A NOVEL MODEL FOR HEART VALVE BIOMATERIAL FATIGUE RESPONSE

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Introduction: For the foreseeable future, bioprosthetic heart valves (BHV) fabricated from xenograft biomaterials will remain the dominant replacement prosthetic valve design. However, BHV durability remains limited to 10-15 years. Failure is usually the result of leaflet structural deterioration mediated by fatigue and/or tissue mineralization. Thus, independent of valve design specifics (e.g. standard stented valve, percutaneous delivery), the development of novel biomaterials with improved durability remains an important clinical goal. This represents a unique cardiovascular engineering challenge resulting from the extreme valvular mechanical demands that occur with blood contact. In the present study a fatigue damage model (FDM) based on our structural constitutive model was developed for heart valve tissues.

Materials and Methods: We utilized the structural modeling approach (Fig. 1) to formulate a novel approach, utilizing our extensive experience with BHV tissues to develop a FDM for the time evolving (i.e. over many thousands of cycles, not beat-to-beat) BHV mechanical properties. One major focus will be to delineate differences in bulk mechanical properties due to tissue-level dimensional and structural changes (i.e. due to permanent set like effects resulting from repeated loading) and the intrinsic changes in the constituent fibers (i.e. changes in effective fiber modulus). Following damage theory convention, we utilized a normalized scalar damage metric variable D(t), which ranges from 0 for new (virgin) material to 1 for completely damage (failed). We assumed D(t) follows first-order kinetics, which can be changed to higher order kinetics as needed. Thus, changes in the effective collagen fiber stiffness η are modeled using $\eta(t) = \eta_0 [1 - D(t)]$, $D(t) = 1 - \exp(-\alpha t)$, where α is the rate constant (approximately equal to the inverse half-life) and t is the implant time. Similar expressions were developed for each model parameter; this normalized approach will allow the time constants for each variable to be directly compared. The choice of an exponential rate function is supported by available data on porcine stentless GLUT fixed BHV, where first-order kinetics appear an appropriate model. The resulting time-evolving strain energy function is expressed as

$$\mathbf{S}(\mathbf{E}) = \frac{\partial \Psi(\mathbf{E})}{\partial \mathbf{E}} = \int_{-\pi/2}^{-\pi/2} R(\theta)\, S_{ens}[E_{ens}(\theta)](\mathbf{N}\otimes\mathbf{N})\,d\theta + \mu(\mathbf{I} - \mathbf{C}^{-1}/C_{33}^{-1}) \quad (1)$$

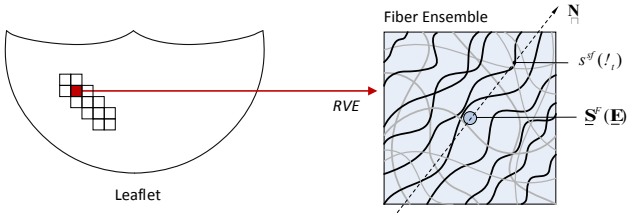

Figure 1 – A schematic of how the BHV leaflet tissue is idealized using RVEs (~1 mm^3 in volume) that contain fibers imbedded in a compliant matrix that represents contribution of all non-fibrous components.

Results and Discussion: Time course changes obtained for D(t) for each parameter was obtained using extensive existing data from our lab [1-5]. From these results we were able to quantify, separately, the rates of change in effective fiber stiffness from the changes in fiber splay R(θ) and collagen fiber recruitment $\Gamma(E_s)$ and their net contributions to tissue level behavior and durability.

Conclusions: We have developed a detailed biomechanical model for the key ECM components (collagen, elastin, GAGs) individually respond as a biomaterial in-vivo, and to simulate changes in their structure and mechanical function at the tissue level. This model is currently being implemented in a finite element framework for the purposes of BHV life prediction.

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References: [1] Sun W, Sacks MS, Sellaro TL, Slaughter WS, Scott MJ. Journal Biomechanical Engineering. 2003;125:372-80. [2] Sun W, Sacks M, Fulchiero G, Lovekamp J, Vyavahare N, Scott M. J Biomed Mater Res. 004;69A:658-69. [3] Wells SM, Sacks MS. Transactions of the Sixth World Biomaterials Congress. 2000;2:794. [4] Wells SM, Sacks MS. Biomaterials. 2002;23:2389-99. [5] Wells SM, Sellaro T, Sacks MS. 2005;26:2611-9.