Designation: F3067 – 14

Guide for Radial Loading of Balloon Expandable and Self Expanding Vascular Stents[1]

This standard is issued under the fixed designation F3067; 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 document provides guidance for developing *in vitro* test methods for measuring the radial strength or collapse pressure of balloon-expandable vascular stents and chronic outward force of self-expanding vascular stents.

1.2 This guide is applicable to balloon-expandable and self-expanding stents of tubular geometry. It covers both stent and stent grafts. It does not cover bifurcated stents. It does not cover stents with non-circular cross-sections or tapered stents.

1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 This guide does not recommend any specific test method or apparatus for measuring the radial strength, collapse pressure, or chronic outward force. Instead, this guide provides examples of test methodologies and equipment that could be used and recommends the format for presenting test results.

1.5 This guide covers only *in vitro* bench testing methods. *In vivo* behavior might be different.

1.6 *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:*

E4 Practices for Force Verification of Testing Machines

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

F2079 Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents

F2081 Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents

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

3. Terminology

3.1 *Definitions (alphabetically listed):*

3.2 *balloon-expandable stent*—a stent that is expanded at the treatment site by a balloon catheter. The stent material is plastically deformed by the balloon expansion such that the stent remains expanded after deflation of the balloon.

3.3 *chronic outward force*—the minimum continued opening force of a self-expanding stent acting on the vessel wall at a specified diameter. The range of chronic outward force is defined by the unloading curve at the maximum and minimum indicated use diameters. Additional loading force considerations for self-expanding stents are evaluated as load excursions and described in Appendix X2. Chronic outward force is not defined for balloon-expandable stents.

3.4 *collapse pressure*—the uniform radial load during testing with a hydraulic or pneumatic apparatus in which a balloon-expandable stent undergoes buckling over a specific region or the entire stent length.

3.5 *load*—a normalized, scalar value of force applied by the stent to the vessel and, at equilibrium, the vessel upon the stent. Load should be normalized by length (newton or millinewton per millimeter length) or by area (pascal or kilopascal).

3.6 *loading line*—for balloon-expandable stents, the line derived from the substantially linear portion of the radial loading curve during initial compression. The term is not defined for balloon-expandable stents tested using collapse pressure apparatus.

3.7 *radial force*—output of radial loading that equals the radial pressure times the stent cylindrical area. The relationship between radial force (F_R) and radial pressure (P) is given in the equation:

$$P = \frac{F_R}{A}$$

where:

P = radial pressure,
F_R = radial force, and

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A = instantaneous stent cylindrical area:

$$A = \pi DL$$

where:

D = instantaneous stent expanded outer diameter, and

L = L_o for length change less than 10 % and $L = L(D)$ for length change greater than 10 %. L:L_o is the expanded stent length for balloon-expandable stents and unconstrained length for self-expanding stents. $L(D)$ is the instantaneous length of the stent as a function of the current instantaneous diameter. $L(D)$ may be either experimentally determined or computationally derived.

3.8 *radial loading*—a mechanical loading mode in which the load is directed perpendicular to the longitudinal axis of a cylinder and applied to the outer cylindrical surface of the stent. The load is applied to the entire outer surface or to at least three areas that are equally distributed around the outer circumference and extend over the entire cylinder length. Load might be expressed as radial force or radial pressure.

3.9 *radial loading curve*—the graph of radial loading output on the *y*-axis versus diametric deformation of a stent on the *x*-axis.

3.10 *radial pressure*—the area normalized output of radial loading equaling the average pressure applied to the stent by the loading fixture in the radial direction toward the stent cylindrical axis.

3.11 *radial resistive load*—the peak load during a compression excursion of a self-expanding stent. The excursion might be a single event or a cycle. A typical example is pulsatile cycling of an implanted self-expanding stent (refer to Appendix X2).

3.12 *radial strength*—a specific load on the radial loading curve that corresponds with a specific and clinically (practically) relevant amount of inward plastic deformation from the unloaded state. The term is defined only for balloon-expandable stents tested whose sole mechanism of expansion is by a balloon. Additionally, the term applies only to stents tested using a segmented head or sling type apparatus and not using a hydraulic or pneumatic pressure apparatus.

3.13 *self-expanding stent*—a stent that expands without the application of external forces or pressure, to a size and shape that is close to the desired final size and shape, when released from the delivery system.

3.14 *stent length*—unstressed length of the stent after deployment. If the stent has marker bands on non-radial force-producing components, the length is measured from the ends of the radial force producing sections. The measured length of mounted or expanded stents should be measured by non-contacting instruments (profile projection, laser micrometer, and so forth) with a resolution of 0.1 mm or better (see Guide F2081).

3.15 *stent graft*—transluminally placed tubular vascular prosthesis, with one or more integral stent components to provide fixation or radial support, or both, residing partially or completely within a vascular conduit to form an internal bypass or shunt between sections of the vascular system.

3.16 *unloading line*—for balloon-expandable stents, the line derived from the substantially linear portion of the radial unloading curve. The term does not apply for balloon-expandable stents tested using collapse pressure apparatus.

3.17 *vascular patency*—a measure of the extent to which the vessel is open (unrestricted). Typically reported as a percent of the reference (unrestricted, adjacent) vessel diameter or cross-sectional area.

3.18 *vascular stent*—a tubular synthetic structure that is implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency. For the purpose of this guide, a stent might be metallic or non-metallic. It might be durable or absorbable.

3.19 *zero compression diameter*—the diameter reference point required for the testing apparatus to fully engage the stent outer surface. Stent compression is calculated in comparison to this diameter.

4. Significance and Use

4.1 Upon deployment, at the site of the vascular stenosis, the stent establishes the patency of the lumen until vascular remodeling occurs. The radial load acting upon the stent is imparted by vessel and lesion stretch. Additionally, the vessel might be affected by excursions due to pulsation (systolic and diastolic variation), muscle-skeletal interactions due to patient movement, as well as external sources (e.g., patient is struck in the neck during a car accident). The excursions vary in magnitude and type based on the location of the vessel.

4.2 In order to maintain vessel patency, the stent has to withstand the forces acting on it without experiencing excessive deformation, migration, or sustained collapse; therefore, it is required that the stent possess adequate resistance to these loads.

4.3 Depending on the type of device and the clinical concern, the resistance to these loads can be presented through multiple test outputs: radial strength, collapse pressure, or chronic outward force.

4.4 The guidelines presented here can be used in the development of test methods to determine the radial loading properties of stents. This guide provides examples of different test apparatus (equipment and tooling), radial loading curves, and calculations. Although the apparatus and methods presented can be used as a reasonable simulation of actual clinical use, they have not been demonstrated to predict the actual *in vivo* clinical performance of any stent.

5. Summary of Guide

5.1 As defined, radial loading is applied uniformly over the entire stent surface at a minimum of three evenly distributed circumferential locations over the full length of the stent. Testing in which a portion of the stent extends outside aperture is not specifically discussed within the guide because it does not result in uniform radial loading since a portion of the stent outside the aperture might also contribute to the load. Further, the direction of loading is radially inward as shown in Fig. 1. The uniform radial loading is applied to at least three areas that

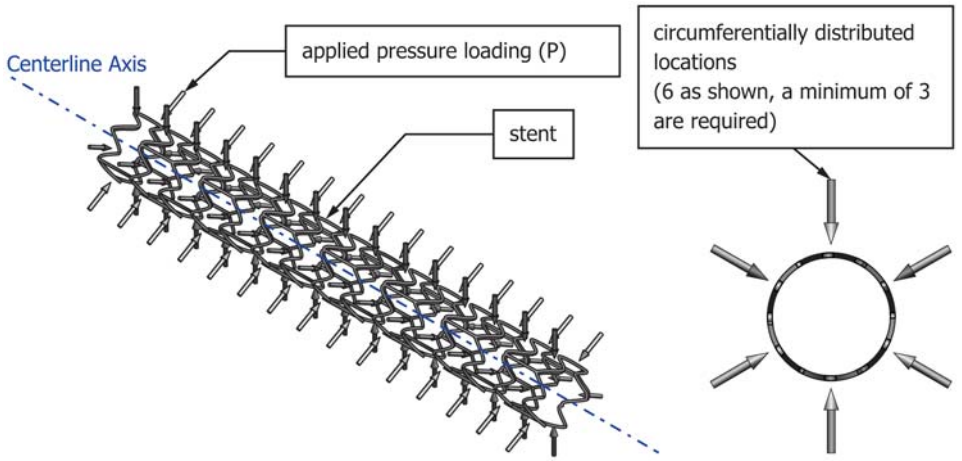

FIG. 1 Radial Loading

are equally spaced around the outer circumference and extend over the entire cylinder length.

5.2 Some stents are designed to have significantly different mechanical properties along their length. In these cases, it might be preferable to test specific regions of the device. This might require apparatus (equipment or tooling) or changes to accommodate local application of loading (e.g., inserts, machined gaps, or having the test article extend past the edge of the fixture). In addition, the assessment of the loading is complicated because the loading of the tested region will be affected by the portion of the stent which is not being tested. The treatment of these modifications and the normalization of loading are not specifically covered in this guide and should be mentioned within the test report.

5.3 Radial testing of stents will differ depending on the stent type (balloon-expandable versus self-expanding) as well as the apparatus used (segmented head, sling, or hydraulic/pneumatic). The apparatus is selected based on clinical effects (concerns) and limited by the stent type. For example, the hydraulic/pneumatic apparatus cannot typically be used for testing of self-expanding stents from the sheath to the unloaded diameter because the tubing is likely to flatten or rupture within the large test range. The following summary outlines different apparatus, based on stent type, and the associated clinical effects that can be evaluated (see Fig. 2).

5.4 In order to distinguish between different stent types as well as the apparatus used, separate test outputs are defined in order to clarify, and limit, the comparisons between test results. For example, a distal ring (edge, local) collapse of a balloon-expandable stent as measured (collapse pressure) using a hydraulic/pneumatic test apparatus might not directly convert or correlate to the radial strength output of the same device tested using a segmented head apparatus. Further, because the loading behavior of balloon-expandable and self-expanding stents are very different, the self-expanding stent test output terminology is chronic outward force rather than radial strength or collapse pressure. Different test output terms are utilized in order to clarify the differences and limit comparisons.

5.5 The clinical effects listed in Fig. 2 are separate from the device effects. The device effects are directly observed stent events, while the clinical effects are the anticipated concerns associated with the event. The clinical concerns presented are examples; other clinical concerns might be identified from the same list of device effects.

