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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~~recommendations 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~~ recommendations and considerations for the ~~development of~~ development, verification, validation, and reporting of structural finite element models used in the evaluation of the performance of a metallic vascular stent design ~~under~~undergoing 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~~ This standard guide does not directly apply to non-metallic or absorbable stents, though many aspects of it may be applicable. The purpose of a structural analysis of a stent is to determine quantities such as the displacements, stresses, and strains within a device resulting from external loading, such as crimping or during the catheter loading process, and ~~*analysis*~~*in-vivo* ~~results. Finally, the recommended content of an engineering report covering the mechanical simulations is presented.~~processes, such as expansion and pulsatile loading.

1.2 ~~*Limits:*~~ *Limitations—*

~~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.~~ The analysis technique discussed in this guide is restricted to structural analysis using the finite element method. This document provides specific guidance for verification and validation (V&V) of finite element (FE) models of vascular stents subjected to uniform radial loading using ASME V&V40 as the basis for developing and executing risk-informed V&V plans.

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~~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.~~

1.2.1 ~~This guide~~Users of this document are encouraged to read ASME V&V40 for an introduction to risk-informed V&V, and to read ASME V&V10 for further guidance on performing V&V of computational solid mechanics models. This document is not intended to ~~include complete descriptions of the finite element method, nor its theoretical basis and formulation.~~ cover all aspects of developing a finite element model of radial deformation of a stent. It is intended for a FE analyst with structural modeling experience.

1.2.2 While risk-informed V&V is encouraged, it is not required. Analysts may utilize alternate V&V methods. The methodology employed should be developed by knowledgeable stakeholders with consideration as to the expectations and requirements of internal teams and external bodies that will assess the performance of the stent and the credibility of the model used to make performance predictions.

1.2.3 If an alternative V&V method is employed, then Sections 5, 6, 7, and 10 that follow ASME V&V40 guidelines may be viewed as suggestions only. Other portions of the document that refer to question of interest, risk, and context of use may be viewed in the same manner.

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

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/E8M Test Methods for Tension Testing of Metallic Materials
E2655 Guide for Reporting Uncertainty of Test Results and Use of the Term Measurement Uncertainty in ASTM Test Methods
F2477 Test Methods for ***in vitro*** Pulsatile Durability Testing of Vascular Stents
F2516 Test Method for Tension Testing of Nickel-Titanium Superelastic Materials
F3067 Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents

2.2 *Other Standards:*

ASME V&V10–2019 Standard for Verification and Validation in Computational Solid Mechanics[3]
ASME V&V10.1–2012 An Illustration of the Concepts of Verification and Validation in Computational Solid Mechanics[3]
ASME V&V20–2016 Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer[3]
ASME V&V40–2018 Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices[3]
ASME PTC-19.1 Test Uncertainty[3]
ISO 14971 Medical Devices—Application of Risk Management to Medical Devices[4]
JCGM 100 Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement[5]

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.
[3] Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Two Park Ave., New York, NY 10016-5990, http://www.asme.org.
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[5] Available from Bureau International des Poids et Mesures (BIPM), Pavillon de Breteuil, F-92312 Sèvres Cedex France, http://www.bipm.org.

3. Terminology

3.1 *Definitions:*

3.1.1 *balloon-expandable stent, n*—a stent that is expanded at the treatment site by a balloon catheter. The stent material is plastically deformed by the balloon expansion such that the stent remains expanded after deflation of the balloon.

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

3.1.3 *fatigue life, N_f, n*—the number of cycles of a specified character that a given specimen sustains before failure of a specified nature occurs. Fatigue life, or the logarithm of fatigue life, is a dependent variable.

3.1.4 *fatigue limit, S_F, n*—the limiting value of the median fatigue strength as the fatigue life, N_f, becomes very large.

3.1.5 *fatigue strength at a specified life, n*—the maximum load the test specimen can be expected to survive for a specified number of cycles with a stated confidence and reliability.

