Designation: F2624 – 12 (Reapproved 2016)

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 test method 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 test method to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.*

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.

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.

[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.

Current edition approved Dec. 1, 2016. Published December 2016. Originally approved in 2007. Last previous edition approved in 2012 as F2624 – 12. DOI: 10.1520/F2624-12R16.

[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.

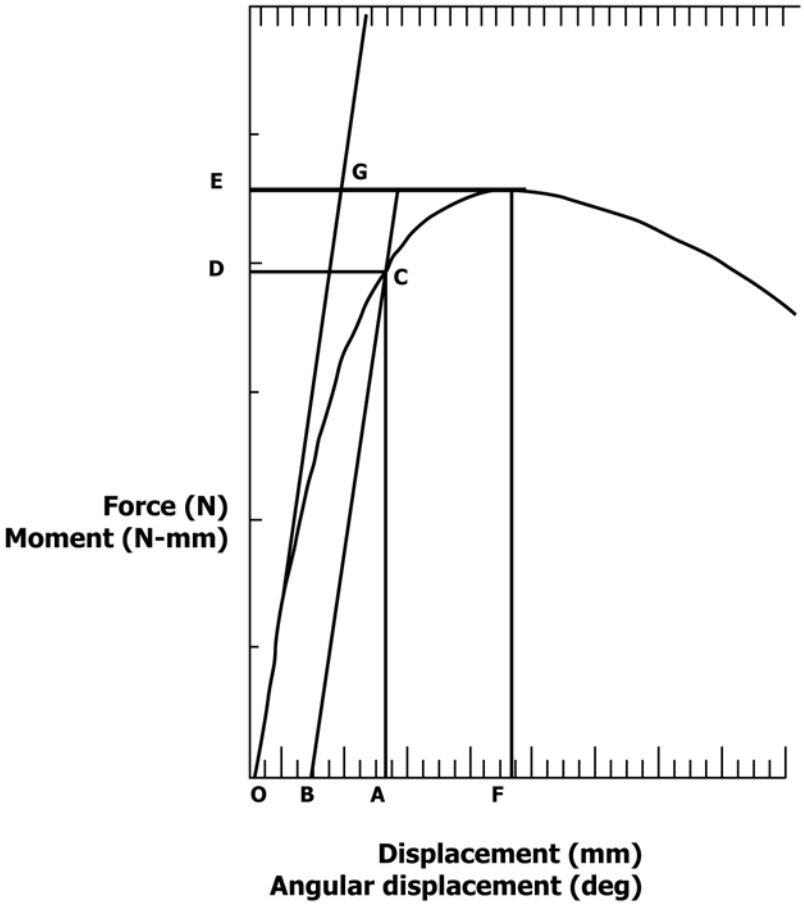


FIG. 1 Typical Force Displacement Curve

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 is to bisect the sagittal plane between 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 or function or material properties due to causes other than that associated with 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

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 Line OG—Fig. 1)—the slope of the initial linear portion of the force-displacement or moment-degree curve.

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*—(Distance OB—Fig. 1)—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 Point B 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)*—(Displacement OF—Fig. 1)—the displacement associated with the ultimate force.

