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Standard Guide for *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents[1]

This standard is issued under the fixed designation F2942; 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 includes three separate cyclic deformation durability guides related to vascular stents: bending, axial, and torsional.

1.2 This guide does not address flat plate, local crush durability, or multi-mode testing. Although this guide does not address multi-mode testing, the information included herein could be applicable to developing this type of test.

1.3 This guide applies to balloon-expandable and self-expanding stents fabricated from metals and metal alloys. It does not specifically address any attributes unique to coated stents (i.e., ~~stent~~stents with a surface layer of an additional material(s)), monolithically polymeric stents, or absorbable stents, although the application of this standard to those products is not precluded.

1.4 This guide applies to endovascular grafts ("stent-grafts") and other conduit products commonly used to treat aneurismal disease, peripheral vessel trauma, or to provide vascular access. The information provided herein does not address all issues related to testing of these devices.

1.5 This guide is applicable to testing of stent(s) (or a representative portion of a stent). While durability testing of coupon samples (e.g., a scaled-up portion of the stent structure) can provide useful information, it is not within the scope of this guide.

~~1.5 This guide applies to endovascular grafts ("stent-grafts") and other conduit products commonly used to treat aneurismal disease, peripheral vessel trauma, or to provide vascular access. The information provided herein does not address all issues related to testing of these devices.~~

1.6 This guide applies to *in vitro* modeling of stent durability from non-radial arterial motions. Such motions may arise from musculoskeletal activities, including walking and breathing, and cardiac motion. ~~ASTM~~ Test Methods F2477 addresses pulsatile (i.e., radial) durability of vascular stents.

1.7 This guide does not provide the *in vivo* physiologic deformation conditions for a vascular stent. It is incumbent upon the user of the standard to develop and justify these boundary conditions (e.g., by literature review, *in vivo* studies, cadaver studies, or modeling of stent vessel interaction) in these durability bench tests. Additional conditions that may be considered include vessel calcification, vessel taper, eccentric lesions, loading excursions (e.g., exercise), and vessel remodeling.

1.8 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *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]

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

F3211 Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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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.

2.2 *Other Documents:*

ASTM STP 588 Manual on Statistical Planning and Analysis, R.E. Little, 1975

~~ISO 25539 Cardiovascular Implants–Endovascular Devices–Part 2: Vascular Stents~~

~~FDA Guidance Document #1545 "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" (Issued April 18, 2010)~~

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *axial, adj*—compression or tension of a stent and/or mock vessel along its longitudinal axis.

3.1.2 *bending, adj*—deformation on the longitudinal axis of a stent and/or mock vessel to achieve a specified stent radius of curvature.

3.1.3 *fracture, n*—~~the~~ complete separation of a stent ~~structural feature.~~element or component (e.g., strut, apex, bridge, marker).

3.1.3.1 *Discussion*—

Fracture of a stent does not necessarily constitute failure (i.e., loss of functionality).

3.1.4 *mock vessel, n*—a simulated vessel typically manufactured from an elastomeric material.

3.1.5 *radius of curvature, n*—the inner, outer or centerline bend radius of a stent.

3.1.6 *specimen, n*—article consisting of an implantable device or a representative portion of an implantable device, that is tested according to this guide.

3.1.7 *torsional, adj*—twisting of a stent and/or mock vessel about its longitudinal axis.

4. Summary of Test Guides

4.1 This guide covers *in vitro* durability testing of vascular stents using modes that represent those that might be observed *in vivo* such as bending, axial, or torsional deformation modes. Examples include, but are not limited to, the axial and bending deformation that occurs in the superficial femoral artery during the walking gait, the bending that occurs in the renal artery during respiration, and the bending that occurs in the coronary artery during the cardiac cycle. This guide provides details and guidance for separate tests for each deformation mode: axial, bending, and torsional. This guide allows the direct fixation of the ends of the stent or indirect fixation inside a mock vessel. Direct fixation of the ends of the stent allows better control of stent deformation; however, ~~this can result~~ such fixation might not be representative of *in vivo* conditions and care should be taken to minimize attachment-induced test artifact.

