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Standard Guide 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.

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

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.

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

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

5.1.4 Selection and validation of the appropriate finite element model and type of element(s) used.

5.1.5 Calibration, validation, and verification of model input, parameters for the numerical simulation, solution results and comparison to experimental tests.

5.1.6 Definition of all important loading steps.

5.1.7 Selection and application of appropriate boundary conditions, such as symmetry.

5.1.8 Effective and proper application of the finite element analysis program for the intended evaluation.

5.1.9 The generation and interpretation of results to perform an effective evaluation.

5.1.10 Documentation of the analysis, including all supporting citations and references, analysis methodology, and assumptions, results interpretation, and overall stent design evaluation.

6. Input Data

6.1 Finite element analysis is a numerical technique use for simulating the mechanical response of structures. A finite element structural analysis requires input to numerically represent geometric and material information, as well as mechanical support and loading conditions. Two important parts of any finite element analysis is the proper representation of material properties and the definition of load cases and boundary conditions. These must reflect the entire process and performance history and environment of the device. The load history should include all relevant manufacturing loads and all steps of the intended clinical end use of the device. If all steps are not included, the reason for the omission should be described.

6.1.1 *Geometric Data:*

6.1.1.1 Finite element models are based on a geometric representation of the device being studied. The source of the details of the geometry can be drawings, computer aided design (CAD) and solid models, preliminary sketches, or any other source consistent with defining the device model geometry.

6.1.1.2 Finite element modeling is used extensively in the design phase of product development, many times before any prototyping has occurred. As such, models are often based on preliminary designs from CAD drawings. Changes associated with the progress of the development of the design and manufacturing processes should be addressed in the finite element model to accurately represent actual stent geometry.

6.1.1.3 Stent geometry is often determined by measuring and inspecting representative samples of stents that have undergone all processing steps prior to insertion in the body. This processing may include, but is not limited to, cleaning, polishing, and crimping. Most evaluations use the nominal dimensions for the evaluation. It is also most appropriate to consider the possible effects of variability in dimensions or design parameters within the finite element analysis, such that the manner in which the variability influence performance and safety.

6.1.2 *Preliminary Models*—During the preliminary design phase, detailed geometric and/or material data may not be warranted and/or readily available. In these cases, it is appropriate to use initial design geometries and material data from standard engineering references. The results of such simulations will be considered preliminary results.

6.1.3 *Material Property Tests:*

6.1.3.1 Mechanical properties of the material should be determined from rigorous experimental testing of the material that has undergone all pertinent manufacturing processes including finishing, cleaning, and sterilization, if appropriate. The mechanical material properties for a finite element analysis are most often determined through tensile testing of the material. During the test, load and displacement data is to be collected to define the entire material curve. All relevant hysteresis and/or temperature effects on the material response must be included.

6.1.3.2 When testing for material properties, extreme care should be taken to ensure accurate measurements using suitable fixturing and appropriately calibrated devices for measuring both load and displacement.

6.1.3.3 If warranted by the material, the material curve(s) should be measured at the appropriate temperature(s) of the intended use. The effects of temperature on the material response are extremely critical for superelastic alloys. Differences in the material behavior in tension and compression should also be considered along with any load history dependent tension/compression asymmetry phenomena or work hardening of the material.

6.1.4 *Material Property Validation:*

6.1.4.1 The material mechanical property values must be converted into a format and form consistent with the finite element representation.

6.1.4.2 Validation tests should be performed to validate the material model used in the analysis. The effects of the test specimen size or shape (tube, wire, sheet) must be considered in applying the material model to the validation model.

6.1.4.3 A material validation test could include the determination of the load-displacement behavior of a finite element model of a simple tensile test. For example, a model is first created of a simple geometric specimen of material using the element type for which the validation is being performed. The geometry and number of elements in the validation model should be sufficient to enable the definition of proper loading and constraints, yet simple enough to isolate the key load-displacement behavior for correlation. A validation simulation is performed using the appropriate tensile loading and constraint conditions. The deformations at various loading steps are recorded, plotted, and then compared to appropriate tensile test data. The correlation between the tensile test data and the finite element validation model results should be sufficient to provide confidence that the finite element representation of the material is an accurate representation of the actual material over its range of use.

