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Standard Guide for Three-Point Bending of Balloon Expandable Vascular Stents and Stent Systems¹

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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.

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.

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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.

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 (1/4 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 (1/4 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 resist specimen bending, and so forth). The upper load applicator should be parallel to, and horizontally centered between, the lower static supports. Alternative designs for the upper load applicator should ensure that the applied loads result in bending, not kinking, buckling or crushing, of the test article.

5.1.3 The bending fixture's lower (static) support diameters and upper (dynamic) load applicator diameter should be appropriate for the span length and test article diameter (that is,

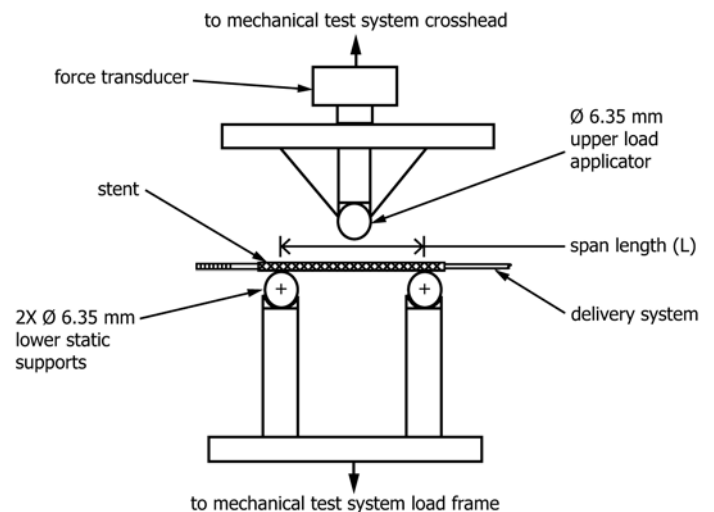


FIG. 1 Schematic of Three-Point Bending Apparatus with Stent System

span length > lower support diameter + upper support diameter + 2 × (test article diameter)).

5.1.4 **Table 1** provides span length and maximum deflection recommendations for the variable span length method. The deflection listed in **Table 1** is a maximum deflection recommendation. Actual test deflections should be lower, especially if it is desired to avoid plastic deformation. Alternative span lengths and deflections for deployed stent flexibility characterizations may be based on stented vessel flexure conditions anticipated for the intended implant location(s) or other appropriate considerations. Alternative span lengths and deflections for stent system flexibility characterizations may be based on vessel curvature conditions anticipated along the intended delivery pathway(s) or other appropriate considerations.

5.1.5 The span length used for the fixed span method should be small enough to permit evaluation of the minimum stent length to be tested using the selected maximum deflection. It is recommended that span length be at least 4 mm smaller than the minimum stent length to be evaluated.

5.1.6 The apparatus should have adequate displacement (deflection) rate control and the displacement rate should be sufficiently slow to avoid excessive loads due to inertial effects. Consideration should also be given to the displacement rate(s) expected clinically if the test article is sensitive to strain rate variations between the quasi-static strain rates used to avoid excessive inertial loads and the strain rates associated with clinically relevant displacement rates. Use of similar displacement rates are recommended for device comparison purposes.

5.1.7 The accuracy of the apparatus force and displacement meters should be within $\pm 5\%$ of the maximum reported force and displacement values.

5.2 An inflation device for deploying the stent.

5.3 Means to preheat and maintain the temperature of the test article at $37 \pm 2^\circ\text{C}$, if appropriate.

5.4 Means to hydrate and maintain the hydration of the test article, if appropriate.

6. Test Specimens

6.1 A minimum of three like specimens (same labeled stent diameter and length) should be tested for each test condition (span length, rotational orientation, and so forth) in order to

provide some indication of bending stiffness variation for a given device and test condition. More samples may be needed, depending on the claims to be made based on the test results.

6.2 If using the variable span method, the shortest stent of a given diameter may be used to determine the maximum bending load associated with a given deflection or curvature. Conversely, the longest stent of a given diameter may be used to determine the minimum bending load for a given deflection or curvature.

6.2.1 If using the fixed span method, the variation of bending load with stent length at a given deflection cannot be determined. However, the variation in bending load with curvature may be determined by varying deflection to cause variation in curvature.

6.3 If bending stiffness may be sensitive to the rotational orientation of the test article about its longitudinal axis, the maximum and minimum bending stiffness orientations should be evaluated.

7. Procedure

7.1 If deformation of the stent and/or delivery system occurs during a test, the sample should not be re-tested. Even if deformation is not observed, retesting specimens is not recommended as test results may still be affected by prior tests.

7.2 Prepare the fixture as described in Section 5 with the test article positioned perpendicular to the lower static supports.

7.3 Mount the upper load applicator parallel to the static supports and centered between them. The load applicator should be able to move vertically to the maximum test deflection without crushing the test article.

7.4 If the bending properties of the test article are affected by temperature variation between ambient and 37°C , the test should be conducted while maintaining the specimen temperature at $37 \pm 2^\circ\text{C}$.

7.5 If the bending properties of the test article are sensitive to hydration, the test should be conducted while keeping the test article fully hydrated.

7.6 Mark the middle of the stent to indicate the position and orientation of the applied deflection.

7.7 If a stent system is to be tested, cut the stent system just proximal of the proximal balloon seal.

7.8 If a deployed stent is to be tested, deploy the stent as indicated in the Instructions for Use. Deploy at $37 \pm 2^\circ\text{C}$ if deployment at temperatures between ambient and 37°C may affect stent diameter or flexural stiffness.

7.9 If testing is to be conducted at $37 \pm 2^\circ\text{C}$, preheat the test fixture and test article to $37 \pm 2^\circ\text{C}$.

7.10 Place the test article in the center of the three-point bending fixture and position it such that the dynamic load applicator will contact the midpoint of the stent as marked in 7.6.

7.11 Maintain the test article at $37 \pm 2^\circ\text{C}$ throughout the test, if appropriate.

7.12 Balance (zero) the force transducer.

TABLE 1 Recommended Span Length and Maximum Deflection for the Variable Span Length Method

| Stent Length (mm) ^A | Span Length (mm) ^B | Maximum Deflection ^C |
|--------------------------------|-------------------------------|---------------------------------|
| 10–14 | 6 ^D | 1.2 |
| 15–19 | 11 | 2.2 |
| 20–24 | 16 | 3.2 |
| 25–35 | 21 | 4.2 |
| >35 | (stent length/ 1.093) – 2 | 0.2 × (span length) |

^A Deployed stent length or crimped length of a stent on a stent system.

^B Shorter span lengths may be used provided a span length to test article outer diameter ratio of at least 4:1 is used.

^C Smaller deflections may be used, but the maximum deflection should not be exceeded. See 5.1.4.

^D Span lengths ≤ 6.7 mm will require static and/or dynamic supports that are smaller than the 0.25 in. (6.35 mm) diameter supports recommended in 5.1.1 and 5.1.2; see 5.1.3.