model A - Mechanism 1	5	Bench used marketed catheter, 2.5% dialysate at 37 °C, heads 20–80 cmH2O, and controlled occlusions mirroring early fibrin contact.
Relevance of the validation activities to the COU - Model A - Mechanism 2	5	Tip-down alignment and clean fluid replicated routine posture-induced bias conditions with matched geometry and fluids.

Table 4: Model B credibility factors scored on a 0–5 scale by drainage mechanism.

Credibility factor	Level	Basis
Discretization error - Model B - Mechanism 1	4	Slope changed 1.3% (max 1.5%) between medium and fine meshes; peak wall shear varied up to 2.1%.
Discretization error - Model B - Mechanism 2	4	Slope changed 1.4% (max 1.5%) between medium and fine meshes; end-hole fraction shift <0.8 percentage points.
Model form - Model B - Mechanism 1	4	Shear-thinning and roughness capture intensified entrance effects; slope deviations median 8%, 95th percentile 15%.
Model form - Model B - Mechanism 2	4	Contraction and wall losses reproduced with rheology; tip-down slopes within 5% median, 9% 95th percentile.
Model inputs - Model B - Mechanism 1	4	Carreau–Yasuda fit residuals <5%; k_s=10–40 µm raises slope 6–18%; viscosity ±10% causes ±7.5% slope change.
Model inputs - Model B - Mechanism 2	4	Rheology and roughness ranges bounded; combined variations shift slopes by less than decision bands in clean tip-down.
Output comparison - Model B - Mechanism 1	4	Across occlusions, median slope deviation 8%, 95th percentile 15%; end-hole fraction within 5 percentage points.
Output comparison - Model B - Mechanism 2	4	Tip-down slopes matched with 5% median and 9% 95th percentile deviations; end-hole fraction within 4 points.
Relevance of the quantities of interest - Model B - Mechanism 1	5	Slope and outlet fractions correspond to acceptance bands and mechanism identification used by PD programs.
Relevance of the quantities of interest - Model B - Mechanism 2	5	Computed outputs are identical to those used in posture-related drain assessments.
Relevance of the validation activities to the COU - Model B - Mechanism 1	5	Occlusion surrogates and fluid properties exercised the same failure mode as early-use lateral blockage.
Relevance of the validation activities to the COU - Model B - Mechanism 2	5	Tip-down alignment tests matched the intended posture-induced bias conditions for the marketed device.

Table 5: Model C credibility factors scored on a 0–5 scale by drainage mechanism.

Credibility factor	Level	Basis
Discretization error - Model C - Mechanism 1	5	Slope changed 0.7% (max 0.9%) between medium and fine meshes; end-hole fraction shift <0.4 percentage points.
Discretization error - Model C - Mechanism 2	5	Slope changed 0.9% (max 1.0%) between medium and fine meshes; end-hole fraction shift <0.4 percentage points.
Model form - Model C - Mechanism 1	5	Porous-jump interfaces emulate occluded entrances; median slope deviation 5.3%, 95th percentile 12% across occlusions.
Model form - Model C - Mechanism 2	3	Porous interfaces cannot adjust tip contraction; median slope deviation 12%, 95th percentile 20% in tip-down cases.
Model inputs - Model C - Mechanism 1	4	R_jump calibrated vs wrap open area (R^2=0.97); ±20% in R_jump gives ±9% slope change.
Model inputs - Model C - Mechanism 2	3	Port resistances bounded but less critical; residual bias in tip-dominated flow remains despite input variation.
Output comparison - Model C - Mechanism 1	4	Across 0–75% occlusions, slopes match with median 5.3% and 95th percentile 12% deviations; port flows track dye velocimetry.
Output comparison - Model C - Mechanism 2	3	Tip-down clean slopes overpredicted with 12% median, 20% 95th percentile deviations; end-hole fraction 6–9 points low.
Relevance of the quantities of interest - Model C - Mechanism 1	5	Slope and port fractions directly inform mechanism discrimination and acceptance thresholds.
Relevance of the quantities of interest - Model C - Mechanism 2	5	Same decision metrics reported without surrogate transformations.
Relevance of the validation activities to the COU - Model C - Mechanism 1	5	Bench occlusion surrogates and heads replicate the use-case conditions for lateral blockage.
Relevance of the validation activities to the COU - Model C - Mechanism 2	5	Tip-down alignment tests used the marketed catheter and dialysate at clinical temperatures.