Designation: F3067 – 14 (Reapproved 2021)

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

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

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:*

3.1.1 *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.

3.1.2 *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.

3.1.3 *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.

3.1.4 *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).

[1] This guide 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. 1, 2021. Published August 2021. Originally approved in 2014. Last previous edition approved in 2014 as F3067 – 14. DOI: 10.1520/F3067-14R21.

[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.

3.1.5 *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.

3.1.6 *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:

$$P = \frac{F_R}{A} \tag{1}$$

where:

P = radial pressure,
F_R = radial force, and
A = instantaneous stent cylindrical area:

$$A = \pi DL$$

where:

D = instantaneous stent expanded outer diameter, and
L = L_0 for length change less than 10 % and $L = L(D)$ for length change greater than 10 %. L:L_0 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.

3.1.7 *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.

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

3.1.9 *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.

3.1.10 *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).

3.1.11 *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.

3.1.12 *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.

3.1.13 *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.

3.1.14 *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).

3.1.15 *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.

3.1.16 *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.

3.1.17 *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.

3.1.18 *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 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.

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.

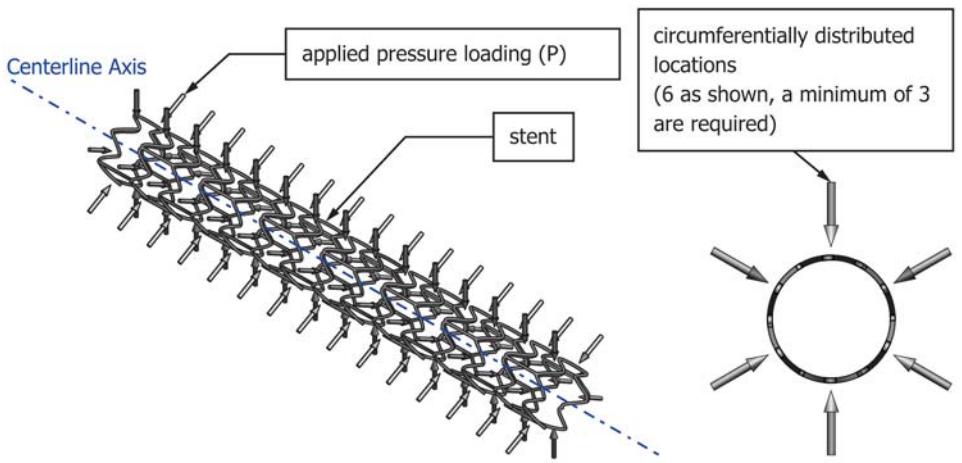

FIG. 1 Radial Loading

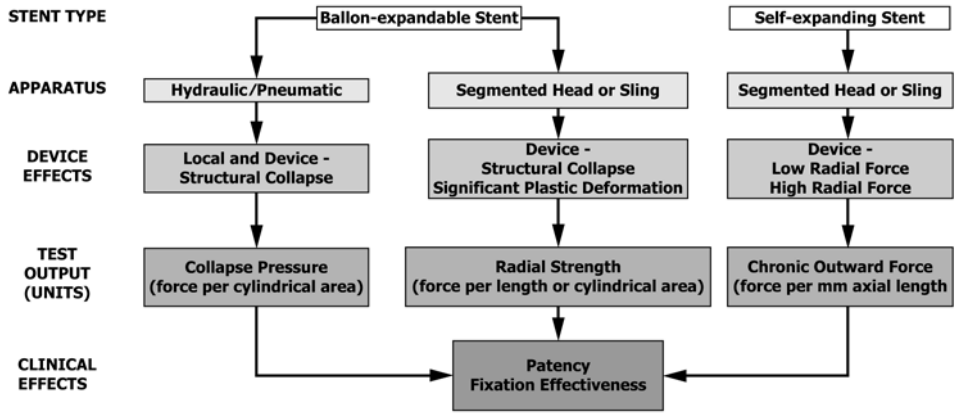

FIG. 2 Summary Guide

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 °C. 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

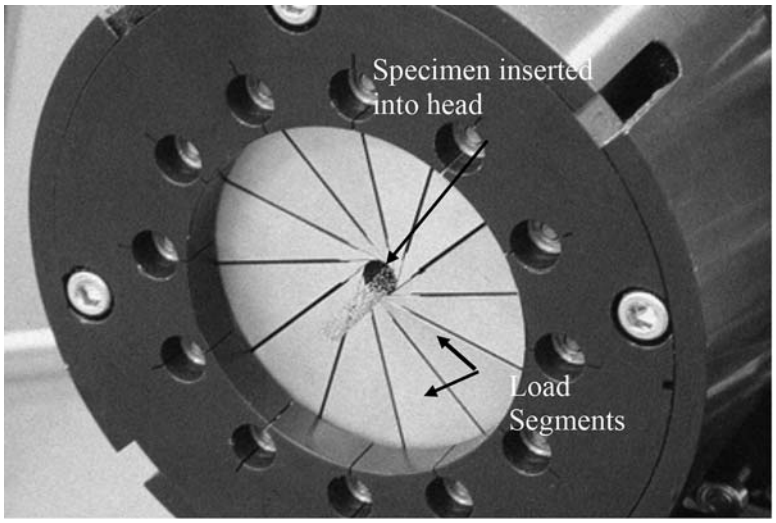

FIG. 3 Segmented Head Fixturing (stent is partially inserted for illustrative purposes)

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.

