Computational Fluid Dynamics for Medical Device Design and Evaluation: Are We There Yet?

Medical device analysis using Computational Fluid Dynamics (CFD) is not yet a required component of premarket notifications and applications submitted to the US FDA. Nevertheless, CFD has already established itself as a pervasive tool in cardiovascular hemodynamics research. This is evident by numerous papers published in CVET and other journals in the field and/or presented at major conferences and workshops that employ CFD to analyze flow patterns and draw conclusions about the performance of a variety of medical devices. In fact CFD is so widespread that is quite common these days to hear in conference presentations or read in journal papers plain references to CFD or “standard CFD” as the method employed to carry out the simulations, with little or no details provided about the specific computational techniques and/or other modeling assumptions. It is, thus, believed by many that CFD is a mature, off-the-shelf, and universally-accepted technology that can be used with little or no scrutiny to guide the design and evaluation of medical devices and make decisions that could ultimately impact patient health and quality of life.

It is because of the prevalence and wide-spread use of CFD in the community that the results presented in the recent study by Stewart *et al.*⁷ are so striking and noteworthy. This paper summarizes the findings of a computational inter-laboratory study, conducted by industry, academia and the US FDA, which employed as a test case a relatively simple, idealized model of a medical device: a cylindrical nozzle with a conical collector and sudden expansion on either side. Complexities commonly encountered in real-life medical devices, like 3D complex geometries with moving boundaries, fluid structure interaction, flow pulsatility, small gaps, *etc.*, were not part of this study. Yet the model problem was cleverly selected to provide a challenging test bed for evaluating the performance of CFD codes across a range of flow regimes, spanning laminar to transitional flows, in a geometry where a host of complex flow phenomena associated with blood damage in real-life medical devices arise—e.g. favorable and adverse pressure gradients, flow separation, intense shear layers and transition to turbulence. The computational phase of the project was

accompanied by Particle Image Velocimetry (PIV) experiments conducted by three laboratories concurrently with the computational studies, which provided benchmark data for validating the predictive capabilities of the various CFD codes. As shown by Stewart *et al.*,⁷ none of the 28 CFD simulations contributed by an international group of researchers, of varying degree of experience and expertise, yielded results that agreed well with the experimental data. What is even more disheartening, however, is the fact that essentially all simulations showed considerable scatter and variation not only from the experimental data but also from each other.

Even though the relatively few computational approaches included in this study by no means represent the state-of-the-art in numerical simulation of cardiovascular hemodynamics today (see Sotiropoulos *et al.*⁶ for a recent review of computational methods for cardiovascular flows), the results do serve to challenge the notion about the universality of the so-called “standard CFD” discussed above. Not all CFD codes are created equal and the details of their inner workings as well as other details pertaining to a specific simulation do matter a great deal in the end.⁷ Issues like the order of accuracy of spatial and temporal discretization techniques, the iterative solvers and schemes used to achieve convergence and the level of convergence achieved in a given simulation, the quality of the mesh and the sensitivity of the solver to mesh quality and density, the treatment of inflow, outflow, and wall boundaries, and, last but not least, the manner via which laminar-to-turbulence transition and fully turbulent flow regimes are handled by the code are of great importance and deserve attention and extensive discussion in CFD studies. Furthermore, this study also underscores the need for continuous, systematic, and thorough experimental validation of CFD codes that will be used one day to assess safety in medical device submissions to the FDA.

A common feature of all CFD models presented in Stewart *et al.*⁷ is the use of statistical turbulence modeling approaches, i.e. the Reynolds-averaged Navier–Stokes equations closed with one or two equation turbulence models. Such models, expedient as they are from a computational standpoint, have been

developed and calibrated for simulating transition mainly in aeronautical applications and, as clearly demonstrated in Stewart *et al.*,⁷ are not adequate for predicting transitional cardiovascular flows. Another inherent limitation of RANS models is that they can only yield information about the Reynolds stresses in the flow, which are a mathematical artifact of the Reynolds averaging and do not represent the mechanical loads experienced by blood cells.³ The instantaneous viscous stresses provide a more relevant metric for quantifying blood damage and hemolysis potential³ but predicting these stresses numerically may only be possible using direct numerical simulation (DNS). While DNS of pulsatile, transitional flows at physiologic conditions are now well within reach both for stenotic flows⁵ and for fluid–structure interaction simulations of prosthetic heart valves,^{1,2} such simulations remain today computationally too demanding to be used in routine engineering calculations for assessing safety in medical device submissions to the FDA. Yet such level of numerical resolution may after all be required if CFD is to emerge as a reliable tool in medical device design and evaluation. The good news though is that: (1) the largest Reynolds numbers encountered in cardiovascular flow applications ($<10^4$) are low enough to make DNS a feasible alternative; and (2) the exponential growth of computing power coupled with major advances in numerical algorithms for cardiovascular flows⁶ have brought us close to the day when routine, affordable DNS and/or large-eddy simulations (LES) for medical device applications will be possible. Coupled with advances in medical imaging modalities, computer science, and immersive virtual reality,^{4,8} high resolution CFD validated with *in vitro* and *in vivo* experimental data is thus destined to evolve in the near future into a powerful and reliable framework for developing, testing, and accelerating the regulatory approval process of a range of medical devices.

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