VirtuCath™ Stiffness Validation Report

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1.0 Purpose

The purpose of this document is to provide validation for the VirtuCath™ bending stiffness prediction. Where the verification reports VR-VC-001 and VR-VC-002 confirmed the mathematical accuracy of the core physics engine against analytical and literature models, this report documents the accuracy of the software's predicted bending stiffness (EI) against **physical measurement**. It benchmarks the software's EI output against manufactured catheter shafts tested on the bench and against an independent, published braided-catheter dataset.

2.0 Scope

This study applies to the VirtuCath composite stiffness model — the module that predicts a shaft's mechanical stiffness directly from its construction (layer geometry, constituent materials, and reinforcement architecture). The scope is restricted to **bending stiffness (EI)** in the linear elastic regime, at room temperature and dry.

The evaluated envelope is the common catheter regime: small-diameter shafts (approximately 2–8 Fr), single-section, multi-layer polymer walls reinforced with metal-wire braid, across the low-to-high braid-angle range typical of commercial devices. Predictions are linear-region; nonlinear/large-deflection, viscoelastic, and hydrated/body-temperature behavior are not addressed here.

2.1 Modeling basis

VirtuCath predicts stiffness from first principles rather than by empirical curve-fit. Layer stiffnesses are built from constituent material properties and geometry using **classical laminate theory (CLT)** and established composite micromechanics (Refs. 3.3–3.4), then combined through classical beam and section mechanics to give the stiffness of the reinforced tube; the discrete wire reinforcement is represented with standard reinforcement mechanics, with stiffness varying with braid helix angle in the physically expected direction. Because predictions follow from mechanics rather than a fit to any particular dataset, the model responds predictably as construction inputs change — the behavior underlying the systematic, construction-correlated error character documented in Section 6.1.

2.2 Outputs not covered

This report validates EI only. The same section-integration engine also computes torsional (GJ) and axial (EA) stiffness, but a comparable bench measurement base for those modes was not available for this study — chiefly because of in-house torsion- and axial-test equipment limitations — so their quantitative validation is deferred. Because GJ and EA derive from the same first-principles laminate and section mechanics as EI, these results give indirect confidence in the soundness of the underlying method across all three outputs.

3.0 Referenced Documents

1. VR-VC-001, *VirtuCath™ Software Verification Report*, v4.0.
2. Goetz, J. & Kesser, Q., *Insights for More Efficient Braided Catheter Development*, Meddux Development Corp. (with Roth Technologies / CathCAD®) — independent published bench data for a 7 Fr braided shaft in three braid patterns.
3. Jones, R. M., *Mechanics of Composite Materials*, 2nd ed., Taylor & Francis, 1999.
4. Daniel, I. M. & Ishai, O., *Engineering Mechanics of Composite Materials*, 2nd ed., Oxford University Press, 2006.

4.0 Validation Methodology

4.1 Model under test

All predictions were generated by the **VirtuCath software** (v1.2.0). Where a construction used materials outside the standard library, the exact constituent properties were supplied to the software, so every result reflects the production model operating on the correct inputs.

4.2 Reference data

Two independent sources of measured bending stiffness were used:

- **In-house bench (three-point bend).** Manufactured catheter shafts tested in three-point bend across multiple support spans with replicates per span. A gauge-length-independent "true" EI was recovered from the multi-span data by a Timoshenko shear-separation fit, which removes short-span shear and test-fixture artifacts. The specimens span multiple manufacturers and constructions. Each was modeled from its nominal engineering drawing (as-drawn, not as-built), with constituent materials assigned from published datasheets; where the exact polymer grade was not identified, a representative grade was used.
- **Independent literature.** Bench-measured flexural modulus for a 7 Fr thin-wall braided shaft in three braid patterns (Ref. 3.2), converted to section EI via the annular second moment.

4.3 Specimen inclusion

Bench specimens were included where the multi-span fit met pre-defined data-quality criteria (adequate fit quality and a monotonic span response). Two bench specimens that did not meet these criteria — one with a poor multi-span fit, one with a non-monotonic span response indicative of test-fixture inflation — were excluded from the headline result. As noted in Section 5.3, their inclusion does not materially change the reported statistics.

4.4 Comparison metric

Because EI spans several orders of magnitude across the specimen set, agreement is reported as the **ratio of predicted to measured EI** and the corresponding percentage error. A ratio below 1.0 indicates the software predicts a lower (more conservative) stiffness than measured.

5.0 Results

The validation set comprised eight qualifying constructions: five manufactured bench specimens and three independent literature braid patterns.

5.1 Accuracy statistics (n = 8)

Metric	**Value**
Median Absolute Error	**11%**
Mean Absolute Error	16%
Mean Bias	−12% (conservative / under-predicting)
Standard Deviation	16%
Within ±15%	6 of 8
Ratio range	0.55× – 1.10×

5.2 Per-construction summary

Ordered by measured stiffness (soft to stiff).