4.1.1 *Axial Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic axial deformation. The stent is deployed into a mock vessel, unless a justification is provided. This test guide is described in more detail in Annex A1.

4.1.2 *Bending Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic bending deformation. There are three suggested bending guides presented in Annex A2, Annex A3, and Annex A4, each involving placement of the stent inside of a mock vessel: column buckling, bending on a mandrel, and bending in an arc without a mandrel. In order to avoid test artifacts, these test guides recommend placement of the stent inside a mock vessel (stent ends not fixed) with subsequent cyclic bending of the mock vessel. When selecting the guide to conduct bending durability testing, consider the potential for the stent design under evaluation to be adversely affected by the methods and test apparatus described by a particular guide and the ability of each test to simulate a particular clinical condition.

4.1.3 *Torsional Durability Test Guide*—The purpose of this test is to subject the stent to a specified amount of cyclic torsional deformation. This guide is described in more detail in Annex A5.

4.2 Each test may utilize either 'test-to-success' (TTS) or the 'fatigue-to-fracture' (FTF) ~~methodology.~~methodology (see Guide F3211). The TTS methodology entails selection of a set of boundary conditions considered physiologically relevant, selection of a sufficient number of specimens, and application of the appropriate number of cycles. The successful completion of the TTS is based upon the number (if any) and type of stent strut fractures. The FTF methodology entails selection of the appropriate number of cycles considered runout (i.e., point to stop testing a specimen), selection of a sufficient number of specimens, and characterization of the stent fatigue performance by applying multiple deformation levels (i.e., loading ~~amplitude)~~amplitudes) and conducting periodic inspections of the stent during testing to obtain ~~some~~ test specimens with ~~fractures~~ and ~~some without.~~without fracture. For specimens that fracture, the number of cycles applied to cause fracture is obtained. The successful completion of a FTF test is based upon a comparison of stent fatigue performance, at the various deformation levels, to the physiologically relevant deformation levels. Selection of deformation levels to characterize the fatigue behavior of the stent may use the methodology described in ASTM STP 588.

5. Significance and Use

5.1 It is important to consider the durability of stent designs in deformation modes that are intended to model *in vivo* conditions. The appropriate amplitude and number of cycles in each of the modes ~~has~~have to be determined independently for the particular clinical use proposed for the stent. These tests do not replicate all varieties and aspects of the deployment process ~~and~~nor the *in vivo* mechanical environment ~~so~~ in its entirety, and as such they cannot be proofs of durability. Instead, the tests provide evidence of durability. The durability tests can also provide a means of assessing design, material or processing changes.

5.1.1 This guide might be useful for development testing, specification acceptance testing, and regulatory submission testing and filings as it provides a basic assurance that the tests are designed, executed, and reported in a suitable fashion.

5.1.2 If the tests are conducted using a ~~well-defined~~ well defined FTF methodology, they can be useful in:

5.1.2.1 Potential design improvement through identification of better and worse geometries, materials, and manufacturing processes;

5.1.2.2 Understanding product durability by estimating the effects of changes in geometry, materials, or manufacturing processes;

5.1.2.3 Estimating the safety factor relative to the amplitudes and other factors in use conditions; and

5.1.2.4 Validating finite element analysis (FEA) and fatigue life models.

5.1.3 As stated in the scope, this guide is not intended to provide the *in vivo* physiologic deformation conditions ~~that~~ to which a vascular stent can be subjected. Reliable clinical data characterizing cyclic vascular deformation may be lacking for some indications. The user should develop and justify the boundary conditions (e.g., by literature review, *in vivo* studies, cadaver studies, or modeling of stent vessel interaction) for the chosen durability bench tests. Additional conditions that may be considered include vessel calcification, vessel taper, eccentric lesions, deformation excursions (e.g., exercise), and vessel remodeling.

