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Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs[1]

This standard is issued under the fixed designation F2624; 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 test method describes methods to assess the static and dynamic properties of single level spinal constructs.

1.2 An option for assessing wear using a weight loss method and a dimensional analysis is given. This method, described herein, is used for the analysis of devices intended for motion preservation, using testing medium as defined in this standard (6.1).

1.3 This test method is not intended to address any potential failure mode as it relates to the fixation of the device to its bony interfaces.

1.4 It is the intent of this test method to enable single level extra-discal spinal constructs with regard to kinematic, functional, and wear characteristics when tested under the specified conditions.

1.5 This test method is not intended to address facet arthroplasty devices.

1.6 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures be established. This test method is intended to facilitate uniform testing methods and data reporting.

1.7 The motion profiles specified by this test method do not necessarily accurately reproduce those occurring *in vivo*. Rather this method provides useful boundary/endpoint conditions for evaluating implant designs in a functional manner.

1.8 This test method is not intended to be a performance standard. It is the responsibility of the user of this test method to characterize the safety and effectiveness of the device under evaluation.

1.9 Multiple test methods are included in this standard. However, it must be noted that the user is not obligated to test using all of the described methods. Instead, the user should only select test methods that are appropriate for a particular device design. In most instances, only a subset of the herein described test methods will be required.

1.10 The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in either degrees or radians. No other units of measurement are included in this standard.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.12 *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. Referenced Documents

2.1 *ASTM Standards:*[2]

E2309 Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

F1877 Practice for Characterization of Particles

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air

F2423 Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses

3. Terminology

3.1 All terminology is consistent with the referenced standards, unless otherwise stated.

[1] This test method 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 *Definitions:*

3.2.1 *center of rotation (COR)*—the point about which the simulated vertebral bodies rotate in performing the range of motion (ROM) specified in this test method.

3.2.2 *compressive bending stiffness (N/mm)*—the compressive bending yield force divided by elastic displacement (see the initial slope of line BC in Fig. 1).

3.2.3 *compressive bending ultimate load (N)*—the maximum compressive force in the *X-Z* plane applied to a spinal implant assembly (see the force at Point E in Fig. 1). The ultimate load should be a function of the device and not of the load cell or testing machine.

3.2.4 *compressive bending yield load (N)*—the compressive bending force in the *X-Z* plane necessary to produce a permanent deformation equal to 0.020 times the active length of the longitudinal element (see the force at Point D in Fig. 1).

3.2.5 *coordinate system/axes*—three orthogonal axes are defined following a right-handed Cartesian coordinate system. The *XY* plane bisects the sagittal plane between the superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The positive *Z* axis is to be directed superiorly. Force components parallel to the *XY* plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z* direction. Torsional load is defined to be the component of moment about the *Z*-axis.

3.2.5.1 *origin*—the center of the coordinate system is located at the center of rotation of the testing fixture.

3.2.5.2 *X-Axis*—the positive *X*-Axis is a global fixed axis relative to the testing machine's stationary base and is to be directed anteriorly relative to the specimen's initial unloaded position.

3.2.5.3 *Y-Axis*—the positive *Y*-Axis is a global fixed axis relative to the testing machine's stationary base and is directed laterally relative to the specimen's initial unloaded position.

3.2.5.4 *Z-Axis*—the positive *Z*-Axis is a global fixed axis relative to the testing machine's stationary base and is to be directed superiorly relative to the specimen's initial unloaded position.

3.2.6 *degradation*—loss of material, function, or material properties due to causes other than wear.

3.2.7 *elastic displacement (mm or degrees)*—the displacement at 2 % offset yield (see Point A in Fig. 1) minus the 2 % offset displacement (see Point B in Fig. 1). (The distance between Point A and Point B in Fig. 1.)

3.2.8 *fluid absorption*—fluid absorbed by the device material during testing or while implanted *in vivo*.