3.1.6 *load, n*—used to denote continuous and time-varying forces, pressures, stresses, strains, torques, deflections, twists, or other parameters that describe the applied fatigue stimuli. Typically, these fatigue stimuli are described by a mean value and an alternating value.

3.1.7 *median fatigue life, n*—the middle value of the observed fatigue lives, arranged in order of magnitude, of the individual specimens in a group tested under essentially identical conditions.

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

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

3.1.10 *radial loading, n*—a mechanical loading mode in which the load is directed perpendicular to the longitudinal axis of a cylinder and applied to the outer and/or inner cylindrical surface of the stent. The load is applied to the entire outer and/or inner surface or to at least three areas that are equally distributed around the outer and/or inner circumference and extend over the entire cylinder length. Load might be expressed as radial force or radial pressure.

3.1.11 *safety factor, n*—ratio of the device performance to the specification requirement (for example, how much stronger the device is than it needs to be to meet its specification requirement).

3.1.12 *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.

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

3.2 ~~*Symbols:*~~*Definitions of Terms Specific to This Standard:*

3.2.1 *catheter load, v*—to secure the stent into a delivery system by radially compressing and inserting the stent into a delivery device, such as a sheath.

3.2.2 ~~*balloon expandable stent,*~~ *computational model, 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.~~mathematical model of a system or a physical process implemented on a numerical analysis software platform.

3.2.3 *conceptual model, n*—~~model produced by analyzing and observing the physical system of interest composed of mathematical~~

~~models and equations representing that system.~~the collection of assumptions and descriptions of physical processes representing the solid mechanics behavior from which the mathematical model and validation experiments can be constructed (ASME V&V10).

3.2.4 *constant life diagram, n*—in fatigue, a plot of one or more curves, each of which is for a single fatigue life, *N*. The curve(s) relates fatigue strength (example loads include alternating stress or strain) to the mean load. The constant life fatigue diagram is usually derived from one or more stress or strain versus number of cycles (*S-N*) curves.

3.2.5 *constant life line, n*—a linear or piecewise linear function connecting fatigue strengths plotted on a constant life diagram. It is used to interpolate a fatigue strength for a mean strain/stress that is between two mean strain/stress values that have a fatigue strength determined through experimental test data.

3.2.6 *context of use (COU), n*—a statement that defines the specific role and scope of the computational model used to address the question of interest (ASME V&V40).

3.2.7 ~~*computational model,*~~*credibility factor, n*—~~implementation of a conceptual model in software.~~elements of the V&V process that are used to establish the credibility of the computational model for the COU (ASME V&V40). Examples include, but are not limited to, software quality assurance, model form, and test conditions. See ASME V&V40 for more details on V&V activities and credibility factors.

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

3.2.9 ~~*delivery system,*~~ *decision, n*—a ~~mechanical system that is used to deliver and deploy a stent at a target site.~~postulated action, or lack of action, that may commence; or a claim that may be made, upon considering all evidence used to answer the question of interest.

3.2.10 ~~*elasto-plastic material,*~~ *fatigue safety factor, n*—~~a material behavioral model that exhibits elastic behavior (recoverable) up to its yield point and plastic behavior (irrecoverable) above its yield point.~~the ratio of the specification limit (fatigue limit or fatigue strength at a specified life) to the predicted stress/strain state.

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

3.2.11 *finite element analysis (FEA), n*—~~a general purpose numerical technique.~~application of the finite element method to analyze a physical phenomenon.

~~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.~~

3.2.12 *finite element material calibration model, n*—a finite element model that is used to hone the parameters that define a material model through comparison of the stress and strain output to experimental test data.

3.2.13 ~~*geometrical nonlinearity,*~~ *finite element method (FEM), n*—a ~~type of nonlinearity related to structural deformation where the relation between strain and displacement are not linearly proportional.~~general-purpose numerical technique used to provide approximate solutions to one or more differential equations.

