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.

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[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.

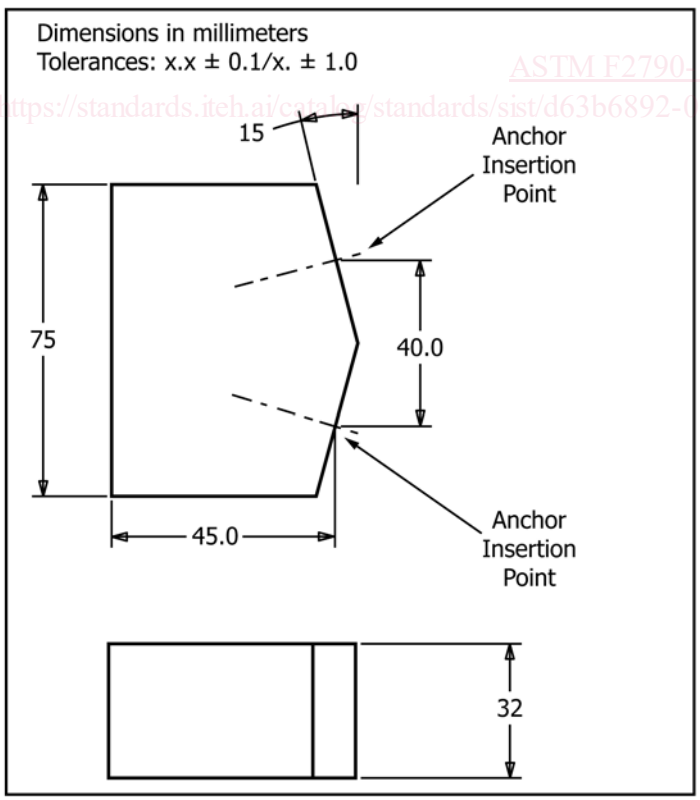


FIG. 1 UHMWPE Test Block

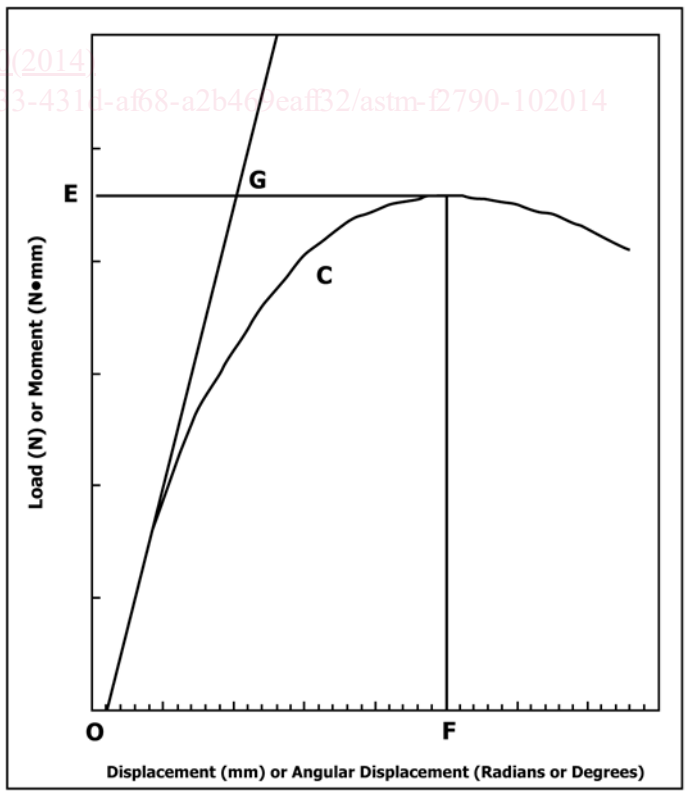


FIG. 2 Typical Load Displacement Curve

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.

