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Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems[1]

This standard is issued under the fixed designation F2606; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides guidelines for quantitatively characterizing balloon-expandable stent and stent system flexibility using three-point bending procedures. Guidelines are provided for characterizing deployed stent flexibility, and for characterizing pre-deployment stent system flexibility in the region of the stent and balloon.

1.2 This guide is not recommended for test articles that cannot be appropriately evaluated using a span length to stent outer diameter (as tested) ratio of at least 4:1. Test articles that do not meet this requirement are likely to exhibit appreciable deformation by modes other than bending.

1.3 This guide does not provide procedures for characterizing the bending flexibility of self-expanding stents, self-expanding stent systems, endoprostheses (stent-grafts), or endoprostheses systems. However, some aspects of this guide may be useful for developing appropriate three-point bending characterization procedures for these devices. While this guide was developed with vascular stents and stent systems in mind, it may be useful for characterizing the bending flexibility of balloon-expandable stents and stent systems used in non-vascular applications.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered standard.

1.5 *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. Terminology

2.1 *Definitions:*

2.1.1 *bending flexibility, n*—a measure of the ability of a test specimen to bend.

2.1.2 *bending stiffness, n*—a measure of the ability of a test specimen to resist bending.

2.1.3 *conformability, n*—the degree to which a stent or stent system matches the native curvature of the vasculature.

2.1.4 *deflection, n*—displacement of the dynamic support (loading anvil) at any point in the test.

2.1.5 *delivery system, n*—catheter that is used to deliver and deploy a stent at the target site. A delivery system for balloon-expandable stents may be similar to a balloon-dilatation (angioplasty) catheter.

2.1.6 *midspan bending moment, n*—a linear estimate of the bending moment at the center of the span. See 8.5.

2.1.7 *midspan curvature, n*—a linear estimate of the curvature of the center of the span. See 8.5.

2.1.8 *span length, n*—distance between the centers of the supports.

2.1.9 *stent system, n*—delivery system with a pre-mounted stent.

2.1.10 *stent, vascular, n*—synthetic structure that is permanently implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency.

3. Significance and Use

3.1 This guide can be used to obtain force versus deflection or midspan bending moment versus midspan curvature curves for stents and stent systems subjected to three-point bending conditions. Bending flexibility of a stent system may be a factor in its ability to track through the vascular anatomy, and may be a factor in vascular trauma along the delivery pathway distal to the guide catheter. Bending flexibility of a deployed stent may be one measure of its ability to flex with a vessel, or to conform to the natural curvature of a vessel. Bending flexibility of a delivery system may also be of interest if it is desired to assess the separate contributions of the delivery system and the mounted stent to the overall flexibility of the stent system.

[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.

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3.2 This guide is not intended to determine material properties, stent system trackability (ability of a stent system to follow a guide wire and/or guide catheter through vascular tortuosity), or stent system deliverability (ability of a stent system to deliver a stent to the implantation site(s) or through particular level(s) of vascular tortuosity). While this guide does not determine stent system trackability or deliverability, it can provide quantitative insight into how stent system bending flexibility affects trackability and deliverability. Similarly, while this guide does not determine conformability of a deployed stent, it can provide quantitative insight into how stent and/or stent system bending flexibility affects deployed stent conformability. Since this guide quantifies bending flexibility, it may be useful in determining the magnitude of bending flexibility effects on bending-related performance differences between the test article and control devices.

3.3 The three-point bending procedures provided in this guide are intended to be used to characterize balloon-expandable stent and stent system flexibility during product development. They may not necessarily satisfy any particular requirements of national or international regulatory bodies.

4. Summary of Guide

4.1 The specimen is loaded onto a three-point bend fixture. The specimen is supported from below by two static supports separated by a known span and bent by a force applied on the top and midway between the lower supports. The bending flexibility of the stent is obtained from force-versus-deflection plots and/or midspan bending moment versus midspan curvature plots. Bending flexibility evaluations may be made on balloon-expandable stent systems, and/or on deployed balloon-expandable stents. Bending flexibility of a delivery system may also be evaluated if it is desired to assess the separate contributions of the delivery system and the mounted stent to the overall flexibility of the stent system.