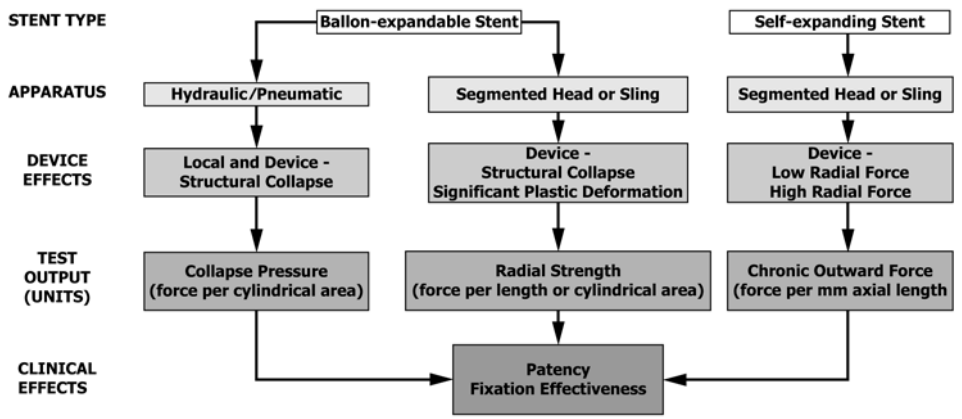

FIG. 2 Summary Guide

5.6 Since the test outputs of load are normalized (either by length or area), it is important to realize that the interpretation of output has inherent limitations for stents that are designed to have significantly stronger (more resistive) and weaker (less resistive) portions. This is truer for the sling and segmented head apparatus than the hydraulic/pneumatic collapse pressure apparatus. The hydraulic/pneumatic tester can visually detect a localized region of weakness that collapses during pressurization.

6. Apparatus

6.1 The key element of radial testing is the selection, or development, of an apparatus (equipment and tooling) that radially loads the stent.

6.2 The type of radial loading, as described in Fig. 1, is a theoretical construct and each type of loading apparatus has some degree of deviation from the perfectly distributed radial loading. There are multiple types of apparatuses that are capable of applying a radial load to a cylindrical stent with adequate uniformity.

6.3 This guide describes three specific types of apparatus that might be considered for radial testing: segmented head, sling, and hydraulic (or pneumatic) chamber.

6.4 This guide does not provide detailed descriptions or guidelines for test apparatus design; thus specific and unique interpretations of the apparatus are expected by the test laboratory or equipment developer. Additional tooling, not described, might be valuable in improving the test method consistency (precision and robustness) and accuracy.

6.5 It is expected that other apparatus (i.e., significant deviations from the equipment design concept) not described within this standard might also be adequate to radially load vascular stents. If another apparatus is utilized, rationale to justify the suitability of that apparatus should be provided. For example, a data correlation to test results from one of the test equipment listed in this guide might be used. It is expected that each apparatus will have specific limitations or requirements when testing specific groups of specimens or testing specific ranges of diameters. Test method development should map the use and limitations of the equipment for test articles.

6.6 It is recognized that the choice of test apparatus is likely to influence the characteristic shape of the radial loading curves and thus the test output. Therefore, direct comparisons between results obtained using different equipment is discouraged unless data correlations are completed.

6.7 Because the specimens are often either destroyed (e.g., balloon-expandable stent testing) or change with repetition (e.g., self-expanding stents), creating a correlation between different test apparatus might require comparing test groups rather than direct specimen correlation (i.e., paired test data).

6.8 The apparatus for testing self-expanding and balloon-expandable stents that are sensitive to temperature in the approximate range of 20 to 40 °C (the range from laboratory to body temperature) should be designed to maintain the temperature at 37 ± 2 ºC. It should have a temperature control system as well as monitoring gauges.

6.9 It is expected that all individual apparatuses and applied methods should have precision evaluated for the intended test articles evaluated. Bias evaluation is not required as there is not an accepted reference value or standard. Terms and concepts for precision and bias may be found in Practice E177. Consistent use of the terms between different laboratories aids in clarity when comparing method assessments as well as test method validation results.

6.10 The loading rate affects test output. The loading may either be displacement-controlled (linear motion on the load tensile test machine for a sling apparatus) or pressure-controlled (pressurization rate for a hydraulic collapse apparatus). The rate of compression (or expansion) or pressurization should be slow enough to minimize inertial effects of moving parts but quick enough to minimize binding caused by static friction. The testing, however, does not require continuous movement. Pausing at intervals might be useful to allow the system to equilibrate. The testing does not need to match physiologic rates of change, but rather should try to increase test result precision and robustness and minimize variation between equipment and laboratories.

6.11 Force and diameter calibration through the entire load path for the segmented head and sling test equipment should be completed. The hydraulic/pneumatic head test equipment requires pressure calibration and also requires calibration of the diameter measurement if so equipped.

6.12 *Segmented Head Apparatus:*

6.12.1 Fig. 3 describes the operation of a segmented head type radial loading apparatus. This fixture employs wedge-shaped elements that are simultaneously activated through an arc. This motion changes the effective diameter of the opening in the center of the head, thus compressing the stent or allowing it to expand. Note that the specimen is shown as partially inserted into the head, simulating the loading of the stent; however, during testing the unit should be fully inserted.

6.12.2 Segmented head equipment measures mean load resistance for an entire stent at a given diameter due to the fact that the wedge segments are rigid. Because of this, the apparatus cannot discriminate between weaker and stronger regions of a stent. In addition, the apparatus maintains a circular (inscribed) cross section. Therefore, if a stent deforms in a non-circular shape, forces might change due to local areas of non-contact with the segments. In this situation the forces might not fully characterize the non-circular stent (which are not in scope of this guide). Preferential deformation along the axial length, as well as edge effects due to vessel collapse, might be better evaluated using a hydraulic or pneumatic apparatus.

6.12.3 The segmented head equipment typically measures the applied load from an actuator that causes a subsequent force application to the test specimen. Thus, the applied load is converted to an actual load (or pressure) on the stent, and a conversion is established. The conversion of measured force/pressure to the applied force/pressure might be done theoretically (e.g., using a free body diagram and force balance) or by measuring both the input and output forces/pressures and creating data conversion curves.

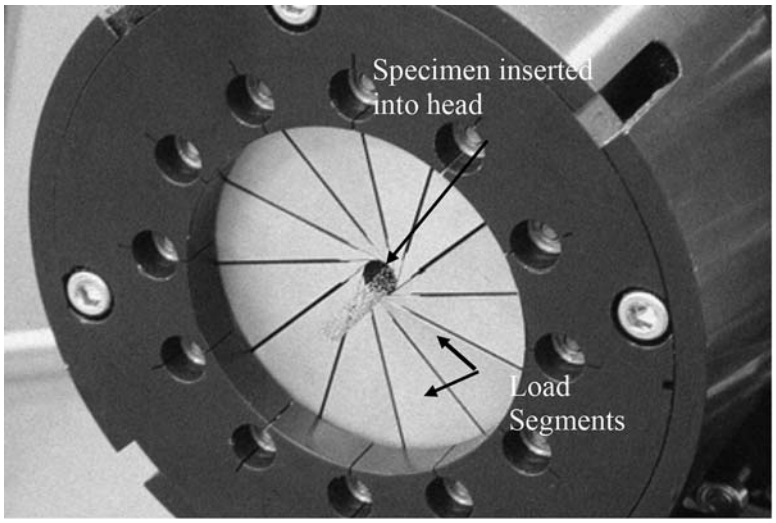

FIG. 3 Segmented Head Fixturing (stent is partially inserted for illustrative purposes)

6.12.4 Segmented head type equipment has the ability to measure radial load over a very large range of diameter. Therefore, for self-expanding stents the radial load can be measured from sheathed to fully unloaded. The equipment might be well suited for investigating the radial forces associated with loading the stent into the deployment device, evaluating chronic outward forces at the minimum and maximum indicated use diameters, and to conduct excursion testing (e.g., pulsatile simulation testing) for self-expanding stents (refer to Appendix X2).

6.12.5 Apparatus friction reduction and monitoring is important, especially for small diameter as well as short length test specimens. The zero load friction effect of the apparatus can be evaluated by running it without a stent in order to capture a baseline friction curve. The baseline friction curve includes both the loading and unloading in the range of diameters and at the same speed as the device is tested. The curve then can be subtracted from all tested device curves or, if negligible, ignored.

6.12.6 The baseline friction associated with the apparatus (noise) should not significantly affect the result (signal) compared to the specification or should be subtracted from the radial loading curve. If the loading result is low (less than 5:1) in comparison to baseline friction (signal to noise ratio), apparatus modifications (shorter head length or segment modification) to reduce friction or other testing techniques e.g., evaluating longer stent lengths or testing multiple stents) should be considered. It is recommended that the apparatus friction be monitored during long term testing to track wear or debris buildup within the segments that limit their smooth motion and cause misalignment to the actuating mechanism.

6.12.7 In addition to the internal friction, the equipment developer and test engineer should consider the friction forces between the head contact surface and the stent outer surface. Significant normal forces might be generated; thus the frictional drag between the stent outer surface and the head segments. These loads will falsely add to the measured radial load. Thus, the design of the fixture, selection of a segment material (or surface finish), and rate of loading (or unloading) should be considered. These loads can vary greatly and might be appreciable at high loads. Unfortunately, these loads cannot be evaluated by operating the apparatus head empty. Indications of high frictional loads might be device twisting (seen post testing) or uneven loading/unloading curves.

6.12.8 The diameter of the segmented head is defined by the inscribed circle defined within the contact segments (see Fig. 4).

6.12.9 Force applied to the stent might affect the apparent diameter of the aperture if the aperture size is measured indirectly. If the error is deemed significant, a force correction curve or table might be used to adjust the diameter measurements.

6.13 *Sling Apparatus:*

6.13.1 Fig. 5 shows the operation of a sling-type radial force tester. This fixture employs a low friction sling which when pulled through a restriction tightens around the stent test article, thus radially compressing the stent. For self-expanding stents the fixture might be used to evaluate forces during the unloading of the stent through the operating range of compression (minimum and maximum indicated use).