6.1.4.4 Since it is possible for material behavior to change during the course of stent processing, it is important that an appropriate and accurate mathematical model of the material behavior be used for all simulations of the device. The

characterization of the mechanical properties of the material should be sufficient to fully represent the behavior of the device in all steps of manufacturing, delivery, and the end use conditions. This may include variations in the properties as a function of process dependent temperatures. In addition, the mechanical material properties for a given simulation should consider the effects of all processing steps up to and including the step being evaluated.

6.1.4.5 The results of the material validation should be included in the report to present the comparison between the experimental and analytical model.

6.1.5 *Loading Conditions:*

6.1.5.1 To represent the behavior of the stent as it undergoes the various stages of its design life, sets of loading steps and conditions are defined. These conditions are in the form of imposed deformations and/or forces and pressures that are applied to the device or portions of the device.

6.1.5.2 The loading must represent that expected and defined. It must not induce any forces or deformations inconsistent with experimental observations or the design intent.

6.1.5.3 This guide is restricted to cases involving uniform radial loading. Such loading may occur during stent manufacturing, stent delivery, or cyclic loading from placement within a pulsating vessel.

6.1.5.4 If possible, the stent deformation from the finite element analysis should be compared with experimental tests. For example, while crimping or loading the stent into a delivery system, the stent should be examined for such responses as strut buckling or twisting, which may later serve as part of the verification of the finite element analysis.

6.1.5.5 Some structural behavior, such as buckling, may be sensitive to mesh size, element type, and spatial distribution. In this case, experimental results can be used to aid in the selection of a suitable mesh size and distribution.

6.1.6 *Loading History:*

6.1.6.1 The loading history of the device, from the initial stages of manufacturing, through deployment and *in vivo* behavior should be analyzed during the evaluation of the stent. It may be necessary to include the effects of residual stresses related to crimping associated with mounting the stent onto the delivery system. Self-expanding stents may require the consideration of a series of mandrel expansion(s) and heat treatment(s) associated with the manufacturing and sterilization processes.

6.1.6.2 The appropriate temperature dependent material representation(s) should be used throughout the loading history of the device. This is an important consideration, especially for devices manufactured from superelastic alloys.

6.1.6.3 In situations where the stent is intended to be radially over-sized relative to the unstented vessel, the mean stress carried by the stent is determined from the sizing protocol associated with the device. For a balloon expandable stent, an estimate for the mean load applied to the stent can be considered to be the balloon expansion for the maximum recommended over-sizing in the largest vessel diameter indicated in the instructions for clinical use (IFU). In the case of a self-expanding stent, an estimate for the mean load can be considered as the difference between the fully expanded stent and the minimum recommended vascular diameter according to the instructions for clinical use (IFU).

6.1.6.4 For self-expanding stents, particularly those that may exhibit appreciable hysteresis (for example, nitinol—**(6 and 7)**), the analysis should consider whether the use of a "touch-up" (that is, "kissing," "post-deployment," etc.) balloon expansion is recommended in the IFU.

6.1.7 *Radial Load Definition:*

6.1.7.1 Uniform radial load used to simulate the expansion or contraction of the stent diameter is often approximated by an expanding/contracting "rigid" or "compliant" cylindrical balloon. The balloon interacts with the inner or outer surface of the stent to induce a corresponding change in the stent diameter. The radial loading is assumed to be uniformly applied around the circumference of the stent.

6.1.7.2 For conditions related to changes in diameter, the change in diameter is defined as the difference between the diameter of the stent in one state and the diameter of the stent in a second state. These states can refer to any of the diametric measurements during the load history. The diametric measurement is most often chosen to be the outside diameter (OD).

$$\Delta D = D_1 - D_2 \tag{1}$$

6.1.7.3 Load conditions related to changes in diameter are commonly expressed as a percentage:

$$\Delta D\% = \frac{D_1 - D_2}{D_1} \times 100\,\% \tag{2}$$

6.1.7.4 The required radial loading should account for the effects of potential over-sizing and/or over-inflation, whether intended or inadvertent.

