Preliminary Results of FDA's "Critical Path" Project to Validate Computational Fluid Dynamic Methods Used in Medical Device Evaluation

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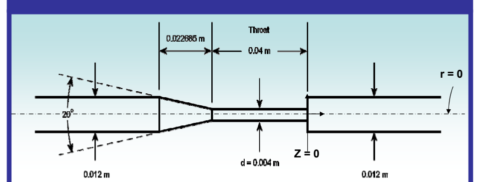
Abstract

Computational fluid dynamics (CFD) to assess device safety in new device submissions to the FDA is limited due to the lack of reliable standardized techniques. To determine suitability of CFD for evaluating device safety, participants from academia, industry, and FDA have begun a study of a benchmark flow model, which consists of a nozzle with a sudden contraction (or expansion) and a conical diffuser (or concentrator, depending on the flow direction). With the aid of ASAIO and other biomedical and computational societies, our project website (www.fda.gov/cdrh/cfd/index) received over 120 requests for information from around the world. Over 40 groups signed up to perform simulations and predict levels of blood damage in the model under different flow conditions. As data was received from participants, the information was blinded and analyzed using statistical techniques appropriate for CFD validation. This presentation will provide preliminary results of the submitted CFD data, compared to quantitative flow visualization measurements obtained in three independent laboratories. These comparisons, along with *in vitro* blood damage experiments, will help to determine how best to extrapolate CFD engineering results to predict the blood damage potential of medical devices.

CFD Benchmark Flow Model Specifications



- Throat Reynolds numbers: 500, 2000, 3500, 5000, 6500
- Flow Rate range: 0.3 – 4.0 L/min
- Fluid Density = 1056 kg/m³
- Dynamic Viscosity = 0.0035 N·s/m² (3.5 cP)
- Simulations were performed in both flow directions

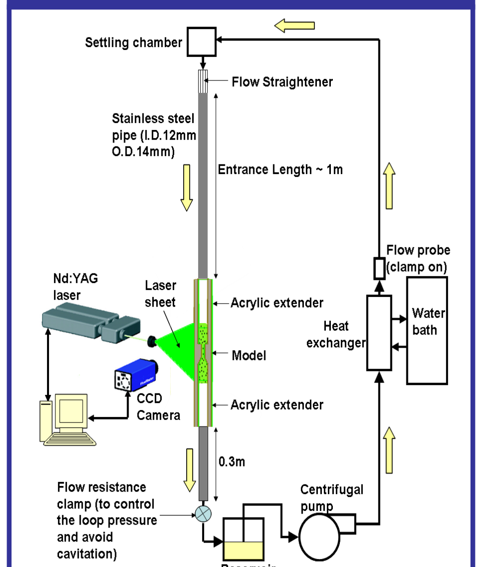
Interlaboratory CFD Study

- Model dimensions, volumetric flow rates, and fluid properties were specified
- Flow solver, mesh density, element shape, inlet/outlet length, boundary condition details, and laminar or turbulence models, were left up to participants
- Participants were asked to do a grid refinement study
- **CFD data was received from 28 groups and blinded prior to analysis**
- CFD results were compared to particle image velocimetry (PIV) data obtained in three laboratories (FDA, Penn State, Rochester Inst. Technology).
- Computational predictions of blood hemolysis were submitted by only 11 participants

Particle Image Velocimetry (PIV)

- Three identical acrylic flow models were fabricated, and hand- and vapor-polished. Quality control insured model dimensions were within 1% of design values.
- Blood analog fluid: Sodium iodide solution (50% NaI, 20% Glycerin, and 30% water by weight)
- Fluid properties (measured by 3 laboratories at 21°C):
  - Viscosity : 6.9 – 8 cP
  - Density : 1.65 – 1.73 g/cm³
  - Refractive index: 1.485 – 1.490
- PIV performed at same Reynolds numbers as CFD
- PIV results were scaled to match CFD fluid properties

