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CARDIOVASCULAR INNOVATION

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- Improve reliability of devices
- Develop innovative solutions that might otherwise have been dismissed
- Accelerate the entire device development process

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IMPROVED OR REDUCED PHYSICAL TESTING

Laser Cut Nitinol Tubing Fatigue Coupon: FEA's Role in Design, Testing, and Endurance Limit Determination

Nitinol medical device implants made from laser cut tubing (i.e. stents, valve structures, etc...) often require a fatigue assessment, which makes determining the material fatigue properties necessary. Towards the goal of determining the strain based endurance limit of **medical grade super-elastic Nitinol tubing**, a coupon was designed and evaluated via FEA using Abaqus software, produced via laser cutting, shape setting, and electro-polishing processes, and then **fatigue tested to 10 million cycles**.

Extensive use of FEA was made to both design the coupon, but also to determine the strain versus alternating displacement amplitude for the coupon. Error due to dimensional tolerances was also quantified with FEA. The coupons where then **fatigue tested in a 37C temperature water bath at alternating strain levels** ranging from 0.75% to 4.0% at zero mean strain. Sample replication was greater than 90%, and the median alternating strain fatigue limit was determined via two methods.

Confidence and reliability with maximum likelihood statistics are used to present a strain based endurance limit for the material.

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Courtesy of Stephen J. Forcucci, MSME, DC Devices, Inc., 2014 SIMULIA Community Conference

MOVE TOWARDS OPTIMIZATION: IMPROVE DESIGNS BY TAKING INTO ACCOUNT TOLERANCES AND VARIATIONS IN DEVICE PARAMETERS

Evaluate Medical Device Design Robustness by Combining Statistical and Probabilistic Tools with Finite Element Analysis

Finite Element Analysis (FEA) has been widely used to **analyze the in vivo structural response of implantable medical devices** and assess device performance, reliability and durability. Take stents for example. Several characteristics like radial force, peak stresses and strains and fatigue safety factors can be determined using these modeling techniques.

As all physical phenomena are stochastic, all design parameters have built-in variability. On the other hand, stents are typically modeled with nominal dimensions and material properties. Minimum and maximum dimensions are used in certain instances, while other dimensional variances are often not considered. In addition, the **in vivo boundary conditions also vary widely across patient population**.

Therefore, in order to obtain a robust design, **parameter variations and their influence on device performance need to be understood**. Probabilistic analysis techniques like Monte Carlo sampling combined with FEA are helpful in understanding these stochastic processes and in determining probability of failure and design reliability.

In this study, FEA using Abaqus is combined with statistical and probabilistic analysis using Isight to demonstrate how these techniques work together to evaluate the robustness of medical device designs.

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Courtesy of Atul Gupta[1], Patrick Koch[2], and Xiangyi (Cheryl) Liu[2], 1-Medtronic Inc., 2-Dassault Systèmes Simulia Corp.,
2012 SIMULIA Community Conference

MOVE TOWARDS OPTIMIZATION: IMPROVE DESIGNS BY TAKING INTO ACCOUNT TOLERANCES AND VARIATIONS IN DEVICE PARAMETERS

Parameterization and Optimization of Balloon Expandable Stent

Vascular stents are deployed in the blocked arteries to restore the passage of the blood flow. By acting as a mechanical scaffold, stenting is effective in preventing and treating coronary occlusion. Commercial markets expect the product to have better recoil without compromising flexibility. The current **stent design analysis and optimization** activity is aimed at improving recoil, flexibility and reducing foreshortening.

Conventional design analysis procedures wouldn't be able to tackle simultaneously the **problems of recoil and foreshortening**, and often it is time consuming. Whereas the numerical simulations and optimization approach discussed in this paper can be comfortably used to **optimize stent design, considering conflicting performance metrics** (recoil, foreshortening).

This paper discusses the use of such advanced techniques to solve stent design problems. The paper would cover the essence of Finite Element Analysis, FE Model Parameterization and Optimization. Finite element modeling (FEM) and analysis with SIMULIA is used to **estimate stress distribution in the stent**. Various design parameters are identified for carrying out optimization using Isight. Different stent designs are generated using the FE model parameterization tools in MeshWorks MORPHER. Optimization based on parametric FE model is carried out to identify best design.

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Courtesy of Karthik Shankaran and Senthil Karrupaswamy, Detroit Engineered Products (DEP) Inc., 2012 SIMULIA Community Conference

