Designation: F2790 – 10 (Reapproved 2014)

Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses[1]

This standard is issued under the fixed designation F2790; 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 practice provides guidance for the static and dynamic testing of Lumbar Total Facet Prostheses (FP). These implants are intended to allow motion and lend support to one or more functional spinal unit(s) through replacement of the natural facets.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future non-biologic FP. These test methods allow comparison of devices with different methods of application to the lumbar spine. These test methods are intended to enable the user to mechanically compare devices and do not purport to provide performance standards for them.

1.3 These test methods describe static and dynamic tests by specifying load types and specific methods of applying these loads.

1.4 These test methods do not purport to address all clinically relevant failure modes for FP, some of which will be device specific. For example, these test methods do not address implant wear resistance under expected *in vivo* loads and motions. In addition, the biologic response to wear debris is not addressed in these test methods.

1.5 Requirements are established for measuring displacements and evaluating the stiffness of FP.

1.6 Some devices may not be testable in all test configurations.

1.7 The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in terms of either degrees or radians.

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D638 Test Method for Tensile Properties of Plastics
E4 Practices for Force Verification of Testing Machines
E6 Terminology Relating to Methods of Mechanical Testing
E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data
F1582 Terminology Relating to Spinal Implants

3. Terminology

3.1 All functional and kinematic testing terminology is consistent with the referenced standards (including Teminology E6 and Terminology F1582), unless otherwise stated.

3.2 *Definitions:*

3.2.1 *coordinate systems/axes*—Global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is parallel to and co-planar with the superior endplate of the inferior vertebral body. Alternative coordinate systems may be used with justification. The global axes are fixed relative to the inferior vertebral body. Lower case letters, *xyz*, denote a local moving orthogonal coordinate system attached to the superior vertebral body with directions initially coincident with those of the global *XYZ* axes, respectively. The 3D motion of the superior relative to inferior vertebra is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z* axial rotation, *x* lateral bend, and *y* flexion-extension).

3.2.1.1 *origin*—center of the global coordinate system that is located at the posterior medial position on the superior endplate of the inferior vertebral body.

3.2.1.2 *X-axis*—positive *X*-axis is to be directed anteriorly relative to the specimen's initial unloaded position.

3.2.1.3 *Y-axis*—positive *Y*-axis is directed laterally (toward the left) relative to the specimen's initial unloaded position.

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

Current edition approved Nov. 1, 2014. Published November 2014. Originally approved in 2010. Last previous edition approved in 2010 as F2790-2010. DOI: 10.1520/F2790–10R14.

[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.

3.2.1.4 *Z-axis*—positive *Z*-axis is to be directed superiorly relative to the specimen's initial unloaded position.

3.2.2 *failure*—functional failure or substantial mechanical failure.

3.2.2.1 *functional failure*—permanent deformation resulting from fracture, plastic deformation, or loosening beyond the ultimate displacement or loosening that renders the spinal implant assembly ineffective or unable to adequately resist load.

3.2.2.2 *mechanical failure*—failure associated with a defect in the material (for example, fatigue crack) or of the bonding between materials that may or may not produce functional failure.

3.2.3 *fatigue life*—the number of cycles, *N*, that the FP can sustain at a particular load or moment before failure occurs.

3.2.4 *intended method of application*—a FP may contain different types of features to stabilize the implant-tissue interface such as threads, spikes, and textured surfaces. Each type of feature has an intended method of application or attachment to the spine.

3.2.5 *insertion point of an anchor*—the location where the anchor is attached to the test block. The insertion points shown in Fig. 1 are to be adhered to if possible. In situations where the design of the spinal implant assembly or the manufacturer's surgical instructions for installation dictate otherwise, the attachment points may deviate from these dimensions.

3.2.6 *longitudinal direction*—the initial spatial orientation between the insertion points in the superior test blocks and the inferior test blocks.

3.2.7 *maximum run-out load or moment*—the maximum load or moment for a given test that can be applied to a FP where all of the tested constructs have withstood 10 000 000 cycles without failure.