Schematic of PIV flow system



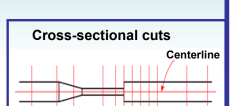
CFD and PIV Comparison Metrics

Along the Centerline

- Velocity components (axial and radial)
- Shear stress magnitude
- Reynolds stress magnitude

At the wall

- Shear stress magnitude
- Pressure



At specific cross-sectional cuts

- Velocity components (axial and radial) vs. radius
- Shear stress magnitude vs. radial distance
- Reynolds stress magnitude vs. radial distance
- Jet width

Results: CFD Methods for 28 Participants

User Experience: (self-ascribed)	
Rating	**Users**
Beginner	9
Intermediate	11
Expert	7

Solvers Used (11)

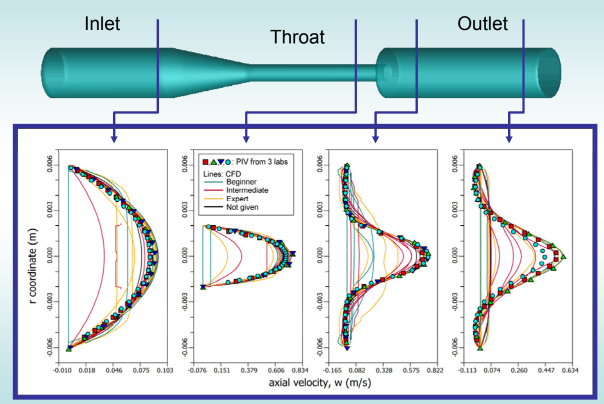
• Adapco StarCD • CFD-ACE-SOLVER • ADINA • CFX • COSMOSFlo Works • Custom • FIDAP • Fluent • OpenFoam • Star-CCM • XNS •

Model Type	#	Element Shape	#
3D	16	Hexagonal	11
		Tetragonal	3
		Octree	1
		Poly	1
Axi-symmetric	12	Quad	9
		Triangle	3

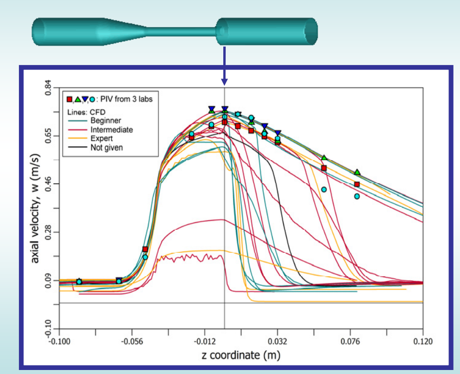
Turbulence Model	#
Shear Stress Transport (SST)	14
k-epsilon	9
k-omega	2
Spalart Allmaras	1
realizable k-epsilon	1
Lounder-Kato's k-epsilon zonal model	1

Results: CFD vs. PIV, Sudden Expansion, Re = 500

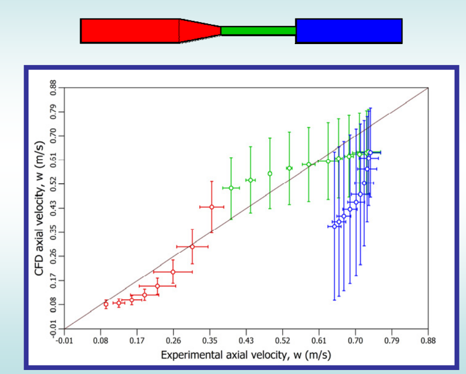
Axial Velocity Profiles



Axial Velocity Along Centerline

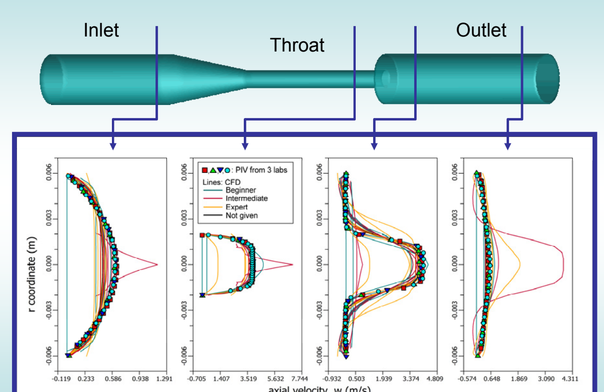


Centerline Axial Velocity: CFD vs. PIV
(Interpolated onto fixed Z coordinates)