3.2.9 *functional failure*—permanent deformation or wear that renders the implant assembly ineffective or unable to adequately resist load/motion or any secondary effects that

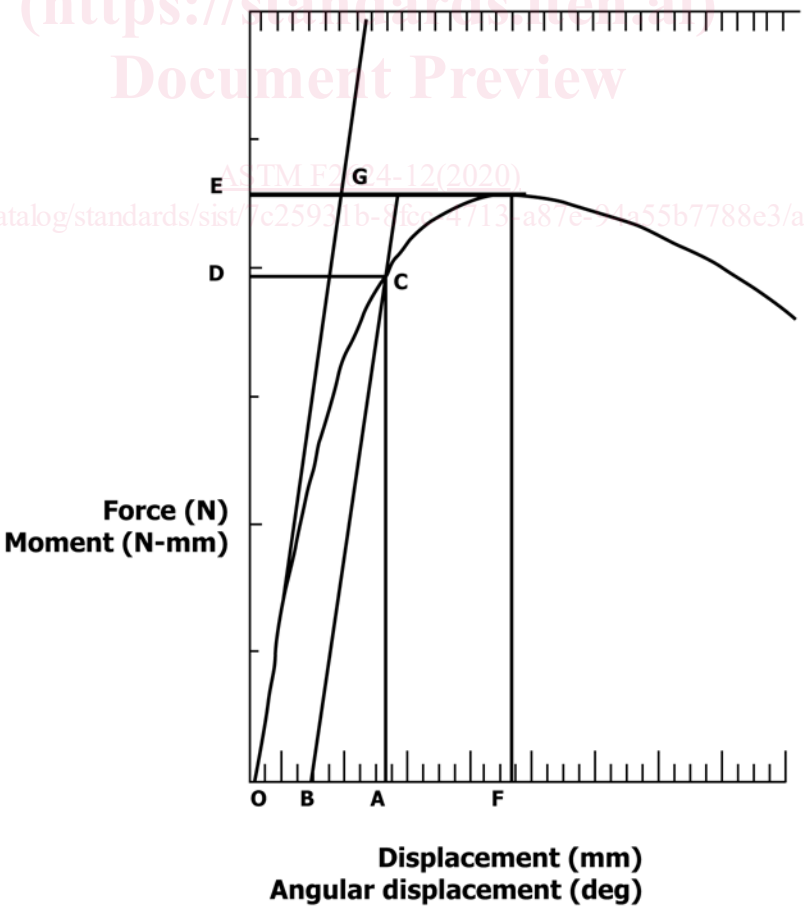


FIG. 1 Typical Force Displacement Curve

result in a reduction of clinically relevant motions or the motions intended by the design of the device.

3.2.10 *interval net volumetric wear rate—VR_i during cycle interval i (mm^3/million cycles)*:

$$VR_i = \frac{WR_i}{\rho}$$

where:

ρ = mass density (for example, units of g/mm^3) of the wear material.

3.2.11 *interval net wear rate—WR_i during cycle interval i (mg/million cycles)*:

$$WR_i = \frac{(NW_i - NW_{i-1})}{(\#\ \text{of cycles in interval}\ \ i)} \times 10^6$$

Note: for $i = 1$, $NW_{i-1} = 0$.

3.2.12 *kinematic profile*—the relative motion between adjacent vertebral bodies that the spinal device is subjected to while being tested (note that rigid devices may have minimal motion between vertebral bodies).

3.2.13 *maximum run-out force or moment*—the maximum force or moment for a given test that can be applied to a single level construct intended for fusion in which all of the tested constructs have withstood 5 000 000 cycles without functional or mechanical failure. For non-fusion devices, the maximum run-out force or moment is defined as 10 000 000 cycles without functional or mechanical failure.

3.2.14 *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.

3.2.15 *net volumetric wear—NV_i of wear specimen (mm^3)*:

$$NV_i = \frac{NW_i}{\rho}$$

at end of cycle interval *i*.

where:

ρ = mass density (for example, units of g/mm^3) of the wear material.

