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

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:

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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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.

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 ($\frac{1}{4}$ 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 ($\frac{1}{4}$ 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

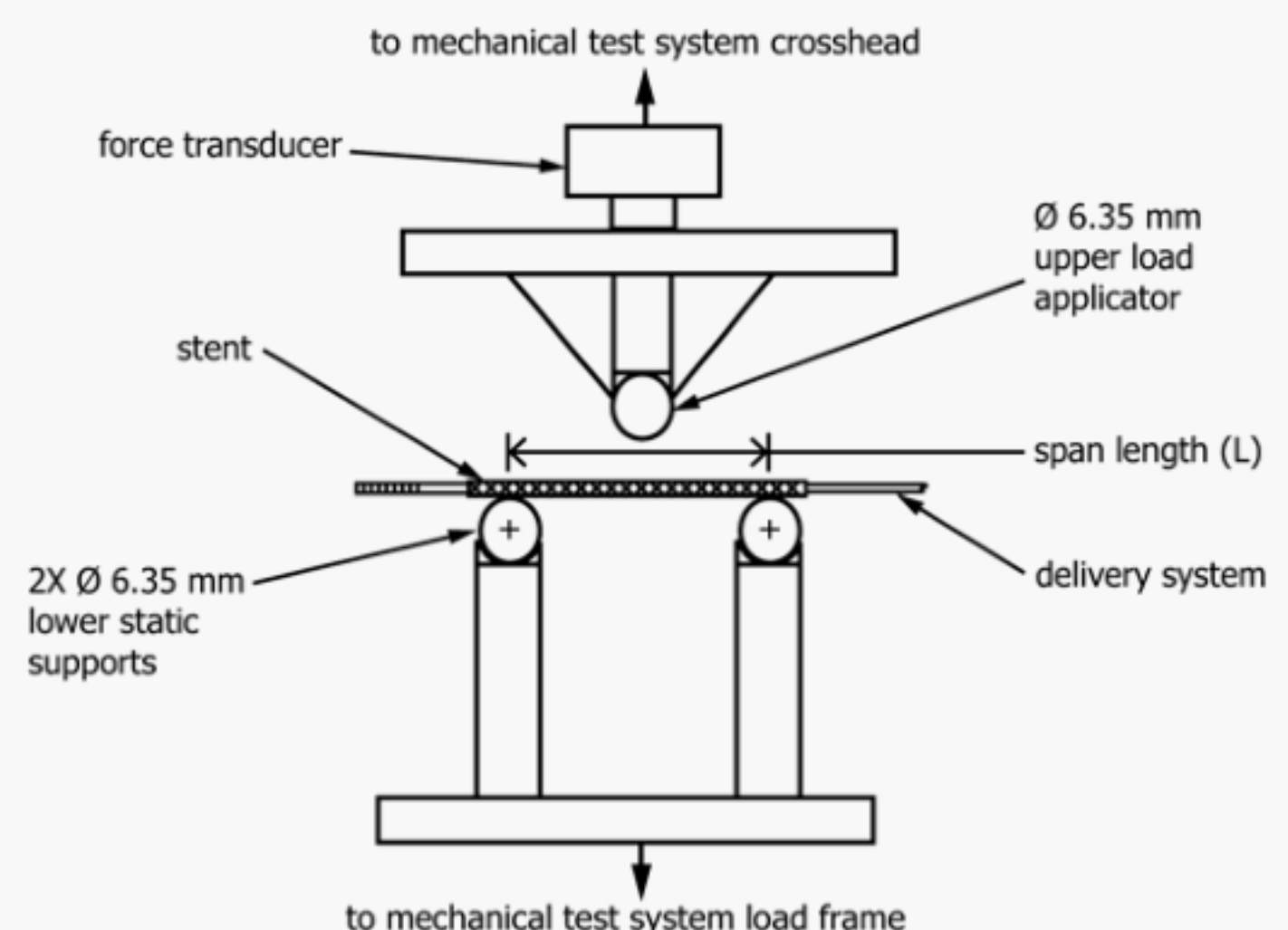


FIG. 1 Schematic of Three-Point Bending Apparatus with Stent System

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, 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 recommend for device comparison purposes.

5.1.7 The accuracy of the apparatus force and displacement meters should be within ±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 ± 2 °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 ± 2 °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 ± 2 °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 ± 2 °C, preheat the test fixture and test article to 37 ± 2 °C.

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.

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 ± 2 °C throughout the test, if appropriate.

7.12 Balance (zero) the force transducer.

7.13 Decide whether to start the test with a small gap between the load applicator and the test article or to start the test with a small preload.

