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StandardGuide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading[1]

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INTRODUCTION

This guide establishes general requirements and considerations for using finite element analysis techniques for the numerical simulation of metallic stents subjected to uniform radial loading. These stents are intended for use within the human vascular system.

1. Scope

1.1 *Purpose*—This guide establishes general requirements and considerations for the development of finite element models used in the evaluation of the performance of a metallic vascular stent design under uniform radial loading. Suggested criteria are provided for evaluating the typical cases of metallic stents under uniform radially oriented and pulsatile loading. Recommended procedures for checking and validating the finite element model(s) are provided as a means to assess the model and analysis results. Finally, the recommended content of an engineering report covering the mechanical simulations is presented.

1.2 *Limits:*

1.2.1 This guide is limited in discussion to the finite element structural analysis of metallic stents of the following types:

1.2.1.1 Plastically deformable metal stents.

1.2.1.2 Self-expanding metal stents.

1.2.1.3 Plastically deformable metal portions of covered stents.

1.2.1.4 Metal portions of self-expanding covered metal stents.

1.2.2 The emphasis of the techniques described in this guide is intended for both elasto-plastic materials such as stainless steel, and superelastic materials such as nitinol. Unique concerns associated with stents designed for shape memory behavior are not addressed within this guide.

1.2.3 This guide does not consider changes to possible time varying conditions or different loadings related to vascular remodeling.

1.2.4 This guide is restricted to cases that involve the application of uniform radially oriented loading.

1.2.5 This guide does not provide guidance in the application or interpretation of FEA in determining fatigue life.

1.2.6 This guide is not intended to include complete descriptions of the finite element method, nor its theoretical basis and formulation.

1.3 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

2. Terminology

2.1 *Definitions:*

2.1.1 *balloon expandable stent, n*—a stent that is expanded at the treatment site by a balloon catheter. The purpose of the balloon is to plastically deform the stent material such that the stent remains expanded after the deflation of the balloon.

2.1.2 *conceptual model, n*—model produced by analyzing and observing the physical system of interest composed of mathematical models and equations representing that system.

2.1.3 *computational model, n*—implementation of a conceptual model in software.

2.1.4 *crimp, v*—to secure the stent on a delivery system by radially compressing the stent into a delivery device such as a catheter or onto an expanding delivery device such as a balloon.

2.1.5 *delivery system, n*—a mechanical system that is used to deliver and deploy a stent at a target site.

2.1.6 *elasto-plastic material, n*—a material behavioral model that exhibits elastic behavior (recoverable) up to its yield point and plastic behavior (irrecoverable) above its yield point.

2.1.7 *endurance limit, n*—stress or strain level at which the material is considered to have "infinite" life.

2.1.8 *finite element analysis (FEA), n*—a general purpose numerical technique.

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2.1.8.1 *Discussion*—In this guide, the structural continuum is discretized into regions known as elements, in which the mechanical behavior is defined. Continuity is enforced at the vertices of the elements where node points are defined. The mechanical behavior of the continuum is then defined according to mathematical expressions of physical laws at the node points. This results in the definition of a set of simultaneous equations that are solved for state variables from which such important quantities as displacements, stresses, and strains can be derived.

2.1.9 *geometrical nonlinearity, n*—a type of nonlinearity related to structural deformation where the relation between strain and displacement are not linearly proportional.

2.1.10 *linear elastic material, n*—a material in which the stress resulting from an applied force is directly proportional to the corresponding strain it produces. Thus, linear elastic materials do not retain any stress or strain when all external loads and boundary conditions are removed and all deformations are recoverable.

2.1.11 *model calibration, n*—the process through which the parameters of a computational model are checked or adjusted to create a model with the proper measure of accuracy.

2.1.12 *model validation, n*—the process of determining the degree to which a computational model accurately represents the real world behavior it was intended to represent. It is an evaluation of the fidelity of the computational model and the real world.

2.1.13 *model verification, n*—the process of assessing that the implementation of the computational model accurately represents the engineer's conceptual model and of the solution to the model. It is an evaluation of the fidelity of the conceptual model and the computational model.

2.1.14 *nonlinear material, n*—a material behavior in which the stress resulting from an applied external load is not directly proportional to the induced strain.

2.1.15 *permanent deformation, n*—residual or irrecoverable strain and deformation in a structure after all loads and boundary conditions are removed.

2.1.16 *plasticity, n*—material behavior characteristic where permanent or irrecoverable deformation remains when the external loading is removed.

2.1.17 *pulsatile, adj*—recurring alternate increase and decrease of a quantity such as the pressure that would occur in an artery.

2.1.18 *self-expanding stent, n*—a stent that expands at the treatment site without mechanical assistance. The material typically used for the stent has the ability to return either partially or fully to a previous size and shape and remain expanded after the delivery system is removed.

2.1.19 *solution sensitivity, n*—a measure of the relative change in solution results caused by changing one or more parameters in a computational model.

2.1.20 *stent, n*—a tubular structure that is permanently implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency. For the purposes of this guide, a stent is metallic and may be covered by a coating, synthetic textile, or tissue graft material.

3. Summary of Practice

3.1 This guide addresses the use of the finite element method for structural analysis of metallic vascular stents under various types of simulated uniform radial loading. The purpose of a structural analysis of the stent is to determine such quantities as the displacements, stresses, and strains within a device resulting from external loading. This includes stresses and strains potentially due, but not limited, to manufacturing processes, to delivery in the body, and to pulsatile loading *in vivo*.

3.2 Current United States government guidelines (**1**)[2] recommend structural analysis of a proposed device under physiologically appropriate loading. The analysis technique discussed in this guide is restricted to the finite element analysis technique (**2-5**), although other techniques may be equally suitable for the required analysis.

3.3 Prior to the finalization of a device design, rigorous experimental testing is recommended to complement the analyses performed. During these tests, care should be taken to represent the loading and boundary support conditions consistent with those used not only in the finite element analysis and experimental tests but also those expected in clinical use. Experimental tests should be carefully monitored. Any behavior that was not captured by the numerical simulation should be identified and evaluated for its effect on safety and reliability.

4. Significance and Use

4.1 Finite element analysis is a valuable method for evaluating the performance of metallic stents and in quantifying quantities such as internal stresses, internal strains, and deformation patterns due to applied external loads and boundary conditions. Many times an analysis is performed to correlate to and plan experimental tests. A finite element analysis is especially valuable in determining quantities that cannot be readily measured.

5. Overall Technical Approach

5.1 The application of finite element analysis is intended for the development of a quantifiable level of confidence in the stent design. The overall approach described in this guide focuses on the development of a systematic technical approach to using the finite element analysis technique to evaluate stent performance. The basic process includes:

5.1.1 Detailed definition of the geometry of the stent being evaluated.

5.1.2 The determination, quantification and validation of the important mechanical material properties.

5.1.3 Selection of the appropriate finite element tools and programs to ensure effective and reliable representations of the stent being evaluated.

[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.