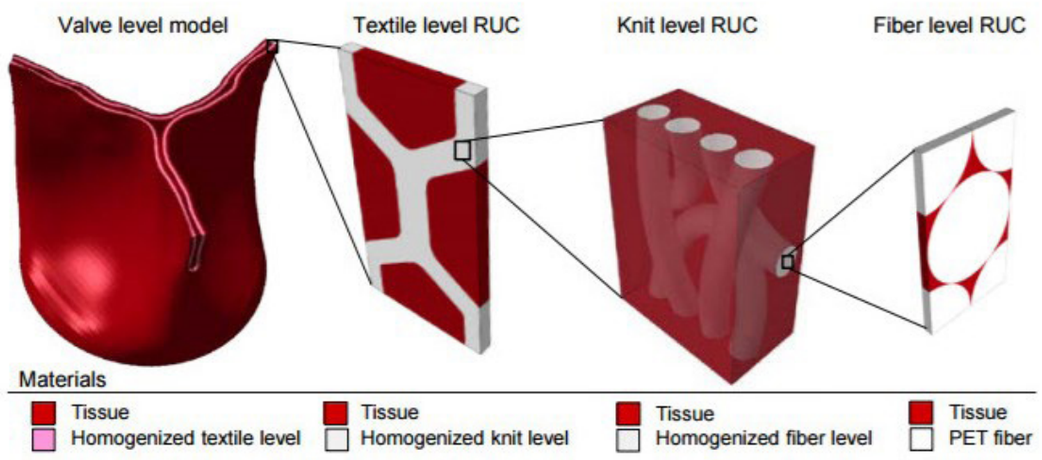
ADVANCED MULTISCALE SIMULATION METHODS FOR NEW MEDICAL DEVICES

Multi-Scale Modelling of Textile Reinforced Tissue Engineered Heart Valves

Transcatheter aortic valve implantation of fibrin-based tissue engineered heart valves with a tubular leaflet construct have been developed as an alternative to invasive traditional surgical heart valve implantation, but currently need reinforcement to withstand pressures found in the aortic position. To increase valve strength, a **PET textile reinforcement has been introduced to the fibrin scaffold**.

However, care must be taken when using a textile reinforcement. Increasing reinforcement may increase the strength, but also increases stiffness which can interfere with the functionality of the valve, prohibiting full valve closure. In order to predict the behavior of the valve, improve design, and eventually optimize valve performance by tailoring the textile reinforcement, a **4-tiered hierarchical multi-scale modelling framework** has been created.

The model includes an individual **fiber scale model, two textile-level models, and a full heart valve model**. Geometry generation based on microscopic images of the composite will be discussed, along with application of boundary conditions and loading application. Fitting the various material models based on homogenization of the smaller scale will be demonstrated. Finally, experimental validation and characterization at various scales will be discussed.



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2016 Science in the Age of Experience

ADD MORE PHYSICS AS NEEDED

Modeling Hemodynamics with Abaqus/CFD Steady State Solver: FDA Benchmark Nozzle Model

Understanding the blood flow dynamics (hemodynamics) and the fluid forces exerted on the blood by implantable medical devices and predicting blood damage is an intricate part of interventional medical device design. Computational techniques such as **Computational Fluid Dynamics (CFD)** are increasingly being used as a tool for describing complex hemodynamics and calculating the fluid forces such as pressure and shear stress. However, this technique is challenged by the lack of standardized methods for validation and verification of the results.

In an effort to standardize the process, the **FDA made an initiative in 2008 to engage the Medical Device/CFD Community worldwide** to participate in an open challenge that involves CFD computation of blood flow and its experimental validation with Particle Image Velocimetry (PIV) on a benchmark nozzle model. The goal of the CFD phase of the study was to understand the limitations of CFD, understand the variability that arises due to choice of software or solver, and the influence of user expertise level and diverse modeling and meshing techniques. This information would then be employed to identify best practices and define the critical techniques necessary to achieve credible results. Though a variety of software packages have been used by 28 different groups from 6 countries, Abaqus/CFD has not been publicly applied in this challenge.

In this study we aim to **assess the performance of Abaqus/CFD in modeling hemodynamics** using the FDA Benchmark Nozzle model.

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Courtesy of Santanu Chandra, PhD[1], Richard Swift, PhD, PE[1], and Ramji Kamakoti, PhD[2], 1-MED Institute Inc., 2-Dassault Systèmes, 2014 SIMULIA Community Conference

BENEFIT FROM ACCURATE ORGAN REPRESENTATIONS

Partial LVAD Restores Ventricular Outputs and Normalizes LV, but not RV Stress Distributions in the Acutely Failing Heart in silico

Purpose

Heart failure is a worldwide epidemic that is unlikely to change as the population ages and life expectancy increases. We sought to detail significant recent improvements to the Dassault Systèmes **Living Heart Model (LHM)** and use the LHM to compute left ventricular (LV) and right ventricular (RV) myofiber stress distributions under the following 4 conditions: (1) normal cardiac function; (2) acute left heart failure (ALHF); (3) ALHF treated using an LV assist device (LVAD) flow rate of 2 L/min; and (4) ALHF treated using an LVAD flow rate of 4.5 L/min.

Methods and Results

Incorporating improved **systolic myocardial material properties in the LHM** resulted in its ability to simulate the Frank-Starling law of the heart. We decreased myocardial contractility in the LV myocardium so that LV ejection fraction decreased from 56% to 28%. This caused mean LV end diastolic (ED) stress to increase to 508% of normal, mean LV end systolic (ES) stress to increase to 113% of normal, mean RV ED stress to decrease to 94% of normal and RV ES to increase to 570% of normal. When ALHF in the model was treated with an LVAD flow rate of 4.5 L/min, most stress results normalized. Mean LV ED stress became 85% of normal, mean LV ES stress became 109% of normal and mean RV ED stress became 95% of normal. However, mean RV ES stress improved less dramatically (to 342% of normal values).

Conclusions

These simulations strongly suggest that an LVAD is effective in normalizing LV stresses but not RV stresses that become elevated as a result of ALHF.

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Courtesy of Kevin L. Sack, Brian Baillargeon, Gabriel Acevedo-Bolton, Martin Genet, Nuno Rebelo, Ellen Kuhl, Liviu Klein, Georg M. Weiselthaler, Daniel Burkhoff, Thomas Franz, Julius M. Guccione, IJAO ©2016

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