7.13.1 If a small gap is present between the load applicator and the test article at the start of the test, the deflection associated with each data point should be reduced by the deflection that occurs between the test start and first measurable load due to sample contact. Care should be exercised to avoid confusing the test start inertial load with initial sample contact load.

7.13.2 If a preload is to be used, apply an appropriate preload that ensures three-point contact and corresponds to zero (negligible) displacement. A suggested nominal preload range is 0.005 to 0.200 N (0.001 to 0.045 lbf). The preload should be subtracted from all data points.

7.14 Start the test. Apply the force at an appropriate constant deflection rate until the desired maximum deflection is achieved.

7.15 Note whether the test article appears to exhibit substantially uniform bending over the span length throughout the test.

7.16 To assess whether elastic recovery has occurred, it is recommended that force and deflection data also be acquired during sample unloading. The unloading deflection rate should be the same as the loading deflection rate.

7.17 Record force and deflection with the data acquisition system using an adequate data collection rate, that is, at least 20 uniformly distributed data points over the applied deflection.

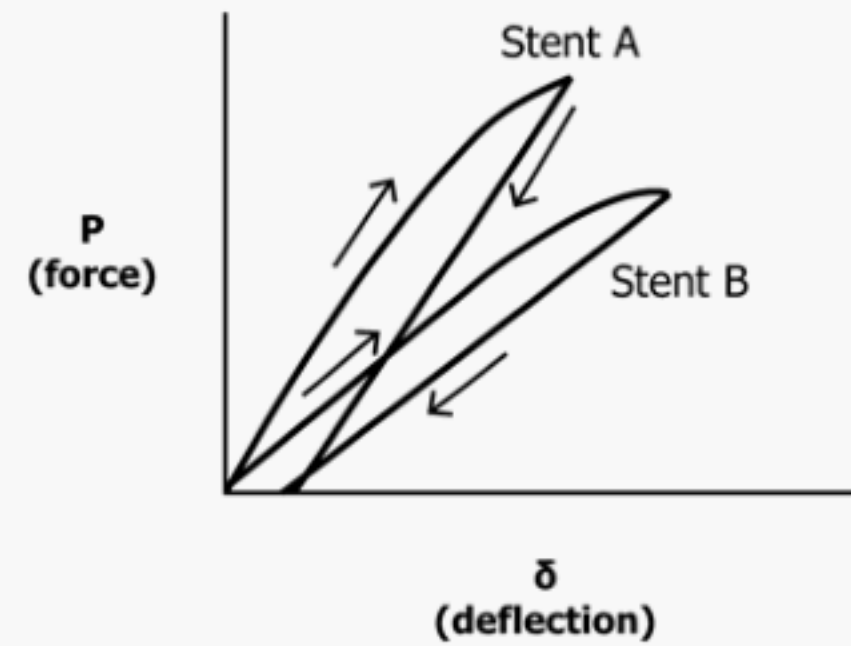
7.18 The test article should be visually inspected for local dimpling at the loading points, kinking, buckling, or crushing. If kinking, buckling, or crushing is observed, the test results should be considered invalid above the kinking, buckling, or crushing force. Slight uniform ovalization of the test article is acceptable.

7.19 If appreciable elongation of the test article is observed during testing, the test results should be considered to be invalid.

8. Calculation and Interpretation of Data

8.1 All the displacement or load data for each test article should be corrected to compensate for the test start gap or the test start preload, whichever is applicable, so that the initial corrected data point for each test article is zero displacement, zero load. See section 7.13.

8.2 It is recommended that the corrected load versus deflection data be plotted with force on the ordinate (y-axis) and deflection on the abscissa (x-axis), as shown in Fig. 2. Plotting the corrected force versus deflection data is recommended to



NOTE 1—Where both extrapolated curve origins coincide with the coordinate system origin. Stent A exhibits a steeper slope and has less bending flexibility than Stent B.

FIG. 2 Example of Plotted Data

aid in data in interpretation and in detection of non-linear force versus deflection behavior. If desired, the data may also be reduced to tabulated numeric values.

8.3 The bending flexibility of two or more test articles evaluated with the fixed span length method may be compared by comparing the bending forces of each test article at a given deflection (curvature) level. A test article with a lower bending load at a given deflection has greater bending flexibility.

8.3.1 Bending loads may also be compared with the variable span method, but bending loads are not solely dependant on the inherent bending stiffness of the test article.

8.4 The bending flexibility of two or more test articles evaluated with the fixed span method may also be compared by comparing the slopes of the corrected force (P) versus deflection (δ) curves within a specific deflection range. The force versus deflection curves should be approximately linear within this range ($R^2 \geq 0.9$) and the range should include the origin of the corrected curves. A test article with a lower slope has greater bending flexibility. This method of comparing bending flexibility reduces the potential for erroneous flexibility comparisons due to non-linear force versus deflection data.

