Designation: F2942 – 13

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.

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 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 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 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., 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

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.

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.

[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.

Current edition approved Aug. 15, 2013. Published September 2013. DOI: 10.1520/F2942-13.

[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.

3.1.6 *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 in 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 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.[3] 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) and conducting periodic inspections of the stent during testing to obtain some test specimens with fractures and some without. 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 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 the *in vivo* mechanical environment so 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 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 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., 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

[3] Gong, X-Y, Chwirut, D. J., Mitchell, M. R., and Choules, B. D., Fatigue to Fracture: An Informative, Fast, and Reliable Approach for Assessing Medical Implant Durability, *Journal ASTM International*, Volume 6, Issue 7, July 2009.

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 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 an appropriate bracketing scheme (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).

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. 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 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.

8.2.2 *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, 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 stretching of the mock vessel. A minimum and a maximum cyclic stent length are justified and applied. During the test each test specimen is monitored for the occurrence of strut fracture.

A1.2 Significance and Use

A1.2.1 This test is used to determine the durability of a stent exposed to cyclic axial deformation. The test may be used to assess conformance to product specifications and/or guidance documents, to support regulatory submissions, and for quality and/or manufacturing control purposes.

A1.2.2 The success of this test depends on the ability of the apparatus and mock vessel to consistently induce the desired length change on the stent at the applied and verified test frequency for the entire duration of the test.

A1.3 Apparatus and Mock Vessel Selection

A1.3.1 The apparatus should provide secure attachment points for the mock vessel (and/or stent, if applicable) and be capable of delivering quantifiable cyclic axial deformation to the stent.

A1.3.2 Select an appropriately sized mock vessel (e.g., silicone tube) for the stent being tested as discussed in section 8.2. The mock vessel chosen for this test should be durable and able to withstand the test conditions without significant creep or change in compliance. If the stent will not be directly secured to the apparatus, care should be taken, and experimentation is recommended, when selecting the mock vessel material, wall thickness, and the relationship between the cyclic mock vessel length and the test specimen length. Due to the difference in axial compliance between the stented and unstented tubing, the displacement of the apparatus may not be equal to the deformation of the stent. If the stent will not be directly secured to the apparatus, mock vessel selection and the stent deformation verification (section 8.6) are critical.

A1.3.3 With appropriate justification, testing by securing the stent ends to the test fixture may be done without a mock vessel. Examples of appropriate justification include experimental deformation measurements, experimental fatigue results, or finite element analysis indicating that the stent peak strains/stresses are in the same location and of the same or greater magnitude at its unconstrained diameter, or the use of FEA to adjust the test to account for the additional stress/strain that would occur due to the constraint of a vessel.

A1.3.4 For direct fixation of the stent to the apparatus, an appropriate method of attachment of the ends of the stent should be selected. The attachment should not induce artificial stresses such that fracture occurs prematurely or at artificial locations due to the fixation method. Also, note that the gauge length should not be the length of the stent.

A1.4 Procedure

A1.4.1 If applicable, perform simulated delivery as indicated in section 6.2.

A1.4.2 *Specimen Deployment:*

A1.4.2.1 *Stent Ends Directly Secured in Test Apparatus:*

(1) The stent should be deployed into the mock vessel in a temperature environment of 37 ± 2°C according to manufacturer's instructions for use, as appropriate. The stent should be deployed into a mock vessel that is not mounted on the testing apparatus. The amount of stretch of the mock vessel during deployment is critically important to the test. For example, if the intent of the axial durability test is to impose an axial shortening on the test specimen, then the mock vessel should be sufficiently stretched upon deployment of the specimen. Thus, when the stretch in the mock vessel is released, the stent will undergo axial shortening and by stretching the mock vessel an appropriate amount, the stent will not be compressed axially by the mock vessel.

(2) After stent deployment into the mock vessel, the stent's deployed length should be measured and recorded. The relationship between the stent's unconstrained deployed length and its deployed length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment. The state of the stent after deployment into the mock vessel prior to mounting on the test apparatus is considered the stent deployed condition.

(3) While maintaining the stretched condition of the mock vessel, move the stented mock vessel to the testing apparatus and secure the ends of the stent to the testing apparatus. Ensure that the stented mock vessel does not twist during mounting. Fill the mock vessel with the test solution as specified in section 8.4. Once mounted, the unsecured stented mock vessel length (i.e., between secured ends) should be adjusted so that axial compression or tension is not applied to the stent relative

to its deployed condition. Verify that the unsecured stent length in the testing apparatus is equivalent to the deployed stent length minus the length of the secured portion of the stent.

(4) When testing without a mock vessel, the stent should be deployed according to the manufacturer's instructions for use to the deployed diameter as discussed in section 6.3.3, and carefully mounted so as not to twist the stent.

A1.4.2.2 *Stent Ends Not Directly Secured in Test Apparatus:*

(1) The stent should be deployed into the mock vessel in a temperature environment of 37 ± 2°C according to manufacturer's instructions for use, as appropriate. The stent may be deployed into a mock vessel that is not mounted on the testing apparatus. Alternately, if the test apparatus is designed to allow deployment of the stent, the mock vessel may be mounted on the system prior to deployment. The amount of stretch of the mock vessel during deployment is critically important to the test. For example, if the intent of the axial durability test is to impose an axial shortening on the test specimen, then the mock vessel should be in a sufficiently stretched position upon deployment of the specimen.

