

Modeling Implantable Medical Device-Tissue Interactions

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Abstract

As an efficient and powerful analytical tool, finite element analysis (FEA) modeling has been used successfully to resolve many challenging issues facing the implantable medical device industry. This paper summarizes some of the modeling demands for evaluating the mechanical interactions between implantable medical devices and tissues. These interactions provide insight into both product safety and function of device such as cardiac pacing and defibrillation leads. There exists a gap between the capabilities of generic FEA software like ABAQUS and the tissue engineering applications, because the current tissue characterizations and studies are more academic in nature and primarily addressed by researchers in the bioengineering sector. In this paper, the tissue engineering technologies will be reviewed briefly. Discussions will cover the development request for advanced FEA algorithms and capabilities to meet the ever-increasing medical device industrial requirements.

Background

FEA is an attractive tool to implantable medical device manufacturers because it is often quite difficult to reproduce the service conditions devices encounter *in vivo* within a test environment. It is very difficult and expensive to test devices *in vivo*. It is extremely difficult to understand the behavior of physiological materials, and it often requires the use of complex constitutive models to predict their behavior. This paper will focus on some of the material property characteristics of cardiovascular tissue, in particular, heart tissue and blood vessels and some of the difficulties associated with representing these characteristics within commercial and custom FEA codes.

The first thing to understand about physiological tissue (Fung, 1993) is that material properties are different for different species and that they are quite variable within species, as well. In addition, these properties are dependent upon age, gender, disease state, and time within the cardiac cycle. Heart muscle tissue behavior consists of a passive and an active or contractile response (McCulloch, 2000). As a ventricle is filling with blood, for example, the material response is only passive, but is highly non-linear in nature. The active response of the tissue, which occurs when individual muscle cells contract in response to electrical activation, is also highly nonlinear and time dependent in nature. The contraction pattern of cardiac muscle cells is critical to the efficiency of the pumping action of the heart and is dependent upon the origin and propagation pattern of the electrical impulses that trigger the mechanical responses. Both mechanical and electrical wave propagation behavior are highly dependent upon the orientation of the cardiac muscle fibers that vary across the heart wall which are arranged, approximately, in a helical fashion. Depending on the specific modeling objective, one or more of these properties must be represented within an FEA model simulating heart-device interaction.

Another class of device-tissue interaction involves the blood vessels. There has been much research conducted to determine the material properties and constitutive models to describe the *in vivo* mechanical properties of blood vessels (Fung, 1993). Approximately 70% of vessel walls consist of water. The other main components are smooth muscle, elastin and collagen. An important determinant of the mechanical behavior of a vessel is the relative amounts of each component contained in the wall. Veins tend to be thinner than arteries and also contain less elastin. Both vein and arterial properties vary along the cardiovascular tree because the percentage of the wall constituents changes as a function of vessel diameter. In general, however, vessel properties are orthotropic, nonlinear and viscoelastic in nature. Arteries are naturally in a state of radial distension and longitudinal stretch. When an artery is excised and released, its length decreases 30-40%. Care must be taken that for any vessel, the physiological range of the wall's stress strain curve is captured in the material model. Another issue to take into account is the fact that vessels are always tethered to surrounding tissues, which will tend to inhibit longitudinal stretch more than radial stretch. The evaluation of the residual stress effects, as observed in experimental tests, is very challenging when applied to FEA.

Challenges

There is a tremendous amount of information available to describe many aspects of the mechanical behavior of cardiovascular tissue (Fung, 1993). There are also many areas where more empirical information is needed to address some of the issues that medical device companies face. More research is needed in the area of diseased and healthy *in vivo* human heart tissue and vein properties and anatomies, for example. More information is also needed regarding the boundary conditions associated with various device-tissue interactions. However, even if all aspects of tissue behavior and device-tissue interaction were perfectly understood, it would be extremely difficult, if not impossible, to incorporate this understanding into workable FEA models.

It is quite difficult to import and mesh actual physiological geometries into FEA pre-processors. As it gets easier to capture actual human anatomies, due to their variability, it would be useful to be able to do this in a timely fashion. A first step might be to add various file formats to the pre-processors and improve surfacing capabilities of cloud point data. Another problem, possibly the

major difficulty, is how to incorporate the complex material and motion behavior of the physiological tissues? Presently, it is fairly simple to approximate the heart tissue behavior as a homogenous hyperelastic material, however that does ignore the active component of the tissue, and is not a truly accurate portrayal of the passive component, either. New elements may need to be created (McCullough, 2000), possibly using ABAQUS user element UEL features to accomplish this goal, as well as more user-friendly, generalized material model creation options using ABAQUS user material UMAT features. Possibly, the addition of a physiological material module would be an option. Finally, the issue of the actual interaction of the device and tissue itself is extremely complex. For example, the interaction may involve penetration of the device into the tissue or else may involve a more ambiguous interaction or tissue failure criteria that are difficult to represent.

To solve some of the problems described above, customized programs may be developed. Some problems experienced with custom codes may include: difficulty of adding device interaction to such models, the non-generalized nature or specificity of these codes, potential issues regarding the robustness of the code, contact intensive computational convergence, and various issues associated with difficulty in transferring, learning and adapting such codes.

Presently, it is quite difficult to simulate device and tissue interaction. There is still research that needs to be done to fully understand tissue behavior and the actual *in vivo* interaction that occurs between devices and tissue. There are also many difficulties associated with attempts made to incorporate physiological and anatomical information into existing commercial FEA software codes and custom codes, as well. The benefits to medical device manufacturers and more importantly to patients needing these devices would be immense, resulting in better products reaching patients in a more timely fashion and at a lower cost.

Opportunities

There is a market demand for device-tissue interaction features or capabilities in commercial FEA packages. Databases of various *in vivo* and *in vitro* test data in the academic and industrial sectors have been accumulated for over three decades. The commercial FEA software companies are in the best position to investigate the feasibility of adding generic FEA capabilities based on existing scientific research and material data sets.

References

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