3.2.14 *key characteristic/parameter/assumption, n*—an educated assumption on what characteristics/parameters/assumptions of a test or computational model meaningfully impacts the output(s) of the test/model.

3.2.15 *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.

3.2.16 *margin of safety, n*—smallest distance between strain/stress state and a constant life line on a constant life diagram.

3.2.17 *mathematical model, n*—the mathematical equations, boundary values, initial conditions, and modeling data needed to describe the conceptual model (ASME V&V10).

3.2.18 *model ~~calibration,~~form, 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.~~conceptual and mathematical formulation of the computational model. It includes not only the form of the governing equations but also the form of the system configuration, system properties, and system conditions (ASME V&V40).

3.2.19 *model inputs, n*—geometry, material properties, boundary conditions, and other information required to completely describe the finite element model.

3.2.20 *model risk, n*—the possibility that the computational model and the simulation results may lead to an incorrect decision that would lead to an adverse outcome (ASME V&V40).

3.2.21 *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.~~model is an accurate representation of the reality of interest.

3.2.22 *model verification, n*—the process of ~~assessing that the implementation of the~~ determining that a computational model accurately represents the ~~engineer's conceptual~~underlying mathematical model and ~~of the~~ its solution ~~to the model. It is an evaluation of the fidelity of the conceptual model and the computational model.~~from the perspective of the intended uses of modeling and simulation (ASME V&V40).

3.2.23 *question of interest, n*—the specific question that is being addressed by the computational model.

3.2.24 ~~*nonlinear material,*~~ *reality of interest, n*—~~a material behavior in which the stress resulting from an applied external load is not directly proportional to the induced strain.~~the physical system and its associated environment to which the computational model will be applied (ASME V&V10).

3.2.25 ~~*permanent deformation,*~~*strain/stress state, n*—~~residual or irrecoverable strain and deformation in a structure after all loads and boundary conditions are removed.~~ the combination of the mean and alternating stress or strain.

~~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.~~

3.2.26 ~~*self-expanding stent,*~~*test conditions, 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.~~the inputs that are used to define a test. Examples include temperature, diameter change rate, device position, etc.

3.2.27 ~~*solution sensitivity,*~~*uncertainty quantification, n*—~~a measure~~ quantification of the ~~relative change in solution results caused by changing~~ effect of uncertainty in the value of one or more ~~parameters in a computational model.~~model inputs on the simulation output(s), or quantification of the uncertainty in the measured or calculated output(s) of an experimental test.

3.2.28 ~~*stent,*~~ *validation point, 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.~~model is validated against experimental results at a specific set of test conditions, which can be referred to as a validation point (ASME V&V10).

3.2.29 *x, n*—a variable used to stand in for an unspecified value.

~~**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~~tool for evaluating the performance of metallic stents and in ~~quantifying~~estimating quantities such as ~~internal stresses, internal strains, and deformation patterns~~ stress, strain, and displacement due to applied external loads and boundary conditions. ~~Many times an analysis is performed to correlate to and plan experimental tests.~~ FEA of stents is frequently performed to determine the worst-case size for experimental fatigue (or durability) testing and differentiation of performance between designs. A finite element analysis is especially valuable in determining quantities that cannot be readily measured.

5. Summary of Practice

5.1 This guide provides a systematic approach to develop, verify, validate, and report the use of a computational model to evaluate stent performance under a uniform radial loading condition. The process includes the following steps:

5.1.1 State the question of interest and the posited decision, and define the context of use of the model (Section 6).

5.1.2 Determine model risk (Section 7).

5.1.3 Define the computational model (Section 8).

5.1.3.1 Determine model form (8.2).

5.1.3.2 Define computational model inputs (8.3).

5.1.4 Select the appropriate finite element analysis software (Section 9).

5.1.5 Establish the verification and validation plan (Section 10).

5.1.6 Carry out the verification and validation plan (Section 11).

5.1.7 Determine if the computational model is credible for the context of use (Section 11).

5.1.8 Simulate stent radial loading/deformation according to the context of use (Section 12).

5.1.9 Describe the model, method, results, and conclusions in the final engineering report (Section 13).

6. ~~Overall Technical Approach~~State Question of Interest and the Posited Decision, and Define the Context of Use of the Model

