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Standard Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices[1]

This standard is issued under the fixed designation F3211; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide is intended to provide an experimental methodology to assess and determine the structural fatigue life of implantable cardiovascular medical devices.

1.2 This guide is also intended to provide methodologies to determine statistical bounds on fatigue life at *in vivo* use conditions using measured fatigue life derived in whole or in part from hyper-physiological testing to fracture.

1.3 This guide may be used to assess or characterize device durability during design development and for testing to device product specifications.

1.4 Fretting, wear, creep-fatigue, and absorbable materials are outside the scope of this guide, though elements of this guide may be applicable.

1.5 As a guide, this document provides direction but does not recommend a specific course of action. It is intended to increase the awareness of information and approaches. This guide is not a test method. This guide does not establish a standard practice to follow in all cases.

1.6 This guide is meant as a complement to other regulatory and device-specific guidance documents or standards and it does not supersede the recommendations or requirements of such documents.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *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]

E178 Practice for Dealing With Outlying Observations

E456 Terminology Relating to Quality and Statistics

E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data

E1823 Terminology Relating to Fatigue and Fracture Testing

F2477 Test Methods for***in vitro*** Pulsatile Durability Testing of Vascular Stents

F2942 Guide for***in vitro*** Axial, Bending, and Torsional Durability Testing of Vascular Stents

F3172 Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

2.2 *ISO Standards:*[3]

ISO 5840-x Cardiovascular implants -- Cardiac valve prostheses -- Part 1: General requirements, Part 2: Surgically implanted heart valve substitutes, Part 3: Heart valve substitutes implanted by transcatheter techniques

ISO 12107 Metallic materials - Fatigue testing - Statistical planning and analysis of data

ISO 25539-x Cardiovascular implants -- Endovascular devices -- Part 1: Endovascular prostheses, Part 2: Vascular stents, Part 3: Vena cava filters

2.3 *Regulatory Guidance:*

Guidance for Industry: Q9 Quality Risk Management, FDA, 2006[4]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *acceptance criteria*—specific numerical limits or ranges or other conditions identified prior to testing that

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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.

[3] Available from International Organization of Standards, http://www.ISO.org/ISO/store.htm

[4] Accessed June 23, 2016 (http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073511.pdf).

establish the required results to support a conclusion, a decision, or meet a specification.

3.1.2 *amplitude*—one-half of the difference between the maximum and minimum measurements of the cyclic waveform.

3.1.3 *censor*—data where the cycle count at failure is only partially known. Run-outs (see definition in 3.1.26) are a form of right-censored data. Tests that use periodic inspections to determine the cycles to fracture are interval censored as the cycle of fracture is unknown but bounded between the previous and current inspection cycle counts.

3.1.4 *component*—a test specimen comprised of a subassembly or an individual part of a cardiovascular medical device in its finished form.

3.1.5 *confidence level*—the probability that the true value for a parameter of interest will fall within a numerical interval. The interval is known as the Confidence Interval. Confidence Intervals are used to establish boundaries for the value of a parameter of interest.

NOTE 1—Confidence levels, typically stated as percentages, are typically chosen through a risk analysis.

3.1.6 *coupon*—a test specimen extracted from a cardiovascular medical device or a component in its finished form.

3.1.6.1 *Discussion*—Often a coupon is "clipped" or cut from an as-manufactured device.

3.1.7 *design curve*—the lower confidence bound for a reliability quantile of the fatigue life distribution. For example, the Load versus fatigue life Number of cycles (S-N) curve for p% survival at c% confidence. See Fig. 1.

3.1.8 *design life*—the number of cycles for which the device is designed to remain functional without significant performance degradation.

3.1.9 *device*—a complete cardiovascular medical implant in its final form, or as deployed, that may be used as a test specimen.

3.1.10 *duty cycle*—a time history of loading conditions.
EXAMPLE—For devices deployed into the vasculature of the lower limbs, a duty cycle may be defined by the number of steps per day, the number of stairs per day, and the number of sit/stand cycles per day.

3.1.11 *failure*—permanent deformation or fracture with complete separation that renders the device ineffective or unable to adequately resist load. Other criteria may be used but should be clearly defined.

