

Computational Fluid Dynamics Modeling Of The FDA Nozzle Using The V&V 20 Standard

G. D'Souza¹, P. Hariharan², R. Malinauskas², R. Banerjee¹, and M. Horner³

¹University of Cincinnati, Cincinnati, OH, ²Food and Drug Administration, Silver Spring, MD, ³ANSYS Inc., Evanston, IL

TITLE OF ABSTRACT (The title should accurately describe the questions answered by the study.)

Presenting Author's Name (underlined), Other author's names.

Authors' affiliated institution(s).

Please note that the information above will be formatted from your entry and should not be on the document you upload.

Introduction: Computational fluid dynamics (CFD) is considered to be a useful pre-clinical tool for the design and testing of blood-contacting medical devices. However, the absence of standardized methods for verifying and validating CFD simulations performed on medical devices has limited the use of this tool in regulatory submissions. Recently, a generic verification and validation (V&V) procedure for CFD modeling and simulation was developed and documented in the ASME V&V 20 standard. The applicability of this standard to medical devices has not yet been demonstrated. Therefore, the goal of this study was to understand the usefulness and limitations of the existing V&V 20 standard by applying it to a CFD analysis of a simplified medical device model (FDA nozzle). The FDA nozzle model (<https://fdacfd.nci.nih.gov>), which mimics the flow field in several medical devices, contains a gradually constricting cone at the inlet, a narrow throat region (4 mm in diameter), and a sudden expansion region (12 mm in diameter).

Materials and Methods: The study focused on applying two main steps documented in the V&V 20 standard to the simulation of flow in the model: a) Solution verification: estimating the numerical error accrued in the solution of the numerical code (numerical uncertainty, u_{num}), and b) Validation: estimating the simulation uncertainty due to uncertainty in the model input parameters (u_{input}). The flow ($Re_{throat}=2000$) through the computational domain representing the nozzle geometry domain was computed using a commercial finite-volume solver (CFX, ANSYS Inc.). In order to estimate u_{num} , a mesh refinement study was conducted and the uncertainty of the numerical scheme was quantified using the Grid Converge Index (GCI) method. After performing the solution verification, u_{input} was estimated using the sensitivity coefficient method. The uncertainty bounds for the input parameters (viscosity, flow rate (Q), and turbulent intensity (TI)) were obtained from an inter-laboratory experimental study in which, velocity was measured at multiple points within the nozzle model. Subsequently, a series of simulations were carried out using different values of the input parameters selected by perturbing their nominal values.

Results and Discussion: The grid convergence for solution verification was monitored using the axial velocity along the nozzle centerline. The values of the centerline velocity were observed to reach a nearly constant value as the mesh density was increased. The u_{num} of the final mesh set ($n=3$) was $< 0.1\%$ where the finest mesh in the set consisted of 1,600,000 cells. Figure 1 shows the u_{input} values for the axial velocity at different locations along the nozzle centerline. The % contribution of each input parameter to the total uncertainty in the axial velocity is indicated by u_{uz}^i where $i = \text{viscosity}, Q \text{ and } TI$. The u_{input} increased in the throat region due to the effect of flow acceleration. The maximum u_{input} value was observed in the sudden expansion region, indicating the effect of downstream turbulence on jet breakdown and flow reattachment.

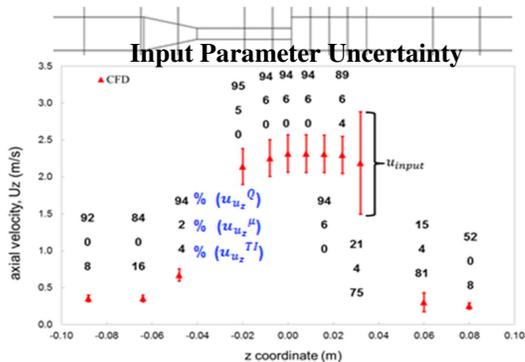


Figure 1. Input parameter uncertainty in the axial velocity along the nozzle centerline.

Conclusions: The accuracy of the CFD model used for evaluating flow across the FDA nozzle was quantified using the steps outlined in V&V 20. The outcomes of this study will aid in the development of the new V&V 40 standard for applying CFD simulations to evaluate medical devices.