(2) After stent deployment, the stent's deployed length should be measured and recorded. The relationship between the stent's unconstrained deployed length and its deployed length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment.

(3) Fill the mock vessel with the test solution as specified in section 8.4.

(4) If the stent is deployed into a mock vessel that is not mounted on the testing apparatus, mount the stented mock vessel on the testing apparatus. Ensure that the stented mock vessel does not twist during mounting. The deployed stent length should be maintained and verified once the stented mock vessel is mounted on the testing system.

(5) Record the stent's position within the mock vessel or mark the exterior of the tubing in order to monitor for migration throughout the test.

A1.4.3 *Stent Diameter Measurement:*

A1.4.3.1 Measure or determine the stent diameter in the mock vessel. The methods provided in appendix X2 of ASTM F2477 may be used to calculate the inner diameter of the stented mock vessel (assumed to be equivalent to stent outer diameter) from the outer diameter of the stented mock vessel.

A1.4.4 *Test Setup:*

A1.4.4.1 *Stent Ends Directly Secured in Test Apparatus:*

(1) Secure the stent and mock vessel to the apparatus. Alignment of the test apparatus for attachment of the ends of the mock vessel and/or stent is critical. Misalignment can lead to artifactual kinking of the stent or unintentional bending deformation. If adequate alignment is attained and kinking of the stent is still occurring, the unsecured length of the stent may need to be shortened. As applicable, the wall thickness of the mock vessel may also need to be adjusted.

(2) Measure the stent length between the grips.

(3) Adjust the apparatus to yield the desired axial stent deformation. The setup procedure established during the stent deformation verification activity (section 8.6) should be followed to ensure that the intended axial deformation will be applied to the stent. For example, if the static axial deformation of the stent was deemed to correlate well with the dynamic deformation, move the tester through a fatigue cycle and measure the stent length at the appropriate positions to verify that the relationship between the deployed stent length, minimum stent length, and maximum stent length are appropriate to yield the desired axial stent deformation.

(4) When calculating percent axial shortening, the following equation should be used:

$$\%AS = \left[\frac{(L_{Free} - L_{Min})}{L_{Free}}\right] \times 100 \qquad \text{(A1.1)}$$

where:

$\%AS$ = percent axial shortening,
L_{Free} = unsecured stent length (as measured in the mock vessel when mounted on system), and
L_{Min} = minimum unsecured stent length throughout fatigue cycle.

(5) When calculating percent axial lengthening, the following equation should be used:

$$\%AL = \left[\frac{(L_{Max} - L_{Free})}{L_{Free}}\right] \times 100 \qquad \text{(A1.2)}$$

where:

$\%AL$ = percent axial lengthening,
L_{Max} = maximum stent length between the grips throughout the fatigue cycle, and
L_{Free} = unsecured stent length (as measured in the mock vessel when mounted on the system).

A1.4.4.2 *Stent Ends Not Directly Secured to the Test Apparatus:*

(1) Secure the mock vessel to the apparatus. Alignment of the test apparatus for attachment of the ends of the mock vessel is critical. Small amounts of misalignment can lead to artifactual buckling of the stent at large compression percentages. If adequate alignment is attained and buckling of the stent is still occurring, the length of the stent may need to be shortened. The wall thickness of the mock vessel may also need to be adjusted.

(2) Adjust the apparatus to yield the desired axial stent deformation. Commonly, axial durability testing is designed to impose axial deformation in only one direction from the deployed length (either only shortening or only lengthening). If this is the case, then at one extreme of the axial deformation, the stent's length should match the previously recorded deployed stent length. For example, if the goal of the test is to simulate axial shortening of the stent, the maximum stent length throughout one fatigue cycle should be equal to the deployed length. The setup procedure established during the stent deformation verification activity (section 8.6) should be followed to ensure that the intended axial deformation will be

applied to the stent at the testing frequency. For example, if the static axial deformation of the stent was found to correlate well with the dynamic deformation, move the tester throughout a fatigue cycle and measure the stent length at the appropriate positions to verify that the relationship between deployed stent length, minimum stent length, and maximum stent length is appropriate to yield the desired axial stent deformation.

(3) When calculating percent axial shortening, the following equation should be used:

$$\%AS = \left[\frac{(L_{Deployed} - L_{Min})}{L_{Deployed}}\right] \times 100 \qquad (A1.3)$$

where:

$\%AS$ = percent axial shortening,
$L_{Deployed}$ = deployed stent length (as measured in the mock vessel when mounted on the system), and
L_{Min} = minimum stent length throughout fatigue cycle.

(4) When calculating percent axial lengthening, the following equation should be used:

$$\%AL = \left[\frac{(L_{Max} - L_{Deployed})}{L_{Deployed}}\right] \times 100 \qquad (A1.4)$$

where:

$\%AL$ = percent axial lengthening,
L_{Max} = maximum stent length throughout fatigue cycle, and
$L_{Deployed}$ = deployed stent length (as measured in the mock vessel when mounted on the system).