3.2.8 *mechanical deterioration*—deterioration that is visible to the naked eye and is associated with mechanical damage to the device under test (for example, initiation of fatigue crack or surface wear).

3.2.9 *permanent deformation*—the remaining linear or angular displacement (axial—mm, angular—degrees or radians) relative to the initial unloaded condition of the FP after the applied load or moment has been removed.

3.2.10 *radius of rotation*—the distance between the center of rotation and the functional position (for example, load-bearing contact point) of the FP, for a given motion (that is, flexion/extension, lateral bending, or axial rotation).

3.2.11 *spinal implant assembly*—a complete spinal implant configuration as intended for surgical use. A spinal implant assembly may contain anchors, interconnections, and longitudinal elements and may contain transverse elements.

3.2.12 *stiffness (axial—N/mm, angular—N·mm/degree or N·mm/radian)*—the slope of the initial linear portion of the load-displacement curve or the slope of the initial linear portion of the moment-angular displacement curve. This is illustrated as the slope of the line *OG* in Fig. 2. The device may not exhibit an isolated linear portion on the load/displacement curve, due to the complicated nature of these devices. As such, these data are information only.

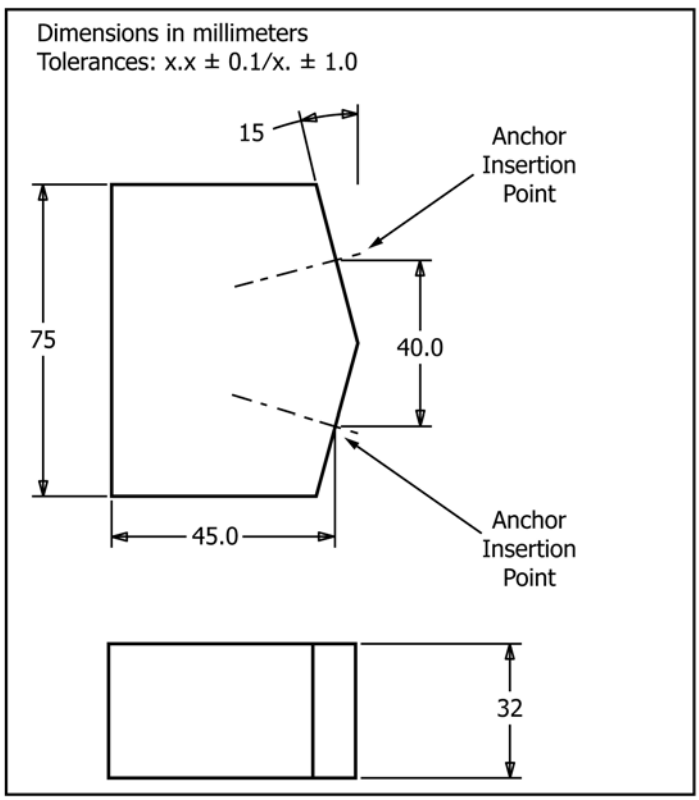


FIG. 1 UHMWPE Test Block

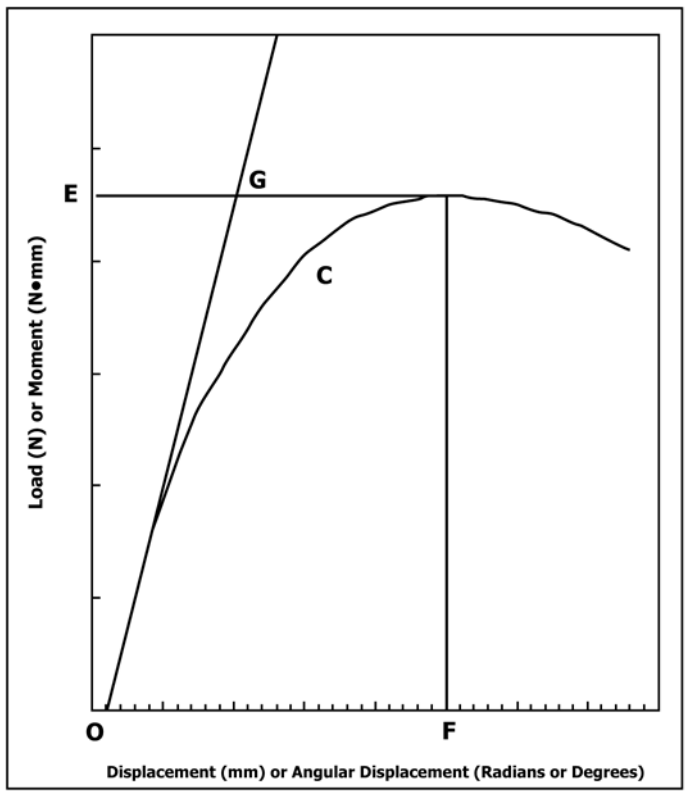


FIG. 2 Typical Load Displacement Curve

3.2.13 *superior/inferior spinal implant construct*—the superior or inferior spinal implant assembly attached to the test block.

3.2.14 *test block*—the component of the test apparatus for mounting the FP in the intended test configuration.

3.2.15 *tightening torque*—the specified torque that is applied to the various fasteners of the spinal implant assembly.