3.2.16 *net wear—NW_i* of wear specimen (g):

$$NW_i = (W_0 - W_i) + (S_i - S_0)$$

Loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval *i*.

3.2.17 *permanent deformation*—the remaining displacement (mm) or angular rotation (degrees) relative to the initial unloaded condition of the intervertebral body fusion device assembly after the applied force has been removed.

3.2.18 *run-out (cycles)*—the maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred.

3.2.19 *single level spinal construct*—a non-biologic structure, which lies entirely outside the intervertebral disc space, intended to support the full or partial load between adjacent vertebral bodies. In this test method, this definition does not include facet arthroplasty devices.

3.2.20 *stiffness (N/mm or N-m/degree)*—the slope of the initial linear portion of the force-displacement or moment-degree curve (the slope of Line OG in Fig. 1).

3.2.21 *test block*—the component of the test apparatus for mounting a single level spinal construct for the intended test configuration (Fig. 3).

3.2.22 *torsional aspect ratio*—the active length of the longitudinal element divided by the distance from the center of rotation to the insertion point of an anchor (for example: 0.78 for a 35 mm active length, X = 40 mm and Y = 40/2 mm).

3.2.23 *two percent (2 %) offset angular displacement (degrees)*—a permanent angular displacement in the *X-Y* plane measured via the actuator equal to 0.020 times the torsional aspect ratio (for example: 0.9° for 0.78 × 0.02 × 180°/pi) (see Point B in Fig. 1).

3.2.24 *2 % offset displacement*—a permanent deformation measured via the actuator equal to 0.020 times the active length of the longitudinal element (for example: 1.04 mm for a 52 mm active length) (see Distance OB in Fig. 1).

3.2.25 *wear*—the progressive loss of material from the device(s) or device components as a result of relative motion at the surface with another body as measured by the change in mass of the components of the implants. Or in the case of non-articulating, compliant components, wear is defined simply as the loss of material from the device. Note that bone interface components of the device are excluded from this definition. See 5.2.2, 5.2.4, and 5.2.5.

3.2.26 *weight S_i of soak control specimen (g)*—S_0 initial and S_i at end of cycle interval *i*.

3.2.27 *weight W_i of wear specimen (g)*—W_0 initial and W_i at end of cycle interval *i*.

3.2.28 *ultimate displacement (mm or degrees)*—the displacement associated with the ultimate force (displacement OF in Fig. 1).

