Comparison of Interlaboratory Computational Simulations of Flow and Blood Damage in the FDA Benchmark Blood Pump

Sailahari V. Ponnaluri[1], Prasanna Hariharan[1], Luke H. Herbertson[1], Richard A. Malinauskas[1], Keefe B. Manning[2,3], Brent A. Craven[1]

[1]Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, US Food and Drug Administration

[2]Department of Biomedical Engineering, Pennsylvania State University

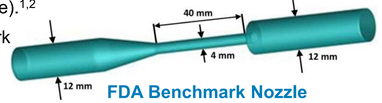
[3]Department of Surgery, Penn State Hershey Medical Center

Introduction

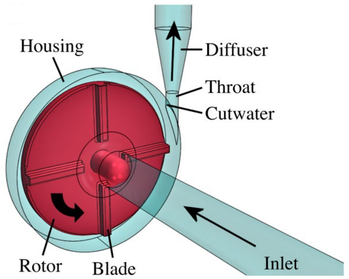
To rely on computational fluid dynamics (CFD) for regulatory submissions, their credibility must first be demonstrated through verification and validation (ASME V&V40, FDA Guidance).[1,2]

There are two FDA Benchmark Validation models:

1. **Nozzle:** simple geometric model with a flow constriction
2. **Blood Pump:** generic centrifugal blood pump



FDA Benchmark Nozzle



FDA Benchmark Blood Pump

Interlaboratory experiments were compared to blinded CFD predictions for both models. Previously, Stewart *et al.* assessed the FDA Nozzle Model submission.[3]

The purpose of this study is to report the interlaboratory CFD study results for the benchmark blood pump.

Materials and Methods

Experimental Methods

The blood pump was fixed in a loop, shown in **Figure 1A**, allowing for particle image velocimetry and hemolysis experiments to be separately performed at six pump operating conditions (**Fig. 1B**). The pump pressure head, velocity fields, and plasma free hemoglobin (fHb) were measured at each condition.

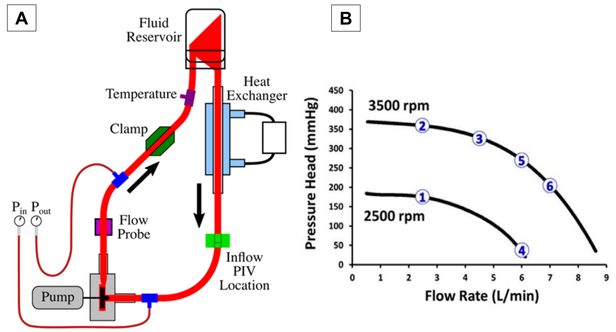


Figure 1. FDA benchmark blood pump **A.** experimental flow loop (adapted from Hariharan *et al.*)[4] and **B.** six pump operating conditions.

Interlaboratory Computational Methods

Table 1: Summary of interlaboratory CFD submissions

Simulation Option	Participant Submissions (24)
CFD Solver	Abaqus/CFD (1), AcuSolve (2), ANSYS CFX (6), ANSYS Fluent (7), code_saturne (1), FlowVision (1), SC/Tetra (1), STAR-CCM+ (5)
Time Integration	Steady (14), Transient (10)
Turbulence Model	k-ω SST (13), Standard k-ε (3), Realizable k-ε (3), Spalart-Allmaras (2), RNG k-ε (1), R_{ij}-ε SSG (1), not provided (1)
Hemolysis Model	Lagrangian stress-based power law (2), Eulerian stress-based power law (4), Unspecified stress-based power law (1), Strain-based model of Pauli et al.[5] (1)
Mesh Topology	Tetrahedral (16), Hexahedral (4), Polyhedral (4)
Num Cells (× 10^6)	Min: 0.53, Max: 76.5, Mean: 11.6, Median: 9.4
Num Nodes (× 10^6)	Min: 0.42, Max: 60.7, Mean: 9.9, Median: 2.8

Materials and Methods (cont.)

Participants were provided the geometry, fluid properties, and inlet velocities and turbulence intensities. The participants were blinded to the experimental data and were free to choose whichever CFD solver, mesh resolution, turbulence model, and other computational parameters they deemed appropriate. This resulted in the submission of 24 CFD results.

Data were first anonymized to prevent bias. Scalar quantities such as pressure head and hemolysis were compared at all operating conditions using a percent error. To compare velocity fields, experimental and CFD data were interpolated to a common high-resolution mesh and a global error (ε) (**EQ 1**)[5] for Quadrant 1, Quadrant 2, and the Diffuser was calculated (**Fig. 2**). Where 'u' was either the PIV or CFD velocity.

Comparative Methods

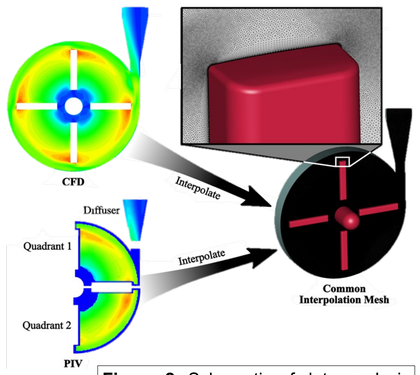
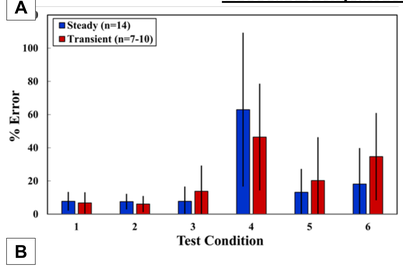


Figure 2. Schematic of data analysis steps by interpolating CFD and experimental velocity field data to a common high-resolution mesh.