3.2.16 *torsional ultimate load (N·m)*—the maximum torque applied to a spinal implant assembly (the torque at Point E in Fig. 2). The ultimate torque should be a function of the device and not of the load cell or testing machine.

3.2.17 *total facet prosthesis*—nonbiologic structure intended to restore the support and motion of the vertebral facet joint.

3.2.18 *ultimate displacement (axial—mm, angular—degrees or radians)*—the linear or angular displacement associated with the ultimate load or ultimate moment. This is illustrated as the displacement, *OF*, in Fig. 2.

3.2.19 *ultimate load or moment (axial—N, angular—N·mm)*—the maximum applied load, *F*, or moment, *M*, transmitted to the FP. This is illustrated as point E in Fig. 2.

3.2.20 *zero displacement intercept (mm)*—the intersection of the straight line section of the load displacement curve and zero load axis (the zero displacement reference Point O in Fig. 2).

4. Summary of Practice

4.1 This practice is proposed for the mechanical testing of FP.

4.2 All tests are to be performed on the prosthesis size with the smallest safety factor for the levels indicated for implantation. If this worst-case size cannot be determined using theoretical or experimental methods such as simple stress calculations or finite element analysis, then all available sizes or a justified selection are to be tested and the complete range of results are to be reported.

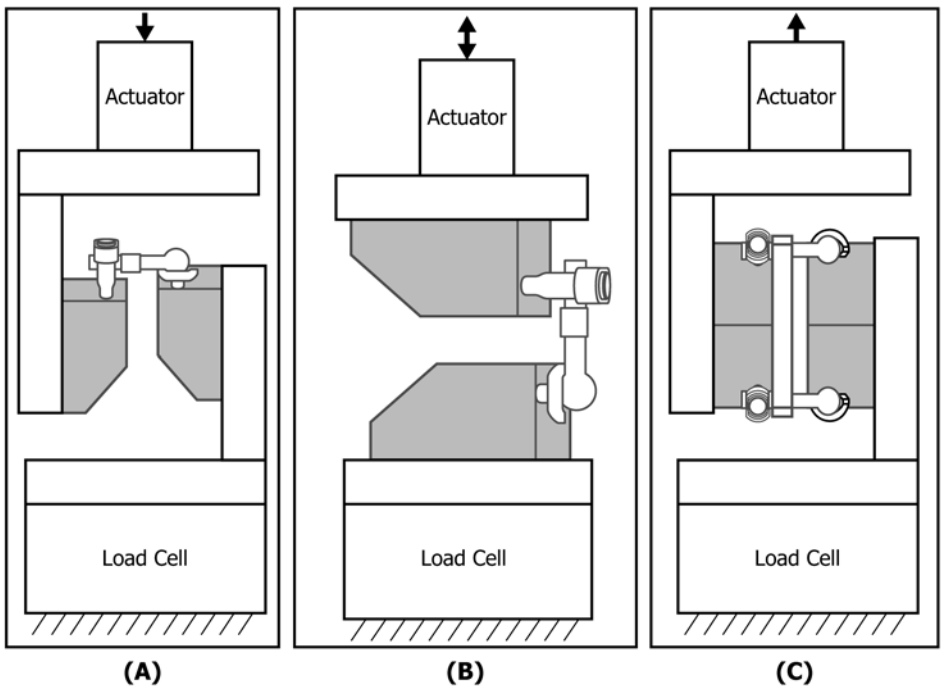
4.3 Static and dynamic testing of the devices will simulate a motion segment via a gap between two Ultra High Molecular Weight Polyethylene (UHMWPE) test blocks (Fig. 1, Fig. 3, or Fig. 4). The UHMWPE used to manufacture the test blocks should have a tensile breaking strength equal to 40 ± 3 MPa (see Specification D638). The UHMWPE will eliminate the effects of the variability of bone properties and morphology for the fatigue tests.