A1.4.5 *Running the Axial Durability Test:*

A1.4.5.1 Zero the counter.

A1.4.5.2 Start the durability test instrument and adjust the frequency to the verified rate.

A1.4.5.3 Perform periodic monitoring of the test at predetermined intervals in order to verify that the desired axial stent deformation and the position of the stent within the mock vessel are maintained throughout the test. The number of stents to be monitored for deformation control should be justified (unless each stent is monitored). At predetermined intervals, stents should be examined for fractures as described in section 8.8.

A1.4.5.4 Terminate the test and perform a post-test inspection as detailed in sections 8.9 and 8.10.

A2. BENDING DURABILITY OF VASCULAR STENTS: COLUMN BUCKLING GUIDE

A2.1 Summary of Test Guide

A2.1.1 The stent is deployed into a mock vessel after which the mock vessel is fixed to a set of bending fixtures. These bending fixtures enable the rotation of the ends of the mock vessel. The bending fixtures are mounted on an apparatus capable of imparting consistent cyclic axial motion. When the distance between the two bending fixtures is reduced, the ends of the mock vessel rotate and the mock vessel containing the stent bends to a radius of curvature. A minimum and a maximum stent bending radii are justified and applied. Each specimen is monitored during the test for the occurrence of strut fracture.

A2.2 Significance and Use

A2.2.1 This test is performed to determine the durability of a stent exposed to cyclic bending deformation. It may be used to assess conformance to product specifications and/or guidance documents, to support regulatory submissions, and for quality and/or manufacturing control purposes.

A2.2.2 The success of this test depends on the ability of the apparatus and mock vessel to consistently induce the desired bending on the stent at the applied and verified test frequency for the entire duration of the test.

A2.3 Test Apparatus and Mock Vessel Selection

A2.3.1 This test requires a durability testing apparatus capable of producing a linear displacement with adequate accuracy and resolution to repeatably obtain the desired change in stent bending radius of curvature. An example fixture that enables column buckling, bending durability testing is shown in Figs. A2.1-A2.3. These drawings are provided to show an

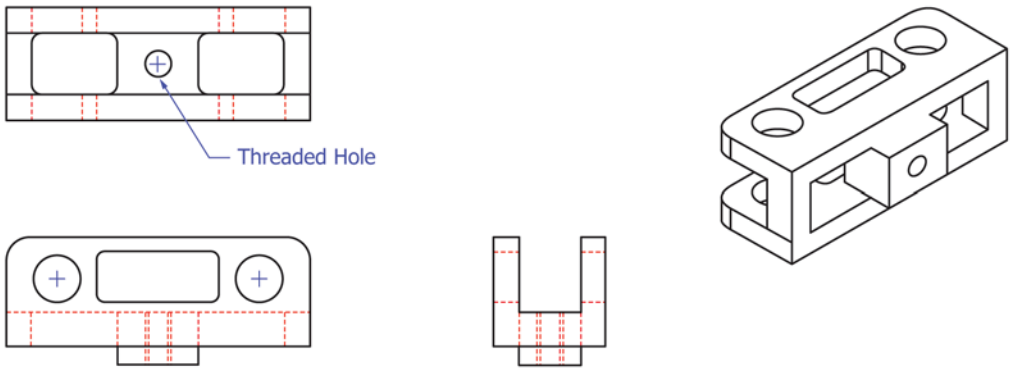

FIG. A2.1 Example of a Bending Fixture Housing (quantity =2)

FIG. A2.2 Example Bending Axle Rod and Attachment Rod (quantity =4)

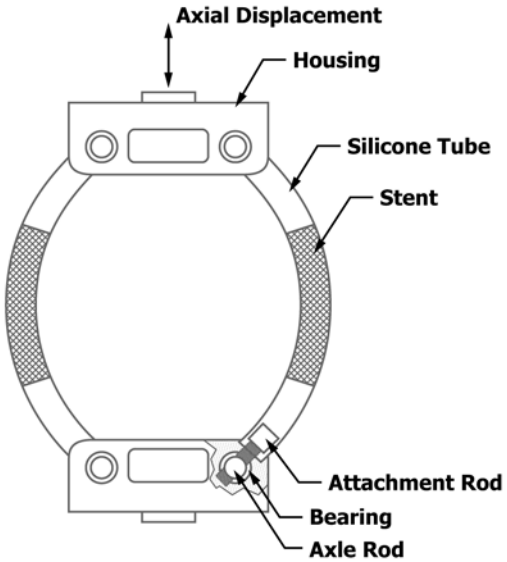

FIG. A2.3 Example of a Bending Fixture Assembly

example of a fatigue apparatus. Alternative fixtures may be used.

A2.3.2 This test requires an appropriately sized mock vessel (e.g., silicone tube) for the stent being tested as discussed in section 8.2. Select a length of mock vessel that ensures that bending of the mock vessel (instead of axial compression) occurs.. The mock vessel may be pressurized to aid in reduction of flattening of its lumen. The user is advised to balance the need to avoid mock vessel flattening with the need to maintain the deployed stent diameter and the need to avoid stent migration. Also, if there is appreciable stent ovalization, the minimum and maximum stent diameter (parallel and perpendicular to the plane of stent bending) at each radius of curvature should be measured/determined to facilitate verification of analytically modeled stent deformations.

