Developing a Risk-Informed Computational Model for a Medical Device: A Credibility-Building Approach

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Introduction

Computational Modeling & Simulation **(CM&S)** is currently used to design, develop, and test medical devices.

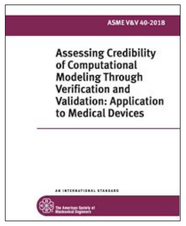
CM&S has the potential to inform regulatory decision-making.

This evidence must be trustworthy with rigor proportional to the risk.

Background

ASME V&V40 Standard
- FDA recognized standard
- Risk informed credibility

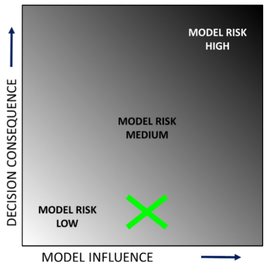
FDA Guidance for Reporting CM&S Credibility
- Verification
- Validation
- Uncertainty Quantification



Methods

Medical Device: Electronic Drug Delivery System (EDDS)

Question of Interest: What are the bioeffects arising from deposition of potential chemicals generated by EDDS onto the oral mucosa?



Context of Use: The computational model will characterize the velocity field and temperature distribution of the fluid flow in a representative mouth cavity.

Model Risk: There is a modest (low-medium) possibility that the use of the computational model leads to a decision that results in patient harm and/or undesirable impacts. (*See the **X** in the gradient above*)

Model: Steady-state air flow system with 0.5 L/min inlet flow rate was simulated using ANSYS CFX solver.

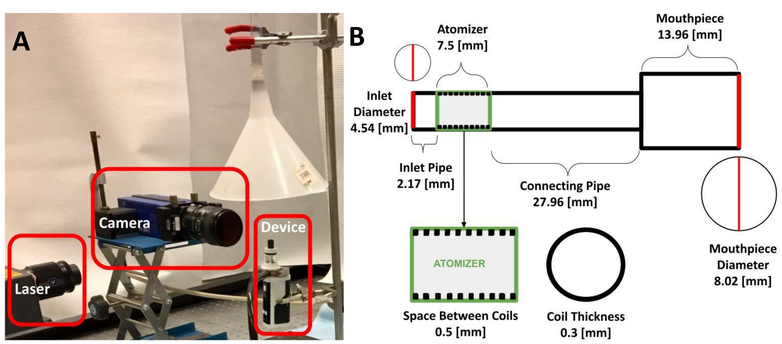
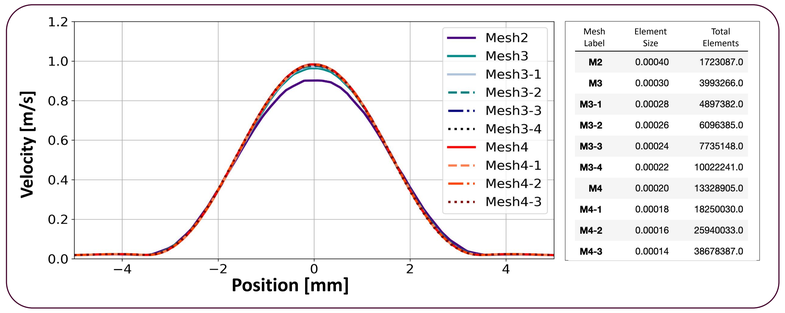


Figure 1. A) EDDS PIV experimental setup. B) CM&S EDDS geometry schematic.

Results

Verification: Code Verification & Calculation Verification



Mesh Label	Element Size	Total Elements
M2	0.00040	1723087.0
M3	0.00030	3993266.0
M3-1	0.00028	4897382.0
M3-2	0.00026	6096385.0
M3-3	0.00024	7735148.0
M3-4	0.00022	10022241.0
M4	0.00020	13328905.0
M4-1	0.00018	18250030.0
M4-2	0.00016	25940033.0
M4-3	0.00014	38678387.0

Figure 2. Mesh refinement of the velocity profile 1mm above the mouthpiece.

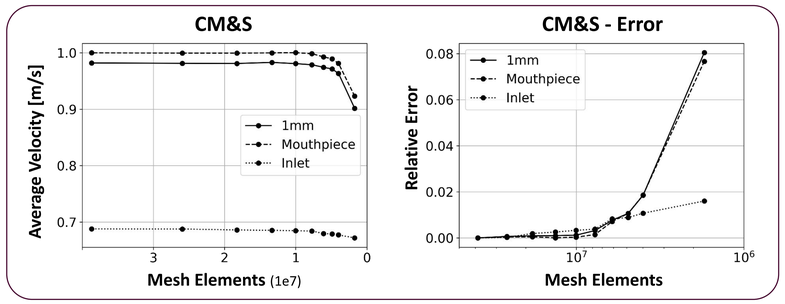


Figure 3. Mesh refinement of the maximum velocity 1mm above the mouthpiece.

