Medical Xpress

New models for validating computational simulations of blood flow and damage in medical devices

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A collaborative effort to improve the development of computational fluid dynamics (CFD) methodologies for evaluating "blood contacting" medical devices—receiving the Willem Kollf Award for top abstract at the ASAIO 2016 conference—is now reported in full in the *ASAIO Journal*.

The study describes two benchmark models evaluated by more than 20 independent groups using CFD techniques to predict blood flow patterns in circulatory support devices and other medical devices that come into contact with blood. The project is an important step toward using CFD to develop safer and more effective medical devices, according to the report by Richard Malinauskas, PhD, of the US Food and Drug Administration and colleagues.

Key Step Forward in Applying CFD Techniques to Medical Devices

The international project to develop benchmark medical device flow models for CFD validation was presented at the ASAIO's 62nd annual conference, where it received the Top Abstract Award for 2016. The full report has now been posted on the website of the ASAIO Journal.

The FDA initiative sought to develop standardized methods for validating CFD simulations and predictions of blood damage for the

safety evaluation of medical devices. Models of blood flow through typical device components were tested at multiple laboratories to provide robust experimental data on blood flow velocities and pressures, as well as on the likely damage to red blood cells (hemolysis).

The results showed some differences between simulated and measured blood flow values, and identified specific regions of the device models where discrepancies tended to occur. Under six test conditions in the blood pump model, 57 percent of the CFD simulation predictions of blood flow pressures were within one standard deviation of the measured values.

Dr. Malinauskas and co-authors note that only 37 percent of the 52 total CFD submissions for the two medical device models contained hemolysis predictions, indicating that more work is needed to develop widely-acceptable and credible hemolysis solvers. The collaborative project aided in the development of an FDA Guidance Document on factors to consider when reporting computational studies in medical device regulatory submissions to the FDA.

The study will be published in the March-April issue of *ASAIO Journal* and highlighted with a podcast and accompanying commentary. The paper will also be featured in an online journal collection of Top Abstract Award papers from each annual ASAIO conference.

More information: Richard A. Malinauskas et al. FDA Benchmark Medical Device Flow Models for CFD Validation, *ASAIO Journal* (2017). DOI: 10.1097/MAT.0000000000000499

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