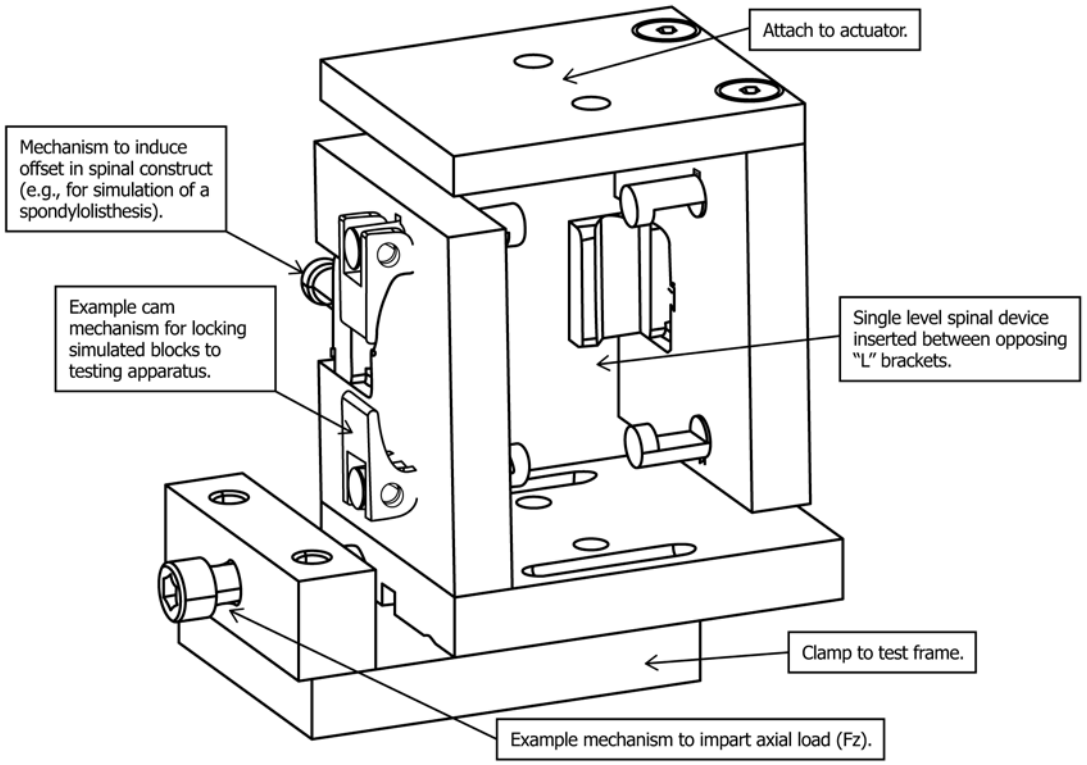
3.2.29 *ultimate load (N or N-m)*—(Point E—Fig. 1)—the maximum applied force, *F*, transmitted by the actuator that can be applied to the spinal construct.

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

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

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 (Fz) 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 purchase 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:*

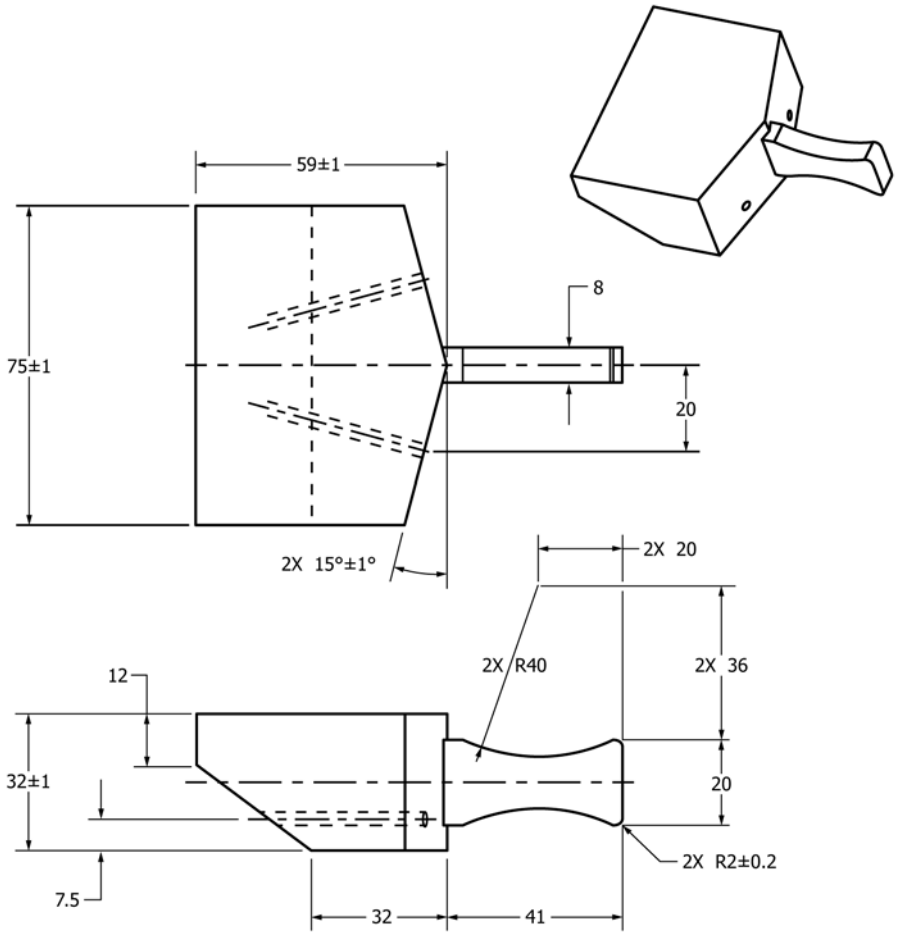
5.2.1 *Test Chambers*—In the case of a multi-specimen machine being used with testing medium, each chamber shall be isolated to prevent cross-contamination of the test specimens. The chamber shall be made entirely of non-corrosive components, such as acrylic plastic or stainless steel, and shall be easy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