8.5 If testing has been performed using the variable span method, the bending flexibility of two or more test articles may be compared by comparing the slopes of the midspan bending moment (M) versus midspan curvature (κ) plots. The midspan bending moment versus midspan curvature plots should be approximately linear within this range ($R^2 \geq 0.9$) and the range should include the origin of the curves. A test article with a lower slope has greater bending flexibility. Midspan bending moment is calculated using the formula $M = PL / 4$, where P is the bending load (reduced by the preload, if appropriate) and L is the span length. Midspan curvature is calculated using the formula $\kappa = 12\delta / L^2$, where δ is deflection (reduced by deflection (gap) prior to load application if appropriate) and L is the span length.

9. Report

9.1 The following should be included in the report:

9.1.1 Complete description of the test article including the part number and lot number.

9.1.2 Labeled and actual stent length and inner diameter.



9.1.3 Whether the test article was a stent system or a deployed stent.

9.1.4 Orientation of the test article with respect to its design and particularly with respect to any asymmetry.

9.1.5 Span length and maximum deflection.

9.1.6 Deflection rate.

9.1.7 Type of test equipment and accuracy of force and displacement outputs within the reported ranges.

9.1.8 Variations from the recommended testing procedure and fixture described in this guide.

9.1.9 Test temperature and a statement whether the test article bending properties are sensitive to temperature variations between ambient and 37 °C.

9.1.10 A statement as to whether test article hydration was maintained during the test, and if so, how. Also a statement as to whether the test article bending properties are sensitive to hydration.

9.1.11 Number of samples tested.

9.1.12 Force-versus-deflection curves.

9.1.13 Midspan moment versus midspan curvature curves, if applicable.

9.1.14 The gap (deflection) or preload offset applied to all data points within each test and used to cause the curve origin to coincide with the coordinate system origin.

9.1.15 Slopes and R^2 values for any linear regressions performed on the curves.

9.1.16 Indicate the minimum, maximum, range, mean, and standard deviation of all measured and calculated values.

9.1.17 Test article deformation description and any other relevant observations. Note whether the test article appeared to exhibit substantially uniform bending along the span length. Note whether local dimpling occurred at the loading points, whether buckling or crushing occurred, and at what point during the test. Note any appreciable elongation of the test article. Photographic documentation of the deformations and observations are preferred.

10. Keywords

10.1 bending; delivery system; elasticity; flexibility; flexural; flexure; stent; stent system; stiffness

APPENDIX

(Nonmandatory Information)

X1. BENDING COMPARISONS USING VARIABLE SPAN LENGTHS

X1.1 Since curvature is a geometric measure of arcs such as curved vessels, curvature is useful in comparing the test results to the curvature of the arteries that the stent may be deployed in and/or that the stent system may be delivered through. The preferred unit for curvature is 1/mm.

X1.2 Since midspan bending moment versus curvature charts scale with span length and deflection, for any given specimen in a small deflection three-point bending test, the recorded force and deflection values will yield the same slope on the moment curvature diagram (assuming linear elastic material properties). The preferred units for midspan bending moment is N-mm when the force is in Newtons and the length is in millimetres.

X1.3 The midspan bending moment and curvature may be calculated from the equations in [Table X1.1](#).

X1.4 The midspan bending moment (M) should be plotted on the y-axis versus midspan curvature, (κ) on the x-axis.

X1.5 The slope of the midspan bending moment versus midspan curvature plot equals the material elastic modulus (E) multiplied by the effective area moment of inertia ($I=M/E\kappa$).

TABLE X1.1 Equations Used for Explaining Validity of Comparing Slopes of Midspan Bending Moment versus Midspan Curvature Curves to Compare Bending Flexibility of Test Articles Evaluated Using Variable Span Length Method of Evaluating Bending Flexibility

NOTE 1—Assumptions: (1) Linear Elastic Beam Theory; (2) Small Deflection; (3) Constant Area Moment of Inertia (I); and (4) Isotropic Material Properties.

$$\delta = PL^3/48 EI$$

$$M = PL/4$$

$$\kappa = 12\delta/L^2$$

$$EI = M/\kappa$$

Where:

M = midspan bending moment,

δ = midspan deflection,

κ = midspan curvature,

I = area moment of inertia,

E = elastic modulus, and

P = applied bending load.

X1.6 At a given diameter the effective area moment of inertia will be a constant, and thus the slope will be constant within a given design at multiple span lengths.

X1.7 Therefore two different designs at different span lengths can be compared.



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