6.1.7.5 Cyclic radial loading can be defined using "displacement-based" or "pressure-based" approaches.

6.1.7.6 Under implant conditions, the cyclic load imposed on a stent originates from pulsatile motion of the heart. Its magnitude is determined by the pulsatile expansion of the vessel at the intended treatment site. In the absence of clinical or experimental test data, type and magnitude of the pulsatile loading applied to the stent may be determined from estimates of the pulsatile expansion of the intended implantation site during the cardiac cycle.

6.1.7.7 Other estimates of pulsatile loading may be used with adequate justification. For example, the change in diameter under physiological loading may be determined by performance of *in vitro* testing using compliant tubing with a specified pressure load or limit on the displacement range.

6.1.8 *Design Loading Conditions:*

6.1.8.1 If a single stent is intended for use over a range of vessel diameters, analysis should be performed to ensure that the conditions considered in the analysis are consistent with those of the most severe conditions.

6.1.8.2 The intent of the loading definition is to impose a set of conditions that will result in maximum response for the device evaluation. The process used to select these conditions should be described.

6.1.9 *Special Loading Considerations:*

6.1.9.1 During loading or manufacturing processes where residual (irrecoverable) stresses are important, additional steps may be required in the analysis. For example, residual stresses

from the loading applied during stent mounting to the deployment device may significantly affect subsequent behavior. In this case, the residual stresses need to be accounted for and propagated through any subsequent analyses.

6.1.9.2 In loading or manufacturing processes where heat treatment steps are applied to relieve residual stress, these steps and their resulting influence on the device should be included in the analysis. Appropriate material characteristics under heat treatment must be considered.

6.1.9.3 Spring back (recoil) of the stent upon release of the balloon may also be accounted for in additional analysis steps whereby all loads are appropriately reduced or removed. Recoil upon balloon deflation should include removal of the internal balloon load and application of the external vessel load. This should also be verified to be consistent with experimental observations.

6.1.10 *Boundary Conditions and Symmetry:*

6.1.10.1 A set of displacement boundary conditions should be applied to the model to prevent rigid body motion in the model. Care should be taken in the application of these conditions so as not to over-constrain the model and develop fictitious internal forces.

6.1.10.2 Boundary conditions may require considering the possibility that portions of the model may come in contact with surfaces that provide a form of restraint for the model. Special finite elements or methods can be used to simulate the contact regions.

6.1.10.3 Many stent designs are composed of repeating patterns that exhibit symmetry. Under circumferentially symmetric uniform radial or pulsatile load, this repetition may allow for the use of a submodel of the stent to be analyzed while enforcing appropriate conditions of symmetry on truncated boundaries. Results should be reviewed to ensure that all boundary conditions have been applied correctly and are consistent with experimental observations.

7. Analysis

7.1 The material, loading and boundary condition input parameters described above are intended for use in combination with the stent geometry within a numerical analysis framework to create a finite element model.

7.2 *Software Requirements:*

7.2.1 The analysis and modeling system(s), programs or software used for the finite element model creation and analysis should be capable of simulating the type(s) of behavior required to fully characterize the stent. Any assumptions used to create or analyze a finite element model must not be as a result of circumventing the lack of a significant analysis capability of a finite element analysis program, unless proper justification is provided to support the assumptions and/or simplifications. This is of particular concern in analyses of structures with either nonlinear material or nonlinear geometry or both.

7.2.2 The analysis and modeling system(s) must be of a quality that would generally be considered to be "state of the art commercial grade." Whether or not the program or software is available commercially, it must have the general characteristics that it is based on sound engineering principles and established procedures, it must be validated for use via a set of established and documented validation problems, and must have an error reporting procedure. Any errors and/or limitations in the program or software must be communicated to users of the software on a timely and regular basis. Errors detected in the software must be addressed in accordance with established procedures.