Construction	Measured EI (N·mm²)	Predicted EI (N·mm²)	Ratio	Error
Literature — diamond pattern	200.5	180.0	0.90×	−10%
Literature — regular pattern	201.6	212.9	1.06×	+6%
Literature — half-load pattern	193.4	212.9	1.10×	+10%
Bench specimen A	466.4	408.5	0.88×	−12%
Bench specimen B	1 340.1	1 177.2	0.88×	−12%
Bench specimen C	2 169.7	2 047.2	0.94×	−6%
Bench specimen D	17 991.7	9 903.8	0.55×	−45%
Bench specimen E	36 219.6	27 064.2	0.75×	−25%

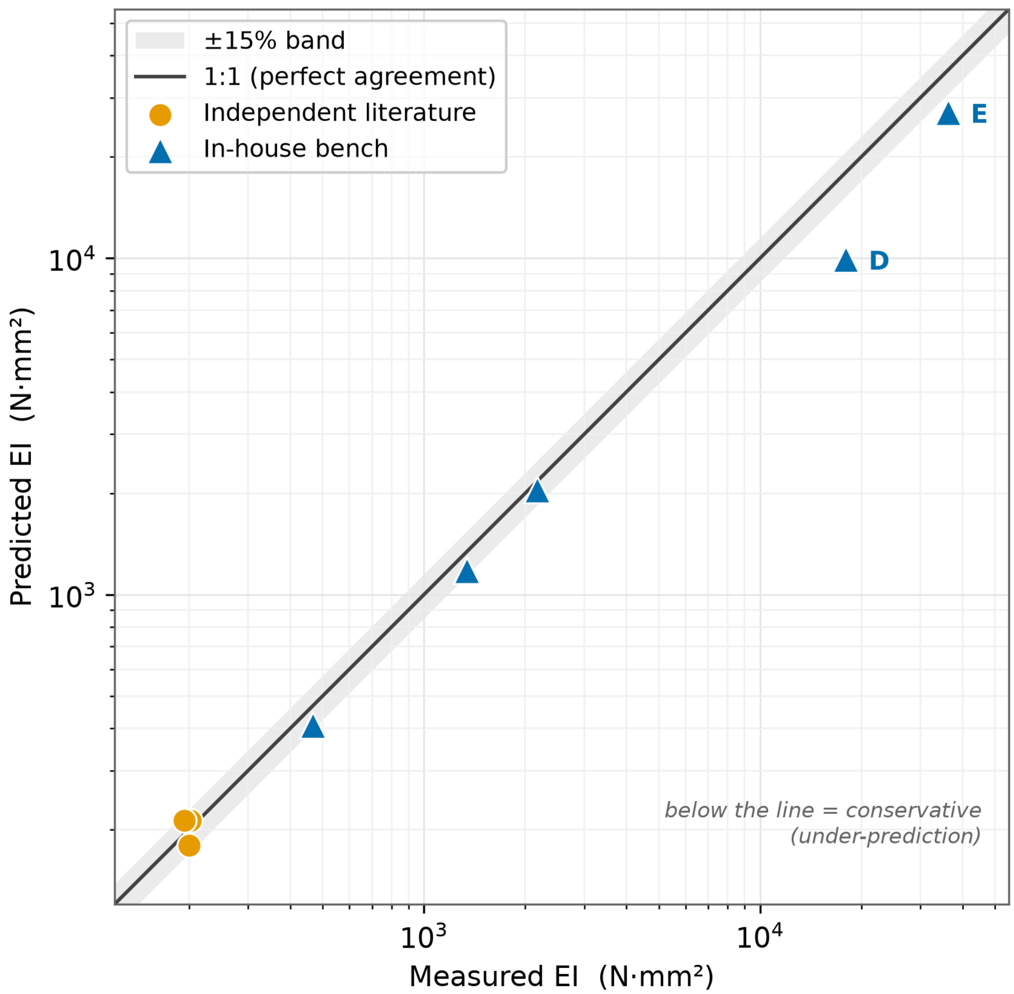

Figure 1. VirtuCath predicted vs. measured bending stiffness (log–log). Points below the 1:1 line indicate conservative under-prediction.

5.3 Robustness

Including the two data-quality-excluded specimens (Section 4.3), the Median Absolute Error moves from 11% to 12% and the within-±15% count from 6/8 to 6/10. The result is therefore not sensitive to the treatment of the marginal data.

6.0 Analysis

Overall agreement. Across the qualifying set the software predicts EI with a median error of 11%, and within ±15% on six of eight constructions. On constructions that sit squarely within the evaluated envelope, the model is an accurate estimator of bending stiffness.

Independent corroboration. The three literature patterns were reproduced to within approximately 10% across three distinct braid patterns, including the correct relative softening of the diamond pattern.

6.1 The error is systematic, not random — validity as a comparison tool

The prediction error is **systematic rather than random**. Its direction is consistent — the software under-predicts on six of eight constructions — and its magnitude is **correlated with construction type**, growing in an orderly way with stiffness and braid angle rather than scattering unpredictably from one specimen to the next. Constructions of similar type carry a similar bias.