4.4 Static and dynamic tests will evaluate the devices. The user of this practice must decide which series of tests are applicable to the device in question. The user of this practice may choose to use all or a selection of the tests described for testing a particular device.

4.5 This practice is intended to be applicable to FP that support and transmit motion by means of an articulating joint or by use of compliant materials and/or design. Ceramics, metals, and/or polymers may be used in FP design, and it is the goal of this practice to enable a comparison of these devices, regardless of material and type of device.

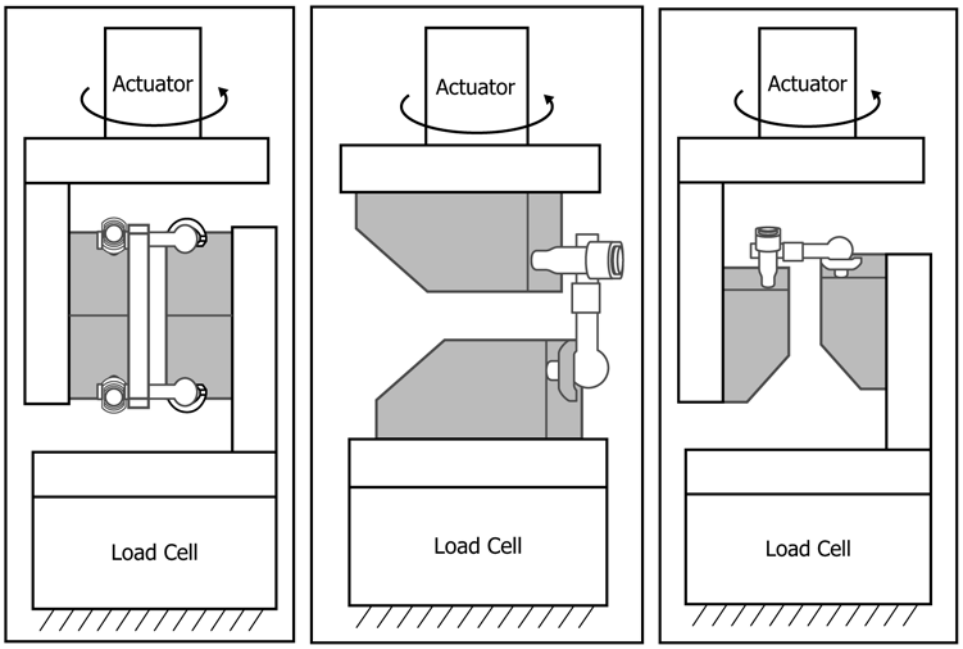
5. Significance and Use

5.1 *Facet Prosthesis Components*—The facet replacement may comprise a variety of shapes and configurations. Its forms



NOTE 1—(*A*) Anterior-Posterior, (*B*) Superior-Inferior, (*C*) Medial-Lateral setups are shown. These setups require one translational actuator and may require specific fixturing. Test blocks are shown in grey. The arrow indicates the loading direction.

