The Living Heart: A Clinically Relevant Fluid-Structural Model to Evaluate Medical Devices
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Introduction: The role of computational modeling in the evaluation of medical devices has grown significantly in recent years. In 2016, the FDA released a guidance for reporting on computational modeling in medical device submissions, further encouraging the use of computational studies for device development, evaluation, and verification and validation. As computational models become more sophisticated, a clinically relevant model of the human heart is increasingly possible, which may help computational models in accurate evaluation of cardiovascular devices. This study aims to model clinically relevant cardiovascular flow using the Living Heart Human Model as a baseline for future use in evaluating novel medical devices.

Materials and Methods: The SIMULIA Living Heart Human Model (LHHM), as provided by Dassault Systemes, is used to simulate the full electromechanical system of a beating heart throughout the cardiac cycle. The electrophysiology and solid mechanics of the heart are modeled using Abaqus FEA (Dassault Systemes). The fluid dynamics are modeled using STAR-CCM+ (Siemens PLM), using a turbulence flow (k-ε) model and blood modeled as a non-Newtonian single-phase fluid. Fluid-structure interaction is coupled using the co-simulation capabilities of STAR-CCM+ and Abaqus FEA. The electromechanical model of the heart provides the moving wall boundary conditions in the fluid simulation through fluid-structural interaction (FSI), with flow pressure conditions derived from physiological conditions of a healthy adult. The hemodynamics of the left ventricle and aorta are of primary interest, as these regions are most relevant to cardiovascular medical devices.

Results and Discussion: The electromechanical simulations performed demonstrated good agreement between left ventricle (LV) volumetric change and published values. Additionally, the calibrated lumped parameter model values of pressure in the ventricles and atria fall within established ranges for a healthy human heart. The change in left ventricle diameters through transverse cross-sections of the ventricle was in the range of 30-70%, depending on location, corresponding to published values in the range of 30-60%. Furthermore, the change in mitral valve diameters throughout a pulsation cycle were conservative relative to published values, indicating a conservative effect on the flow environment. The structural time-dependent deformation is used to control the wall dynamics of the fluid flow model. This enables us to obtain rich detail of the complex flow patterns and hemodynamics of the healthy LV and aortic flow.

Figure 1. The Living Heart Human Model in diastole (left) and systole (right). The entire heart is shown here for visualization purposes; the structural deformations used to drive the fluid calculations in this study included the left ventricle only.

Translational Impact: This study is an initial step towards performing more clinically relevant simulations of cardiovascular flow in a realistic heart model, including simulations that incorporate novel medical devices. Future steps involve: strong, two-way FSI coupling, the use of lumped parameter models for co-simulation of 0D and 3D models to obtain physiologically accurate flow boundary conditions, inclusion of suspended blood elements to track damage, and patient specific models. These computational tools can eventually be used to evaluate potential device designs, predict hemodynamic and blood damage performance of novel devices, provide highly resolved data to supplement regulatory submissions, and aid in patient-specific surgical planning.

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