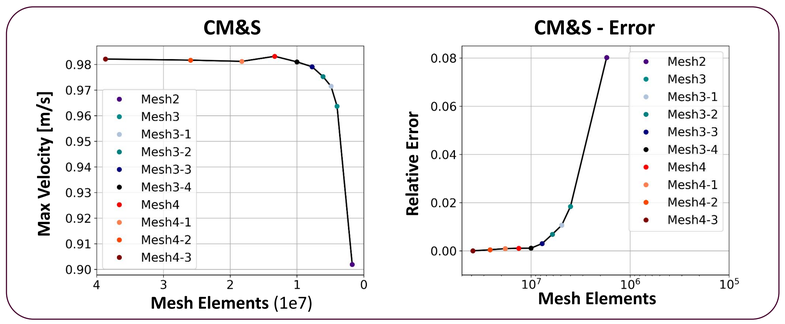


Figure 4. Mesh refinement of the average velocity 1mm above the mouthpiece.

Validation: Computational Model Characterization

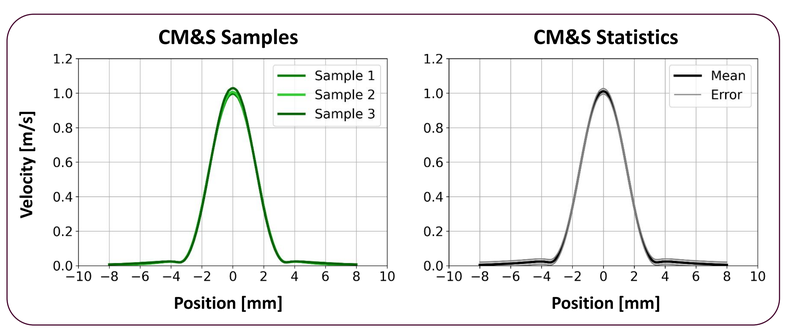


Figure 5. CM&S velocity profile at 1mm above the mouthpiece.

Validation: Comparator Characterization

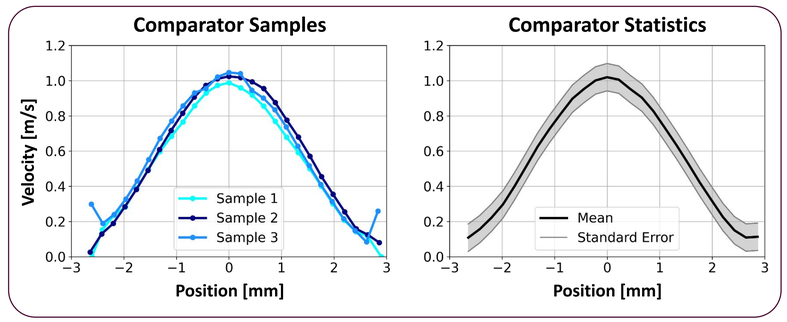


Figure 6. Validation experiments for velocity at 1mm above the mouthpiece.

Validation: Assessment of simulation against comparator

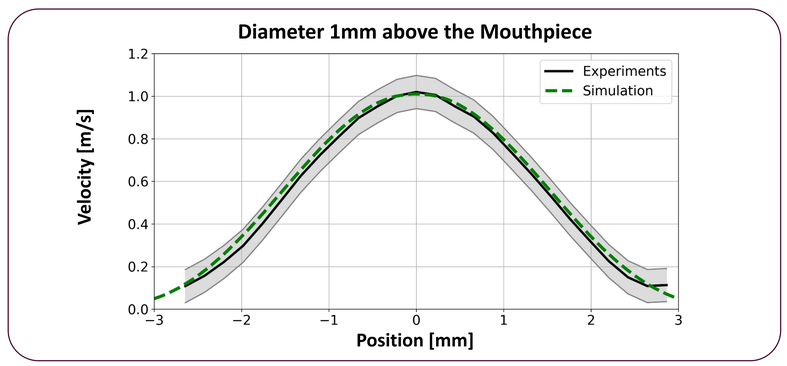


Figure 5. Assessment comparing 3 experiments with a single CM&S.

Discussion

The mesh refinement study demonstrated that the CM&S reached convergence (Figures 3, 4, and 5).

Figure 2 shows that as the mesh became coarser, the model underestimated the flow rate.

The validation study generated three CM&S samples that were used to obtain a single nominal model that was compared with probabilistic experimental results (Figure 5).

Based on the model risk, we believe that this analysis is adequate.

Future Work

Propagate all input uncertainties through the EDDS CM&S.

Improve the rigor of the validation assessment by quantifying the validation uncertainty based on relevant probabilistic uncertainties.

Increase model complexity by adding heat transfer at the coils.

Acknowledgements

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