A2.3.3 This test requires a means of securing the mock vessel to the attachment rods (e.g., hose clamps).

A2.4 Procedure

A2.4.1 If applicable, perform simulated delivery as indicated in section 6.2.

A2.4.2 Deploy the test specimen into the mock vessel in a temperature environment of 37 ± 2°C according to device instructions, as appropriate.

A2.4.3 After stent deployment and prior to mounting the stented mock vessel on the testing apparatus, the stent's deployed length should be measured and recorded. The relationship between the stent's unconstrained deployed length and its deployed length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment.

A2.4.4 Fill the mock vessel with the test solution described in section 8.4 and attach the mock vessel containing the test specimen (e.g., with tubing clamps) to the bending fixtures mounted on the fatigue testing apparatus. There should be sufficient distance between the attachment of the mock vessel to the axial rod and the stent, such that the bending of the stent is uniform from end to end. Due to the potential for test artifact, fixation of the stent to the axial rod is not recommended. Pressurize the mock vessel as applicable.

NOTE A2.1—Depending upon the stent design, the rotation of stented mock vessel relative to the applied bending axis might be important to the durability evaluation and should be considered.

A2.4.5 Measure or determine the stent diameter in the pressurized (if applicable) mock vessel. The methods provided in appendix X2 of ASTM F2477 may be used to calculate the inner diameter of the stented mock vessel (assumed to be equivalent to stent outer diameter) from the outer diameter of the stented mock vessel.

A2.4.6 Adjust the minimum displacement (acting to bend the mock vessel) of the tester to obtain the desired maximum stent radius of curvature (see Fig. A2.4). Set the maximum displacement (acting to bend the mock vessel) of the tester to obtain the desired minimum stent radius of curvature. The inner radius of curvature of the stent or the centerline radius of curvature of the stent (i.e., average of the inner and the outer radius of curvature) may be used.

NOTE A2.2—For the example fixture shown in Fig. A2.3, adjustment of the position of the attachment rods can be used to adjust the relative radii of curvature of the two mock vessels in the assembly.

A2.4.7 The setup procedure established during the stent deformation verification activity (section 8.6) should be followed to ensure that the intended minimum and maximum radii of curvature are applied to the stent. If the verification activity established that the static applied radii of curvature correlate well with the dynamic applied radii of curvature, a static measurement procedure might be appropriate. For example, with the tester at the minimum and maximum displacement

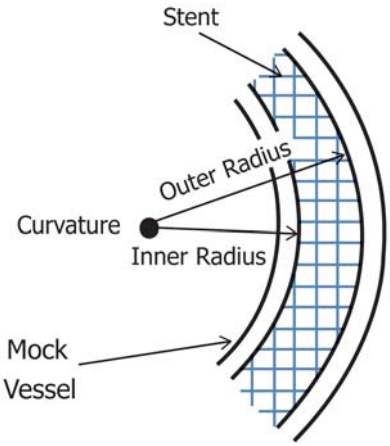

FIG. A2.4 Inner and Outer Radius of Curvature

settings, take images with adequate resolution of the mock vessel, including a reference measurement object in the plane of the mock vessel. Using the image measurement software calibrated with a reference object, measure the minimum and maximum radii of curvature. If the stent cannot be viewed through the mock vessel, measure the mock vessel radii of curvature and adjust the radii by the wall thickness of the mock vessel. Other methods to verify radii of curvature are acceptable, such as a calibrated template with multiple radii mounted behind the test specimen to which the radius of curvature of the mock vessel may be compared. For setting the tester minimum and maximum displacements dynamically, a high speed camera or strobe light with a calibrated radii template may be used.

A2.4.8 Zero the test counter and initiate the test.

A2.4.9 Start the durability test instrument and adjust the frequency to the verified rate.

A2.4.10 Perform periodic monitoring of the test at predetermined intervals in order to verify that the desired minimum and maximum radii of curvature and the position of the stent in the mock vessel are maintained throughout the test. The number of stents to be monitored for deformation control should be justified (unless each stent is monitored). At predetermined intervals, stents should be examined for fractures as described in section 8.8.

A2.4.11 Terminate the test and perform a post-test inspection as detailed in sections 8.9 and 8.10.

A3. BENDING DURABILITY OF VASCULAR STENTS: BENDING ON A MANDREL

A3.1 Summary of Test Guide

A3.1.1 The purpose of this test is to cyclically bend a stent that is deployed within a mock vessel between two specified bend radii. To create the bending action, a cylindrical mandrel is utilized to form a specific minimum bending radius for a portion of the stent within the mock vessel. This may be accomplished in two ways: *(1)* one or both ends of the mock vessel are moved through an arc such that the mock vessel wraps around the mandrel, resulting in the target minimum stent radius of curvature, *(2)* alternatively, the mock vessel is held straight and the mandrel is moved into the mock vessel, enabling the mock vessel to wrap around the mandrel while the ends of the mock vessel are moved closer together.