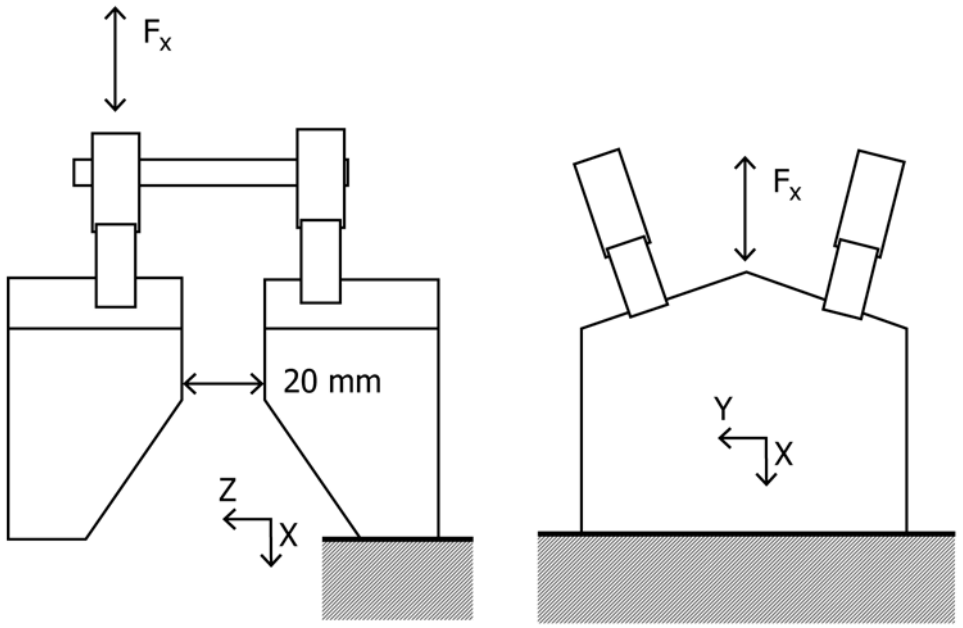


FIG. 4 Schematic of Anterior/Posterior Shear Testing Apparatus

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

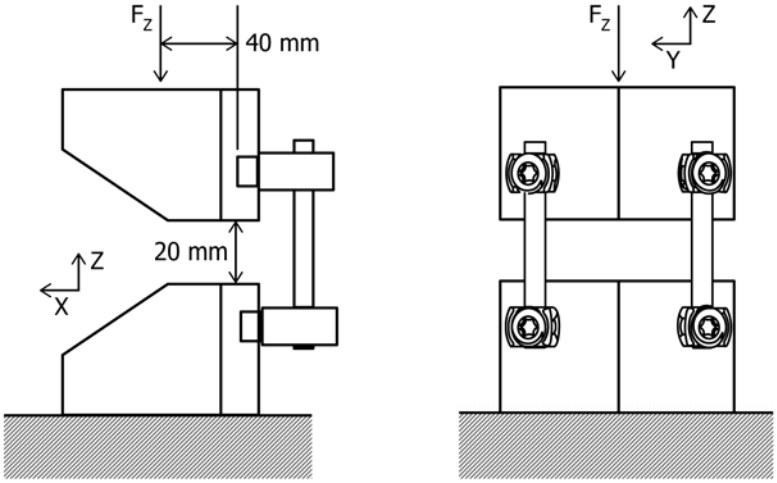


FIG. 5 Schematic of Single Level Compression Bending Test

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

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 is to 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 of a frequency may adversely affect an accurate determination of the construct's properties.