6.13.2 As the sling aperture is reduced the sling material will stretch. Thus, the compliance of the material will affect the length of sling material. Because the sling material stretches, Eq 3 is used to determine the "effective" diameter. Eq 4 is used to determine the radial force from the linear force.

$$D = D_0 - \frac{2}{\pi}\left(\Delta x + \frac{F_L}{K}\right) \tag{3}$$

where:

D = diameter as a function of crosshead position (computed),
D_0 = initial diameter (directly measured), and
Δx = change in linear displacement of the crosshead (may be less than zero depending on x and x_0):

where:

$$\Delta x = x - x_0$$

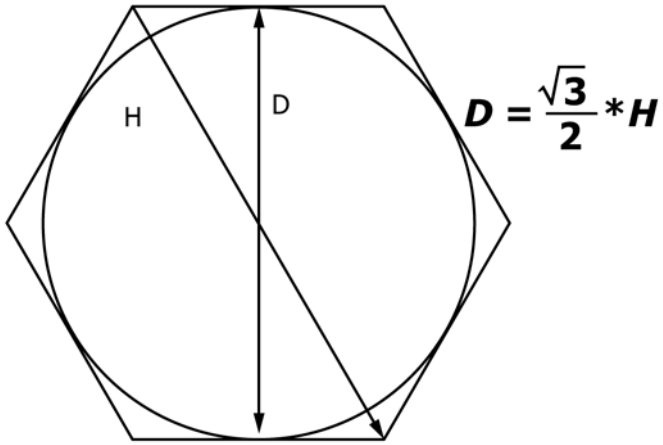

FIG. 4 Equivalent Diameter for Segmented Head (Example of a Hexagon)

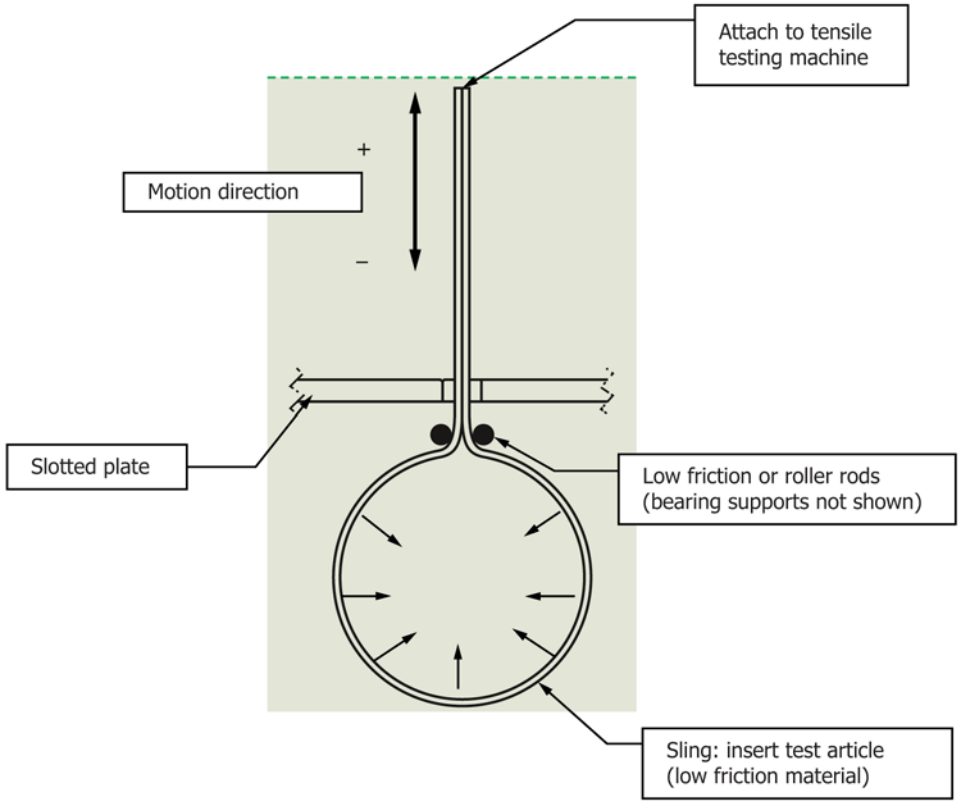

FIG. 5 Sling Type Radial Loading Fixturing

x_0 = initial position of crosshead,
x = position of crosshead (up direction is positive as shown),
F_L = linear force measured by tensile machine, and
K = spring constant associated with sling:

where:

$$K = \frac{2EA}{L_0}$$

E = elastic modulus of sling in tensile direction
A = cross sectional area of the sling material
L_0 = relaxed length of sling material from attachment location.

$$F_R = \pi F_L \quad (4)$$

F_R = radial force (computed), and
F_L = linear force measured by tensile machine.

6.13.3 Because of these considerations, the sling should be made of a material that has a low bending stiffness but high tensile stiffness. This is more critical for small diameter test specimens.

6.13.4 Loads due to sling bending and apparatus friction associated with the sling, rods, and plates can be partially evaluated by running a load and unload cycle (for self-expanding stents in the elastic region of the device) with the loop empty. This is useful for both developing the apparatus design (e.g., gaps between rods, sling material, sling thickness) and for monitoring the apparatus over time. However, it should be realized that sling bending and friction loads might be a function of stent radial load and stent diameter. This might not be linear and might be appreciable at high radial loads and or small stent diameters. Low and consistent friction is critical.

6.13.5 If the stent result to friction obtained by running the loop empty (signal to noise ratio) is low (perhaps less than 5:1), apparatus modifications (e.g., different sling material or change in fixture gap) to reduce friction, or other methods (e.g., test longer stent length, test multiple stents, or pause to allow friction dissipation), should be considered.

6.13.6 In addition to the internal friction, the equipment developer as well as the test engineer should consider the friction forces between the sling and the stent outer surface. Significant normal forces might be generated and thus frictional drag between the stent outer surface and the sling increases. These loads will falsely add to the measured radial load. Thus, the design of the fixture, selection of a sling material (or at least contact surface) with high lubricity, and rate of loading or unloading should be considered. Friction forces also tend to build up during compression and expansion. Multiple stop points might be used in order to allow friction forces to be released and measured force values to stabilize. Indications of high frictional loads might be device twisting (seen post testing) or uneven loading/unloading curves.

6.13.7 Repeated calibration or verification of the initial diameter of the sling should be established to adjust for slippage within the fixture or plastic deformation of the sling.

6.13.8 The force testing equipment, which is connected to the sling apparatus, should be calibrated in accordance with Practices E4. In practice, the error of the force test equipment should be significantly less than the artifactual loads associated with the sling apparatus.

6.13.9 The displacement range needed for the sling computed diameter range should be within the verified range of displacement for the force test equipment.

6.14 *Hydraulic or Pneumatic Chamber Apparatus:*

6.14.1 If one wishes to test one specimen over a large range of diameters, the hydraulic (or pneumatic) chamber, as described, is not considered suitable. Since self-expanding stent testing often requires relatively large diameter ranges, it is often not suitable for use for these devices. However, for a narrow range it is an acceptable apparatus.

6.14.2 Fig. 6 describes the operation of a pressurized hydraulic or pneumatic radial force tester.

6.14.3 This fixture employs a pressurization system that applies a load to a stent deployed in a thin elastic tube. Optionally, an optical system can be used to measure the stent or elastic tubing diameter in order to determine the onset of collapse. The system generally measures the deployed stent through a clear glass or plastic window within the chamber. The elastic tubing is sealed to the chamber wall, ensuring that there is no fluid or air leakage during the pressurization. It is acceptable to either: *(a)* deploy directly into the tubing, measure the stent or stented tube diameter, and then install into the apparatus or *(b)* to install the elastic tubing in the apparatus, deploy the stent, and then measure the diameter. In either method, the diameter measurement system should be calibrated. If an introducer is used, it remains open during the test to ensure that the stent inner diameter remains at zero gage pressure (laboratory nominal pressure).

6.14.4 If it is desired to estimate the stent diameter during pressurization, the stent outer diameter might be indirectly approximated by subtracting twice the tube wall thickness from the measured elastic tube outer diameter. For small changes in tubing diameter, or axial stretch, the unloaded tube wall thickness is adequate; however, for large changes the tube wall thickness should be evaluated as a function of the tube condition (stretch, material, and wall thickness; reference Test Methods F2477, Appendix X2, for calculations).

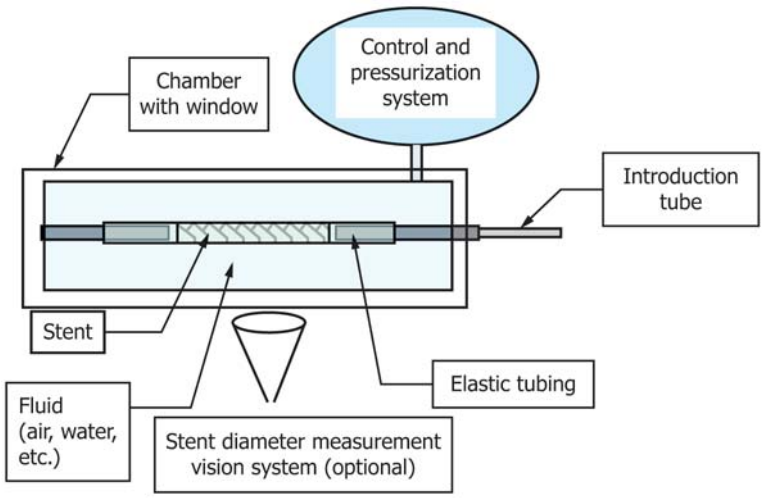

FIG. 6 Typical Hydraulic or Pneumatic Radial Loading Apparatus

6.14.5 The tubing should generally be as thin and elastic as practical so as to not shield the device from the applied pressure load.

6.14.6 Tubing wall thickness and material should be considered for durability and resistance to pinhole leaks. Pressure monitoring or visual inspection, if water is used, is recommended to detect leaks.

6.14.7 Tubing wall thickness variation might affect tubing compliance and therefore the loading applied to the stent. The test method should provide for the evaluation (e.g., pre-test characterization testing) or controls (e.g., storage conditions and shelf-life) to ensure tubing elastic and dimensional consistency.

6.14.8 Changes in tube elasticity due to aging might affect the test results. If the tubing is to be stored for an extended period of time, the tube material should be evaluated for its compliance change with aging. If applicable, the test method should provide controls to limit tube aging effects or otherwise account for the effects during data analysis.

6.14.9 The length of unsupported mock vessel between the inner edge of rigid chamber tube and the stent will contribute to an edge effect by either aiding or resisting stent compression as the test progresses. Some gap might be necessary for clinical representative loading at the stent ends. The desired gap should be determined based upon elastic tubing characteristics (outer diameter, wall thickness, and compliance), stent and chamber tube outer diameters and the expected reduction in stent outer diameter prior to the initiation of collapse. Generally, the gap should be less than one diameter in length. It is recommended that the test method or apparatus provide for controlled positioning of the deployed stent to achieve the desired gap.