FIG. 3 Diagrams of Possible Test Setups for Translational Loading of a FP



NOTE 1—(*A*) Simulated Flexion-Extension, (*B*) Axial Rotation, (*C*) Lateral Bending setups are shown. These setups require one rotational actuator and may require specific fixturing. The arrow indicates the rotation direction. Test blocks are shown in grey. The position of the axis of rotation should be based on the information in Table X1.1.

FIG. 4 Diagrams of Possible Test Setups for Rotational Loading of a FP

may include, but are not limited to, ball and socket articulating joints, joints having a free-floating or semi-constrained third body, metallic load-bearing surfaces, and spring and dampening mechanisms. Additionally, it may be a unilateral or bilateral design.

5.2 These test methods are designed to quantify the static and dynamic characteristics of different designs of FP. The tests are conducted *in vitro* in order to allow for analysis of individual devices and comparison of the mechanical performance of multiple designs.

5.3 The loads applied to the FP may differ from the complex loading seen *in vivo*, and therefore, the results from these tests may not directly predict *in vivo* performance. The results, however, can be used to compare mechanical performance in different devices.

5.4 Fatigue testing in a simulated body fluid or saline may cause fretting, corrosion, or lubricate the interconnections and thereby affect the relative performance of tested devices. This test should be conducted in a 0.9 % saline environmental bath at 37°C at a maximum rate of 10 Hz for all metallic devices and 2 Hz for non-metallic devices. Other test environments such as a simulated body fluid, a saline drip or mist, distilled water, other type of lubrication or dry could also be used with adequate justification. Likewise, alternative test frequencies may be used with adequate justification to ensure that it does not impact the device performance.

5.5 It is well known that the failure of materials is dependent upon stress, test frequency, surface treatments, and environmental factors. Therefore, when determining the effect of changing these parameters (for example, frequency, material, or environment), care should be taken to allow for appropriate interpretation of the results. In particular, it may be necessary to assess the influence of test frequency on device fracture while holding the test environment, implant materials and processing, and implant geometry constant.

6. Apparatus and Setup

6.1 Test machines will conform to the requirements of Practices E4.

6.2 The test apparatus will allow multiple loading regimes to be applied to all forms of FP.

6.3 The test block should be created according to Fig. 1. Variations from this design to accommodate a device's fixation method or features should be reported and justified.

6.4 The interpedicular spacing (superior-to-inferior center-to-center distance between bone anchors) shall be set at 38 mm when installing the device and at the beginning of each test. The implants should be placed in the UHMWPE blocks according to the recommended surgical technique. For devices that do not require pedicular fixation appropriate test blocks should be manufactured to ensure proper evaluation of the fixation components.

6.5 Install the FP in the UHMWPE blocks according to the manufacturer's instructions. If necessary, utilize an aluminum spacer block between the superior and inferior UHMWPE blocks to fix them with respect to each other during installation and remove after installation is complete. The spacer block should ensure that the device is installed with the proper active longitudinal length.

6.6 The motion of the superior test construct relative to the inferior test construct shall be constrained in three-dimensional space except for the components in the direction of specified test motions/loads.

6.7 *Translational Test Option Setup:*

6.7.1 The linear actuator of the test frame is connected to the superior test block so that its axis is collinear with the test direction (Fig. 3).

6.7.2 The inferior test block should be rigidly attached to the base of the test frame so that it is aligned appropriately with respect to the superior construct.

6.8 *Rotational Test Option Setup:*

6.8.1 The superior test block should be attached to the rotational actuator of the test frame so that the point of rotation is aligned with the indicated axis of rotation for the given test setup (Fig. 4). Specific fixtures may be required to accommodate this positioning of the test blocks.

6.8.2 The inferior test block should be rigidly attached to the base of the test frame so that it is aligned appropriately with respect to the superior construct.