A3.2 Significance and Use

A3.2.1 This test is to determine the durability of a stent exposed to cyclic bending deformation. The test may be used to assess conformance to product specifications and/or guidance documents, to support regulatory submissions, and for quality and/or manufacturing control purposes.

A3.2.2 The success of this test depends on the ability of the apparatus and mock vessel to consistently induce the desired bending on the stent at the applied and verified test frequency for the entire duration of the test.

A3.3 Test Apparatus

A3.3.1 The test apparatus should facilitate cyclic bending of the stent in the mock vessel to the specified minimum and maximum stent radii of curvature (see Fig. A2.4) by the two methods summarized in section A3.1.1. An example apparatus in which the mock vessel is wrapped around a mandrel in an arc is depicted in Fig. A3.1. In this method, a movement control arm is actuated by a rotational mechanism (e.g. stepper motor or similar technology) to rotate between two defined angles. During this rotational motion, the stented mock vessel is in contact with a fixed diameter mandrel to achieve the desired minimum stent bending radius.

A3.3.2 For both methods (moving the mock vessel in an arc or moving the mandrel into the mock vessel), the movement of the end or ends of the mock vessel should be set to minimize the amount of axial stretching of the stented mock vessel as it is wrapped around the mandrel. The mandrel should also be sufficiently lubricated, or other means should be used, so that the mock vessel does not stick to the mandrel as it is pulled around it, thereby minimizing undesirable deformation of the stent. The mandrel may also be recessed with a concave groove with a radius matching the outer diameter of the mock vessel. Alternatively, a set of mating blocks may be used around the mock vessel (see Fig. A3.2). An appropriately verified method (section 8.6) is used to control the minimum and maximum stent bending radii.

A3.3.3 The mock vessel may be pressurized to aid in reduction of flattening of its lumen. The user is advised to balance the need to avoid mock vessel flattening with the need to maintain the deployed stent diameter and the need to avoid stent migration. Also, if there is appreciable stent ovalization,

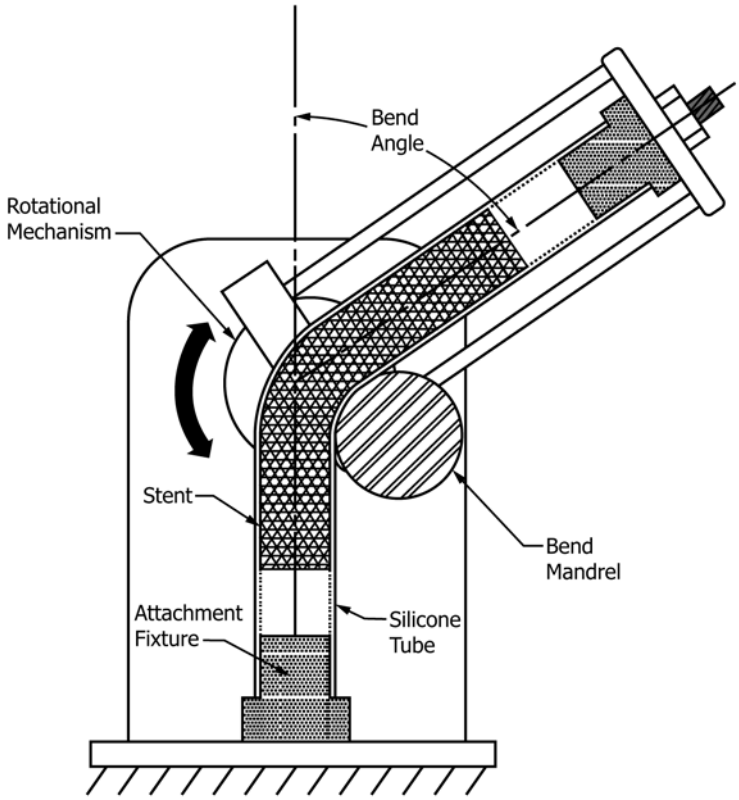

FIG. A3.1 Example Bending on a Mandrel Where the Mock Vessel is Moved in an Arc

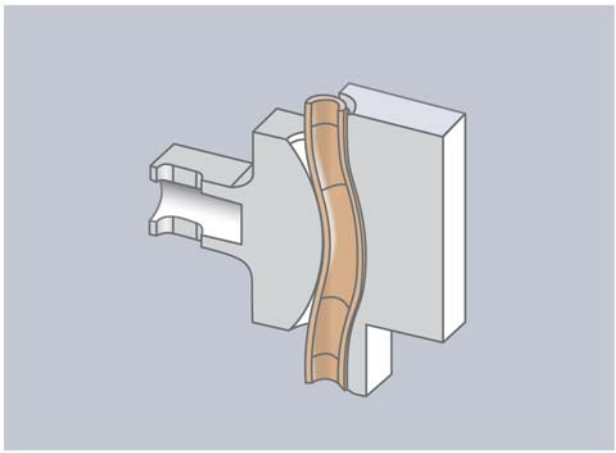

FIG. A3.2 Example Bending on a Mandrel Using Mating Blocks (cross sectional view showing blocks and mock vessel)

the minimum and maximum stent diameters (parallel and perpendicular to the plane of stent bending) at each radius of curvature should be measured/determined to facilitate verification of analytically modeled stent deformations.