6.14.10 If the stent diameter is measured and if the chamber is hydraulic (rather than pneumatic) the effect of water refraction must be included in vision system calibration. The compressibility of the fluid (air, water, etc.) will affect the ability to pressurize the system quickly. A gaseous fluid (e.g., air) will require a slower rate of pressurization in order to precisely measure the system response. An appropriate maximum pressurization rate should be established. Additionally, pausing at stepped intervals might limit the variability associated with the pressurization rate and fluid compressibility.

6.14.11 An advantage of the hydraulic/pneumatic apparatus is that it might be able to identify radial resistive characteristics associated with a regional stent design difference. For example, an increased ring spacing or reduced strut thickness in one region of the stent could be evaluated. Additionally, the transition between the stented and un-stented region of the vessel might be evaluated for edge-loading effects and injury potential.

6.14.12 If stent diameter is being measured, taking measurements in at least two orientations 90° apart is recommended to account for non-circularity that might impact the identification of collapse. Either a root mean square calculation for equivalent diameter based on the measurement or, for simplicity, the arithmetic mean of the measurements can be used as the "equivalent" diameter.

6.14.13 For devices with large gaps (for example, gaps to allow for vessel side branch access) there might be localized tubing collapse at high pressures. This should be evaluated in terms of the clinical relevance of the test to determine if any localized collapse is of concern for the tested device.

7. Radial Loading Measures and Interpretations

7.1 *Categories of Characteristic Radial Loading Curves:*

7.1.1 There are characteristic loading curves (load versus. diameter) based on the type of test apparatus (segmented head, sling, or hydraulic/pneumatic) and the type of stent (balloon-expandable or self-expanding) evaluated. The following sections illustrate the characteristic curves (radial load versus diameter) that are generated during testing and the data interpretation that might be used. The curves and interpretations are divided into the following three categories (see Fig. 2).

7.1.1.1 Radial strength testing of balloon-expandable stents using segmented head or sling apparatus.

7.1.1.2 Chronic outward load testing of self-expanding stent testing using a segmented head apparatus or sling apparatus.

7.1.1.3 Collapse pressure testing of balloon-expandable stents using hydraulic/pneumatic apparatus.

7.1.2 It is best to describe the mechanical action of the apparatus and the resultant load versus diameter curves simultaneously because it clearly and graphically describes both the testing and results. The following sections are presented for the three categories identified.

7.2 *Balloon-Expandable Stent Loading Curve for Segmented Head or Sling Apparatus:*

7.2.1 A plot for a balloon-expandable stent using a segmented head or sling apparatus establishes the radial loading curve. An example is shown in Fig. 7.

7.2.1.1 The load is shown as one complete cycle and separated into four segments: *(1)* initial loading, *(2)* loading with increased plasticity, *(3)* unloading, and *(4)* return.

7.2.1.2 The radial load (*y* axis) should be expressed either as a force normalized by the initial stent deployed length (N/mm) or as a force normalized by area (kPa). If using area normalized radial load, use the instantaneous stent diameter, instead of the starting diameter, multiplied by the initial deployed length (see Eq 1). The fixture diameter (*x*-axis) is expressed in millimeters (mm). When the stent is in complete circumferential contact with the fixture then the stent outer diameter equals the fixture diameter.

7.2.1.3 As shown in Fig. 7, Detail A, there might be a substantially non-linear portion of the initial load curve as the fixture begins to engage the stent. This portion of the curve is not considered to represent the response of the stent as many of the struts have not yet fully contacted the fixture loading surfaces. A marked increase in radial loading can be observed once the fixture starts to fully engage the test specimen.

7.2.1.4 After engagement of the stent, the initial portion of the loading cycle is approximately linear (see Fig. 8). The loading line is created by the steepest, substantially linear portion of the loading curve. One technique of establishing the zero compression diameters is to use the intercept of the loading line with the *x*-axis (as shown in Fig. 7). Other valid techniques for determining the zero compression diameter include using a specified pre-load or a slope (or rate of change

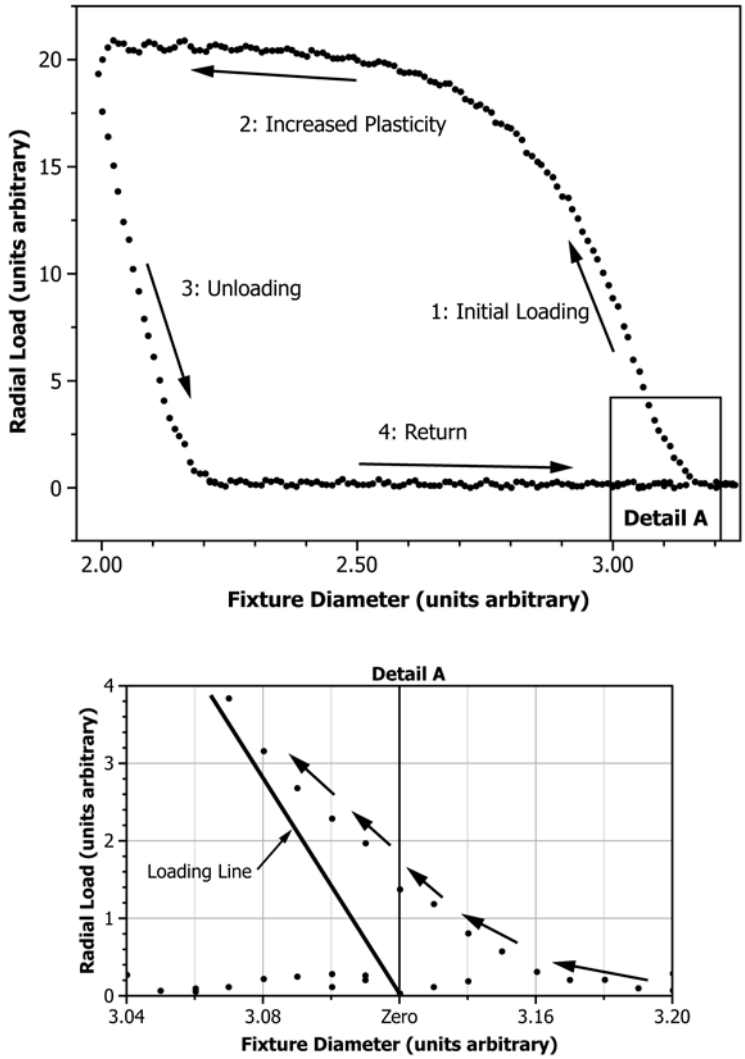

FIG. 7 Typical Radial Loading Plot of Balloon-Expandable Stent Using a Segmented Head or Sling Apparatus

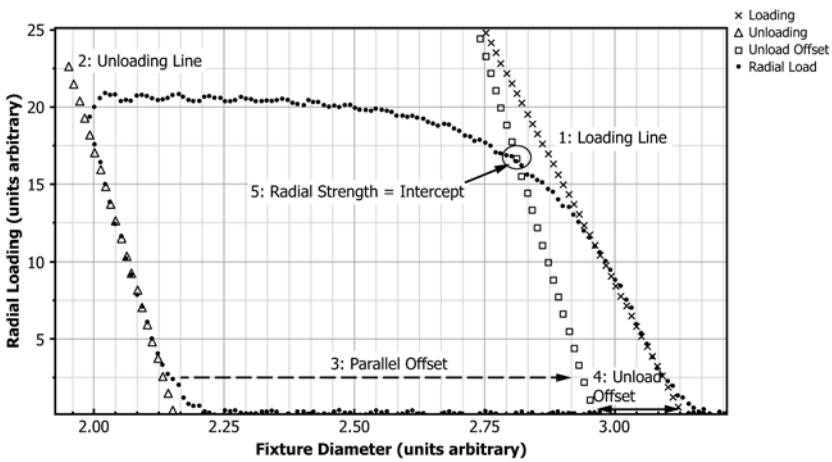

FIG. 8 Typical Radial Loading Determination for a Balloon-Expandable Stent using a Segmented Head or a Sling Type Apparatus

of slope) criterion. This reference diameter marks the start of stent compression. It should be similar to or slightly smaller than the measurement of the intrinsic recoiled outer diameter of the stent (see Test Method F2079).

7.2.1.5 The initial linear part of the curve might be elastic or a combination of elastic and plastic deformation. Eventually the stent undergoes increased plastic deformation as the curve starts to flatten (the load increases at a decreasing rate) with greater compression.

7.2.1.6 The stent must be compressed to a greater deformation than is expected clinically in order to obtain the loading data required to compute the radial strength output result. Once this maximum compression is reached the stent is unloaded. It has been observed, in a limited number of stent designs, that the unloading lines are approximately parallel for a relatively wide range of maximum compression diameters (see Appendix X1). This observation allows for the use of an offset line parallel to the unloading line and is a key premise to the measurement of radial strength.

7.2.1.7 In a similar manner to the loading line, the steepest portion of the substantially linear unloading curve is used to create the unloading line. The difference between the loading line *x* axis intercept and unloading line *x* axis is the diametric plastic deformation of the stent due to compression.

7.2.1.8 The measured unloading line can be offset parallel so that its intercept with the *x*-axis is at a specific amount of plastic deformation from the initial diameter. The intersection of this offset line with the loading curve establishes a specific point (load) that is expected to produce the specified amount of plastic deformation created by the offset value. This plasticity might have clinical significance.

7.2.1.9 Clinically relevant compressions might be based on the following possible criteria:

(1) Stent migration (fixation effectiveness).

(2) Inadequate acute vessel patency.

7.2.1.10 For stent designs with load deformation curves similar to that of Fig. 8, the intersection of the offset unloading line with the loading curve establishes the maximum compression (*x*) for radial strength determination. The radial strength for the chosen offset is the maximum radial load which occurs at or before the intercept of the offset line and the radial loading curve. Fig. 8 illustrates the condition where the intercept of the offset line and the loading curve is the maximum load, and thus the radial strength. In some designs, however, the peak load might occur prior to the intercept. When this occurs, the radial strength is the peak load prior to the intercept and not the load associated with the intercept of the offset line and the radial loading curve (see Fig. 9). Thus, the radial strength is the corresponding maximum load for a given, clinically important, permanent deformation.

7.2.1.11 The test noise needs to be minimized adequately, based on the selected offset, to avoid erroneously low radial strength measurement.