5.2.14 *Cycle Counter:*

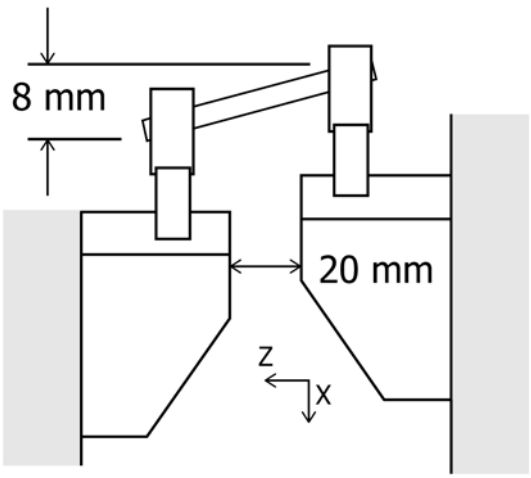
5.2.14.1 One complete motion is the entire range from starting position, through the range of motion and returning to the starting position. Cycles are to be counted using an automated counting device.

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 temperature- (at 37°C) and environment-dependent, testing shall be conducted in physiologic solution as described at 37°C (see 6.1.3).

[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

6.1.2 If the device does not have articulating surfaces or surfaces that move relative to one another, the user may test at ambient temperature in air or in a solution containing 0.9 % saline.

6.1.3 If the device contains articulating surfaces, or surfaces that move relative to one another, the device shall be tested in a testing medium containing bovine serum diluted to a protein concentration of 20 g/L in deionized water. The user should reference Guide F2423 for more information on the use of serum in the testing medium.

6.1.4 To retard bacterial degradation, freeze and store the serum until needed for testing. In addition, the testing medium should contain 0.2 % sodium azide (or other suitable antibiotic/antimycotic) to prevent the growth of microorganisms (fungi, yeast, bacteria, and so forth) that can degrade the lubricating properties of the serum, and can contaminate samples of wear particles that are subsequently isolated from the serum. Other lubricants should be evaluated to determine appropriate storage conditions. It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the testing medium containing serum at a concentration of 20 mM to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been shown to strongly affect the friction and wear properties, particularly of polyethylene/ceramic combinations. The addition of EDTA to other testing mediums should be evaluated.

6.1.5 The bulk temperature of the testing medium shall be maintained at 37 ± 3°C unless otherwise specified.

6.1.6 The user is cautioned that internal heating of the implant may cause localized temperatures to fall outside the 37 ± 3°C of the testing medium. Internal local temperatures may depend on a number of factors including, but not limited to, joint friction, material hysteresis, conductivity of the device-fixture materials, design, and test frequency. Localized elevated temperatures may have an effect on the mechanical as well as the wear properties of the implant. If the device experiences localized elevated temperatures, the user must describe the effect the selected frequency and resultant localized temperature have on the test results, or justify that the effects are physiologically relevant. Refer to Section X1.5 for further information.

7. Sampling Test Specimens

7.1 It is suggested that a minimum sample size of five be used for the static tests and a minimum of two to be used for each load or motion in the wear testing of the device. For fatigue testing, it is recommended that the user develop a load-cycle curve with at least 6 data points, with an evaluation of two samples demonstrating the maximum run out load. However, it should be noted that, as for any experimental comparison, the total number of needed specimens will depend on the magnitude of the difference to be established, the repeatability of the results (standard deviation), and the level of statistical significance desired.