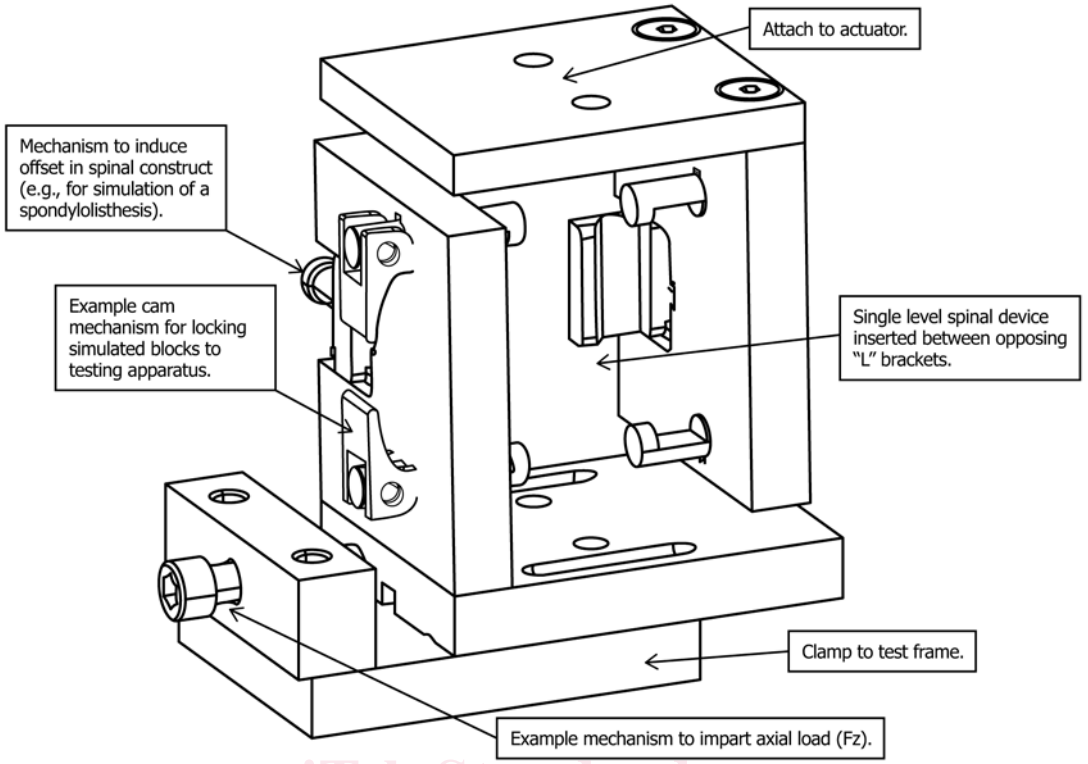
3.2.29 *ultimate load (N or N-m)*—the maximum applied force, *F*, transmitted by the actuator that can be applied to the spinal construct (Point E in Fig. 1).

3.2.30 *yield displacement*—the displacement (mm or degrees) when a spinal construct has a permanent deformation equal to the offset displacement (Distance OA in Fig. 1).

3.2.31 *yield force*—the applied force, *F*, or moment transmitted by the actuator required to produce a permanent deformation equal to the offset displacement (Point D in Fig. 1).

4. Significance and Use

4.1 This test method is designed to quantify the static and dynamic characteristics of different designs of single level spinal constructs. Wear may also be assessed for implants that allow motion using testing medium (see 6.1) for simulating the physiologic environment at 37 °C. Wear is assessed using a weight loss method in addition to dimensional analyses. Weight loss is determined after subjecting the implants to dynamic profiles specified in this test method. This information will allow the manufacturer or end user of the product to



NOTE 1—This example depicts a 3D rendering of a possible method for implementing of the rotational testing apparatus. In this example, adjustment mechanisms are employed to impart both axial load (F_z) and a spondylolisthesis offset prior to locking the spinal assembly in the apparatus. The actuator is rotated to apply flexion/extension moments. Spinal constructs are also tested in lateral bending and axial torsion in this same test setup with appropriate modifications.

FIG. 2 Rotational Testing Apparatus

understand how the specific device in question performs under the test conditions prescribed in this test method.

4.2 This test method is intended to be applicable for single level extra-discal spinal constructs. Three different types of fixtures are specified for testing single level extra-discal spinal constructs See Fig. 2, Fig. 4, and Fig. 5. See also Table 1.

4.3 Implants may be designed using a variety of materials (for example, ceramics, metals, polymers, or combinations thereof), and it is the goal of this test method to enable a comparison of the static, dynamic, and wear properties generated by these devices, regardless of material and type of device.

5. Apparatus

5.1 *Implant Components*—The device may comprise a variety of shapes and configurations. Some known forms include screws which rigidly grip the vertebral bodies coupled with flexible, elastic members; other forms may include rigid members coupled in a constrained (for example, pedicle screws) or semi-constrained manner (for example, screws and rods connected with a universal joint with defined motion limitations). Forms of these devices which employ hooks that engage posterior spinal elements are also envisioned; these devices may support extension loading only or loads in both flexion and extension.