7.2.1.12 This approach is based on a loading curve characteristic in which the unloading line is approximately parallel for a relatively wide variety of compressions including the specific compression that would have resulted in a final, critical plastic deformation. Treatment of the condition where this is not true is illustrated in Appendix X1. The methodology of cyclic stepped loading in Appendix X1 may always be used instead of the above approach because it does not assume the unloading curves to be approximately parallel. If a cyclic stepped load approach cannot be performed due to instability in the unloading (e.g., buckling), an alternate approach should be developed.

7.3 *Self-Expanding Stent Characteristic Loading Curve for Segmented Head or Sling Apparatus:*

7.3.1 Fig. 10 shows a typical radial unloading and loading curve for a self-expanding stent using a segmented head or sling type apparatus.

7.3.2 It is a key decision to begin the testing by either: *(1)* directly deploying into the test apparatus or *(2)* compressing from the free-state (fully unloaded).

7.3.3 For the direct deployment technique, the aperture is adjusted to larger than the sheathed diameter (2.5 mm as shown) but smaller than the minimum diameter of use (5.0 mm as shown). There are three squares shown in Fig. 10, as examples, indicating that there is a range of deployment diameters available. The effect of deployment diameter should not have a significant impact on the resultant chronic outward force if selected near enough to the sheathed diameter. However, if there is a practically significant difference in

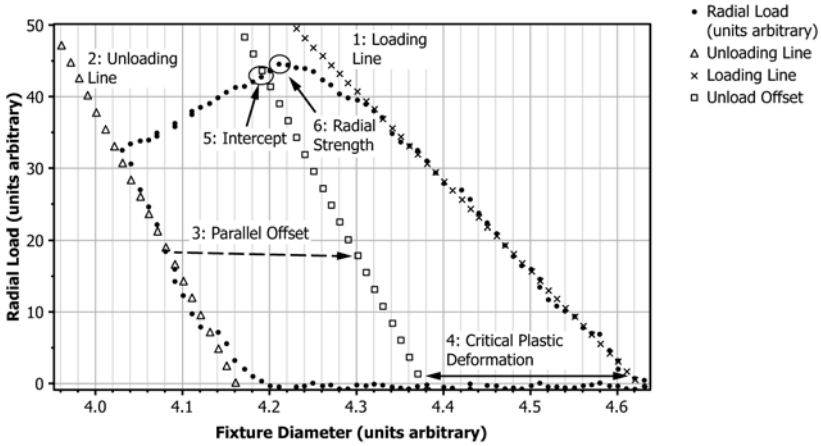

FIG. 9 Typical Radial Loading Determination for a Balloon-Expandable Stent using a Segmented Head or a Sling-Type Apparatus with the Peak Load greater than the Intercept

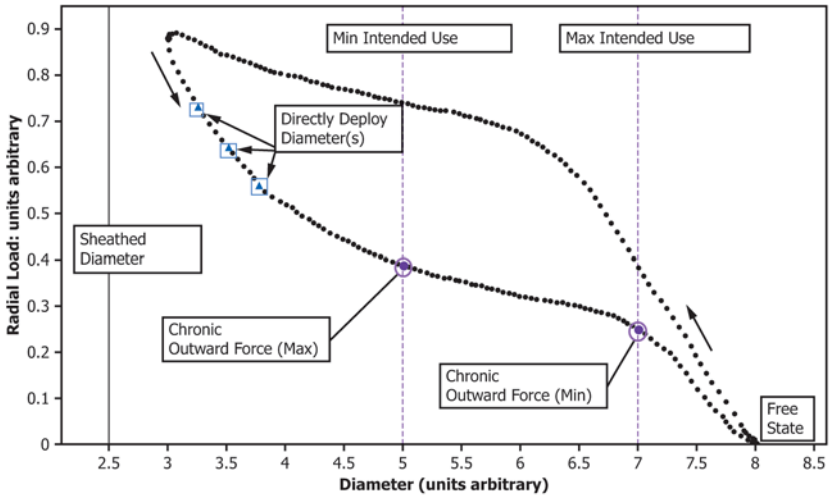

FIG. 10 Typical Loading Determination for a Self-Expanding Stent

chronic outward force, stent deployment should be performed at a smaller aperture (closer to the sheathed diameter).

7.3.4 The direct deployment from the delivery system provides the most clinically similar load history for the test device; however, it might be very difficult to control the deployed length and difficult to visually detect an incomplete, compressed, or elongated deployment. Because results are normalized per stent length, and the stretched/compressed shape might affect the overall stent resistive force, the variability in deployed length and expansion evenness might result in high test variability (worse precision). The more clinically similar load history, though, is expected to provide more accurate test output. Controls and verification of proper deployment and length are important test considerations.

7.3.5 For testing that starts from the freely deployed condition, the evaluator first deploys the stent from the finished product, or mock deployment system, if justified, per the instructions for use (IFU). Because the behavior of a self-expanding stent is dependent on its deformation path, and because these stents loaded in the delivery system remain constantly under radial compression, it is desirable to establish that the radial loading and unloading curves are similar between free-state and direct deployment.

7.3.6 If testing from the free-state deployment, the test begins by reducing the device to a diameter well below the minimum indicated use diameter but greater than the sheathed diameter. The evaluator might need to control the rate of compression (and possibly temperature) to be similar to loading the stent into the delivery system in order to more accurately match the expected material conditions and deformed shape of a stent loaded into a delivery system. If a temperature other than body temperature is used, the apparatus and stent should be allowed to adjust to body temperature prior to increasing the diameter of the aperture (unloading the stent).

7.3.7 The unloading phase for both methods is the same. The size of the aperture is increased and the stent is slowly unloaded toward the minimum indicated use diameter (5.0 mm in Fig. 10). This compression diameter is the smallest labeled diameter associated with the indicated usage. The length normalized force at this diameter is the maximum chronic outward force.

7.3.8 The opening continues to increase until the maximum indicated use diameter (7.0 mm in Fig. 10) is reached. The normalized force at this diameter is the minimum chronic outward force. All deployed chronic outward force is intermediate between these values; thus, these results bracket the range of clinically expected chronic outward force.

7.3.9 Indicated use diameters, rather than equilibrium diameters, are used. These are selected because they are independent of vessel compliance and are sufficiently accurate to obtain reasonable estimates of the chronic conditions.

7.3.10 The rate of aperture opening (rate of diameter increase) should be slow enough that the chronic outward force is not significantly affected. Testing at multiple opening rates in order to determine the selected speed should be done as part of the method development. Test rate does not reflect clinical expansion rates but rather the one used to obtain consistent test output.

7.3.11 Lastly, there are a variety of load excursions (e.g., pulsatile motion or muscle-skeletal forces associated with walking) which the stent might be subjected to after implantation and which might be tested. These cyclic and non-cyclic load excursions are not discussed within this guide as they are unique to the device and its usage and thus are outside of the scope of the standard. Refer to Appendix X2 for an illustrative example of pulsatile loading excursion testing.

7.4 *Balloon-Expandable Stent Characteristic Loading for Hydraulic/Pneumatic Collapse Pressure Testing:*

7.4.1 Fig. 11 shows a typical radial loading curve for a balloon-expandable stent using a hydraulic or pneumatic collapse apparatus. Though a radial loading curve (load versus diameter) is not required, it is preferred for this type of apparatus to measure diameter prior to and during pressurization to aid in the determination of collapse. Thus, a more

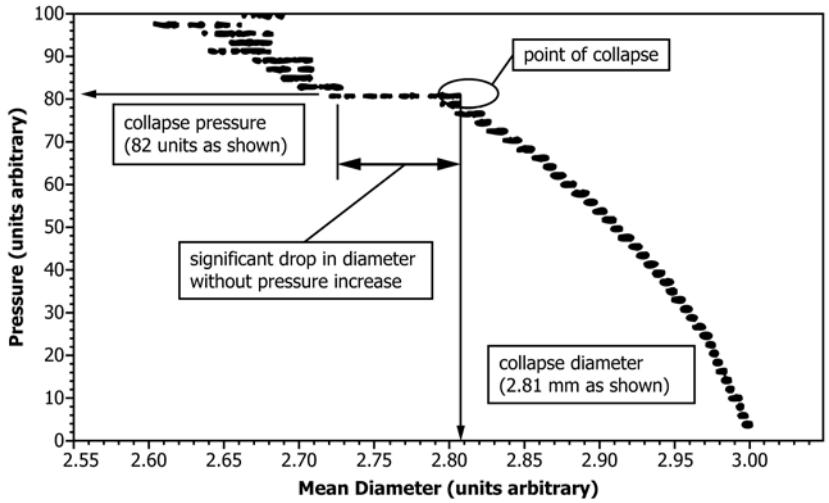

FIG. 11 Typical Loading Plot for a Balloon-Expandable Stent Loaded using a Hydraulic/Pneumatic Apparatus

precise estimate of collapse pressure might be gained by measuring the diameter during testing.

7.4.2 The diameter might be measured using an optical or laser system. If measured, a minimum of two directions circumferentially distributed around the stent (90º for two directions or 60º for three directions) is recommended. This allows for the expected compression of the test article into an oval shape during testing. Multiple diameter measurements along the longitudinal axis of the stent might be taken to obtain a better estimate of the overall stent diameter or to evaluate stent regions (e.g., end ring collapse). The stent diameter is reported as an arithmetic mean value of measured diameters for either the whole stent or in evaluated regions.

7.4.3 If visual examination is utilized, adequate controls and evaluator training are recommended to ensure repeatable determination of collapse. A visual standard or a video of collapse synchronized with pressure might be required to adjudicate collapse pressure output.

7.4.4 Both the mechanical action of the apparatus and the resultant load versus diameter curves are discussed simultaneously because they more clearly and graphically describe both the apparatus dynamics and test results.

7.4.5 Video synchronized diameter with a load is an ideal technique for identifying failure both visually or by changes in the load curve, or both..

7.4.6 The test article is deployed into the tubing. Diameter selection is based on the indicated diameter of the stent and the desired overexpansion to ensure adequate engagement of the stent outer diameter with the tubing. Stent post-dilation (post deployment expansion of a stent with a balloon catheter) might be necessary, depending on the diameter and compliance of the delivery system as well as the tubing diameter and compliance.

7.4.7 In order to avoid shielding the device from the pressure load, the tubing is typically thin and compliant; however, it should be robust enough to avoid pinhole leaks and ruptures prior to stent collapse. The fraction of the load supported by the tubing should be quantified experimentally or analytically using known compliance values to determine if the tubing is sharing a significant amount of the load. The effects of the tubing should be found to be negligible.

