

Simulation of Heart Valve Biomaterial Fatigue

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Seminar on September 22, 2015 at 11:00 am in 2004 Black

Seminar host: Ming-Chen Hsu

Abstract

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. In the present work we utilized a meso-scale structural constitutive modeling approach to formulate a novel approach. We focus on a FDM for the time evolving (i.e. over many thousands of cycles, not beat-to-beat) BHV mechanical properties. One major focus was 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). Conventional fatigue damage approaches are clearly not applicable to BHV tissues due to their mechanical and structural complexity. Thus, we will start with the structural modeling approach laid out in the previous section 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 was delineation of the 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 (1), we will utilize a normalized scalar damage metric variable $D(t)$, which ranges from 0 for new (virgin) material to 1 for completely damage (failed). We will initially assume $D(t)$ follows first-order kinetics, which can be changed to higher order kinetics as needed. Since similar expressions can be developed for each model parameter, this normalized approach will allow the time constants for each variable to be directly compared. As a modification from our original formulation, we note that exogenous chemical cross-links present at the collagen molecular level induce a great increase in effective fiber stiffness. We were able to quantify, separately, the rates of change in effective fiber stiffness from the changes in fiber splay and collagen fiber recruitment and their net contributions to tissue level behavior and durability. The model was then implemented utilized in ABAQUS to simulate the permanent set effects previously observed by our lab. We were able to simulate permanent set effects at the organ level (i.e. prosthetic device). This fact was important in of itself, as changes in prosthetic device level will affect leaflet stress distributions. We are currently extending the model to understand how 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.

Professor **Michael Sacks** is the W. A. "Tex" Moncrief, Jr. Simulation-Based Engineering Science Chair and a world authority on cardiovascular biomechanics. His research focuses on the quantification and modeling of the structure-mechanical properties of native and engineered cardiovascular soft tissues. He is a leading international authority on the mechanical behavior and function of the native and replacement heart valves. He is also active in the biomechanics of engineered tissues, and in understanding the in-vitro and in-vivo remodeling processes from a functional biomechanical perspective. Dr. Sacks is currently director of the ICES Center for Cardiovascular Simulation and Professor of Biomedical Engineering. His recognitions include Fellow of ASME, Biomedical Engineering Society, American Institute for Medical and Biological Engineering, Van C. Mow Medal of American Society for Mechanical Engineers Bioengineering Division and Chancellor's Distinguished Research Award from University of Pittsburgh.

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