5.2 *Spinal Testing Apparatus:*

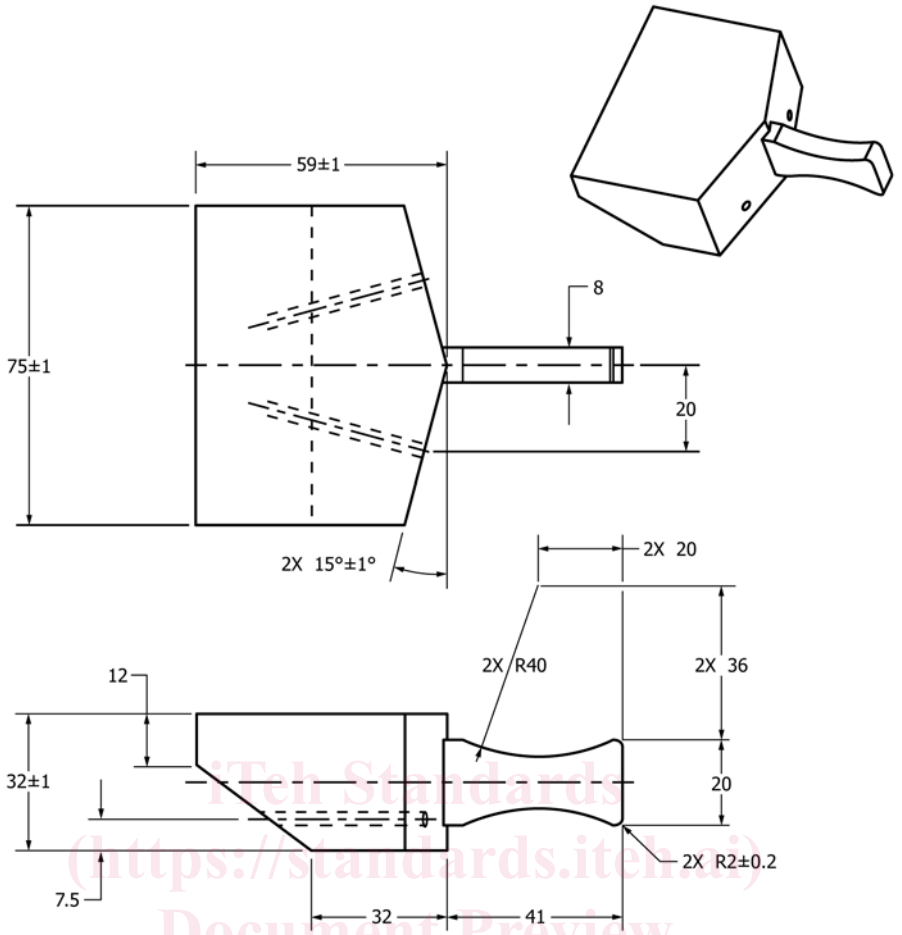
5.2.1 *Test Chambers*—In the case of a multi-specimen machine being used with testing medium, each chamber shall be isolated to prevent cross-contamination of the test specimens. The chamber shall be made entirely of non-corrosive components (such as acrylic plastic or stainless steel) and shall be easy to remove from the machine for thorough cleaning between tests.

5.2.2 For wear testing, the test chamber also must isolate the device/construct from wear centers created by the testing fixtures.

5.2.3 The user must determine the appropriate degrees of freedom for the device depending on its intended use (see 5.2.6).

5.2.4 *Component Clamping/Fixturing*—Since one of the purposes may be to characterize the wear properties of the spinal device, the method for mounting components in the test chamber shall not compromise the accuracy of assessment of the weight loss or stiffness variation during the test. For example, implants having complicated surfaces for contacting bone (for example, sintered beads, hydroxylapatite (HA) coating, plasma spray) may be specially manufactured to modify that surface in a manner that does not affect the wear simulation.

5.2.5 The device should be securely (rigidly) attached at its bone-implant interface to the test fixtures.



NOTE 1—All dimensions are in mm.