(EQ 1) $$\varepsilon = \sqrt{\frac{1}{n}\sum_{i=1}^{n}\left(\frac{u_{CFD,i} - u_{PIV,i}}{\max(u_{PIV})}\right)^2}$$

Results

Pressure Comparison



Large variability in CFD predictions was observed across all conditions.

- greatest error for condition 4

No obvious dependence on:

- mesh resolution
- transient versus steady (**Fig. 3A**)

Three turbulence models generally performed well and were within two standard deviations for all six conditions (**Fig. 3B**)

- k-ω SST
- realizable k-ε
- Spalart-Allmaras

Figure 3: Percent error associated with CFD pump pressure head predictions when compared with experimental measurements as a function of **A.** steady versus transient and **B.** turbulence models.

Results (cont.)

Velocity Comparison

Generally, CFD was less accurate at predicting the flow in the outlet diffuser (**Fig. 4A**)

CFD accuracy was not strongly correlated with:

- Turbulence Model
- Mesh Resolution

Transient results generally agreed more closely to PIV within the rotor region (**Fig. 4B**) than steady simulations, as steady models underpredicted the velocity (**Fig. 5**).

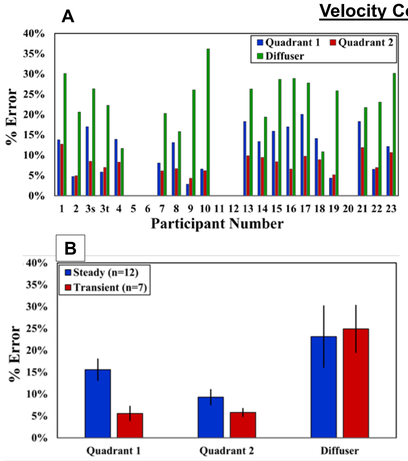


Figure 4: Condition 5's global error for **A.** quadrant 1, quadrant 2, and the diffuser regions and **B.** as a function of steady and transient simulations.

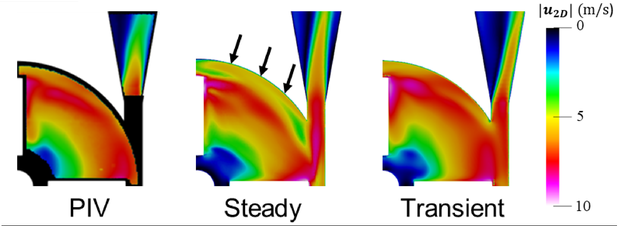
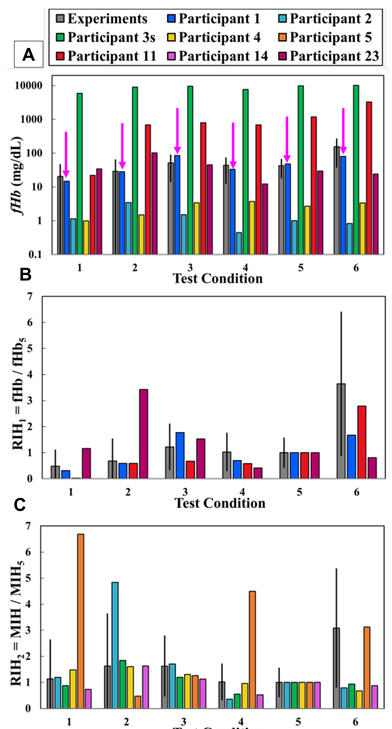


Figure 5: Planar velocity magnitude contours from PIV, a steady case, and a transient case for Condition 5, demonstrating a velocity magnitude underprediction within the rotor for steady cases, as indicated by the arrows.

Hemolysis Comparison



Only eight participants submitted hemolysis results as they required custom codes.

- seven used stress-based power law models and one used a strain-based model

Participant 1 predicted accurate fHb across all conditions (**Fig. 6A**)

Participants were more successful at predicting the relative index of hemolysis (RIH)

- RIH was normalized by condition 5
- Participants calculated RIH two ways (**Fig. 6B,C**)

Figure 6: A. CFD and experimental absolute fHb **B.** RIH normalized by condition 5's fHb. **C.** RIH normalized by condition 5's modified index of hemolysis (MIH).

Discussion

No single participant accurately predicted both pressure and velocity at all operating conditions.

Participants 2, 4, 14, 19, and 21 were within two standard deviations of pressure and 20% of velocity measurements at most operating conditions. In summary these participants used:

- Turbulence model: k-ω SST (2), realizable k-ε (1), Spalart-Allmaras (2)
- Steady (3) and transient models (2)
- Moderately fine meshes: 11-16 million computational cells

Participant 1 correctly predicted fHb at all operating conditions despite not accurately predicting pressure or velocity

Conclusion

This study implies that CFD modeling of blood pumps should be carefully validated across the entire range of relevant operating conditions for all quantities of interest.

Some conditions or regions are more challenging to predict than others as demonstrated by condition 4 and the diffuser region of the FDA blood pump model. It is important that all intermediate quantities of interest, such as pressure and velocity, in addition to the final applicable biological parameters, be validated. As shown by participant 1, it is possible to accurately predict hemolysis despite having an incorrect velocity field and pump pressure head which are two parameters critical for decision making.

Pump design and PIV data *available at:*
https://nciphub.org/wiki/FDA_CFD/ComputationalRoundRobin2Pump

References

1. ASME V&V 40-2018, *American Society of Mechanical Engineers*, 2018
2. CM&S Draft Guidance, FDA-2021-D-0980, 2022.
3. Stewart, S. F., et al, *Cardiovascular Engineering and Technology* 2012.
4. Hariharan, P., et al, *Cardiovascular Engineering and Technology* 2018.
5. Ponnaluri, S. V. et al., *Annals of Biomedical Engineering,* 2022.

Acknowledgements

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