A3.4 Procedure

A3.4.1 If applicable, perform simulated delivery as indicated in section 6.2.

A3.4.2 Deploy the stent into the mock vessel following the manufacturer's instructions for use.

NOTE A3.1—Depending upon the stent design, the rotational orientation (relative to the longitudinal axis of the stent) of the stented mock vessel might be important to the durability evaluation and should be considered.

A3.4.3 After stent deployment and prior to mounting the stented mock vessel in the testing apparatus, the deployed length of the stent should be measured and recorded. The relationship between the unconstrained deployed stent length and the deployed stent length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment.

A3.4.4 Mount the mock vessel with stent(s) into the durability test system. In order to avoid test artifacts, this test guide recommends fixation of the ends of the stented mock vessel to the system by clamping of the mock vessel only onto the fixture.

A3.4.5 Fill the mock vessel with the test solution (section 8.4). Pressurize the mock vessel as applicable.

A3.4.6 Measure or determine the stent diameter in the pressurized (if applicable) mock vessel. The methods provided in appendix X2 of ASTM F2477 may be used to calculate the inner diameter of the stented mock vessel (assumed to be equivalent to stent outer diameter) from the outer diameter of the stented mock vessel.

A3.4.7 The mandrel and mock vessel wall thickness assure that the desired minimum radius of curvature (see Fig. A2.4) of the stented mock vessel is attained; however, the length of the stent within the mock vessel that is bent around the mandrel should be verified. The maximum radius (see Fig. A2.4) of curvature of the same region of the stented mock vessel that is subjected to the minimum radius of curvature should be verified by the setup procedure established during the stent deformation verification activity (section 8.6). If the verification activity established that the static stent radius of curvature correlates well with the dynamic stent radius of curvature, a static measurement procedure might be appropriate. For example, set the tester to the maximum bend radius setting and take an image with adequate resolution of the stent including a reference measurement object in the plane of the mock vessel. Using image measurement software calibrated with a reference object, measure/determine the stent radii of curvature. If the stent cannot be viewed through the mock vessel, measure the mock vessel radii of curvature and adjust the measurement by the wall thickness of the mock vessel. Other methods that verify the stent radii of curvature are acceptable, such as use of a calibrated template with multiple radii mounted behind the test specimen to which the radius of curvature of the stent may be compared. For setting the stent radii of curvature dynamically, a high speed camera or strobe light with a calibrated radii template may be used.

A3.4.8 Zero the test counter and initiate the test.

A3.4.9 Start the durability test instrument and adjust the frequency to the verified rate.

A3.4.10 Perform periodic monitoring of the test at predetermined intervals in order to verify that the desired maximum and minimum stent radii of curvature and the position of the stent in the mock vessel are maintained throughout the test. The number of stents to be monitored for deformation control should be justified (unless each stent is monitored). At predetermined intervals, stents should be examined for fractures as described in section 8.8.

A3.4.11 At the conclusion of the test cycling, verify that the desired maximum and minimum stent bending radii in the region of interest are achieved and similar to the initial test conditions. The length of the stented mock vessel that is bent around the mandrel should be verified.

A3.4.12 Terminate the test and perform a post-test inspection as detailed in sections 8.9 and 8.10.

A4. BENDING DURABILITY OF VASCULAR STENTS: BEND IN AN ARC WITHOUT A MANDREL

A4.1 Summary of Test Guide

A4.1.1 A stent that is deployed within a mock vessel is bent to obtain maximum and minimum stent radii of curvature. To create the bending action, the end of the stented mock vessel is moved through an arc, resulting in the target maximum and minimum radii of curvature. Each specimen is monitored during the test for the occurrence of strut fracture.

A4.2 Significance and Use

A4.2.1 This test is to determine the durability of a stent exposed to cyclic bending deformation. The test may be used to assess conformance to product specifications and/or guidance documents, to support regulatory submissions, and for quality and/or manufacturing control purposes.

A4.2.2 The success of this test depends on the ability of the apparatus and mock vessel to consistently induce the desired bending on the stent at the applied and verified test frequency for the entire duration of the test.

A4.3 Test Apparatus

A4.3.1 The test apparatus should facilitate movement of either one or both test specimen ends in an arc in the desired bend direction. An example bending apparatus is shown in Fig. A4.1. Similar to the apparatus for bending on a mandrel, this method utilizes a movement control arm that is actuated by a rotational mechanism (e.g., stepper motor or similar technology) to rotate between two defined angles. The minimum bending radius is attained by the reaction of the stented mock vessel to the movement control arm without the use of a mandrel.

A4.3.2 The mock vessel may be pressurized to aid in reduction of flattening of its lumen. The user is advised to balance the need to avoid mock vessel flattening with the need to maintain the deployed stent diameter and the need to avoid stent migration. Also, if there is appreciable stent ovalization, the minimum and maximum stent diameters (parallel and perpendicular to the plane of stent bending) at each radius of curvature should be measured/determined to facilitate verification of analytically modeled stent deformations.

A4.4 Procedure

A4.4.1 If applicable, perform simulated delivery as indicated in section 6.2.