7.3 *Finite Element Model Requirements:*

7.3.1 It is common practice to import CAD drawings into an FEA package for the model geometry; however, equally valid models can also be built directly within the preprocessors included with most FEA packages. In building the finite element model, certain geometric details may be omitted from the stent geometry shown in the CAD drawing if it is determined that they are not relevant to the intended analysis. An explanation shall be given for any omitted geometric details.

7.3.2 While building the finite element model, checks should be performed to ensure that no necessary geometric features are smaller than the smallest desired finite element edge length. Furthermore, the element type and size should be chosen such that they allow for an accurate representation of the intended geometry and the behavior of the device consistent with experimental or clinical observations.

7.4 *Selection of Finite Elements:*

7.4.1 The finite element type selected for the model must have the fundamental capabilities to represent the type(s) of behavior needed from the model, without significant limitations. If a nonlinear behavior is expected, the element formulation must have the ability to represent the nonlinearity without any significant limitations. The type of element used should be selected based on the stent geometry and the expected loading. The element should be able to fully support all material and loading characterizations required in the simulation. The size and shape of all finite elements in the model must be such that they are able to represent the expected behavior without any numerical limitations or complications.

7.4.2 Most finite element programs offer a variety of elements that serve as potential candidates for a stent finite element model. One dimensional bending elements (bars, beams), two dimensional planar elements (plane stress/plane strain elements), two dimensional bending elements (plates, shells) and three dimensional elements (hexahedral "bricks," pentahedral "wedges," tetrahedral "prisms") are all potentially suitable for representing stent behavior when used appropriately.

7.4.3 In selecting an element, all assumptions and governing equations used in the element formulation should be considered. For example, two dimensional planar elements with a plane strain formulation are generally considered inappropriate for stent designs having low thickness to length and width to length ratios. In this case, beam or three dimensional brick elements would be more appropriate.

7.4.4 Care must also be taken to ensure that the chosen element can be adequately applied within the simulation. This can be done by considering the required material and geometric behavior in combination with the applied external loads and boundary conditions. For example, if the stent geometry and

loading occur within a single plane and the deformations are small, a two dimensional analysis with infinitesimal strain assumptions may be considered appropriate. Otherwise, a three-dimensional model with finite strain/large deformation capabilities may be necessary.

7.4.5 The chosen element must be capable of accurately representing the deformation pattern and stress/strain distribution expected in the stent. For example, if a nonlinear stress/strain distribution or concentration is expected in a particular dimensional direction of the stent, then the element, or a collection of elements in that direction, must possess the ability to accurately characterize the nonlinear distribution or concentration in this region.

7.4.6 The element formulation should be considered when modeling stent details such as struts, curves and thickness. Elements with simple formulations are typically more numerically efficient than complex, higher order elements. However, a simpler element formulation often requires more elements to be used. Creating efficient models requires intimate knowledge of the solution algorithms and formulations used within the particular finite element code.

7.5 *Finite Element Mesh Requirements:*

7.5.1 The finite element mesh can be created using automatic meshing (free meshing), manual meshing (mapped meshing), or a combination of the two techniques. The overriding consideration is that the type, the size, and the shape of the elements used must be able to represent the expected behavior without significant numerical limitation or complication.

7.5.2 For all models, basic validation and verification checks should be used to ensure the proper representation of the device and that a sufficient number of nodes and elements are used to represent the geometry and deformation patterns of interest.

7.5.3 The number and spacing of nodes (that is, mesh density) should be consistent with the type of element used and the type of result desired. Traditionally, this may be demonstrated with what is referred to as a mesh density study, whereby a series of models with increasing complexity (increasing number of degrees of freedom) are used to demonstrate solution convergence. In this fashion, the error associated with subsequent models can be ascertained.

7.5.4 Prior to performing the final analysis with the finite element model, a series of checks should be performed to verify that there are no coincident nodes or duplicate elements, or ill-shaped (bad aspect ratio) elements in the model and that the mesh is continuous. Proper connectivity within the finite element model and to any associated devices necessary to complete the simulation should also be verified.