7.4.8 If the tubing is circumferentially stretched it will apply load to the stent; likewise, if the tubing is compressed it will shield load from the stent. If necessary for test accuracy, the associated tubing load, either additive (when stretched) or subtractive (when compressed) at a given measured diameter, should be combined with the measured load. Generally over small diametric changes, the compliance of polymer tubing can be treated as a linear function of the change in diameter.

7.4.9 The equilibrium diameter of the deployed stent is shown in Fig. 11 as the loading value of 0 (units arbitrary). This does not infer that there is zero radial pressure applied to the stent but rather that there is an engagement load associated with the tubing distention. The stent is in static equilibrium with the stretched vessel. Additional loading to collapse will be applied by the apparatus to the tube using the pressurization system.

7.4.10 The system is slowly pressurized either continuously or in increments while the diameter of the stent is measured. Incremental loading (stepped loading) might be required during assessment in order to allow adequate time for visual inspection and system (pressurization system and stented tube) equilibration for dimensional measurements. Specifically, polymer stents might require additional time to reach equilibrium diameter during pressurization (or pressurization steps).

7.4.11 As the device is loaded, the diameter decreases until the onset of catastrophic collapse is observed (82 pressure units as shown in Fig. 11). This onset is observed as an irregular and significant loss in diameter with little or no increase in loading. It is an unstable response related to the buckling of the test article under radial loading. This result is defined as the collapse pressure. The associated average stent diameter at the collapse pressure should be recorded. A clear definition of this significant loss in diameter should be incorporated into the method algorithm (automated or operator-defined).

7.4.12 If the device does not show a clear catastrophic collapse, a criterion based on mean or minimum diameter should be established instead.

7.5 *Load Normalization:*

7.5.1 For all test apparatus and stent types, load normalization is required in order to compare stents of differing length.

7.5.2 For balloon-expandable stents tested for radial strength, the force measurement should be normalized by initial length of the deployed stent or by cylindrical area (excluding non-load bearing end features such as end markers). The decision to utilize length or area normalization will affect the results and might affect the determination of which expansion diameter, largest indicated use diameter or smallest indicated use diameter, has the lowest radial strength for a given stent size.

7.5.3 For balloon-expandable stents tested for collapse pressure (using hydraulic/pneumatic apparatus), the measured pressure output is pressure and no additional normalization is required. The stent cylindrical area (A) is the instantaneous diameter of the article at the time the force measurement was taken multiplied by pi (π) and the initial deployed length (see Eq 1).

7.5.4 For self-expanding stents, the force measurement should be normalized by the free length of the deployed, unloaded stent. The free length might be measured prior to testing if testing was performed on a deployed test specimen. The free length should be measured after testing if testing is started with direct deployment into the test aperture.

7.5.5 For stents with significant length change of greater than 10 % during use, the mean length-versus-diameter relationship for the test group should be determined experimentally or computationally. Frictional forces that confine or stretch the stent axially should be minimized. With the length-versus-diameter relationship, the force normalization, either by length or area (pressure), will be function of stent diameter.

7.6 *Stent Graft Considerations:*

7.6.1 Depending on the design of the stent graft, significant error might be introduced into radial force measurement due to device-to-apparatus friction or interference between the radial force fixture and the graft component(s).

7.6.2 If the stent graft component(s) are not integral to the radial force characteristics of the device, specific components might be removed or modified with justification. Examples include:

7.6.2.1 Anchors designed to attach to the vessel, and

7.6.2.2 Non-load bearing (radial) synthetic or tissue graft material. Short stents with the graft component removed might become unstable during radial compression or expansion making radial loading measurement problematic. In this case, two or more stents of the same design might be connected at the ends to enhance the stability of the stent during radial load testing. The method (material and location) of attachment of the ends of the stents (suture) should not significantly change the radial compression and expansion behavior of the stent. The results should be normalized by the total length of stents tested.

7.6.3 If the graft component(s) are integral to the radial force characteristics then the complete device must be tested and, with appropriate justification, the apparatus might be modified to accommodate the stent graft. Modification examples include:

7.6.3.1 Adding a thin film layer or thin tube between the apparatus and device, and

7.6.3.2 Lubricating the apparatus force application surface.

8. Procedure

8.1 *Balloon-Expandable Stent (Segmented Head and Sling Apparatus):*

8.1.1 The following simplified procedure is applicable only to testing that utilizes a segmented head or sling apparatus. This simplistic procedure is for reference and is only considered illustrative.

8.1.2 Prepare the stent delivery system for inflation in accordance with the instructions for use.

8.1.3 If the stent deployed shape is sensitive to either hydration or temperature, then take the appropriate preparation to soak or control temperature, or both, as necessary prior to, and if necessary, during deployment.

8.1.4 Inflate the stent to the labeled diameter in accordance with the instructions for use. It is recommended that a direct measurement of outer diameter rather than the stented balloon compliance curve be used. If the diameter is labeled as to the inner diameter, accommodation for the nominal strut thickness should be used.

8.1.5 Deflate the balloon.

8.1.6 Measure the expanded stent length after balloon deflation. Exclude non-structural stent end features (for example, radiopaque markers) from stent length measurements. These measurements should be taken after full deflation and after the stent diameter has stabilized.

8.1.7 Considerations of temperature and soaking should be considered for devices that are sensitive to those factors.

8.1.8 Open the radial force test apparatus aperture to allow enough clearance to insert the stent specimen without accidental stent deformation.

8.1.9 Insert the stent fully into radial force test equipment. The entire length of the stent should be placed into the head or sling such that the radial compression is uniform across all regions of the stent.

8.1.10 Close the fixture aperture until a minimum clearance[2] is obtained between the stent and the fixture loading surface(s) is obtained. If applicable, balance the measurement load cell.

8.1.11 Using the apparatus, load the stent to a compression point beyond what is necessary to obtain clinically significant plastic deformation to ensure that the radial strength can be calculated. However, excessive compression might result in a poor estimate of the unloading slope. Experience with the test article will serve to guide the necessary compression.

8.1.12 Use the corresponding load-versus-diameter curve to determine the radial strength.

8.2 *Balloon-Expandable Stent (Hydraulic/Pneumatic):*

[2] The stent will be in contact with only a small portion of the circumferential loading surfaces along the length of the segments such that there is no compressive force on any portion of the stent.

8.2.1 The following simplified procedure is applicable only to testing that utilizes hydraulic or pneumatic apparatus. This simplistic procedure is illustrative and only for reference.

8.2.2 Prepare the stent delivery system for inflation in accordance with the instructions for use.

8.2.3 Adjust the spacing between chamber tubes/barbs to allow for the desired gap between the stent edge and the attachment.

8.2.4 Cut the tubing to length.

8.2.5 The balloon-expandable stent might be either *(1)* deployed directly into the tubing and then have the tubing installed, or *(2)* be deployed into the installed the tubing.

8.2.6 If the stent deployed shape is sensitive to either hydration or temperature, then take the appropriate preparation to soak and or control temperature as necessary prior to, and if necessary, during deployment.

8.2.7 If deployed directly into the tubing (Method 1), inflate the stent to the labeled diameter in accordance with the instructions for use. Either a diameter measurement or balloon compliance curve might be used to ensure proper inflation. Deflate the balloon and measure the stented tube diameter after deflation. Measure diameter in at least two planes separated by 90º to account for stent compression. Measure the tube diameter in more than one axial location to ensure uniform deployment. The stent outer diameter might be estimated by subtracting twice the nominal tube wall thickness. It is not necessary, however, to convert to the stent outer diameter because the diameter measurement is only used to determine instability and the onset of collapse.

8.2.8 Install the tubing (either with deployed stent or empty) into the chamber tubing within the hydraulic or pneumatic chamber. Tubing stretch, or compression, during installation will change the diameter and might also affect the compliance; thus installation technique should be considered. Refer to Test Methods F2477, Appendix X2, for calculation-associated measured vessel compliance and diameter for stretched and unstretched tubing.

8.2.9 If deployed into installed tubing (Method 2), visually center the stent in the tubing. Inflate the stent to the labeled diameter in accordance with the instructions for use. Use either a diameter measurement (preferred) or balloon compliance curve to ensure proper inflation. Deflate the balloon and measure the stent diameter after deflation. Measure in at least two planes circumferentially separated by 90º to account for compression. Measure in more than one axial location to ensure full deployment.

8.2.10 If hydraulic, fill the chamber with water.

8.2.11 If hydraulic, bleed the chamber of air and prepare the pressurization control system.

8.2.12 If the stent diameter is to be measured, prepare the diameter measurement system. Conduct measurement calibration or verification if appropriate. Diameter measurement should start prior to pressurization and at intervals during test pressurization. The measurements should be made at specified, fixed locations.

8.2.13 If a visual system is used for the evaluation of collapse, ready the visual display or recording system.

8.2.14 Slowly pressurize the system, compressing the imbedded stent, while measuring the stent diameter. Measurement requires at least two planes 90º apart in each axial location. Calculate the average diameter for the entire stent or stent region. The pressurization might be continuous or stepped. Stepped pressurization is generally recommended to allow for determination of collapse or to change the measurement location. After determining collapse or final measurement at a given pressure condition, slowly increase the pressure.

8.2.15 Monitor the system pressure stability and visually inspect for leaks.

8.2.16 Use the corresponding pressure-versus-diameter curve if the measurement system is being used (reference 7.4.1). Alternatively, use the established visual criteria and corresponding pressure for determining the onset of catastrophic collapse. This test output is defined as the collapse pressure.

8.3 *Self-Expanding Stent:*

8.3.1 The use of the pneumatic/hydraulic apparatus for testing self-expanding stents is not described in this guide due to the limitations caused by the range of test diameter. As described, either a sling apparatus or a segmented head is suitable for testing self-expanding stents. This simplistic procedure is considered illustrative and is only for reference.

8.3.2 The test article should be loaded into the supplied, or mock, delivery system using the current or simulated manufacturing loading technique. Also, other differences in either processing or the test conditions (such as free-deployment versus direct deployment for self-expanding stents) should be considered and evaluated where significant radial force changes might occur.

8.3.3 Test at 37 ± 2°C if the stent mechanical properties or deployed diameter are dependent on temperature within the 20 to 40°C range.

8.3.4 If directly deploying the stent into the aperture, set the diameter of the apparatus at the minimum desired measurement diameter. This diameter should be, at a minimum, less than the lowest intended use diameter.

8.3.5 If the stent deployed shape is sensitive to either hydration or temperature, then take the appropriate preparation to soak and or control temperature as necessary prior to, and if necessary, during deployment.

