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Comparison of Interlaboratory CFD Simulations of the FDA Benchmark Blood Pump Model

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Purpose of Study: Computational fluid dynamics (CFD) is widely used in the design and assessment of medical devices. To be relied upon to inform regulatory decisions, however, CFD credibility must be established by performing verification and validation. Toward this end, FDA and academic collaborators established a benchmark centrifugal blood pump model for CFD validation. An open interlaboratory study was initiated in which participants from around the world submitted 24 CFD simulations of the pump. Here, we report the complete results of the interlaboratory study including comparisons of the CFD predictions with experimental measurements.

Methods Used: Participants simulated 6 pump conditions with flow rates ranging from 2.5–7.0 L/min and rotational speeds of 2500–3500 rpm. We performed detailed analyses of the anonymized results at three test conditions: (1) 2.5 L/min at 3500 rpm, (2) 6.0 L/min at 2500 rpm, and (3) 6.0 L/min at 3500 rpm. We specifically analyzed predictions of the pump pressure head, velocity distributions throughout the pump, and hemolysis.

Summary of Results: Participants submitted results from 14 steady-state and 10 transient simulations using a wide range of CFD solvers, mesh resolutions, and turbulence models. In general, there was not a strong correlation between mesh resolution or turbulence model with CFD accuracy. Most CFD predictions of the pump pressure head were within two standard deviations of the mean experimental data, except at the 6.0 L/min, 2500 rpm condition for which only 16 of 23 submissions were within this range. Unsteady simulations of the velocity field generally agreed better with the experiments within the rotor region, but showed little advantage over steady simulations in the outlet diffuser. Hemolysis predictions varied widely for the 8 participants who submitted results. This study provides insight into the accuracy of CFD simulations of mechanical circulatory support devices from a wide range of users in the medical device community.

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MCS Devices Induce Abnormal Interactions Between Red Blood Cells (RBCs) and Leukocytes

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Originality: Using flow cytometry, we observed potentially pathologic RBC-leukocyte interactions in human blood perfused through MCS devices. This novel finding may provide insight about mechanisms important to better understand hemocompatibility of these devices.

Methods: In 4 separate experiments, we perfused freshly collected human whole blood through bench-top circulatory loops (150 ml each) connected to either a HeartMate II (HMII), HeartMate 3 (HM3), or CentriMag (CM) at 4L/min of flow against a delta pressure of 80 mmHg for 6h. Samples were collected before perfusion (baseline), at the start (Time 0), and every hour thereafter. RBCs were stained with PE-anti-human CD235a mAb, and leukocytes with APCanti-human CD45 mAb. We defined (1) a CD235a+ singular gate (SG), representing RBCs and their association with leukocyte microparticles, and (2) an aggregate cell gate (ACG) representing larger RBC-leukocyte aggregates.

Results: Upon perfusion, the CD235a+CD45+ events in SG and ACG gradually increased. Compared to CM, HMII and HM3 samples had significantly higher events in SG (Kruskal-Wallis test; p=0.038); and in SG+ACG (p=0.015). At t= 6 h, the statistical significance diminished in the SG, but the difference remained significant with SG+ACG (p=0.039) (Fig.1). HMII events trended higher than HM3, but the difference was not significant.

Conclusion: These observations suggest that MCS-induced blood trauma induces adhesion of leukocyte microparticles to RBCs and the formation of RBC-leukocyte aggregates. Such information may afford further insight of hemocompatibility and the mechanisms of MCS-associated blood trauma.

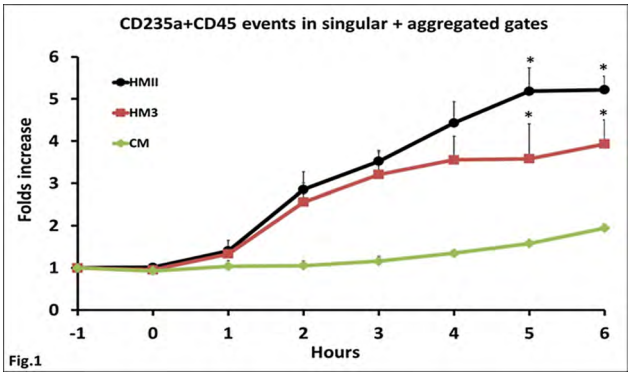

Fig.1