6.1 The question of interest is the specific question the organization is trying to answer utilizing an FEA model as part of the decision-making process. Examples of a question of interest include but are not limited to:

6.1.1 Is the family of stents resistant to fractures that compromise device function when exposed to physiologically relevant radial pulsatile loading boundary conditions over the expected lifetime of the device?

6.1.2 Does the stent experience strains outside the tolerated compressive and tensile range of values for the material during catheter loading?

6.1.3 For all possible geometry and material property combinations within the proposed specification tolerances, does the stent generate adequate radial pressure to seal off blood flow into the aneurysmal sac for all indicated vessel diameter and compliance combinations?

6.2 The decision is the postulated action, or lack of action, that may commence; or a claim that may be made, upon considering all evidence used to answer the question of interest. Examples of decisions for the questions of interest listed in 6.1 are detailed below:

6.2.1 Claim that the family of stents meet the design input requirements for frame durability under pulsatile loading conditions.

6.2.2 The peak minimum and maximum principal strains induced during catheter loading meet the design input requirements and an order for a lot of stents can be placed to be used for delivery system development and radial force testing.

6.2.3 Claim that the stent design meets the minimum radial compression resistance pressure design requirement.

6.3 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:~~ context of use (COU) defines how the FEA model and other supporting evidence are used to answer the question of interest. The context of use may include, but is not limited to, the following elements:

6.3.1 ~~Detailed definition~~A description of ~~the geometry of~~ how the computational model will be used to address the question of interest. An example statement is, "An FE model of each stent size will simulate catheter loading and *in-vivo*~~the stent being evaluated.~~ cycling at various physiological conditions to determine the size and condition combination that is most likely to result in a fracture over the course of the intended implantation lifespan."

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

6.3.2 ~~Selection~~Identification of the ~~appropriate finite element tools and programs to ensure effective and reliable representations of the stent being evaluated.~~output(s) used to address the question of interest and define how it will be used.

6.3.2.1 An example for a balloon-expandable stent is, "The mean and alternating maximum principal stresses are compared to the Goodman line to calculate a safety factor. This safety factor is used to identify the device size with lowest fatigue resistance."

6.3.2.2 The model outputs used for validation are not required to match those used to address the question of interest. For example, stress or strain may be of interest in addressing fatigue resistance, while radial force might be used for validation as it is more easily measured (10.6.5).

~~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.~~

6.3.3 ~~Documentation of the analysis, including all supporting citations and references, analysis methodology, and assumptions, results interpretation, and overall stent design evaluation.~~Details regarding other forms of evidence used to address the question of interest. Examples include benchtop pulsatile fatigue testing, an animal study, or comparison to modeling results for a predicate device that has met performance requirements.

7. Determine Model Risk

7.1 Model risk is the driving factor for determining the amount of verification and validation activities necessary to establish computational model credibility. The model risk is a combination of the influence of the computational model on the decision being made (model influence) and the consequence of an adverse outcome resulting from an incorrect decision (decision consequence). Considerations regarding each of these factors relating to this document are provided in this section. The reader is referred to ASME V&V40 for general guidance on determining model risk through consideration of the influence of the model in making a product-related decision, and the consequence of an incorrect decision.

7.2 It is a good practice to incorporate clinical and risk assessment expertise beyond that of the analyst to determine the influence of the model and the consequence of an incorrect decision.

7.3 *Model Influence:*

7.3.1 Model influence refers to the relative weight that the model has in answering the question of interest.

7.3.2 Evidence other than computational modeling of a stent's performance relative to the COU can be used to address the question of interest. Using other data sources decreases the influence of computational model results on the decision, which may reduce the risk associated with the computational model.