5.1.4 Test methods other than those provided in the annexes of this document might be appropriate, depending upon stent design. However, these methods are beyond the scope of this guide.

6. Specimen Size, Configuration, and Preparation

6.1 Unless otherwise justified, all specimens selected for testing should be taken from fully processed, implant quality product. Sterilization should be performed unless it can be shown not to influence the durability test results.

NOTE 1—Although sterilization may not directly affect the stent itself, it may affect the delivery system and, thus, the condition of the as-deployed stent.

6.2 Prior to deployment and durability testing, specimens loaded in or on their delivery systems should be tracked through a model representative of the vasculature to simulate clinical delivery.

6.3 To reduce the number of specimens to be tested, durability may be evaluated for the worst case ~~justified device size/model. Alternatively, multiple sizes (length and/or diameter) at potentially multiple deployment diameters would need to be tested with~~ device size/model, with specimen selection being justified through appropriate methods (e.g., finite element analysis). If multiple sizes/models or deployment diameters are to be tested, an appropriate bracketing scheme should be employed (e.g., largest and smallest length and/or diameter or models).

6.3.1 *Stent Length*—The axial and torsional durability testing modes act to induce stent deformation normalized with length (length change per length, and transverse angle change per length, respectively). Thus, the fatigue resistance of a stent design with a repeating unit or cell design would also be independent of length and any length may be tested. In cases where the stent design is length-dependent (e.g., non-repeating unit cells), the length predicted or expected to perform worst should be justified (e.g., by finite element ~~analysis or description of stent design).~~ analysis).

NOTE 2—Because of the nature of these test methods, it may not be possible to test the longest stent length within a family of sizes, especially in the overlapped configuration. In such cases, other means may need to be implemented to justify the stent length tested or to allow extrapolation of test conclusions to the lengths not tested (e.g. justification based on finite element analysis).

6.3.2 *Stent Diameter*—The fatigue resistance of any specific stent design might be dependent upon the diameter. A rationale based on finite element analysis or an explanation as to why the particular diameter is predicted or expected to perform worst should be provided. If different labeled diameter stents within a family have significantly different strut patterns, each unique pattern should be considered separately.

6.3.3 *Deployment Diameter*—For each labeled diameter stent tested, the test stent should be deployed to the "worst-case" deployed diameter per the instructions for use (IFU) (see ~~section~~ 8.2 Mock Vessels). The diameter predicted or expected to perform the worst should be justified by means such as finite element analysis.

6.3.4 *Stent Overlapping*—When stents are expected to be overlapped in clinical use, durability testing of overlapped stents should be performed. An overlap length representative of clinical use should be selected. The relative position (rotation and overlap length) of the overlapped stents should be selected to ensure sufficiently challenging application of strain. Fretting and/or wear might lead to fracture of overlapped stents during durability testing. Thus, further analysis (e.g., scanning electron microscopy (SEM)) of the stents after durability testing might be necessary to determine the failure mode.

6.4 The number of specimens tested for each stent size and/or geometry should be sufficient to support any claims made based on the test results. The results of testing according to this guide in combination with other tests, animal and clinical tests, analysis

(such as FEA), and/or comparisons to predicate devices can be sufficient to enable demonstration of ~~an~~ adequate durability. In this guide, one stent or a set of two overlapped stents should be considered one specimen.

7. General Apparatus Requirements

7.1 The axial, bending and torsional dynamic displacements of the test equipment should be verified at the selected test frequencies. The dynamic stent deformation verification documentation should include justification of the verification means (see ~~section~~ 8.6).

7.2 *Dimensional Measurement Devices*—Devices such as linear variable displacement transducers (LVDTs), lasers, and high-speed cameras should be calibrated.

7.3 *Cycle Counting System*—The apparatus should include a cycle counting system for measuring the number of deformation cycles applied to the stent. The cycle counting system should be verified at the test frequencies and the verification should be documented.