FIG. 3 Simulated Vertebral Body Testing Block

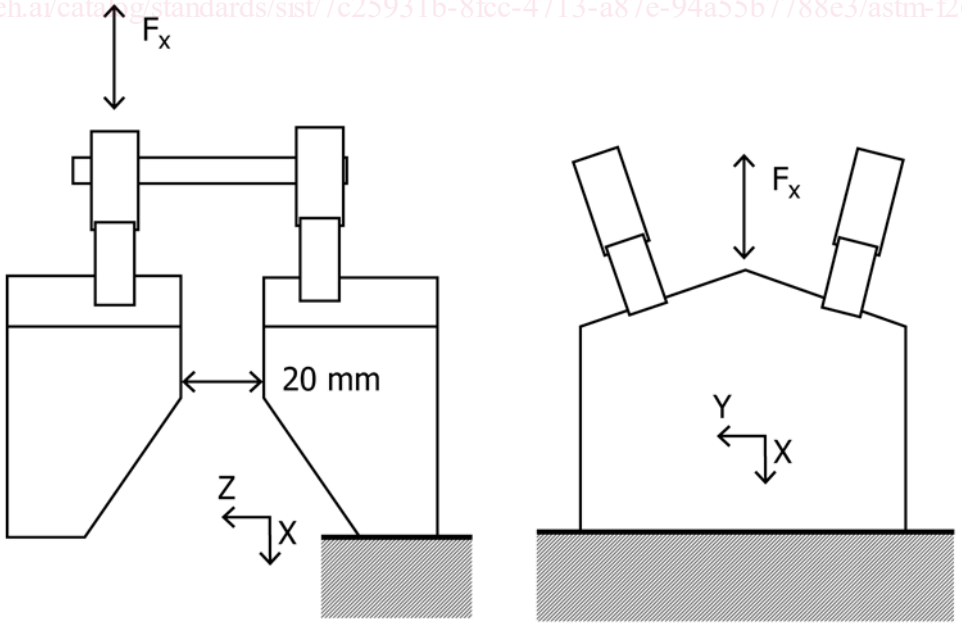


FIG. 4 Schematic of Anterior/Posterior Shear Testing Apparatus

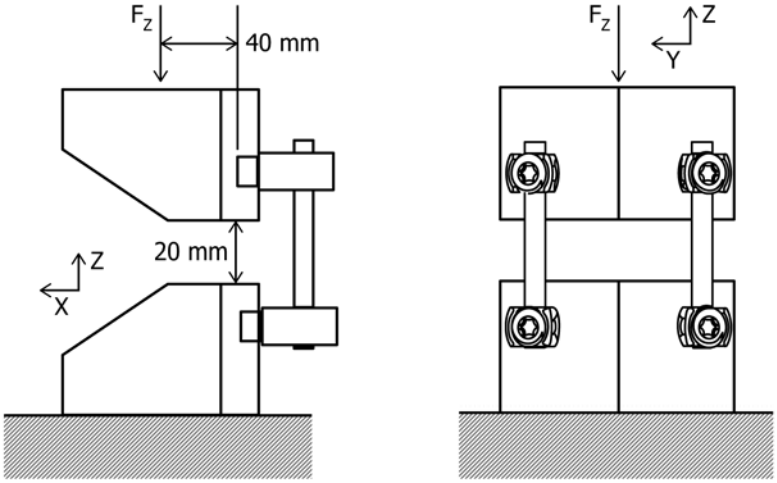


FIG. 5 Schematic of Single Level Compression Bending Test

TABLE 1 Loading Modes and Associated Apparatus Listing Possible Tests That May Be Conducted (see 1.9)

NOTE 1—For all loading modes, static, dynamic, and wear tests are described in this test method.

NOTE 2—"Offset" refers to 8 mm of offset induced in the spinal construct (see Fig. 6) before subjecting the construct to rotational flexion/extension moments (see Fig. 2).

