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Introduction: The Medical Device Innovation Consortium (MDIC) is a public-private partnership that was established between the U.S. Food and Drug Administration (FDA) and the medical device industry in 2012. The goal of the MDIC is to improve the processes for development, assessment, and review of new medical technologies. Computational modeling has been recognized as a regulatory science tool that can help to accomplish this mission. One of the focus areas of the MDIC computational modeling community is the in silico evaluation of mechanical blood damage, i.e. hemolysis and thrombosis. The final evaluation of mechanical blood damage presented to regulatory authorities is typically based on bench and/or animal testing. The opportunity for computational modeling to augment safety evidence led to the formation of the MDIC Blood Damage Working Group (MDIC BD WG) in 2014. One goal of this working group is to generate data using experimental systems that can assess blood damage under a variety of conditions and to provide measures of precision and multi-laboratory reproducibility. Another goal is to evaluate and/or develop computational models that can predict blood damage. To examine the various simulation methodologies for predicting blood damage, computational modelers will develop in silico models that replicate the bench testing and then compare the model outputs with the experimental results. The computational modelers and experimentalists are working in close collaboration to ensure that all data required to develop and validate the computational models will be available.

Materials and Methods: The experimental systems enable the controlled generation and quantification of blood damage in vitro. The hemolysis test system (Figure 1) applies a rapid pressure force onto a plunger that drives a blood sample through a needle or orifice. An Eppendorf tube placed downstream of the flow model collects the blood sample for quantification of hemolysis as plasma-free hemoglobin. The thrombosis test system (Figure 2) uses a recirculating flow loop with serial stenotic sections to continually expose a fixed quantity of blood to a non-uniform shear environment. Thrombus formation on the walls of the tubing is visually characterized for adhesion location and thrombus size.

Results and Discussion: Preliminary experiments with both test systems have been conducted to refine the test systems, test conditions, and analytic methods. These experiments form the input data for the computational modeling round robin, which is currently underway. However, the test systems have not been finalized and further modification may be required based on the experimental and computational results.

Translational Impact: Upon completion, the MDIC BD WG will publish experimental details, protocols, and results, along with computational modeling approaches and comparative analyses, in peer-reviewed scientific journals, conferences, and/or other venues (e.g., a public database) to ensure scientific rigor, industry awareness, and broad access.

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