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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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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.

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.

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).