7.3.3 An example is using computational modeling as part of an assessment of a stent's fatigue resistance to *in-vivo* pulsatile loading. This example is developed further in Example 1: Evaluating Model Risk.

7.4 *Decision Consequence:*

7.4.1 The decision consequence refers to the potential consequence of a harm to the patient and/or non-patient-related impacts as a result of an incorrect decision. The consequence of the incorrect decision can be categorized on a scale of the analyst's or organization's choosing. Examples of an incorrect decision include but are not limited to:

7.4.1.1 Determining that the family of stents met pulsatile durability requirements when one or more sizes would not if properly assessed. The root cause may be that the models were inadequate to differentiate between some of the sizes, the testing did not sufficiently replicate the physiological conditions, errors were made in calculating the boundary/loading conditions, or another issue tied to any of the sources of data. The consequence of an incorrect decision is not answering the question of "What if the model is wrong?" but "What if the decision that was made based on the entirety of evidence is in error?"

7.4.1.2 The FE model underestimates the peak maximum principal strain, which is actually above the maximum allowed value per the design input requirement, seen by the stent during catheter loading when it was claimed that it was below the maximum allowed value.

7.4.1.3 The combination of near least material geometry and near minimum strength material properties results in a stent that does not meet the minimum radial compression resistance pressure design requirement when the decision was to claim that the design did meet the design requirement.

7.4.2 When categorizing the impact of an incorrect decision, the determination may consider both the severity and the rate of occurrence of clinical sequelae. Since these factors are integral to risk assessment methodologies such as ISO 14971, existing risk

assessments for the stent can be used to evaluate decision consequence. The chosen gradation should reflect what is a reasonable consequence for the targeted patient population.

7.4.3 With respect to modeling radial loading of stents, an incorrect decision could lead to insufficient radial force and/or stent fracture. For example, fractures of stents resulting from radial pulsatile loading have been reported to lead to various clinical sequelae. Sequelae leading to morbidity and mortality include thrombus formation, neo-intimal tissue growth, artery perforation, migration, and restenosis (**1, 2**).[6] An example regarding stent fracture is developed further in Example 1: Evaluating Model Risk.

7.5 An example that incorporates model risk in determining the extent of validation activities to perform is detailed in Example 2: Model Form Exploration.

Example 1: Evaluating Model Risk

Medical Device: Peripheral vascular stent

Question of Interest: Is the family of stents resistant to fractures that compromise device function when exposed to physiologically relevant radial pulsatile loading boundary conditions?

Posited Decision: The family of stents have met the design input requirements for frame durability under pulsatile loading conditions.

Context of Use: The computational models are used to predict the combination of stent size and physiological boundary conditions (that is, vessel diameter, compliance, pulse pressure) most likely to lead to an *in-vivo* fracture during the expected lifetime of the implant. Mean and alternating maximum principal stresses are compared to the Goodman line to calculate the fatigue safety factor, which is used to identify the device size with the lowest fatigue resistance. The combination will be fatigue tested to a ten-year life expectancy. The decision is based primarily upon the results of the fatigue test, with the lowest fatigue safety factors for each stent size determined by the computational model also weighing on the decision.

Model Influence: The fatigue safety factors for each stent size are determined by the computational model, but the stent durability assessment is based upon the benchtop fatigue test performed according to Test Method F2477. The fatigue test is used to confirm the prediction of fatigue resistance for the worst-case condition determined by the computational model. Because of the similarities between the stents within the family, the benchtop test can be considered representative of other sizes. Therefore, the computational model has a low-medium influence on the decision.

Decision Consequence: An incorrect decision on the durability of the device family under pulsatile loading conditions can result in a clinically significant fracture that requires physician intervention but is not life-threatening. This decision consequence is categorized as medium.

Model Risk: The combination of a low-medium model influence and medium for decision consequence yields a model risk of low-medium.