8.3.6 Deploy the stent into the apparatus from the delivery system or mock delivery system.

8.3.7 If testing starting at the load-free state, deploy the stent using, where applicable, the instructions for use. Increase the aperture of the radial force apparatus to allow for insertion of the stent. Insert the stent. Decrease the diameter of the fixture aperture by compressing the stent to a minimum diameter between the sheath diameter and the minimum indicated use.

8.3.8 Start the unloading by slowly increasing the diameter of the radial force measurement fixture to the load-free state. Measure the force at the minimum and maximum indicated use diameter.

8.3.9 Remove the stent from the aperture and measure the length of the stent to the nearest 0.1 mm. The normalized load at the minimum indicated use diameter (force per unit stent

length) is the maximum chronic outward force and likewise the normalized load at maximum indicated use diameter is the minimum chronic outward force.

9. Report

9.1 Test information in the report should include:

9.1.1 A complete summary of the materials, methods, and results, including any rationale(s) for choices within the test guide.

9.1.2 Deviations from this guide, the detailed test protocol, the standard test procedure, or combination thereof.

9.1.3 The effects of any such deviations on the significance of the test results.

9.1.4 All real, artifactual, and anomalous observations, including a justification for considering negative findings as artifacts or discounting their clinical importance.

9.2 Test reports should include:

9.2.1 Purpose/objective statement, such as:

9.2.1.1 Design verification.

9.2.1.2 Sponsored evaluation.

9.2.2 Scope statement regarding the type of stent being tested (e.g., balloon-expandable stent graft), stent sizes (diameter, length, and any other relevant descriptor), and type of apparatus (e.g., hydraulic collapse pressure tester).

9.2.3 A description of the test method, including:

9.2.3.1 A basic description of apparatus.

9.2.3.2 A basic description of the test method.

9.2.4 Traceability information (e.g., part number and lot number).

9.2.5 Sterilization status.

9.2.6 Statement on how representative the specimens are of the finished product.

9.2.7 Number of specimens used.

9.2.8 Rational for sample size (or list as provided by the sponsor).

9.2.9 Test parameters, such as:

9.2.9.1 The rates of compression, rates of expansion, as well as pausing steps that done during testing.

9.2.9.2 Test temperature including stent deployment temperature for temperature-sensitive stents (e.g., nitinol self-expanding stents).

9.2.10 For testing using a collapse pressure test, the tubing inner diameter, tube wall thickness, and material. Provide the rationale for tubing selected.

9.2.11 Statement to hydration level for hydration-sensitive stents (e.g., polymer stent with hygroscopic material).

9.2.12 Expanded stent length (balloon-expandable stent) or force-free (self-expanding stent) length to the nearest 0.1 mm.

9.2.13 For balloon-expandable stents, both the nominal deployed inner diameter and the measured initial outer diameter after balloon deflation (to the nearest 0.1 mm).

9.2.14 For self-expanding stents the minimum and maximum indicated use outer diameter (to the nearest 0.1 mm).

9.2.15 Test results for each specified test article and selected attributes listed below (SI units shall be reported):

9.2.15.1 Radial strength (length or area normalized).

9.2.15.2 Collapse pressure (area normalized).

9.2.15.3 Chronic outward force, minimum and maximum (length normalized).

9.2.16 One or more characteristic output curves for each specimen tested. In addition, each curve that requires specific discussion or explanation (e.g., test outlier or artifact).

9.2.17 The result output resolution should be appropriate for the expected output and within the instrument resolution.

9.2.18 If a test protocol or standard test method is utilized, deviations from the test protocol or test method and rationale for deviations.

9.2.19 If acceptance criteria have been established, they should be stated and the results compared to the requirement. If rationale for acceptance criteria is available, provide the rationale or reference.

APPENDIXES

X1. BASIS FOR USE OF UNLOADING LINE TO EVALUATE RADIAL STRENGTH OF BALLOON-EXPANDABLE STENTS

X1.1 Scope

X1.1.1 The following section applies to balloon-expandable stents which are tested in a segmented head or sling apparatus. These stents have the test outputs of radial strength.

X1.1.2 It does not apply to balloon-expandable stents that are tested using hydraulic or pneumatic apparatus.

X1.1.3 It does not apply to self-expanding stents.

X1.2 Comparison Between Traditional Material Testing and Radial Testing

X1.2.1 Radial testing of balloon-expandable stents and the subsequent analysis of the loading curves is similar philosophically to uniaxial tensile material testing. The test output of radial strength is analogous to tensile yield strength for material testing and the slope of the loading line is similar to elastic (or Young's) modulus for materials. There are key differences which deserve recognition.

X1.2.2 The primary difference is that stent radial testing is affected by both stent material and design geometry. As a stent is compressed, it deforms and this affects the resistance to loading. Uniaxial material testing is typically done with test specimens which have insensitive shapes (e.g. tensile dog bone) to test output and thus is a material property rather than design-dependent value.

X1.2.3 The second difference is that material testing is generally carried out to material separation failure. In this type of evaluation the unloading line is not available because the

test specimen is broken. Stent testing is not generally completed to specimen failure.

X1.2.4 In typical uniaxial tensile material testing, the loading line is utilized for the evaluation of the elastic modulus and subsequently the line is offset parallel. This offset is used for the determination of yield strength (analog to radial strength). The key concept in this offset method is that the loading line and unloading line are characteristically parallel (see Fig. X1.1) and thus the slopes are the same.

X1.2.5 If testing is stopped prior to failure, the intercept of the unloading line with the displacement axis is the plastic deformation at a given peak load (see Fig. X1.1).

X1.2.6 Because the loading and unloading lines are parallel, either one might be utilized for the offset. Because testing is done to separation in typical materials testing, it is the loading rather than the unloading line that is utilized. But, either the loading or unloading line for this type of material testing is perfectly satisfactory for use to establish an offset line.

X1.3 Use of Multi-Cycle Testing to Characterize Balloon-Expandable Stents Radial Testing

X1.3.1 As stated previously, the primarily difference in materials testing and the testing of balloon-expandable stents is that the geometry of the stent affects the measurement as the stent is compressed.

X1.3.2 One clarifying technique for understanding the loading and unloading of a stent is to compress the stent in a stepped manner. The stent is initially loaded to a low level (initial deformation) and then subsequently unloaded and reloaded to a slightly higher level (initial deformation plus an increment). This process is repeated several times with magnitude of the load at each step equaling the last deformation load plus an increment. This pattern is referred to as "multi-cycle stepped loading."

X1.3.3 The advantage of this technique is that it allows the plasticity to be directly measured at a range of loads. From this technique, a paired load versus plasticity curve might be generated and evaluated.

X1.3.4 An example of this type of load sequence can be seen in Table X1.1

X1.3.5 An illustrative example shows a five-cycle test in which a stent with a nominal outer diameter of 3.2 mm (inner diameter of 3.0 mm) was cyclically loaded (see Fig. X1.2). The starting fixture diameter is 3.5 mm in order to allow easy insertion of the test article into the aperture. The initial compression was from 3.2 to 2.8 mm. The increment step was 0.2 mm. There was a delay of 1 s prior to initiating each increment. After each step, the unit was unloaded to the initial diameter of 3.5 mm.

X1.3.6 Evaluation of each loading and unloading curve allows the test developer to compare the loading, unloading, and reloading lines.

X1.3.7 It is observed that, characteristically, the initial loading line (Cycle 1) is shallower than all subsequent unloading lines (Cycle 2 … Cycle 5). Critically, by inspection the last unloading line (Cycle 5) is approximately parallel to all unloading lines and to all reloading lines. The slope of the Cycle 5 unloading line is graphically shown in as a triangle. As a comparative shape, this triangle was copied four times as comparisons to the unloading lines for cycles 2 through 4 (while being vertically centered on the midpoint of the cycle). The slope triangles support the assertion that the initial loading curve differs from the subsequent unloading curves and the unloading curves are similar in slope (i.e., triangle in shape).

X1.3.8 This characteristic difference is of key importance, in that, a single cycle test might be conducted and the unloading line might be offset parallel to any point along the x-axis corresponding to critical deformation. The intersection

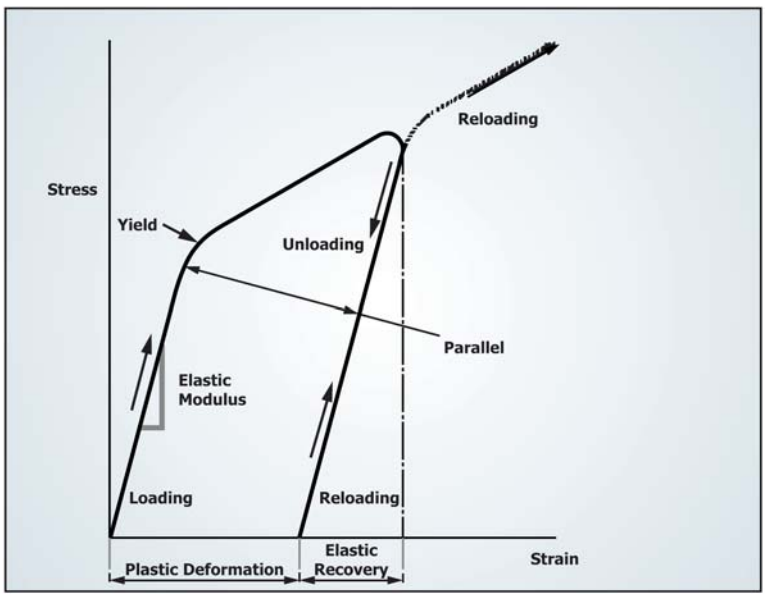

FIG. X1.1 Typical Loading-Unloading Parallel Path (adapted)[3]

TABLE X1.1 Typical Load Sequence

Time, s	Diameter, mm	Cycle
0	3.5	
7	2.8	1
8	2.8	
15	3.5	
24	2.6	
25	2.6	2
34	3.5	
45	2.4	
46	2.4	3
57	3.5	
70	2.2	
71	2.2	4
84	3.5	
99	2	
100	2	5
115	3.5	

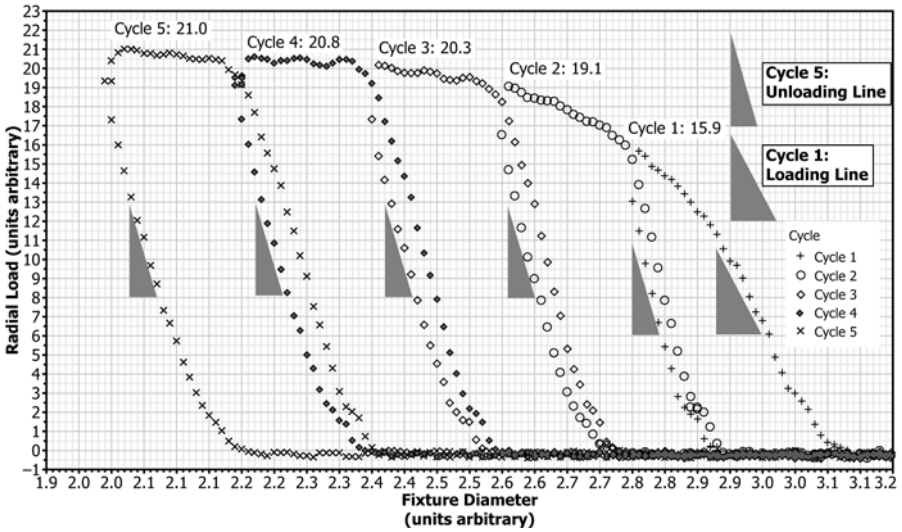

FIG. X1.2 Typical Loading and Unloading of a Parallel Line for a Stepped Multi-Cycle Test

of the offset line and the original loading curve would give both the critical load and critical compression that would have resulted in the unloaded plastic deformation of concern. Thus, we arrive at the simplified method described in 7.2.