7.6 *Analysis and Results:*

7.6.1 All analyses should include a representation of all relevant loading steps and boundary conditions.

7.6.2 In all cases, the finite element results should be examined to determine if the model boundary conditions and applied loads have been appropriately defined in the analysis and properly represent the behavior being analyzed. The predicted deformation patterns should also be examined and compared to any available experimental data. If possible an experimental validation should be performed.

7.6.3 The evaluation of the stresses or strains in the device should be based on the appropriate material behavior. The stress and strain components chosen for the evaluation must be appropriate to perform such an evaluation. Normal, shear and principal stresses and strains, in addition to effective stress and strain quantities should be considered. The influences of nonlinear behavior, permanent (irrecoverable) deformation and/or residual stresses and strains must be included in the interpretation of the results.

7.6.4 In addition, the choice of whether stress or strain components are used in the evaluation is an important issue. Some path dependent or temperature dependent material behavior is more accurately represented using material strains, as is the case with superelastic alloys.

7.7 *Validation and Verification:*

7.7.1 An effort should be undertaken to ensure that any and all solution steps in the analysis have converged to a stable equilibrium condition. This effort should include an appropriate validation to ensure that the results are an accurate representation of the simulated behavior. The validation can take the form of, but is not limited to, comparisons to experimental test, comparisons to linear analyses, or comparisons to analytical and/or established solutions.

7.7.2 Numerical validation of both linear and nonlinear solutions may be performed by considering a mesh density study. In such a study, a series of analyses are performed using one reference geometry with a number of different mesh sizes. Typically, the number of nodes/elements is doubled in each step of the series. Key quantities of the analyses are compared to determine the nature of the convergence of the solution. The convergence of the solution is demonstrated by this approach and the possible numerical uncertainty in using a particular finite element mesh can be quantified.

7.7.3 It is important to note the there may be additional considerations in the mesh density study arising from nonlinear deformations, nonlinear materials, or temperature effects. These important aspects of behavior should be considered in the evaluation of a suitable finite element mesh.

7.7.4 A mesh density study is also a very useful technique for determining whether stress variations and potential stress concentrations have been accurately characterized. Simulation specific influences of mesh gradations and mesh transitions can also be identified.

7.7.5 A mesh density study can form the basis for determining the convergence of an analysis to a numerical solution. Most mesh density studies entail the use of a set of models whose mesh densities are progressively increased (that is, more elements). A proper mesh size can be chosen by comparing the results of analyzing the progressive meshes. Typically, a specific result quantity as a function of the number of nodes, elements or degrees of freedom in the progressive meshes is plotted. The resulting plot will help to identify a mesh size that demonstrates increasing the mesh density does not appreciably change the solution.

7.7.6 A validation process such as a mesh density study can be performed at any stage of the analysis process as long as it

can be shown that the mesh chosen for the final validation analysis is of proper density and distribution for the desired accuracy.

7.7.7 If contact elements are used in the model, the contact parameters should be validated to ensure proper behavior in contact regions of the model. The sensitivity of the solution results to variations in contact parameters should also be considered in the validation of the model.

7.7.8 When performing an analysis that includes nonlinear behavior, it is important to verify the proper numerical convergence of the solution. Determination of solution convergence is typically a combination of a user defined or default numerical tolerance combined with a measure of equilibrium. The value of the numerical tolerance defines when equilibrium is reached and a load step or iteration is completed. It should be demonstrated that smaller tolerance values do not change the results of interest. (Certain codes have well defined default values of tolerances which are known to work in majority of the cases.)

7.7.9 The method used to perform the numerical solution should be evaluated to determine the possible effects of numerical tolerance. If an iterative solver is used for linear or nonlinear analyses, the sensitivity of the solution to the selection of the numerical tolerance value should be evaluated.

8. Deviations

8.1 Any deviations from the protocol outlined in this guide or in what is considered to be widely accepted "good engineering practice" for applying the finite element analysis technique shall be recorded and reported.