A4.4.2 Deploy the stent into the mock vessel following the manufacturer's instructions for use.

NOTE A4.1—Depending upon the stent design, the rotation of the stented mock vessel relative to the applied bending axis might be important to the durability evaluation and should be considered.

A4.4.3 After stent deployment and prior to mounting the stented mock vessel in the testing apparatus, the deployed stent length should be measured and recorded. The relationship between the unconstrained deployed stent length and the deployed stent length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric

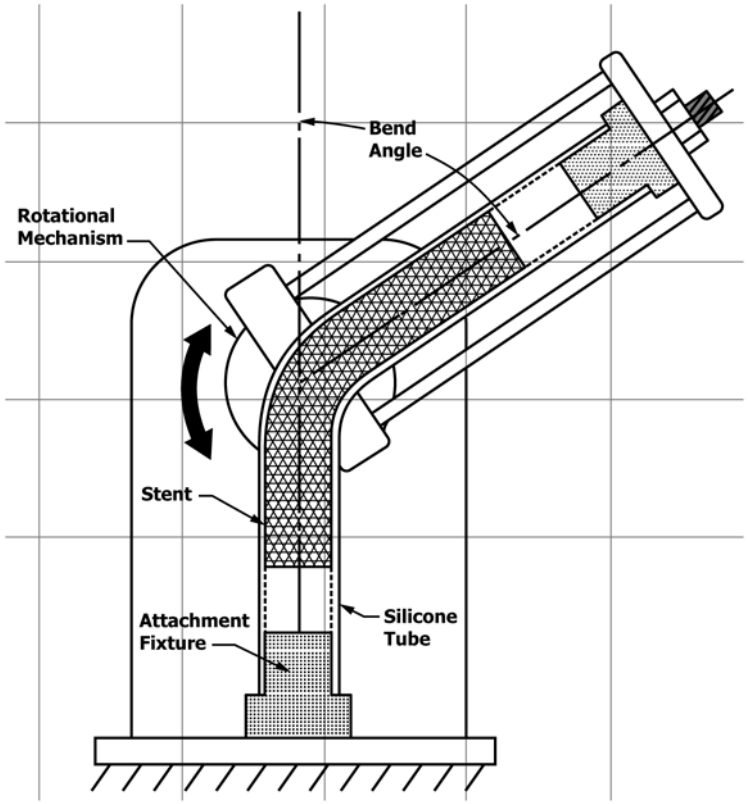

FIG. A4.1 Example Diagram of Bend in an Arc Without a Mandrel

changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment.

A4.4.4 Mount the mock vessel with stent(s) into the durability test system. In order to avoid test artifacts, this test guide recommends fixation of the ends of the stented mock vessel to the system by clamping of the mock vessel only onto the fixture.

A4.4.5 Fill the mock vessel with the test solution (section 8.4). Pressurize the mock vessel as applicable.

A4.4.6 Measure or determine the stent diameter in the pressurized (if applicable) mock vessel. The methods provided in appendix X2 of ASTM F2477 may be used to calculate the inner diameter of the stented mock vessel (assumed to be equivalent to stent outer diameter) from the outer diameter of the stented mock vessel.

A4.4.7 Verify that the desired minimum and maximum stent radii of curvature are achieved. The setup procedure established during the stent deformation verification activity (section 8.6) should be followed to ensure that the intended radii of curvature are applied to the stent. If the verification activity established that the static applied radii of curvature correlate well with the dynamic applied radii of curvature, a static measurement procedure might be appropriate. For example, set the tester to provide the minimum and maximum stent bend radii and take images with adequate resolution of the stent including a reference measurement object in the plane of the mock vessel. Using the image measurement software calibrated with a reference object, measure the minimum and maximum stent radii of curvature. If the stent cannot be viewed through the mock vessel, measure the mock vessel radii of curvature and adjust the measurement by the wall thickness of the mock vessel. Other methods that verify radii of curvature are acceptable, such as a calibrated template with multiple radii mounted behind the test specimen to which the radius of curvature of the stent may be compared. For setting the tester minimum and maximum positions dynamically, a high speed camera or strobe light with a calibrated radii template may be used.

A4.4.8 Zero the test counter and initiate the test.

A4.4.9 Start the durability test instrument and adjust the frequency to the desired verified rate.

A4.4.10 Perform periodic monitoring of the test at predetermined intervals in order to verify that the desired maximum and minimum stent radii of curvature and the position of the stent in the mock vessel are maintained throughout the test. The number of stents to be monitored for deformation control should be justified (unless each stent is monitored). At predetermined intervals, stents should be examined for fractures as described in section 8.8.

A4.4.11 At the conclusion of the test cycling, verify that the desired maximum and minimum stent bending radii in the region of interest are achieved and similar to the initial test conditions.

A4.4.12 Terminate the test and perform a post-test inspection as detailed in sections 8.9 and 8.10.