Note: The scale for model risk is determined by the analyst or the analyst's organization. This example used a five-point scale of low, low-medium, medium, medium-high, and high, but this should not be considered as guidance or a recommendation. The degree of assessed model risk influences the extent of verification and validation activities that are performed. A model with a low model risk would require successful completion of limited activities and meet loose acceptance criteria to be deemed credible for its intended use. Users of this standard are encouraged to determine goals, delineated by risk level, for each V&V activity (see Example 2) apriori to evaluating the risk associated with the computational model. A goal that is associated with a lower model risk can be performed instead if deemed more appropriate for the application, and a more rigorous goal can be pursued without justification.

8. ~~Input Data~~Define the Computational Model

8.1 The model is a representation of the stent exposed to relevant uniform radial loading conditions. The model can include simplifying assumptions on the underlying physics, geometry, material properties, boundary conditions, symmetry, and applied loads.

8.2 *Model Form:*

8.2.1 The assumptions made and governing equations used are important factors when formulating a model. Examples of model form decisions include, but are not limited to: using simplified geometry, using symmetry, 2D versus 3D, linear versus nonlinear material properties, and dynamic versus static.

8.2.2 The influence of various assumptions can be explored by comparing the output of the model to a different or more complex model, or to empirical test data.

8.2.3 Consider the required accuracy, the expected cost (time and resources) of the simulation, and how the output will be used in decisions that can impact the device development and/or patient safety when selecting an appropriate model form.

8.2.4 Many stent designs are composed of repeating patterns that exhibit symmetry. Under circumferentially symmetric uniform radial load, this repetition may allow for the analysis of a stent subsection while enforcing appropriate conditions of symmetry on

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

truncated boundaries. Results may be reviewed to ensure that all boundary conditions have been applied correctly and that deformations are consistent with experimental observations.

8.2.5 Stent edge radii are typically excluded from the finite element model to simplify meshing, improve mesh quality, and/or reduce element count. If the edge radius is expected to significantly change the cross-sectional area of a strut, then a justification should be provided as to why the results are still valid. Justification could include an FEA study of the impact of including/excluding the edge radius on the quantities of interest, either on a complete stent model or a sub-model.

8.2.6 The influence of the contact formulation used between the stent and radial compression and/or expansion surface, and contact of the device with itself (selfcontact), on the model output and stent deformations should be considered.

8.2.6.1 Some contact methods or parameter values can result in the device diameter not matching that of the constricting surface. For example, nodal penetration due to softened contact or when there is a mismatch between the mesh density of the stent and constricting surface. Direct diameter measurement or verification of apposition of the stent to the constricting surface can be used to assess the intended deformation.

8.2.6.2 For computational models of balloon expansion, the value of the friction coefficient used in the contact definition can be chosen to match the quantities observed on the bench such as the fore-shortening/elongation characteristics of the stent.

8.2.6.3 Contact definitions for braided stents can require special attention due to the wire-to-wire overlap at crossover points.

8.2.7 Interactions between a balloon-expandable stent and the balloon can impact the uniformity of stent deformation. Approximating the expansion of the stent with a rigid cylinder is a common practice, but consideration should be given as to whether it is appropriate for the context of use of the model.

8.2.8 The extent of the exploration of the assumptions and/or simplifications to the model's form is dependent on the model risk.

8.2.9 Example 2: Model Form Exploration illustrates the steps in this standard guide up through defining the model form.

Example 2: Model Form Exploration

Medical Device: Balloon-expandable peripheral vascular stent

Question of Interest: Does the proposed stent design meet or exceed the radial stiffness target when expanded to the minimum indicated diameter?

Posited Decision: The proposed stent design meets the radial stiffness target for the minimum indicated diameter and therefore a small lot of the new design will be manufactured.

