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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 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 recommendations and considerations for the development, verification, validation, and reporting of structural finite element models used in the evaluation of the performance of a metallic vascular stent design undergoing uniform radial loading. 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 *in-vivo* processes, such as expansion and pulsatile loading.

1.2 *Limitations*—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.

1.2.1 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 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 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

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[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.

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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]

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.

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3.2 *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 *computational model, n*—a mathematical model of a system or a physical process implemented on a numerical analysis software platform.

3.2.3 *conceptual model, n*—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 *credibility factor, n*—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

[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.

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 an expanding delivery device, such as a balloon, by radially compressing the stent.

3.2.9 *decision, n*—a 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 *fatigue safety factor, n*—the ratio of the specification limit (fatigue limit or fatigue strength at a specified life) to the predicted stress/strain state.

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

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 *finite element method (FEM), n*—a 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 form, n*—the 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 model is an accurate representation of the reality of interest.

3.2.22 *model verification, n*—the process of determining that a computational model accurately represents the underlying mathematical model and its solution 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 *reality of interest, n*—the physical system and its associated environment to which the computational model will be applied (ASME V&V10).

3.2.25 *strain/stress state, n*—the combination of the mean and alternating stress or strain.

3.2.26 *test conditions, n*—the inputs that are used to define a test. Examples include temperature, diameter change rate, device position, etc.

3.2.27 *uncertainty quantification, n*—quantification of the effect of uncertainty in the value of one or more 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 *validation point, n*—a 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.

4. Significance and Use

4.1 Finite element analysis is a valuable tool for evaluating the performance of metallic stents and in estimating quantities such as stress, strain, and displacement due to applied external loads and boundary conditions. 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.

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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. 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 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 A description 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* 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."

6.3.2 Identification of the 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).

6.3.3 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.

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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. 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 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.

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

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ASTM F2514-21

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 *Computational Model Inputs:*

8.3.1 *Geometric Data:*

8.3.1.1 Finite element models are a geometric representation of the device being studied. The source of the details of the geometry 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 In the design phase of product development, finite element modeling may be used even before any physical prototyping has occurred. As such, models are often based on 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 The as-manufactured stent geometry can be determined by measuring and inspecting representative stent samples that have undergone all processing steps prior to loading onto the catheter. This processing can include, but is not limited to, cleaning and polishing.

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 The mechanical material properties for a finite element analysis are commonly determined through tensile testing of the material, but compressive properties can also be relevant to predicting the radial force, stress, strain, and deformation of a stent.

8.3.2.3 Mechanical properties of the material should be determined from material samples (coupons) that have undergone all pertinent manufacturing processes, including relevant thermal processes, finishing, cleaning, and sterilization. If material samples are not subjected to all relevant processing steps, then the omissions should be described and rationalized.

8.3.2.4 For materials with a known tension-compression asymmetry (such as nitinol), differences in the material behavior in tension and compression may also be considered along

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ASTM F2514-21

with any load history dependent tension/compression asymmetry phenomena, or work hardening of the material.

8.3.2.5 Test Method E8/E8M provides a standard test method for tension testing of metallic materials. Test Method F2516 provides guidance for tensile test methods appropriate for nitinol.

8.3.3 *Material Property Calibration:*

8.3.3.1 The correlation between the material test data and the finite element material calibration 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.

8.3.3.2 For self-expanding superelastic materials with pronounced hysteresis, the material model calibration should include the relevant loading direction(s). For example, if a stent is simulated to be radially compressed and then released, the material model calibration should include both loading (tension) and unloading.

8.3.3.3 Comparisons between material stress-strain data and finite element material calibration model results may include individual sample stress-strain results to illustrate sample-to-sample variability in addition to the averaged curve of material test data. Incorporation of multiple lots in the test samples may induce greater, and more representative, variability in the output. If material property uncertainty is considered, then representative nominal and stochastic FEA material curves may also be reported.

8.3.4 *Loading Conditions and History:*

8.3.4.1 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.

8.3.4.2 For analyses including the implantation of a stent, the applied loading steps should include the delivery system loading, implant deployment, and recoil (if applicable). The steps should also include representative uniform radial loading conditions that the implant is expected to experience *in vivo*.

8.3.4.3 This guide is restricted to cases involving uniform radial loading. Such loading can occur during stent manufacturing, stent crimping, stent delivery, or cyclic loading from placement within a pulsating vessel. It is important to note that the sequence of loading events for a balloon-expandable stent will differ from a self-expanding stent.

8.3.4.4 The loading history of the device, from manufacturing through deployment and *in-vivo* use as applicable to the question of interest, may be analyzed.

8.3.4.5 It may be necessary to include the effects of residual stresses, such as from attaching a graft (covering) to the stent and/or loading the stent on the delivery system.

8.3.4.6 It may be necessary to include the effects of residual stresses resulting from the use of crimping to mount the stent onto the delivery system. The fatigue strength of nitinol has been found to be sensitive to residual stresses from crimping with increases or decreases in fatigue life possible depending on the magnitude and sense of the crimp loading (**3**).

8.3.4.7 Common methods for determining the deformations of an implanted device subject to radial loading include, but are not limited to:

(1) The load applied by the vessel as a function of the vessel diameter and the blood pressure;

(2) Empirical measurements of a device implanted *in vivo* or in a mock vessel; and

(3) Calculations that incorporate the stiffness or compliance of the vessel, the force-versus-diameter relationship of the stent, and blood pressure.

8.3.5 Material, dimensional, and loading conditions variabilities can create a range for a stent's performance and safety. Methods for assessing variabilities include:

8.3.5.1 Modeling the maximum and minimum geometry and/or material properties based on either specification tolerances or the mean plus and minus *x* standard deviations, which is unlikely to be representative of a device that is manufactured, but may represent the extremes of possible geometry and/or material properties.

8.3.5.2 Creating a mathematical model of the stent's performance and/or safety margin with dimensions, material properties, and loading conditions as variables, with limits spanning the possible variability from manufacturing and expected use. A Monte Carlo-like approach can then be applied to analyze a large number of design possibilities within manufacturing limits to identify conditions that may be outside the acceptable performance metric.

8.3.5.3 When performing a Monte Carlo analysis, one might consider a broad design space beyond the assumed manufacturing and use limits. Having data beyond the manufacturing limits enables the understanding of how a design could perform if the tolerances are expanded, as well as alerting the analyst if a possible design is near a region of unsatisfactory safety margin or performance.

9. Finite Element Software Capabilities

9.1 The requirements of finite element software used in the analysis of radial loading of metallic stents will vary depending on the specific analysis being performed. One may end up with large model form error if the finite element software does not meet the model form requirements for a given question of interest. For this reason, the following capabilities in combination are important for the user to consider when selecting FEA software for modeling of radial deformation of stents.

9.1.1 *Computer-Aided Design (CAD) Integration*—The ability of the software to import or have integrated CAD may be important for the user to access the stent geometry.

9.1.2 *Meshing*—The software used to mesh the stent should be capable of providing all element types under consideration for the analysis. The meshing capabilities of the FEA software can be considered when selecting software, although the meshing software may be different from the software used to create the model, run the simulation, or view the results.

9.1.3 *Large Deformations*—Simulation of manufacturing processes, deployments, and physiological loading may generate large displacements, rotations, and strains of the structures. Large deformation formulations should therefore be activated in the simulation software to capture these geometric nonlinearities.

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