Associated Apparatus	Associated Figure	Loading Mode
Rotational	Fig. 2	Flexion Extension Lateral Bending Axial Rotation
	Fig. 2 and Fig. 6	Offset Flexion and Offset Extension
Shear	Fig. 4	Anterior/Posterior Shear
Compression Bending	Fig. 5	Compression Bending

5.2.6 The construct mated with the testing fixture shall be constrained with the appropriate degrees of freedom for the intended use. For example, some devices may only be intended to provide stability in one motion, which would dictate that the test fixture may be constrained in all other motions. Other devices, which provide stability along multiple degrees of freedom, would necessitate having more degrees of freedom incorporated into the testing fixture. The user shall determine and justify the appropriate degrees of freedom of the test fixture.

5.2.7 Blocks are to be made from polyacetal homopolymer (minimum ultimate tensile strength shall be no less than 61 MPa). It is suggested that the simulated spinous process be made from stainless steel (minimum ultimate tensile strength of 500 MPa). Other materials may also be used based on the design intent of the implant being tested (for example, some devices may depend on spinous process bone compliance to properly function, which would preclude using stainless steel as the spinous process material.)

NOTE 1—304 stainless steel is used for the simulated spinous process for rigidity purposes to enable the user to accurately characterize the mechanical performance of the extra-discal implant.

5.2.7.1 The simulated spinous process is only needed if the implants are intended to be attached to the spinous process *in vivo*.

5.2.7.2 If a simulated spinous process is used, the entire simulated vertebral body (Fig. 3) shall be made from stainless steel (minimum ultimate tensile strength of 500 MPa). Modifications (including a material change) to the testing blocks are allowed to conform to device design and the manufacturer's intended use of the extra-discal implant. Note that if wear between the implant and the spinous process is expected, the user should consider altering the surface finish of the simulated spinous process to offer a more appropriate test model for assessing the mechanical characteristics of the implant.

5.2.8 *Rotational Test Apparatus*—The single level spinal construct is assembled per the manufacturer's instructions. The spinal construct is placed in a fixture, which is capable of inducing a rotational torque to test the single level construct under flexion/extension, axial rotation, and lateral bending. Fig. 2 depicts an example testing fixture for testing the spinal construct in flexion/extension. Note that the represented testing fixtures, which attach to the simulated vertebral bodies (Fig. 3) and the testing instrument, are for illustrative purposes only. The user must design the appropriate fixtures for the device being tested and means by which they are rigidly fixed to the testing instrument. Note that the use of this fixture may produce shear (side) loads on the actuator. To address potential adverse effects on the performance of the actuator and the readings of the load cell, the user may wish to restrict this side load by blocking translation of the actuator or by using appropriate bearings and/or joints to remove this side load.

5.2.9 *Anterior-Posterior Shear Apparatus*—The single level spinal construct is assembled per the manufacturer's instructions. One simulated vertebral body is rigidly connected to the actuator of the testing instrument. The other simulated vertebral body is constrained along the *X*-axis. Load, *Fx*, is applied along the *X*-axis as indicated in Fig. 4.

5.2.10 *Compression Bending Apparatus*—The single level spinal construct is assembled per the manufacturer's instructions. The inferior vertebra is rigidly attached to the test frame, and the actuator is attached to the superior block to apply loads/displacements along the *Z*-axis (Fig. 5). For certain implants, it may not be desirable for the superior block to rotate during testing. In this case, the rotation may be blocked, thereby eliminating a degree of freedom in the test. To do this, place an aluminum block between the modified polyacetal block and the superior fixture to stop rotation of the simulated vertebral body and eliminate a degree of freedom. The total clearance between a rigid block (for example, aluminum or stainless steel), a polyacetal block, and a base plate shall not exceed 0.10 mm. By blocking rotation, the test effectively becomes an axial compression test. Note also that the inferior plate should be free to translate in the *XY* plane to avoid uncontrolled forces in the *Fx* direction.