6.8.3 *Rotational Load and Motion:*

6.8.3.1 Flexion load and motion are positive moment and rotation about the *Y*-axis.

6.8.3.2 Extension load and motion are negative moment and rotation about the *Y*-axis.

6.8.3.3 Lateral bending load and motion are positive and negative moments and rotations about the *X*-axis.

6.8.3.4 Axial rotation load and motion are positive and negative moments and rotations about the *Z*-axis.

7. Sampling

7.1 All components in the FP shall be previously unused parts only; no implants shall be retested. All implants shall be production quality parts. Any deviations from intended marketed product must be noted in the final report.

7.2 Use the UHMWPE test blocks for only one test. The UHMWPE used to manufacture the test blocks should have a tensile breaking strength equal to 40 ± 3 MPa (see Test Method D638). When alternate designs of test blocks are used, then all UHMWPE components should be replaced after each test.

7.3 All static tests should have a minimum of five samples. Examination of each load-displacement curve may reveal a laxity in the fixture. After the laxity has been removed, then the initial linear portion of the curve will define the straight line section of the load-displacement curves. The intersection of the straight line section and zero load axis is the zero load displacement.

7.4 The results of the fatigue testing will provide a curve of cyclical load or bending load versus the number of cycles to failure. If a specimen does not fail by 10 000 000 cycles, then testing of that component should be considered run-out. The final sample size is recommended by Practice E739. The differences between the maximum run-out load and a load that results in a failed construct should be less than 10 % of the ultimate strength in the same load direction. Conduct a regression analysis on the load or moment versus number of cycles to failure data.

8. Procedure for Static Tests

8.1 *Procedure for Translational Test Setups (for each test setup described in 6.7 and illustrated in Fig. 3):*

8.1.1 Load the test apparatus by displacing the actuator at a rate up to a maximum of 25 mm/min until failure is observed.

8.1.2 Record the load and displacement data.

8.2 *Procedure for Rotational Test Setups (for each test setup described in 6.8 and illustrated in Fig. 4):*

8.2.1 Load the test apparatus by angularly displacing the actuator at a rate up to a maximum of 60 degrees/min (1.05 radians/min) until failure is observed.

8.2.2 Record the moment and angle data, and the direction of angular displacement.

9. Procedure for Fatigue Tests

9.1 *Procedure for Translational Test Setups (for each test setup described in 6.7):*

9.1.1 Apply a sinusoidal load to the test apparatus. The loading should be maintained via a constant sinusoidal load amplitude control. The end of the test is defined as failure of the construct or attainment of 10 000 000 cycles without failure. However, any mechanical deterioration should be noted at the 10 000 000-cycle point (for example, surface wear, crack initiation, crack propagation, and so forth).

9.1.2 An *R*-value of 10 shall be used for all tests.

9.1.3 The frequency of the fatigue test shall be determined by the user of these test methods and recorded (see X1.6).

9.1.4 Evaluate at least six specimens in fatigue in each test mode until the difference between a load in which a construct has failed and the maximum run-out load is no greater than 10 % of the ultimate load. Evaluate two specimens at the maximum run-out load (no specimens fail before 10 000 000 cycles). A regression analysis of the moment versus number of cycles to failure data should be reported per Practice E468. A semi-log fatigue graph of maximum applied load, *F*, versus the number of cycles to failure is to be plotted and a regression analysis shall be conducted on the load versus number of cycles to failure data.

9.1.5 Note the initial and secondary failures, modes of failure, and deformations of components prior to removing the spinal construct from the test apparatus. Evaluate all surface changes.

9.2 *Procedure for Rotational Test Setups (for each test setup described in 6.8):*

9.2.1 Apply a sinusoidal moment to the test apparatus. The moment loading should be maintained via a constant sinusoidal torsional load amplitude control. The end of the test is defined as failure of the construct or attainment of 10 000 000 cycles without failure. However, any mechanical deterioration should be noted at the 10 000 000-cycle point (for example, surface wear, crack initiation, crack propagation, and so forth).

9.2.2 An *R*-value of 10 shall be used for all single direction tests and an R-value of –1 shall be used for all reverse-direction tests.

