APPROVED STORY

SOFTWARE MODELING PROVIDES A NEW TOOL FOR UNDERSTANDING SOFT TISSUE, FIBROATHEROMA AND STENT DESIGN BEHAVIOR.

MSC.Patran modeling software enables simulation providing otherwise unobtainable knowledge of soft tissue and stent behavior.

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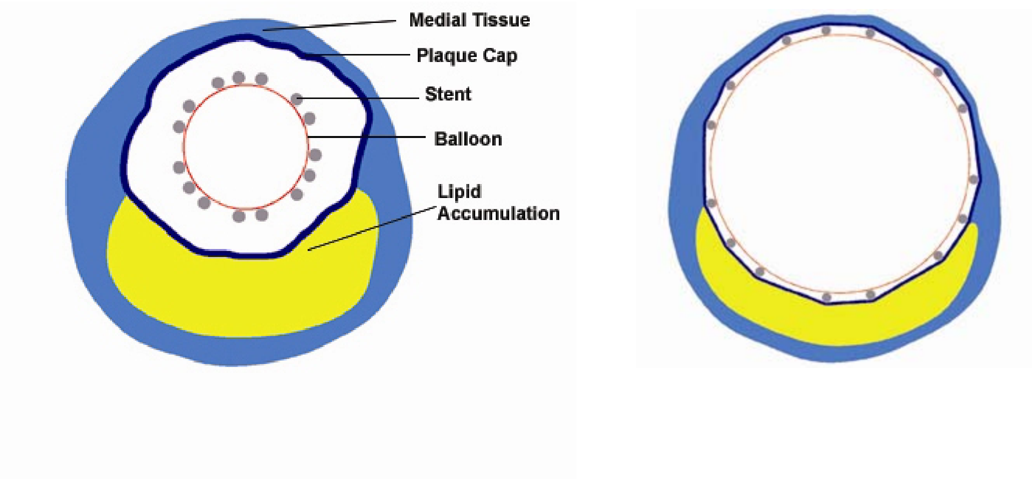
Contrary to historical schools of thought, all heart attacks are not caused by the gradual narrowing of one or more a coronary artery segments or the slow progressive development of flow-limiting coronary lesions. An unstable lesion, which has been classified as a fibroatheroma, can rupture due to unexpected triggers and, according to recent research by the medical community, may be the cause of many heart attacks. Testing interventional therapies for treating a fibroatheroma can be very expensive and time consuming because creating a bench top model of arterial soft tissue with multiple constituents presents a challenge. However, finite element modeling (FEM) technologies, such as MSC.Patran, enable computer modeling of soft tissues and interventional devices and allow medical device design engineers to evaluate new concepts in treating a human fibroatheroma.

According to Christopher Feezor, engineer, Guidant Corporation, “It can be challenging to conceptualize how to construct a real-world bench top model that will allow us to evaluate whether a device that we develop is having a positive or negative impact on a fibroatheroma. Finite element modeling of the soft tissue constituents that are characteristic of a fibroatheroma provides both a tool which will facilitate the development of an bench top model and a mechanism by which we can evaluate the performance of any device or concept that we imagine."



Models generated with MSC.Patran of 2D cross section of artery, stent and angioplasty balloon. Image on right is before expansion of angioplasty balloon and image on left is after expansion.

Computational modeling of arterial soft tissue is an inherently complex task that can be simplified by making educated assumptions about the material, the geometry or both. For example, the complex nonlinear material behavior of the arterial tissue may be represented as a linear elastic material based on assumptions about the physiological loading range of interest. However, educated assumptions can affect the breadth to which the results can apply. Ensuring the accuracy of results over a larger dynamic range of responses, may require addressing more complex soft tissue behavior, such as nonlinear elasticity or hyperelasticity, tissue plasticity or viscoelastic effects, such as creep (sustained deformation under constant load) and stress relaxation (diminishing load under a constant deformation). Adding an interventional device to the analysis serves to increase the complexity of the model because of the intricate behavior of the device and the complications associated with the introduction of contact between the tissue and the device. Despite the application of any simplifying assumptions about the response of the tissue or the behavior of the device, analyzing the interaction between the arterial soft tissue and the device is complex and requires nonlinear analysis.

Geometry Creation

Creating geometry for soft tissue models requires more than importing the geometry of a well-defined mechanical part from CAD software. Typically soft tissue and arterial geometry evolve from images taken with one of many medical imaging systems. Methodologies for extracting data on the geometric structure and morphology of soft tissue employed by Guidant's New Ventures Group are based on one of many medical imaging modalities such as intravascular ultrasound (IVUS), optical coherence tomography (OCT) or magnetic resonance imaging (MRI). These systems yield 2-dimensional images, 3-dimensional data sets or a series of 2-dimensional images taken along a particular axis, which can be reconstructed into 3-dimensional data sets.

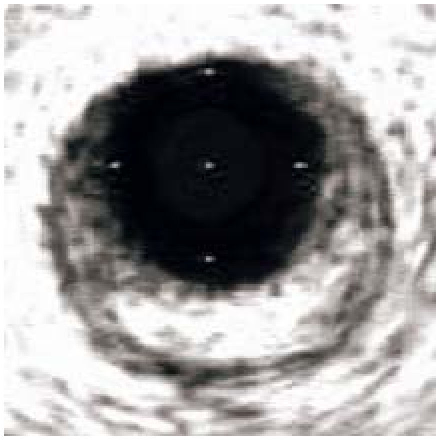


Image from intravascular ultrasound (IVUS) is one of several medical imaging modalities used to begin the process of developing a soft tissue engineering model.