7.4 *Temperature Control System*—The apparatus should include a calibrated temperature control and measurement system to maintain the temperature of the stents being tested.

8. General Test Parameters

8.1 Completion of the durability test for stents deployed within a mock vessel, in air alone, or in fluid alone, depends on the deformation mode (i.e., axial, torsional, or bending), the material used to construct the stent (i.e., self-expanding or balloon-expandable), as well as the test purpose. For example, cyclic axial tests that are being conducted to predict stent durability under *in vivo* use conditions are likely to be conducted in a mock vessel. For cyclic axial tests that are being conducted as part of a development process or as part of a FTF investigation, it may be possible to complete the testing without a mock vessel. Regardless of the test configuration, the user of the standard should provide justification for the test conditions. If testing is conducted in air, heating of the stent resulting from applied accelerated cyclic deformation might occur. In such a case, means (e.g., convection cooling) should be implemented to minimize heating and evidence provided that any remaining heating does not significantly increase the fatigue life.

8.2 *Mock Vessels*—The mock vessel should be durable, capable of withstanding the test conditions, and able to maintain the desired stent deformations. The inner diameter (ID) of the mock vessel is important to the outcome of the durability tests in this standard guide. The stented mock vessel ID should be appropriate for the selected stent deployed diameter as described in ~~section~~ 6.3.3 ~~above,~~ , and should remain essentially constant ~~(i.e.~~(i.e., not drift with time) over the duration of the test. The wall thickness, coefficient of friction, and elasticity of the mock vessel might influence the testing results. For example, during the bending durability test, undesired kinking may result with an inappropriate mock vessel, or during the axial durability test the stent may not elongate or compress as intended if the friction between the mock vessel and stent is too high or too low. Measures to reduce excessive diameter reduction during axial testing (effect of incompressibility of elastomers or conservation of volume), ovalization during bending testing, and localized instability during torsional testing, should be used, where appropriate. For, example, appropriate mock vessels may or may not need a physiologically relevant compliance and stiffer and/or thicker walled mock vessels may be used in order to obtain the desired deformation of the stent.

8.2.1 It is important for the stent not to migrate in the mock vessel during testing. The mock vessel should be designed to minimize stent migration.

8.2.2 ~~It is important for the stent not to migrate in the mock vessel during testing. The mock vessel should be designed and/or modified to minimize stent migration.~~ When simulating expected *in vivo* deformations with a TTS methodology, it is important that the expected deformations be simulated as close as reasonably possible.

8.2.3 *Stent Deployment*—The test specimens should be deployed in the mock vessel in such a manner as to minimize end effects where the vessel is connected to the test apparatus and at a sufficient distance from other test specimens that may be deployed in the same vessel. In the case of testing overlapped stents, the length of overlap should be justified.

8.3 *Temperature*—The temperature of the test specimen should be maintained at 37 ± 2°C for the duration of the test. If another temperature is used, a rationale stating why the particular temperature is considered relevant should be provided.

8.4 *Solutions*—The test solution should be phosphate buffered saline (PBS) or equivalent, unless testing in a different environment (such as in distilled water or in air) can be justified. The pH of the PBS should be adjusted to 7.4 ± 0.5 with the appropriate buffering chemicals (e.g., sodium phosphate dibasic (Na_2HPO_4) to raise the pH and sodium phosphate monobasic (NaH_2PO_4) to lower the pH). The pH should be verified at the beginning and at the end of the test. Biological growth can affect the post-test evaluation of the stent surface characteristics. A biological growth inhibitor (such as an algaecide or chemical agent) may be used unless such use would negatively impact the test by unintended degradation of the specimen or the test setup.

8.5 *Test Frequency*—The test should be run at a frequency that provides a consistent cyclic deformation (e.g., with minimal secondary harmonics) that enables the application of the desired deformation of the stent.