4.2 Bending flexibility assessments may be made using a fixed span between the lower supports or by using a span that increases with the specimen length.

4.2.1 The fixed span length method permits force versus deflection comparisons that are independent of stent length. This method may be useful when comparing the flexibility of stents with different diameters or structural designs, and it may permit bending flexibility to be evaluated at multiple longitudinal positions along longer test articles.

4.2.2 The variable span length method allows the bending moment arm length to be maximized for any given stent length in order to minimize the potential for non-bending deformation at a given applied load and/or deflection. Bending flexibility comparisons may be made at different span lengths by comparing midspan bending moments at given midspan bending curvatures. The variable span length approach also permits the study of bending load variation with span length, but the bending loads are not solely dependent on the inherent bending stiffness of the test article.

4.2.3 Both the fixed and variable span length methods permit the study of bending load variation with test article curvature by varying deflection to cause variation in curvature. In the variable span length method, test article curvature may also be varied by changing the span length.

5. Apparatus

5.1 The three-point bend test apparatus consists of a means of applying and accurately measuring various loads and deflections to a specimen mounted in a three-point bending fixture. Stents can be tested in the deployed state and stent systems can be tested prior to stent deployment. The three-point loading fixture consists of two lower static supports and one upper load applicator as shown in Fig. 1. As the stent is deflected, the force and deflection values are recorded. The test system should include a computerized data acquisition system.

5.1.1 The two lower static supports should be parallel cylinders with a diameter of 6.35 mm (¼ in.), unless another geometric shape and/or diameter is more appropriate for the span and/or to minimize adverse stent/support interaction, for example, to minimize resistance to stent movement over the support during loading. The static supports may contain circumferential grooves or shoulders to keep the test article axis perpendicular to the supports during testing. Alternative lower supports should be designed to ensure that the applied loads result in bending, not kinking, buckling or crushing, of the test article. It is recommended that the lower static supports be designed to minimize friction by using materials such as polytetrafluoroethylene (for example, Teflon), acetal polyoxymethylene (for example, Delrin) or other low-friction material, or by allowing support rotation with bearings. The height of the static supports needs to be sufficient to provide adequate distance for deflection.

5.1.2 The upper dynamic load applicator should also be a cylinder with a 6.35 mm (¼ in.) diameter, unless another geometric shape and/or diameter is more appropriate for the span and/or minimization of adverse stent/support interactions (for example, to minimize the potential local deformation (kinking or crushing), to minimize the resistance to movement of the specimen over the lower supports during specimen bending, to minimize the potential for the upper support to

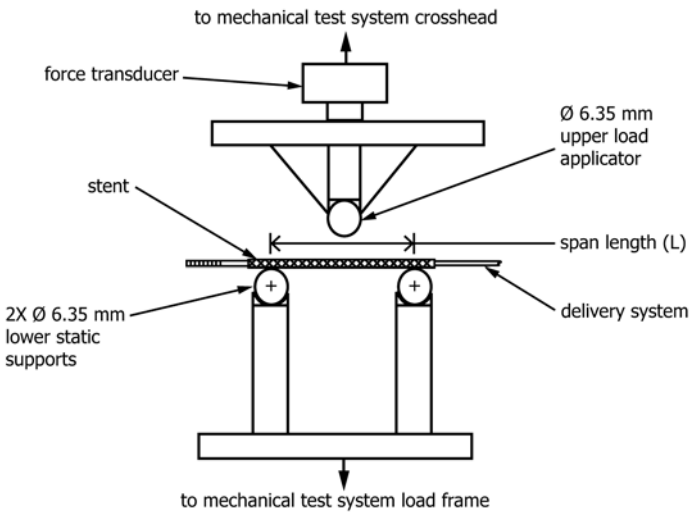

FIG. 1 Schematic of Three-Point Bending Apparatus with Stent System