This property is what makes the tool valid for its intended use. VirtuCath is a design-stage instrument for **comparing constructions and exploring trade-offs**, not for certifying an absolute stiffness value. When two constructions of similar type are compared, their shared directional bias **largely cancels**, so the predicted *difference* and *rank-ordering* between them are preserved with substantially higher fidelity than the absolute error on either one alone would imply. A tool whose error is a consistent, construction-correlated offset remains a sound basis for relative comparison across the evaluated envelope — including near the stiff-braid edge — provided comparisons are drawn between constructions of similar type.

6.2 Input material properties as a dominant, user-controlled uncertainty

A significant portion of the specimen-to-specimen spread reported in Section 5 is attributable to **input material uncertainty, not to the model**. Bending stiffness scales approximately linearly with constituent modulus ($EI \propto E$), so error in the assumed polymer modulus propagates almost directly into predicted EI. The as-tested, in-use modulus of an extruded polymer differs from its published datasheet flexural modulus — owing to extrusion-induced anisotropy and viscoelastic relaxation — by on the order of **±15%**. Because EI is linear in that modulus, this single input uncertainty can account for a comparable share of the observed prediction spread on polymer-dominated constructions.

This is an uncertainty the **user controls**, and it is separable from the model's own accuracy: supplying application-specific, as-tested material properties in place of nominal datasheet values narrows the prediction directly. The residual error attributable to the model itself is therefore smaller than a comparison made against nominal-modulus inputs indicates. Material characterization is the single most effective lever a user has to tighten agreement.

Two further input-fidelity factors widen the observed spread independently of the model. Each specimen was modeled to its nominal engineering drawing rather than to as-built dimensions; because EI is sensitive to wall thickness and diameter, ordinary manufacturing tolerance introduces error that is not the model's. Likewise, constituent materials were taken from published datasheets, and for a few specimens the exact polymer grade was estimated — carrying the modulus uncertainty above. Both are input-side, separable from the model's own accuracy, and reducible with as-built dimensional and as-tested material data.

6.3 Worst-case behavior

Consistent with the verification findings of VR-VC-001, the software's worst-case accuracy is contained at an edge of the evaluated envelope — here, the stiffest, highest-braid-angle steel-braided constructions (specimens D and E), where the model under-predicts EI by 25–45%. This behavior is well-measured — the underlying bench fits are of high quality — and consistent in direction across both stiff-braid specimens, so it is a characterizable property of that corner rather than random scatter. It is localized to a describable region of the design space, so users can be advised precisely where additional conservatism applies — and, per Section 6.1, relative comparison between similar constructions in this region remains valid even where the absolute magnitude is under-predicted.

6.4 Limitations and validity domain

5. **Specimen count.** The quantitative claim rests on a single-digit number of distinct manufactured constructions plus one independent literature construction. Results are therefore stated as typical magnitudes rather than guarantees.
6. **Stiff-braid corner.** Absolute accuracy is strongest in the common catheter regime and degrades (conservatively) at the stiff, high-braid-angle edge, as described in Section 6.3. Relative comparison in this region remains valid (Section 6.1).
7. **Input material properties.** As-tested polymer modulus is the dominant input-side contributor to prediction spread (~±15%) and is controlled by the user through material characterization (Section 6.2).
8. **Input fidelity.** Specimens were modeled to nominal drawings (not as-built), with datasheet materials and, for a few specimens, an estimated polymer grade; as-built dimensions and as-tested materials would tighten agreement (Section 6.2).
9. **Regime.** Linear-region, dry, room-temperature bending only.

7.0 Conclusion

The VirtuCath™ bending stiffness prediction is **validated** against physical measurement across the common catheter regime, predicting EI with a median error of approximately 11% and within ±15% on the majority of qualifying constructions, including approximately 10% agreement with an independent, published braided-catheter dataset. The model's error is bounded, predominantly conservative, and **systematic rather than random**: it is correlated with construction type, so it largely cancels when constructions of similar type are compared. VirtuCath™ is therefore a valid instrument for its primary purpose — relative comparison and trade-off exploration between constructions — across the evaluated envelope, including near the stiff, high-braid-angle edge where absolute stiffness is under-predicted.

A meaningful share of the observed spread is further attributable to **user-controlled input material uncertainty** rather than to the model: because EI scales approximately linearly with constituent modulus, the ~±15% difference between datasheet and as-tested polymer modulus propagates directly into predicted EI, and supplying as-tested properties narrows the prediction accordingly.

As with any predictive tool, absolute results near the boundaries of the evaluated envelope should be confirmed by physical testing before being relied upon for safety-critical or product-release decisions. This document describes validation methodology and observed accuracy; it is not a regulatory submission and does not substitute for the design-verification and validation activities required by applicable quality-system frameworks.