Context of Use: The computational model is used to predict the radial stiffness of an expanded and recoiled peripheral stent concept at nominal geometry. If the concept meets the minimum expectations, then the design may be manufactured, and the stiffness predictions confirmed via benchtop radial force testing. The computational model simulates the test method that includes crimp to the minimum process diameter, expansion to the deployed diameter, and then radial compression to measure the stiffness.

Model Influence: The model is the only source of data used to make the decision. Therefore, the computational model has a high influence on the decision.

Decision Consequence: The consequence of an incorrect decision is an expenditure of resources and project time to manufacture a test concept that does not meet the radial stiffness requirements. This decision consequence is categorized as low.

Model Risk: The combination of a high model influence and low decision consequence yield a low-medium risk level.

Goals of Model Form Validation Activities by Model Risk:
- •Low: No model assumptions and/or simplifications are explored to determine their influence on the output of the computational model.
- •Low-Medium & Medium: One or more key model assumptions and/or simplifications are explored to determine their influence on the output of the computational model.
- •Medium-High: All key model assumptions and/or simplifications are explored to determine their influence on the output of the computational model.
- •High: All model assumptions and/or simplifications are explored to determine their influence on the output of the computational model.

Define the Model:
- •Material Model: Elastic-plastic
- •Solver: Quasi-static
- •Geometry: 3D 1/8th circumferential symmetry, full length
- •Constraints: Theta and axial on the cut surfaces
- •Radial Expansion: Rigid cylindrical tool
- •Radial Compression: Rigid cylindrical tool
- •Contact: No overclosure (hard contact), friction applied

Model Assumptions and Simplifications:

•The geometry does not include the edge rounding created during electropolishing.
•A 1/8th circumferential symmetry model with theta and axial constraints is representative of the full stent.
•Geometric and radial force differences between a model that uses a rigid cylinder for expansion versus a simulated balloon are insignificant.
•Geometric and radial force differences between a model that uses a rigid cylinder for compression versus a multi-plane iris are insignificant.

Note: The model form activities to be pursued are what the developers of the model and users of the model's data think are appropriate based on the risk assigned to the computational model. In this fictitious scenario, the expected activity for a model with a low-medium risk grade are for one or more key model assumptions and/or simplifications to be explored for their influence on the output of the computational model. The symmetry model form assumption is chosen based on its simplicity. If a tested device deviates from the predicted output of the model, the unexplored assumptions and simplifications are an option for investigating the deviation. The low-medium and medium model risk have the same model form goal in this scenario as the number of gradations of goals for each credibility factor do not have to match the number of model risk levels.

8.3 ~~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.~~*Computational Model Inputs:*

8.3.1 *Geometric Data:*

8.3.1.1 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,~~ may include drawings, computer-aided design (CAD), preliminary sketches, imaging (for example, visual microscopy, CT, SEM), or any other source consistent with defining the device model geometry.

8.3.1.2 ~~Finite element modeling is used extensively in~~ In the design phase of product development, ~~many times before any~~ finite element modeling may be used even before any physical 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.~~ idealized geometry. As prototypes are built, the measured dimensions can be substituted to reflect the dimensions of the prototype devices. Differences between the geometry of the tested prototypes and idealized geometry can lead to performance predictions that differ from the results of the benchtop tests.

8.3.1.3 ~~Stent geometry is often~~The as-manufactured stent geometry can be determined by measuring and inspecting representative stent samples ~~of stents~~ that have undergone all processing steps prior to ~~insertion in~~loading onto the ~~body.~~catheter. This processing ~~may~~can 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.~~cleaning and polishing.

~~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.~~

8.3.2 *Material Property Tests:*

8.3.2.1 The two main types of stents are balloon-expandable and self-expanding. Each type is produced from different types of materials that have specific needs for material property testing and calibration.

8.3.2.2 ~~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~~ commonly 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.~~ material, but compressive properties can also be relevant to predicting the radial force, stress, strain, and deformation of a stent.

8.3.2.3 ~~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.~~ Mechanical properties of the material should be determined from material samples (coupons) that have undergone all pertinent manufacturing processes, including