8.6 *Stent Deformation Verification*—Applied displacement is the translation of the motion of the actuation mechanism to the mock vessel and/or stent that results in ~~the~~ deformation of the stent. The gripping technique, slip between the mock vessel and the

stent, or dynamic forces might result in stent deformation (i.e., axial, bending, torsional) that is greater or less than intended. Thus, the investigator should demonstrate that during the cyclic displacement the test specimen is subjected to the intended deformation at the frequency used in the durability test. The verification activity should be performed on a test specimen or a stent similar in structure to the test specimen. Stent deformation verification is not required for every test specimen. The number of stents used for the deformation verification should be adequate and justified. The results of this verification activity should be used to establish the procedure for controlling the deformation of each test specimen. For example, if it can be shown that the cross head displacement of the axial testing apparatus adequately correlates with the intended deformation of the ~~stent,~~ stent (e.g., with high speed imaging), this may be used to control the deformation during testing. Using a mathematical relationship between the cross head displacement and the stent deformation might also be appropriate.

8.7 *Acceptance Criteria*—A detailed prospective test protocol that describes all procedures, including those unique to the stent being evaluated, should be written. The specific failure modes to be identified, the inspections to be performed during and/or after durability testing to identify those failures, and any prospective acceptance/rejection criteria should be included in this protocol.

8.8 *Fracture Detection*—Detection of stent strut fractures while the stent is deployed in the mock vessel and mounted on the testing apparatus can be difficult. Clear or translucent mock vessels can allow for better visualization of the stent. Also, a strobe light can aid in identifying fractures during testing. The use of a bore scope or high resolution x-ray can also be appropriate for detecting stent strut fractures. Care should be taken not to damage the stents during the inspection process. Re-deployment of stents in the mock vessel following removal from the mock vessel for fracture inspection is not recommended as the stent configuration might change and the stent might be damaged during this procedure. If the stented mock vessel is removed from the test apparatus for fracture inspection, use some means to ensure stent orientation can be maintained when remounting (especially for bending durability) and consider verifying stent deformations after remounting.

8.9 *Test Termination*—The choice of the test end point can be varied and is dependent on the purpose of the durability testing. For example, the end of the test could be triggered by a prespecified duration or by a certain event like the first fracture.

8.10 *Post-Test Inspection:*

8.10.1 After the test end point is reached, a thorough evaluation of all specimens is recommended to determine all fracture locations. For certain stent designs or configurations, (e.g., braided stents or overlapped stents), fretting wear should also be evaluated. The test specimen should be removed from the test apparatus (keeping track of stent orientation for bending durability tests). Carefully remove the stent from the mock vessel (if applicable) and inspect with light microscopy or SEM to identify through-strut fractures. Identify and record the location of any through-strut fractures. Also note the direction of bending, if applicable. Other anomalies (e.g., significant wear, cracks) should be recorded.

8.10.2 SEM images may be taken of fracture surfaces and fracture locations to characterize the nature and origin of the fracture. Consideration should be given to whether or not the boundary conditions related to the testing apparatus (e.g., gripping method) might have resulted in artifactual strut fracture.

8.10.3 If testing is continued beyond the first fracture, it may become difficult to correctly determine the cause of additional fractures in the same stent. In such cases, the first fracture and all subsequent fractures should be recorded in the sequence observed, if possible. Where possible, the root cause(s) of the first fracture and all subsequent fractures should be identified, through the provision of evidence-based rationale (e.g., SEM, fractrographic analysis, FEA comparisons).

9. Test Report

9.1 The test report should include a complete summary of the materials, methods, and results, including any rationale(s) for choices within the test guide and deviations from this standard guide and/or the detailed test protocol. The effects of any such deviations on the significance of the test results should be reported. All real, artifactual, and anomalous observations should be reported, including a justification for considering negative findings as artifacts or discounting their clinical significance.