7.2 The test assemblies (that is, spinal components in the tested configuration) shall be labeled so they can be traced and must be kept in a clean environment to avoid contamination. The test assembly can be disassembled to facilitate examination of surface conditions.

7.3 Polymeric specimens may require pre-conditioning, as device stiffness may depend on temperature and/or hydration of the polymer. In addition, the user may also wish to consider the effects of polymer aging on the mechanical properties of the device (the user should reference Practice F2003 for more information.)

8. Preparation of Apparatus

8.1 The functional surface of the implantable form of the device to be tested is produced using equivalent manufacturing methods as the implantable form of the construct, including sterilization.

8.2 It is permissible to exclude non-functional features that may interfere with obtaining wear/functional measurements. For example, bone implant interfaces such as HA, plasma-spray titanium, and beads may be omitted since they may abrade the fixtures and thus produce an unwanted mixture of functional and not-functional component wear particles (see 5.2.2).

8.3 The requirements of Guide F1714, Section 5 on "Specimen Preparation" shall be followed.

9. Procedure

9.1 Not all devices are designed to resist loading in all motions specified in this test method. The user must therefore determine which motion profiles and tests are appropriate for a given device (Table 1).

9.2 Angular motions shall be controlled with an accuracy of ±0.5°, and loads shall be controlled with an accuracy of ±5 % of the maximum load.

9.3 Mount the spinal device to the polyacetal homopolymer blocks (Fig. 2). Install the anchors according to the manufacturer's instructions with the following stipulation: anchors shall be inserted in the blocks in a manner that prevents the impingement of any potentially pivoting or rotating features of the anchor against the test block. This may be achieved by inserting the anchor such that, at full angulation of any of the potentially pivoting or rotating features, clearance is always maintained with respect to the test block. Note that modifications to the blocks may be required to adapt the test blocks to the spinal device.

9.4 The distance between the simulated endplates of the vertebral bodies shall be 20 mm (that is, simulated disc space height) in the final assembled configuration. Other distances may be appropriate if justified.

NOTE 2—Assuming a normal distribution of anterior disc space heights in the population, 20 mm is within three standard deviations of the mean and represents an upper limit for anterior intervertebral disc space heights of the reported L4-L5 and L5-S1 intervertebral disc space heights (**3**, **4**).

9.4.1 *Rotational Testing Apparatus*—In order to account for the axial preload the device would be subjected to *in vivo* in the neutral position, the test blocks/fixture shall be designed such that the implant, for static, fatigue and wear testing, is subjected to a nominal axial load of 300 N (Fz) when the

implants are in the neutral position at the start of the test. See Note 3. (Note: the torque imparted to the implants shall be monitored and tared to zero prior to commencement of the rotational test.) If the implant has viscoelastic characteristics, this nominal axial load may change significantly throughout the test. If a significant change in this axial load is expected during the test, the user should characterize the load response to the axial preload as a function of time. A load cell may be mounted along the *Z*-axis to characterize the axial load throughout the duration of the test. Note that this is only possible for devices that can resist compressive forces. The user must determine the appropriate methodology to exert this axial preload on the device. As an example, the user may design a *Z*-direction axial offset for the position of the axis of rotation such that the device, in its final assembled form, is being compressively loaded with 300 N (see Fig. 2 for an example fixture). Loading with a dead weight in the *Fz* direction is also a possible alternative. Note that other preloads may be appropriate with proper justification. For example, certain devices may be assembled *in vivo* with tensile preload forces; in this case, the application of appropriate tensile forces on the device in the final assembled form on the test blocks would be necessary.

NOTE 3—Note the rationale for a 300 N axial load. Assuming an approximate 1000 N load (based on intradiscal pressure measurements made by A. Nachemson, 1966, 1981) axially on the spinal column, one can equally assume that approximately ⅓ of this load is resisted by the posterior elements yielding approximately 300 N of load, which would be applied to the extra-discal elements described in this test method.

9.5 *Procedure for Static Rotational Tests*—Evaluate only the load parameters in the relevant direction.

9.5.1 *Static Flexion Test:*

9.5.1.1 Install the spinal construct in the rotational testing apparatus as indicated in Section 5 such that the actuator rotation generates flexion rotation about the *Y*-axis.