9.2.3 The frequency of the fatigue test shall be determined by the user of these test methods and recorded (see X1.6).

9.2.4 Evaluate at least six specimens in fatigue in each test mode until the difference between a load in which a construct has failed and the maximum run-out load is no greater than 10 % of the ultimate moment. Evaluate two specimens at the maximum run-out load (no specimens fail before 10 000 000 cycles). A regression analysis of the moment versus number of cycles to failure data should be reported per Practice E468. A semi-log fatigue graph of maximum applied moment, *M*, versus the number of cycles to failure is to be plotted and a regression analysis shall be conducted on the moment versus number of cycles to failure data.

9.2.5 Note the initial and secondary failures, modes of failure, and deformations of components prior to removing the spinal construct from the test apparatus. Evaluate all surface changes.

10. Precision and Bias

10.1 *Precision*—Data establishing the precision of this practicehas not yet been obtained.

10.2 *Bias*—No statement can be made as to bias of this practice since no acceptable reference values are available, nor can they be obtained because of the destructive nature of the tests.

11. Keywords

11.1 dynamic stabilization; dynamic test; facet arthroplasty; posterior instrumentation; spinal implants; static test

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR TEST METHODS

X1.1 FP may be manufactured in a variety of sizes, materials, and shapes with various design features. The purpose of this practice is to allow for a consistent, repeatable comparison of different total facet prosthesis designs through a series of mechanical tests.

X1.2 The spinal implants that fall into the category of facet prostheses are intended for the purpose of facet replacement. All of the implants may reside on the posterior aspect of the adjacent vertebral bodies. This practice will allow for comparison of these devices since the methods and loading configuration remain consistent regardless of method of application. Biologic replacements are excluded from the scope of this practice since biologic structures that share the *in vivo* loads vary among designs, making these test methods inappropriate.

X1.3 Since one purpose of a FP is the long-term restoration of function, runout has been defined as 10 000 000 cycles. As justification for this runout cycle count, flexion/extension is expected to be the dominant loading condition influencing the facets. While estimates vary on the number of significant bends (flexion/extension) a person makes per year, a conservative estimate is 125 000 bends/year, which equates to 1.25 million significant bends in ten years.[3] Therefore, 10 000 000 cycles would correspond to 80 years worth of significant bends. However, note that there has been much debate on what should be defined as a realistic target lifetime for *in vitro* testing, target clinical lifetime, and the minimum acceptable clinical lifetime for the FP. Therefore, if appropriate and justified, the user may choose to define a lower runout cycle count that is more applicable for the device being tested and the clinical setting in which the device will be used.

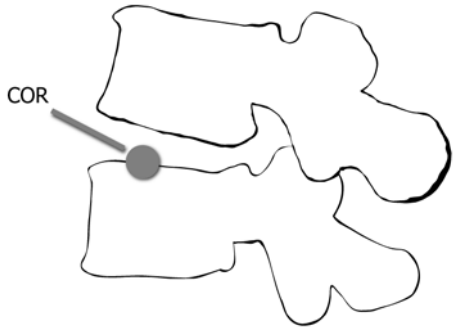
X1.4 Testing the prosthesis using constraints on 3D motions other than specified in this guide (which are intended to simulate conditions expected after *in vivo* implantation) could produce different results. Thus, use of different constraints must be justified with respect to those occurring *in vivo* after implantation, or that so doing produces insignificant differences in results.

X1.5 While reports of the center of rotation are variable throughout the literature (and throughout the motions of the FSU), for simplicity of testing it is positioned at a fixed location at the anterior third of (and on) the superior endplate of the inferior vertebral body and centralized medio-laterally (Fig. X1.1, Fig. X1.2, and Fig. X1.3). Morphologic data was compiled to quantify the radius of rotation for all motions and a two standard deviation method was used to ensure representation of the majority of the population. This fixed center of rotation allows for simpler combined motion testing, while still representing realistic radii of rotation. To calculate the flexion-extension radius of rotation values, two-thirds of the anterior-posterior measurement of the vertebral body[4] is added to the anterior-posterior length of the pedicle.[5] Additionally, while the center of rotation for lateral bending has been reported to be as far away from the facet as the opposite lateral edge of the

[3] Hedman, T. P., Kostuik, J. P., Fernie, G. R., and Hellier, W. G., " Design of an intervertebral disc prosthesis," *Spine*, Vol 16, No. 6, Suppl., 1991, pp. S256–S260.