A5. TORSIONAL DURABILITY OF VASCULAR STENTS

A5.1 Summary of Test Guide

A5.1.1 This test guide describes a torsional durability test in which the stent has been deployed into a mock vessel. The purpose of this test is to induce cyclic torsional deformation in a stent. To induce cyclic torsion to the stent, the ends of the mock vessel in which the stent has been deployed are attached to an apparatus that cyclically rotates on one end of the mock vessel while the opposite end of the mock vessel remains fixed. It is also acceptable to apply cyclic torsion to the stent by securing both the stent and mock vessel to the test apparatus. The testing apparatus should be adjusted so that the amount of rotation between the mock vessel or stent attachment points is appropriate to induce the desired torsional deformation in the stent. If the stent itself is not directly secured to the apparatus, the tubing that is selected for this test should enable verification of the deformation of the stent within the mock vessel. This verification could be completed through rotation measurement of the stent through a translucent mock vessel or by other properly justified means.

A5.2 Significance and Use

A5.2.1 This test is to determine the durability of a stent exposed to cyclic torsion deformation. The test may be used to assess conformance to product specifications and/or guidance documents, to support regulatory submissions, and for quality and/or manufacturing control purposes.

A5.2.2 The success of this test depends on the ability of the apparatus and mock vessel to consistently induce the desired torsional deformation in the stent at the applied and verified test frequency for the entire duration of the test.

A5.3 Test Apparatus

A5.3.1 The apparatus should include secure attachment points for the mock vessel (and stent if applicable) and be capable of delivering quantifiable cyclic torsional deformation to the stent.

A5.3.2 The mock vessel chosen for this test should be durable and able to withstand the test conditions without significant creep or change in compliance. If the stent will not be directly secured to the apparatus, care should be taken and experimentation is recommended when selecting the mock vessel material, wall thickness, and the relationship between the mock vessel torsion and the test specimen torsion.

A5.3.3 With appropriate justification, testing by securing the stent ends to the text fixture may be done without a mock vessel. Examples of appropriate justification include finite element analysis indicating that the stent performs equally or worse at the unconstrained diameter and the use of finite element analysis to adjust the results to account for the additional stress/strain that would occur due to the constraint of a vessel.

A5.3.4 For direct fixation of the stent to the apparatus, an appropriate method of attachment of the ends of the stent should be selected. The attachment should not induce artificial stresses such that fracture occurs prematurely or at artificial locations due to the fixation method. Also, note that the gauge length should not be the length of the stent.

A5.3.5 The equipment used to induce torsion of the mock vessel and stent should have an accuracy of ±1 degrees.

A5.4 Procedure

A5.4.1 If applicable, perform simulated delivery as indicated in section 6.2.

A5.4.2 *Specimen Deployment:*

A5.4.2.1 The stent should be deployed in the mock vessel in a temperature environment of 37 ± 2°C according to the manufacturer's instructions for use, as appropriate. The stent may be deployed into a mock vessel that is or is not mounted to the testing apparatus.

A5.4.2.2 After stent deployment the deployed stent length should be measured and recorded. The relationship between the unconstrained deployed stent length and the deployed stent length in the mock vessel might have a significant impact on the durability testing results. Stent length during deployment may be affected by the stent geometric changes that occur during the expansion process and the deployment procedure (e.g., inadvertent movement of the delivery system during deployment). Therefore, the manufacturer should have a criterion for the deployed stent length; for example, the stent's deployed length should be within ± 10% of the labeled length. Observe and note the uniformity of deployment.

A5.4.3 Measure or determine the stent diameter in the mock vessel. The methods provided in appendix X2 of ASTM F2477 may be used to calculate the inner diameter of the stented mock vessel (assumed to be equivalent to stent outer diameter) from the outer diameter of the stented mock vessel.

A5.4.3.1 The portion of the stent length intended to be tested (i.e., unsecured) should not be altered during mounting of the stented mock vessel to the testing apparatus (e.g., stretching the stented mock vessel). Alternately, if the test apparatus is designed to allow deployment of the specimen, the mock vessel may be mounted on the system prior to deployment. Record the position of the stent within the mock vessel

or mark the exterior of the tubing in order to monitor for migration (axial or rotational) throughout the test.

A5.4.4 *Test Setup:*

A5.4.4.1 Once the stented mock vessel has been mounted on the test system, measure and record the stent test gage length.

A5.4.4.2 Adjust the apparatus to yield the desired torsion per stent length. The setup procedure established during the stent deformation verification activity (section 8.6) should be followed to ensure that the intended torsion is applied along the entire unsecured length of the stent. If the verification activity established that the static stent torsional deformation correlates well with the dynamic stent torsional deformation, a static measurement procedure might be appropriate. For example, set the tester at the minimum and maximum angular displacement settings and verify that the intended maximum and minimum torsional deformation of the stent are attained.

A5.4.5 *Running the Torsional Durability Test:*

A5.4.5.1 Zero the counter.

A5.4.5.2 Start the durability test instrument and adjust the frequency to the verified rate.

A5.4.5.3 Perform periodic inspections at predetermined intervals in order to verify that the minimum and maximum torsional stent deformation and position within the mock vessel is maintained throughout the test. The number of stents to be monitored for deformation control should be justified (unless each stent is monitored). At predetermined intervals, stents should be examined for fractures as described in section 8.8.

A5.4.5.4 Terminate the test and perform a post-test inspection as detailed in sections 8.9 and 8.10.