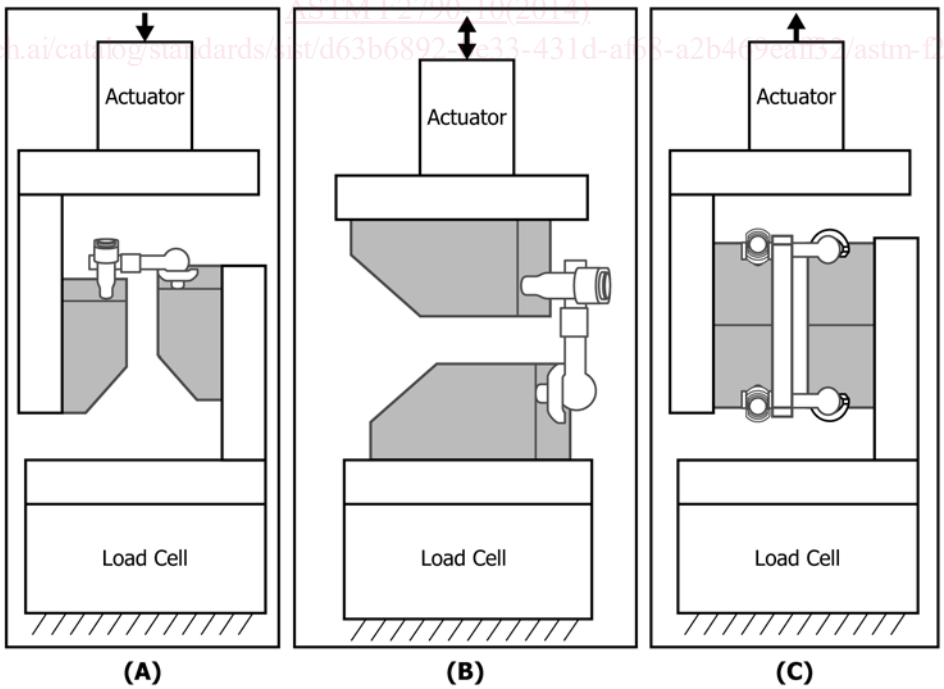
4.3 Static and dynamic testing of the devices will simulate a motion segment via a gap between two Ultra High Molecular Weight Polyethylene (UHMWPE) test blocks (Fig. 1, Fig. 3, or Fig. 4). The UHMWPE used to manufacture the test blocks should have a tensile breaking strength equal to 40 ± 3 MPa (see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

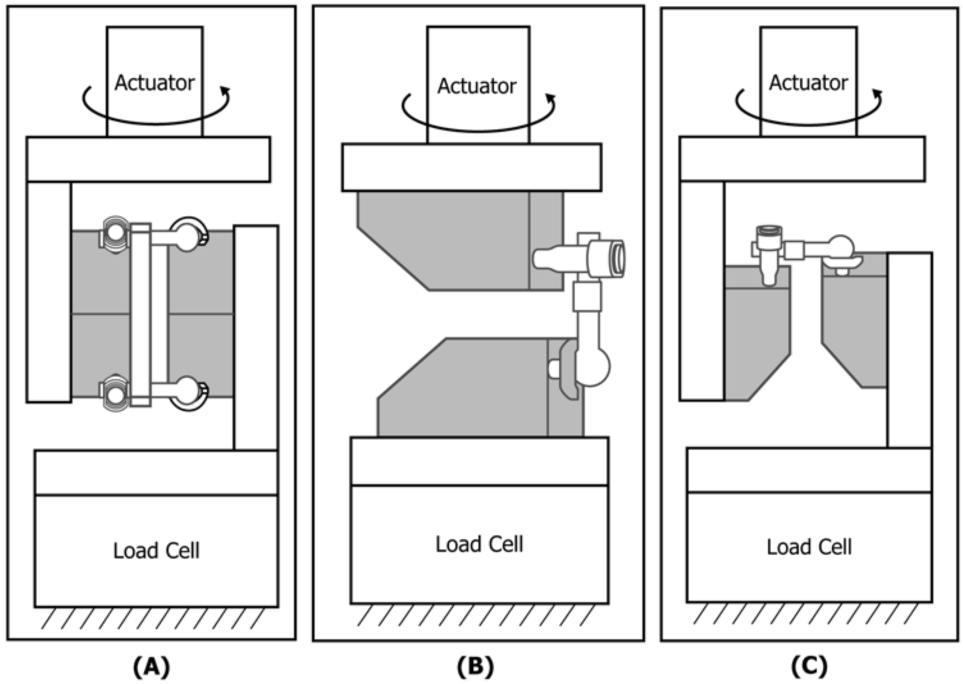
5. Significance and Use

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.