The data generated by any of these imaging modalities typically takes the form of a bitmap image and can be processed in one of many paint or image processing applications. The image analysis capabilities that exist within some commercial image processing packages developed for the art and graphics industry, such as Adobe Photoshop, have an unexpected application in the bioengineering arena. These commercial packages can provide the foundation for creating geometric models of soft tissue based on the data sets exported from a medical imaging system. “These software applications allow us to isolate features or highlight particular constituents within the wall of the coronary artery that will play an important roll in the final geometric model,” says Mr. Feezor.

If soft tissue models are destined for engineering analysis, the bitmap images must be converted into a vector-based geometry through a process that is generally referred to as tracing. Tracing coaxes data into a form that MSC.Patran can recognize. A host of applications and techniques from both the academic and commercial communities exist to facilitate this operation and each accomplishes this task in a different manner. While the automatic tracing capabilities may be limited in some commercially available graphics applications, such as Adobe Illustrator, they can provide some simple tools for handling this conversion by allowing a user to trace highlighted features within a bitmap image. When working with a few images in a 2D space, a manual tracing process is not very cumbersome; however, as the data sets and analyses are extended to 3D or the number of 2D images increases, automated processes must be explored. Mr. Feezor said, “Looking at some of the software employed to accomplish these tasks, it is easy to see that some aspects of soft tissue mechanics is a blend of the artistic and engineering world. We begin with medical images of the free-form structures characteristic of soft tissues and reconstruct them as geometric objects for engineering analysis.”

With the conversion of tissue components of interest into a vector-based data set or solid model, the geometry can be imported into MSC.Patran where the more common activities associated with finite element analysis begin. The models are divided into pieces to address various objectives of the simulation. Mr. Feezor said, “Once the geometry is opened in MSC.Patran, we modify the basic arterial geometry, breaking it into pieces to apply specific boundary conditions or to define specific interactions. Essentially, we proceed with the standard model construction process as if we were building a model of any other mechanical device. In the world of soft tissue mechanics, we just begin with a lot more free-form shapes, which presents a challenge when working with many traditional CAD or modeling software packages. That’s why a significant amount of preparatory work prior to importing our geometry into MSC.Patran is required.”

With a soft tissue model in place, the focus of model development shifts to the device with which the tissue is to interact. Ultimately, the objectives of the finite element analysis drive the origin of device geometry. It can originate from a CAD model, extracted from a previous analysis or simply created on the fly in MSC.Patran to perform a preliminary evaluation of a new concept or interaction. In the case of modeling the interaction between arterial soft tissue and an interventional device, the analysis may demand device geometry as simple as a cross-section of an angioplasty balloon or a stent in order to perform a particular 2D analysis. Regardless of its source, a certain amount of processing is typically required to extract the specific device geometry that is pertinent to the analysis and, at times, generating the appropriate geometry data can become an arduous and time consuming task.

An embedded capability in MSC.Patran allows a user to create scripts to automate a variety of operations. In the current example provided by Guidant, a series of proprietary PCL routines have been written to generate stent geometries for use in a variety of analyses. The automation provided by these custom PCL scripts offers Guidant the capability to gain the most understanding of how a device will impact the tissue by allowing them to efficiently evaluate a number of different stent parameters. Mr. Feezor said, “In order to create a matrix of information, we model many different stent parameters to evaluate how the stents are impacting the tissue. The capability to write PCL scripts to perform some of these processes automatically is a very beneficial feature of MSC.Patran, because there just isn’t enough time to manually step through the processes required to perform certain analyses and create device models with every design perturbation.”

Material Properties of Soft Tissue

Many different material models of soft tissues have been developed in past years. These models include simple linear elastic materials, hyperelastic materials, viscoelastic materials and even poroelastic materials. As with most soft tissue analyses, compromises must be made based on an evaluation of costs versus benefits. For example, a linear elastic representation of arterial tissue is both simple and computationally less expensive than a hyperelastic model. Fundamentally, a linear elastic material requires a single number for a complete material definition. However, this representation may not adequately represent the response of an artery over the entire range of deformations that occur during delivery of an interventional device. A hyperelastic model or a material model with plasticity may provide a better representation of arterial behavior over the entire range of deformation to which an artery may be subjected during device delivery, but these material structures are computationally more expensive. In addition, increasing the complexity of the material model also adds an additional cost when considering the expenses associated with developing and running more complex experiments to define multiple material parameters or coefficients.

Loading

Defining loads can be an overwhelmingly complex task if all of the loads that affect the arterial tissue and an interventional device, such as a stent, are taken into account. Typically, an analysis may be simplified by strategically selecting the loads that dominate the response. If intuition and experience do not provide enough justification for including or excluding a particular load, small parametric studies often help determine which loads are important to include in the final analysis. Nonetheless, the simplest starting point is to look at the physical problem being modeled and identify the important loading conditions for each component.

Focusing on the delivery of a stent, there are three primary components, an angioplasty balloon, a stent and the coronary artery, interacting at the site of a coronary lesion when a stent is deployed. Reviewing the dynamics of an interventional procedure suggests that the dominant loads that need to be considered are the arterial blood pressure applied to the lumen of the coronary artery, a balloon inflation pressure and contact interactions between the various components. In the end, expansion of the coronary artery beyond what is generated by a blood pressure load occurs as a passive response to the expansion of a stent, which is facilitated by the inflation of an angioplasty balloon.

Mr. Feezor said, “We are still working to expand the breadth of information that we acquire from the soft tissue analyses that we perform because there are still a number of questions that remain to be answered. How do various tissue constituents influence the stent expansion process? Will we get more expansion here because of a particular lipid constituent in the artery? Or, will it expand less because of a calcified region of the artery? A variety of model enhancements that we have in the works will allow us to get at many of these answers.”