

Finite Element Analysis (FEA) role in the design of bio-medical devices

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FEA is accepted by a growing number of companies developing medical devices as a method to predict the device performance. Moreover, regulatory authorities such as the American FDA usually require FEA as part of the product approval process. However, only a limited number of companies are using FEA as an every day design tool. Typical analysis of implantable medical devices is challenging due to the highly nonlinear nature of the physical problem. The sources of nonlinearities are large geometric changes, contact and material behavior. The current presentation will show three real world cases in which ABAQUS, a commercial FEA package, was used to simulate the structural behavior of medical products at various operational stages. The cases shown are: coronary stent by EXISTENT, Vena Cava filter by RMT (Raphael Medical Technologies) and angioplasty scoring catheter by ANGIOSCORE Inc. In each case the modeling techniques and analysis approach will be discussed. The examples show how FEA can be used to simulate the manufacturing, assembly, deployment and fatigue life of the product. Various aspects of integrating FEA in the design work-flow such as product optimization, need of physical experiments and computation time will be highlighted.

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