5.2.11 *Simulated Spondylolisthesis Offset* (for use in rotational testing apparatus—see Fig. 2 and Table 1). Induce an offset along the positive *X*-axis such that one vertebral body is displaced 8 mm. This number represents the limit of a grade 1 spondylolisthesis based on a 32 mm vertebral body dimension in the sagittal plane (Wolf, 2001 (**1**)[3] and Chaynes, 2001 (**2**)) relative to the other vertebral body and fix the spinal construct in this configuration (Fig. 6). Attach the longitudinal member to the simulated vertebral bodies and tighten fasteners according to the manufacturer's instructions.

5.2.12 *Range of Motion (ROM):*

5.2.12.1 Axial compressive loads/motions are applied in the direction of the negative *Z*-axis.

5.2.12.2 Flexion loads/motions are generated by positive rotation about the *Y*-axis.

5.2.12.3 Extension loads/motions are generated by negative rotation about the *Y*-axis.

5.2.12.4 Lateral bend loads/motions are generated by positive and negative rotation about the *X*-axis.

5.2.12.5 Torsional loads/motions are generated by positive and negative rotation about the *Z*-axis.

5.2.12.6 Anterior/posterior shear loads are applied in the direction of the positive and negative *X*-axis.

5.2.12.7 *Center of Rotation (COR)*—See the Appendix (X1.7) for a discussion on the COR. Since the COR will vary according to device design and intended use, it is impossible to artificially specify the coordinates of the COR for testing. Therefore, the COR must be determined by the end user of this test method for the specific device being tested. The user should specify the COR based on the expected *in-vivo* COR.

5.2.13 *Frequency for Fatigue and Wear Tests:*

5.2.13.1 Test frequency shall be determined and justified by the user of this test method. For wear and dynamic testing, the test frequency for devices with polymeric components shall not exceed 2 Hz without adequate justification, ensuring that the applied motion (load) profiles remain within specified tolerances and that the frequency does not adversely affect determination of the construct's wear and functional characteristics. For devices with all metal components, the test frequency may be increased to 5 Hz. Other frequencies, with adequate justification, may be used during fatigue testing if an accurate determination of the construct's properties is not compromised. The user is cautioned that care should therefore be taken to select an appropriate test frequency as testing at too high a frequency may adversely affect an accurate determination of the construct's properties.

5.2.14 *Cycle Counter:*

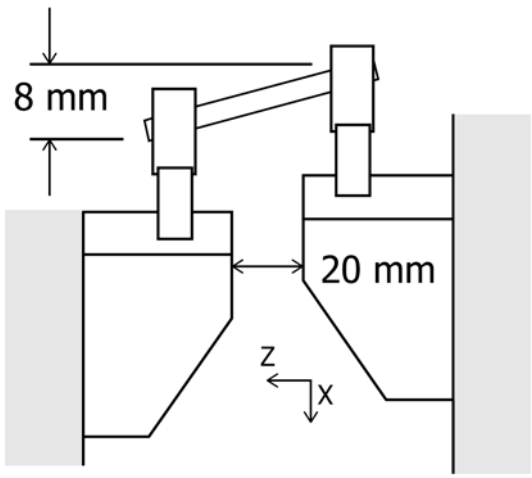
5.2.14.1 One complete motion is the entire range from starting position, through the range of motion and returning to the starting position. Cycles are to be counted using an automated counting device.

6. Reagents and Materials

6.1 *Testing Medium:*

6.1.1 The user has the option of testing the spinal implant in ambient conditions or in a testing medium, as determined by the end user of the standard. If the devices are known to be

[3] The boldface numbers in parentheses refer to a list of references at the end of this standard.



NOTE 1—Induce 8 mm offset in construct prior to attaching the longitudinal member.

FIG. 6 Schematic of Simulated Spondylolisthesis Offset for Flexion/Extension Test in Rotational Testing Apparatus