X1.3.9 It is further noted that the re-loading line is parallel to the unloading line characteristically (see Fig. X1.2), thus the line takes on additional meaning with respect to pulsatile excursions.

X1.3.10 During normal pulsatile loading it can be expected that the stent would behave elastically and the motion would be described by:

$$\Delta D_P = \frac{\Delta P}{S} \quad \text{(X1.1)}$$

where:

ΔD_p = range in diameter during pulsation,
ΔD = systolic pressure – diastolic pressure, and
S = slope of unloading or reloading line (same).

X1.3.11 Thus, even though it is recognized that the analogies (yield stress and elastic modulus) of uniaxial tensile testing are imperfect when applied to a stent because of the geometry, they do provide a construct for a valid engineering estimate of the critical load (radial strength) that results in clinically (or practically) important plastic deformation. In distinction to materials testing, though, the use of unloading line is preferred for the radial evaluation of balloon-expandable stents.

X1.4 Consideration For Characteristic Curves Which Do Not Have Approximately Parallel Unloading Lines

X1.4.1 In most observed instances, a single cycle evaluation provides enough information and multi-cycle unloading and reloading is not necessary to evaluate permanent plastic deformation; however, there are certainly devices which might not agree with this type of treatment.

X1.4.2 In these cases, it might be necessary for the evaluator to conduct multi-cycle, stepped loading and unloading as part of the radial loading evaluation. If the peak load is paired with the subsequent permanent plastic deformation (using the data from Fig. X1.2) a curve might be generated or interpolated (see Fig. X1.3) to determine the radial strength.

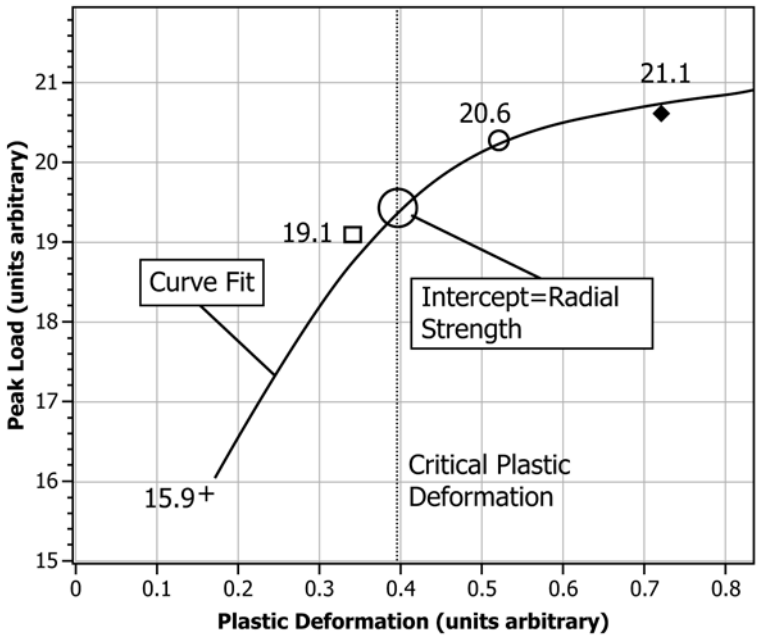

FIG. X1.3 Example of a Load-Versus-Plastic Deformation Curve in Multi-Cycle Stepped Testing

X2. EXAMPLE OF PULSATILE EXCURSION TESTING FOR SELF-EXPANDING STENTS

X2.1 Scope

X2.1.1 The following section applies to self-expanding stents which are tested using either a segmented head or sling apparatus. No addition or changes are expected in the apparatus in order to conduct testing.

X2.2 BACKGROUND

X2.2.1 It is recognized that the in-vivo interaction of a self-expanding stent has both baseline value of loading and chronic outward force, as well as peak loads which are induced by excursions.

X2.2.2 Excursions might be due to a variety of causes including pulsation, interaction loads due to anatomical impingement (e.g., muscle-skeletal forces due to walking), post-delivery angioplasty, deployment of an additional overlapped stent, and external trauma forces (e.g., accidental physical blow). Excursions might be single cycle or repetitive.

X2.2.3 Because there are a wide variety of excursions and the purposes for evaluation are often for input into other evaluations or for research purposes, the excursion testing has been included in this guide.

X2.2.4 One key example of a typical excursion is the case of pulsatile loading. Appendix X2 provides an example curve and discussion that illustrates a pulsatile excursion test.

X2.2.5 The purpose for evaluating a pulsatile excursion is often to measure the range of cyclic forces for input into finite element analysis (FEA) models, fatigue evaluation or developing cycling conditions for the radial durability bench testing.

X2.2.6 Other types of excursions will have different concerns and rationales for evaluation. The purpose of measuring the excursion is important in all cases and should be clearly delineated in the report detailing the results.

X2.3 Characteristic Pulsatile Load Curves

X2.3.1 It is useful to discuss both the mechanical change in the apparatus simultaneously with the graphical description of the test outputs (see Fig. X2.1).

X2.3.2 Pulsatile testing can be initiated from the same start point as is used for the other self-expanding testing. The stent is directly deployed into the aperture of the apparatus at a diameter that is larger than the sheathed diameter (Region 1).

X2.3.3 The testing begins as the aperture is increased and the stent is slowly unloaded toward the maximum compression diameter. This equilibrium diameter is the expected diameter of the stent after implantation at the minimum indicated use diameter. If there is not a practically significant difference between the end results of testing at the equilibrium diameter or the minimum indicated use diameter, the indicated use diameter should be used.

X2.3.4 The excursion testing is centered on the maximum compression equilibrium (or indicated use) and cycles due to the range of pulsation "±Δ." Because of practicality, the typical excursion would continue by opening to the "+Δ" condition to establish the minimum load of the cycle (circled in Fig. X2.1). This load is the maximum chronic outward force.

X2.3.5 The testing is then reversed, and the stent is compressed to the maximum compression diameter "–Δ". This compression will result in the peak load during the cycle (Region 2 peak, circled). This force is referred to as the radial resistive load of this particular cycle.

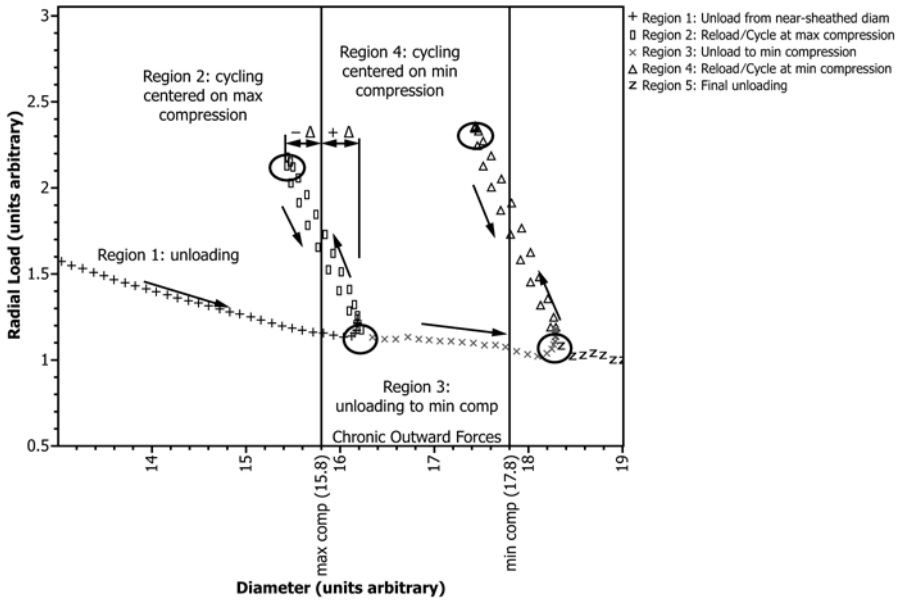

FIG. X2.1 Pulsatile Excursion Testing Example

X2.3.6 If the curve changes upon repeated cycles, this cycle can be repeated between the "+Δ" or "–Δ" condition several times until a steady-state radial resistive load is obtained. The example shown was tested only once for clarity; however, a single cycle might also be justified based on multiple cycle testing or justified based on a "worst-case" rationale.

X2.3.7 Excursion evaluation at both extremes of the indicated compression is preferred in order to understand the range of response; therefore, the test aperture is then opened to the minimum indicated compression and cycled at this condition. Another paired response of radial resistive load (circled in Fig. X2.1) and chronic outward force (circled in Fig. X2.1) can be obtained.

X2.3.8 Because the chronic outward force of the cycle differs from the chronic outward force range evaluated in standard testing, it should be identified by the cycle (e.g., chronic outward force, max compression cycle). Similarly the radial resistive load should be paired and thus named in a similar convention (e.g., radial resistive load, max compression cycle). The test report should highlight the cycle which was completed and the method of determining the values.

X2.3.9 Cyclic testing is generally done by cycling between two diameters (distention-based testing) and repeated; however, if necessary, the cycling might be equivalently done between two load values (force-based testing). This might be more difficult in practice as most apparatus is distention-controlled and utilizes feedback to allow for force-based test control.

X2.3.10 If the loading and unloading forces are sensitive to rates of diameter change between quasi-static and physiologic pulsation rates, use of physiologic pulsation rates are recommended provided that inertial loads can be appropriately established (without the device) and subtracted from the device loads.