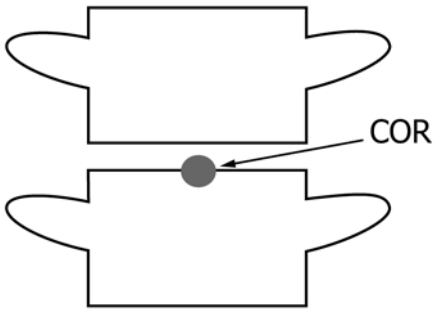
[4] Panjabi, M.M., Goel, V., Oxland, T., Takata, K., Duranceau, J., Krag, M., and Price, M., "Human Lumbar Vertebrae: Quantitative Three-Dimensional Anatomy," *Spine*, Vol. 17, No. 3, 1992, pp. 229–306.

[5] Krag, M., Weaver, D., Beynnon, B., and Haugh, L., "Morphometry of the Thoracic and Lumbar Spine Related to Transpedicular Screw Placement for Surgical Spinal Fixation," *Spine* , Vol. 13, No. 1, 1988, pp. 27–32.



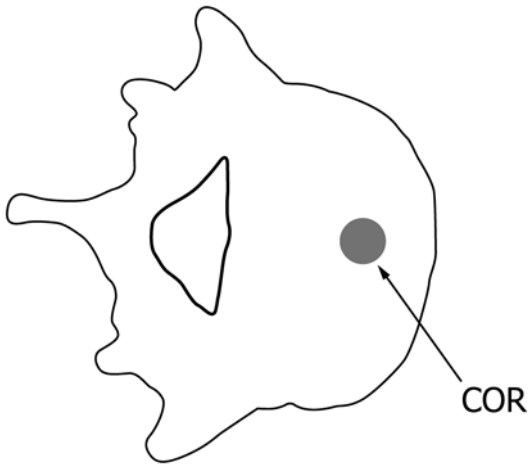
NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.1 Image Demonstrates the Center of Rotation as Visualized in the Lateral View



NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.2 Image Demonstrates the Center of Rotation as Visualized in the Anterior-posterior View



NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.3 Image Demonstrates the Center of Rotation as Visualized in the Axial View

vertebral body, it is represented in this practice as being centralized medio-laterally, for simplicity of test setup. As such, the interfacet distance is calculated as the interpedicular distance at the posterior aspect of the pedicle utilizing the canal

TABLE X1.1 Test Profiles and Associated Radius of Rotation for Rotational Test Setup

Test profile	Radius of Rotation, mm
Flexion/Extension	44.8[A]
Rotation	52.6[A]
Lateral Bending	27.5[A]

[A] Approximate distance to natural facet location based on location of a fixed center of rotation (COR) at the anterior-third of the disc and centralized in the medial-lateral direction (see X1.5).

width[4] plus the pedicle width[6] and accounting for the pedicle angle.[5,6] Half of this interfacet distance is thus equal to the lateral bending radius of rotation. To calculate the radius of rotation for axial rotation, the sum of the squares may be calculated from the lateral bending and flexion extension rotational radii. The resultant measurements to be used for the rotational radii are listed in Table X1.1.

X1.6 Frequencies over 10 Hz may result in heating and subsequent softening of the test blocks or a change in behavior of the device under test due to the temperature rise. Since this phenomenon is device and environment specific, the user of these test methods is left to discern an appropriate cyclic frequency. For reference, the physiologic range of frequencies is noted to be typically between 0.1 and 8.0 Hz.

[6] Wolf A, Shoham M, Michael S, and Modhe R, "Morphometric Study of the Human Lumbar Spine for Operation-Workspace Specifications," *Spine*, Vol. 26, No. 22, 2001, pp 2472–2477.