In-silico Prediction of Bioprosthetic Heart Valve Function with In-vivo Operation

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Introduction: Bioprosthetic heart valves (BHV) remain the design of choice for most clinical applications due to their low thrombogenicity and excellent hemodynamics. However, durability remains to be the central issue hindering BHV designs and even marginal improvements to the current lifespan of 10-15 years can have significant clinical impacts. To address this limitation, we have developed a novel, mechanism-based mathematical/numerical model of BHV responses to long-term valve operation via a permanent set mechanism [1-2]. In the present study, we demonstrate that this model can be used to predict BHV evolving geometry, microstructural, and material property changes under simulated in-vivo conditions.

Materials and Methods: We developed and utilized a computational pipeline based on a detailed structural model of the permanent set mechanism [1,3]. Simulations were conducted using the Edwards Perimount valve geometry and collagen fiber distributions aligned with the circumference direction with the standard deviation of 30°. There are four main stages in simulating permanent set: 1) modeling the initial state composed of BHV geometry, material properties and mapped collagen fiber architecture, 2) quasi-static simulation of the BHV using finite element method under physiological transvalvular pressure, 3) updating the material properties for the next time step, and 4) updating the BHV geometry for the next time step. Steps 2-4 are repeated for each subsequent time step until we reach the prechosen maximum number of cardiac cycles.

Results and Discussion: The key result here is that permanent set induces major changes in all parameters, especially in the belly region, center of the free edge, and the regions near the commissures where the leaflets make contact. These regions are also the most common regions of failure in BHVs. Due to the change in reference configuration, the collagen fibers in these regions recruit more quickly and may even held in a constant extended state. This can have dramatic consequences on the likelihood of failure of these collagen fibers due to their low extensibility and could be a major failure mechanism. We note too that these effects slow down after 20 million cycles and nearly cease after 50 million cycles. This important structural response allows us to predict the final reference geometry of the BHV. Because collagen fibers have high rates of failure after being extended by 7-8%, more evenly distributing the stresses can reduce this mode of failure. Thus, by optimizing the initial BHV design so that the peak stress is minimal in the configuration after permanent set has seized, we can potentially improve the durability of BHVs by minimizing the load on the collagen fibers (Figure 1).

Figure 1. Predicted shape of the valve leaflet at 50 million cycles for different starting geometries. Note that here we show the max strains, where a simple extension of the leaflet (Design B) produces smaller permanent set strains, which could lead to lower stress concentrations and potentially extended durability.

Translational Impact: We have developed a time-dependent framework for the simulation of BHVs under long-term cyclic loading. This framework utilizes the predictive mechanism based constitutive model for the permanent set effect in exogenously crosslinked soft tissues. We observed that most of these effects occur by ~50 million cycles and result in changes in leaflet geometry with cycling (Figure 1). What is novel here is our ability to predict permanent set effects on BHV geometry in-silico and develop means to compensate for it in a design setting.