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.

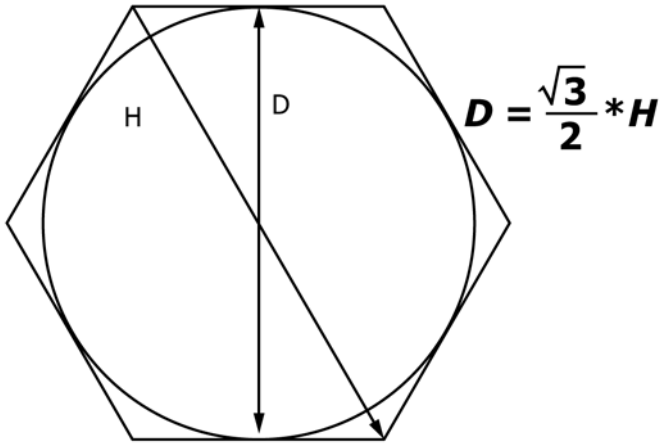

FIG. 4 Equivalent Diameter for Segmented Head (Example of a Hexagon)

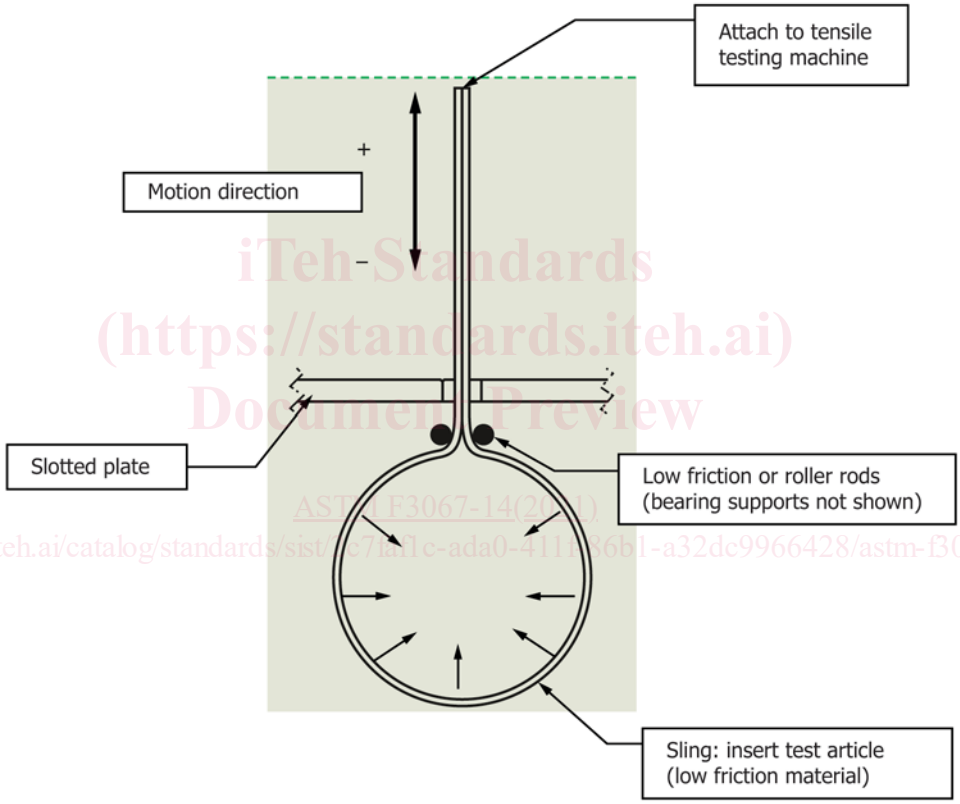

FIG. 5 Sling-Type Radial Loading Fixturing

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

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):

$$\Delta x = x - x_0$$

where:

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:

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

where:

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

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

where:

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

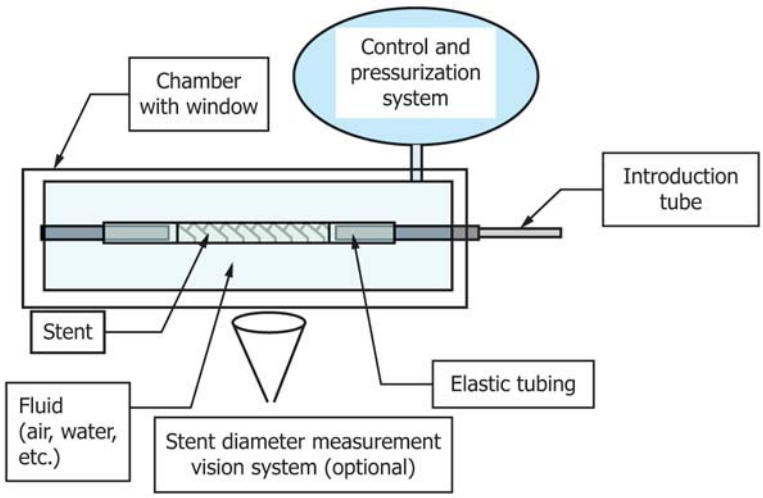

FIG. 6 Typical Hydraulic or Pneumatic Radial Loading Apparatus