3.1.12 *failure mode*—a combination of an external load type, a fracture location or locations, and a fracture type. The external load can be single modes such as bending or twisting torques, radial loads, tension-compression axial loads, and so forth, or combinations of such loads. Fracture locations are positions on a device at which fracture occurred such as in a stent connector, stent apex, or stent strut. The fracture type is characterized by the surface morphology and the material cause or causes of the fracture such as tensile overload, transverse shear, mixed-mode, high cycle fatigue, or low cycle fatigue.

3.1.13 *fatigue factor of safety*—the ratio of the Fatigue Strength at a Specified Life with prescribed reliability and confidence levels to the load at the specified use condition. The Fatigue Factor of Safety is specific to a single failure mode.

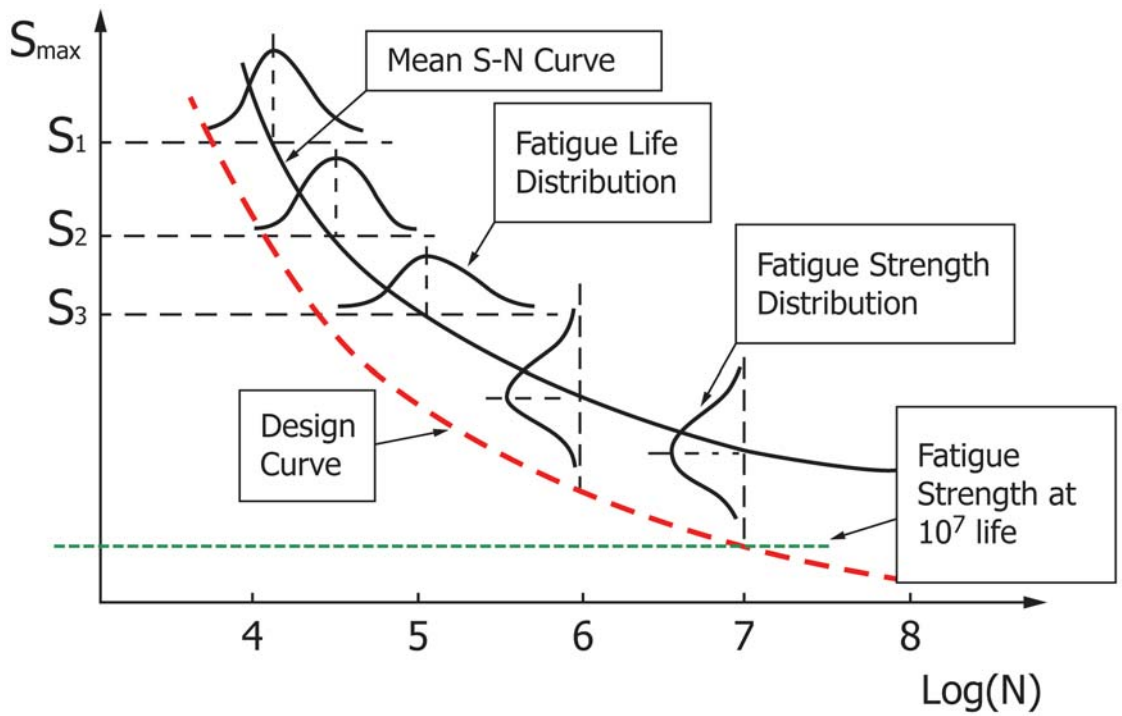

FIG. 1 Fatigue Life Model Depicting Terminology Where S is Load Parameter and N is Fatigue Life, Number of Cycles to Fracture

3.1.13.1 *Discussion*—When mean loads are considered along with the alternating loads, the ratio calculation must be defined and preferably shown on a constant life fatigue diagram.

3.1.13.2 *Discussion*—In communicating a Fatigue Factor of Safety, a clear statement of its intended purpose and the assumptions associated with its calculation is necessary for proper interpretation. For example, a safety factor estimate based on the average amplitude at fracture at the design life relative to the amplitude at the typical use condition will be substantially different from a safety factor based on the 90 % reliability/95 % confidence amplitude at fracture at the design life relative to a conservative estimate of the most challenging use condition amplitude.