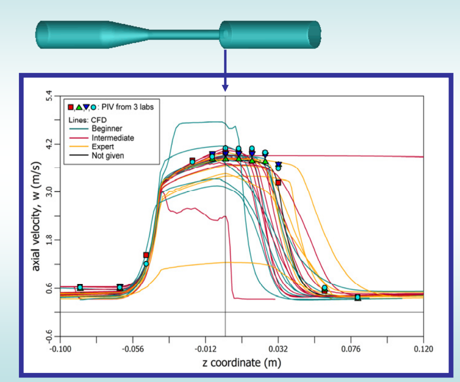


Results: CFD vs. PIV, Sudden Expansion, Re = 3500

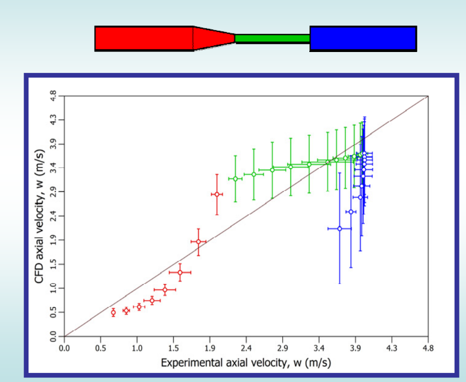
Axial Velocity Profiles



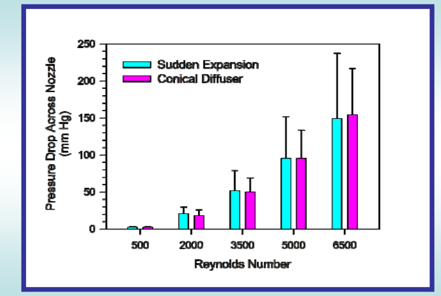
Axial Velocity Along Centerline



Centerline Axial Velocity: CFD vs. PIV
(Interpolated onto fixed Z coordinates)

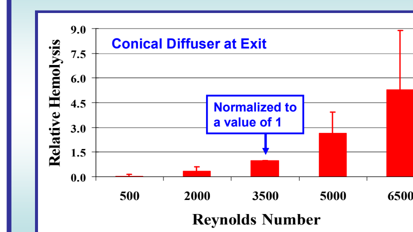


Results: CFD Pressure Drop



Relative Hemolysis Predictions

Hemolysis Predictions from 11 groups



Conclusions

- Preliminary analysis of the 28 CFD interlaboratory data sets revealed the variety in decisions for performing simulations (solver code, 2D vs. 3D, grid generation, element shape, turbulence modeling, boundary conditions, etc.). While the benchmark nozzle is a simple geometry, the range of tested laminar, transitional, and turbulent flows still requires careful modeling decisions.
- At both Re = 500 and 3500, CFD-predicted centerline axial velocities were similar in the entry region and conical contraction, but considerable scatter was observed in the throat region and downstream of the sudden expansion (variability = 65 to 75%). In comparison, variability in the downstream PIV experimental centerline velocities measured in three laboratories was < 20%.
- Self-ascribed experience did not seem to affect the "goodness of fit" when comparing axial centerline velocity predicted by CFD to that measured by PIV.
- Pressure drop and predicted hemolysis in the CFD simulations increased similarly with Re number, with variability around 60% at high flow rates.
- Further analysis and collaboration is needed to develop guidelines to assist users in making modeling decisions.

Future Work

- Complete analysis of CFD and experimental data for the Nozzle model
- CFD study on Benchmark Model #2: Ventricular Assist Device (Late 2009)
- Blood damage testing in three laboratories for comparison to CFD predictions
- Development of FDA Guidance Document on use of CFD in medical device evaluation
- **We encourage you to submit design ideas for benchmark flow models for further testing**

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