9. Acceptance Criteria

9.1 The number and distribution of nodes and elements used in the final finite element model for the analyses should be based on the results of a series of test and validation models described in this guide. The purpose of the test and validation models is to demonstrate the basic stability and continuity of the finite element model, to test the adequacy of the material representation entered into the finite element program, to exercise the method for applying loading and boundary conditions and to demonstrate the convergence of the mesh density to a solution.

9.2 In cases where the loading is expected to result in nonlinear deformation, it is good practice to first perform a simplified linear analysis on the model. The model should be analyzed a minimum of one time with limited loading or with linear material properties such that the deformation and the corresponding stresses are within the linear elastic range for the constitutive relation. The model should then be analyzed to include the nonlinear behavior and the results compared to ensure behavior consistent with the expected nonlinearity.

9.3 The model checks suggested in the above discussion are considered to be good practice and helpful tools to aid the analyst. In most cases, they are not an end result in themselves. As such, they are not generally included, or are only briefly mentioned in the final analysis report.

9.4 Prior to completion of the design, regulatory guidelines recommend experimental testing of the device. Comparisons of experimental test and analysis can serve as a confirmation of both methods. Care should be taken such that comparisons and confirmation based on experimental testing are properly represented in the numerical analysis (**1**).

10. Report

10.1 The finite element analysis for the evaluation of a stent will be fully documented in an engineering report. The actual format of the report should comply with any acceptable proprietary or non-proprietary engineering report format; however, the report shall include, but is not limited to, the following:

10.1.1 A complete description of device being analyzed including detailed dimensions. If the evaluation is not being performed on the final design of the device or if there are other significant assumptions that may limit the use of the results, this must be clearly stated.

10.1.2 A summary of relevant product specifications from which intended use and loading environment (both thermal and mechanical) can be determined.

10.1.3 An outline of the analysis methodology to be applied in the analysis and a description of its relation to the type of analysis to be performed.

10.1.4 A statement of the significance of the particular analysis in the engineering design process and the role of the result in design verification and validation.

10.1.5 A description of mechanical material test results used to determine the material model used in the analysis, including any special conditions under which the tests were performed (for example, different temperatures, different material lots, etc.).

10.1.6 A description of finite element material model validation tests and comparisons with material tests and test data.

10.1.7 A summary of the finite element modeling and analysis system(s) used for the analysis. If current versions of widely used, commercially available software are used, this summary can be by program name and the version used. For non-commercially available, proprietary tools, or custom user modification of commercially available software, sufficient technical background and results of test problems should be provided to demonstrate the utility, validation, applicability, and limitations of the software tool.

10.1.8 A description of the procedure used to convert the geometric or CAD representation of the device to the finite element model.

10.1.9 A description of the finite element model and its relation to the device being evaluated. The number of nodes and elements (or the degrees of freedom in the model), the finite element type selected including its capabilities, and any special considerations involved in the model should be included.

10.1.10 A summary of the analysis approach, load steps, boundary conditions, and assumptions applied during the analysis. The summary should include a discussion of the intended purpose of each step and any special processing, loading, temperature, or material issues influencing the results of each step.

10.1.11 A complete description of the device being analyzed including detailed dimensions and assumptions such as symmetry. All special modeling techniques, analysis techniques, or assumptions should be described. The potential effects of these on the analysis results should be described and any limitations resolved.

10.1.12 Any and all deviations from this guide or widely accepted finite element industry practice are to be noted and justified.

10.1.13 A description of mesh validation/model convergence considerations and how they were applied to the analysis.

10.1.14 A description of any numerical considerations or convergence issues associated with the analysis.

10.1.15 A summary of analysis results using all appropriate forms of text, graphics and tabular representations of data to highlight the key behavioral characteristics involved in the evaluation.

10.1.16 An engineering evaluation of the analysis results.

10.1.17 Engineering conclusions or recommendations, as appropriate.

10.1.18 All relevant references and supporting documentation and drawings.

11. Keywords

11.1 contact; cyclic loading; displacement; fatigue loading; finite element analysis (FEA); model calibration; model validation; model verification; nonlinear models; radial loading; shape memory alloys; solution sensitivity; stents; strain; stress

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