3.1.14 *fatigue life model*—a mathematical equation that describes the relationship between fatigue life and loading parameters with prescribed reliability and confidence, statistically derived from experimental fatigue data. See Section 7.2 .

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

3.1.15.1 *Discussion*—The Design Curve at a specified life may be used to show this graphically. See Fig. 1.

3.1.15.2 *Discussion*—The Fatigue Strength is specific to a single failure mode. See Terminology E1823.

3.1.16 *fracture*—complete separation of any device component due to stress with exposure of new surfaces that were previously together.

NOTE 2—A fracture does not necessarily represent a device functional failure.

3.1.17 *FtF*—acronym for Fatigue-to-Fracture.

3.1.18 *hyper-physiological test conditions*—test loads that exceed the expected *in vivo* use conditions.

3.1.19 *load*—used to denote continuous and time-varying forces, 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.

NOTE 3—Units and symbols are dependent on the parameter of interest.

3.1.20 *physiological loads*—loads expected on the device during *in vivo* use.

3.1.21 *preconditioning*—simulated use preparation of the specimen prior to testing. See Section 6.12.

3.1.22 *protocol*—a set of instructions that typically defines the specimens, test procedures, analysis procedures, and acceptance criteria.

3.1.23 *quantile*—value such that a fraction of the sample or population is less than or equal to that value. See Terminology E456.

3.1.24 *reliability*——the probability of survival to the specified design life at a given loading condition.

3.1.24.1 *Discussion*—For the purpose of this standard, this is a narrow statistical measure of reliability of the device based on *in vitro* data and modeling. In general, higher reliability in FtF is expected to increase the clinical reliability.

3.1.25 *risk analysis*—(1) a methodical analytical approach to determine and address identified system or component failure modes and their associated causes, based on the probability of occurrence and the severity of their effects on system performance and patient safety; (2) an estimate of the risk associated with identified hazards in accordance with FDA Q9 Quality Risk Management.

3.1.26 *run-out*—no fatigue failure at a specified number of load cycles. See Terminology E1823. This number is typically specified prior to beginning the testing.

3.1.27 *sample size*—the quantity of individual specimens tested. The sample size is typically chosen to establish conformance to a pre-determined specification with appropriate statistical confidence levels.

3.1.28 *load versus life (S-N) curve*—graphical representation of fatigue life data (see Fig. 1). The curve indicates the load versus cycles-to-fracture relationship for a specified probability of survival, for example, the 50^{th}, 90^{th}, or 95^{th} percentile.

NOTE 4—For N, a log scale is commonly used. For loads in stress or strain, either a logarithmic or a linear scale is commonly used. See Terminology E1823. For the purpose of analysis, the S-N curve is commonly modeled using a load-life relationship, for example a Power Law or Coffin-Manson equation.

3.1.29 *strength distribution at life N*—the probability of fracture at the life N as a function of load. The distribution may be computed by integrating the fatigue life distribution at each load from 0 to N.

3.1.30 *surrogate*—a test specimen constructed to represent a device, component, or region of interest of a cardiovascular medical device in its finished form.

3.1.31 *test artifact*—spurious test results attributable to conditions that are not present during *in vivo* use conditions (failure at the grips, for example).

3.1.32 *test specimen*—a test article that is subjected to fatigue loading conditions. A test specimen (also referred to as specimen) may be classified as a *device*, *component*, *coupon*, or *surrogate*.

3.1.33 *test-to-success*—a paradigm for assessing or characterizing the fatigue durability of medical devices whereby specimens are tested at a chosen factor of safety at or near simulated cyclic physiological loads where no fractures are expected. For example, the device "passes" and the test is successful if no devices fail by structural fracture or if all devices maintain sufficient functional integrity. See Test Methods F2477.

3.1.34 *use conditions*—the conditions to which the device will be subject, including the cumulative effects of the final manufacturing state, the process of device delivery and deployment, and the *in vivo* operating environment. See 6.1 and 6.12.

4. Summary of Guide

4.1 The fatigue-to-fracture (FtF) paradigm provides a methodology whereby whole devices, device components, coupons