9.2 Test reports should include:

9.2.1 Purpose/objective statement, such as:

9.2.1.1 Design verification.

9.2.1.2 Scope statement regarding stents and implant locations to which the testing is considered applicable.

9.2.2 Test parameters, acceptance criteria, and justifications:

9.2.2.1 Test parameters, such as:

(1) Mock vessel material and dimensions (as applicable).

(2) Test solution including any anti-microbial agents used and temperature requirements.

(3) Test specimen gauge length.

(4) Average minimum and maximum test specimen axial deformation as a percentage of gauge length.

(5) Average minimum and maximum test specimen radii of curvature (inner or centerline).

(6) Average minimum and maximum test specimen torsion angles per gauge length.

(7) Justification for applied deformation and acceptable deformation limit.

(8) Test monitoring intervals to verify stent deformations.

9.2.2.2 Acceptance criteria, when applicable.

9.2.3 Test specimen information:
9.2.3.1 Number of test specimens.
9.2.3.2 Size (diameter, length, or other relevant dimensions) of all test specimens.
9.2.3.3 Rationale for the number of test specimens and the sizes used.
9.2.3.4 Statement regarding how representative the specimens are of the finished product.
9.2.3.5 Sterilization condition of specimens.
9.2.3.6 Traceability information.
9.2.4 Equipment used:
9.2.4.1 Test equipment.
9.2.4.2 Mock vessels.
9.2.4.3 Measurement devices.
9.2.4.4 Inspection equipment.
9.2.5 Description of test method, including all justifications and rationales recommended by this guide.
9.2.6 Summary of stent deformation verification activity.
9.2.7 Description of and justification for protocol deviations.
9.2.8 Storage location of raw data.
9.2.9 Test results:
9.2.9.1 Fracture reporting:

(1) Report inspection intervals for stent fracture. Report the number of cycles when the first fracture was detected. It may be appropriate to select inspection intervals on a log scale to capture low cycle fatigue fractures accurately.

(2) Fractures may be described according to various literature classification schemes or by clear descriptions in the report.

(3) Include the location of all fractures on a diagram, plus representative photographs. If multiple fractures occur within a single stent, the order of fractures should be reported, if possible.

(4) Root cause assessment of fractures may be warranted. This type of analysis may include a comparison of fracture location to FEA predictions and fractography to detect the initiation site.

(5) For the FTF methodology, data should be presented in tabular form providing the load level and number of cycles when fracture was observed. The number of cycles corresponding to the last inspection interval when fractures were not observed should also be reported. In addition to the tabular presentation of data, data may be presented in a figure showing the load level and number of cycles when fracture was observed.

(6) For the TTS methodology, data should be presented in tabular form identifying specimens with and without fractures and the corresponding number of cycles when the test was terminated or when fractures were observed. The number of cycles corresponding to the last inspection interval when fractures were not observed should also be reported.

9.2.9.2 Fretting wear reporting:

(1) The evaluation of fretting wear should be reported for braided stents and overlapped stents.

9.2.10 Conclusions.

10. Precision and Bias

10.1 Intra-laboratory and inter-laboratory reproducibility has not been systematically determined.

11. Keywords

11.1 axial fatigue; bending fatigue; coronary stent; durability test; endovascular cardiology; endovascular graft; endovascular prostheses; fatigue test; interventional cardiology; intravascular device test; peripheral stent; stent durability; stent fatigue; stent-graft; stent test; torsional fatigue; vascular stent

ANNEXES

(Mandatory Information)

A1. AXIAL DURABILITY OF VASCULAR STENTS

A1.1 Summary of Test Guide

A1.1.1 This test guide describes an axial durability test where the purpose is to subject the stent to a specified amount of cyclic axial deformation. The stent is deployed into a mock vessel, unless suitable justification is provided for the testing of the stent without a mock vessel as described above in ~~section~~ 8.2. This guide describes approaches for direct fixation of the ends of the stent and mock vessel to the testing apparatus or placement of the stent inside a mock vessel (stent ends not fixed) with subsequent cyclic