9.5.1.2 Load the test apparatus with a moment (+*Y* rotation) at a rate up to a maximum of 60°/min.

9.5.1.3 Record the load displacement curves. If the device has linear elastic characteristics, establish the ultimate displacement (degrees) at 2 % offset yield, elastic angular displacement (degrees), flexion bending yield load (N-m), flexion bending stiffness (N-m/degree). If the device does not have linear elastic characteristics, record only the flexion bending ultimate displacement (degrees) and flexion bending ultimate load (N-m). Note that if the blocks meet prior to failure of the device, the displacement value and force value at this displacement are to be used for the flexion bending ultimate displacement (degrees) and flexion bending ultimate load (N-m).

9.5.2 *Static Extension Test:*

9.5.2.1 Install the spinal construct in the rotational testing apparatus as indicated in Section 5 such that the actuator rotation generates extension rotation about the *Y*-axis.

9.5.2.2 Load the test apparatus with a moment (-*Y* rotation) at a rate up to a maximum of 60°/min.

9.5.2.3 Record the load displacement curves. If the device has linear elastic characteristics, establish the displacement (degrees) at 2 % offset displacement, elastic angular displacement (degrees), extension bending yield force (N-m), and extension bending stiffness (N-m/degree). If the device does not have linear elastic characteristics, record only the ultimate displacement (degrees) and ultimate load (N-m). Note that if the blocks meet prior to failure of the device, the displacement value and load value at this point are to be used for the extension bending ultimate displacement (degrees) and extension bending ultimate moment (N-m).

9.5.3 *Static Axial Rotation Test:*

9.5.3.1 Install the spinal construct in the rotational testing apparatus as indicated in Section 5 such that the actuator rotation generates axial rotation about the *Z*-axis.

9.5.3.2 Load the test apparatus at a maximum rate up to 60°/min.

9.5.3.3 Record the torque-angular displacement curves. For devices, which exhibit linear elastic behavior, determine the angular displacement (degrees) at 2 % offset displacement, elastic angular displacement (degrees), yield torque (N-m), and torsional stiffness (N-m/degree). For devices, which do not exhibit linear elastic behavior, simply record the torque at 10º rotation.

NOTE 4—If the device is symmetric about the *X-Z* and *Y-Z* planes bisecting the device, only left or right rotation need to be conducted.

9.5.4 *Static Lateral Bending Test:*

9.5.4.1 Install the spinal construct in the rotational testing apparatus as indicated in Section 5 such that the actuator rotation generates axial rotation about the *X*-axis.

9.5.4.2 Load the test apparatus with a moment (± *X*-Axis rotation) at a rate up to a maximum of 60°/min.

NOTE 5—If the device is symmetric about the *X-Z* plane bisecting the device, only left or right lateral bending need be conducted.

9.5.4.3 If the device has linear elastic characteristics, establish the displacement (degrees) at 2 % offset displacement, elastic angular displacement (degrees), extension bending yield force (N-m), and extension bending stiffness (N-m/degree). If the device does not have linear elastic characteristics, record only the ultimate displacement (degrees) and ultimate load (N-m). Note that if the blocks meet prior to failure of the device, the displacement value and load value at this point are to be used for the extension bending ultimate displacement (degrees) and extension bending ultimate moment (N-m).

9.6 *Procedure for Procedure for Dynamic Rotational Tests*—Evaluate only the load parameters in the relevant direction. For all fatigue tests, this test method prescribes testing in load control if possible.

9.6.1 Add testing medium to the tank (6.1) if required.

9.6.2 *Flexion/Extension Fatigue*—Apply a sinusoidal moment (±*Y*-Axis rotation) to the spinal construct. The loading should be maintained via a constant sinusoidal load amplitude control. A constant load ratio (*R*) for all tests should be established. If testing in displacement control, displacements shall be maintained via constant sinusoidal displacement amplitude control. The end of the test occurs when the spinal construct has a failure or reaches run out.

9.6.3 Note that one specific load ratio cannot be standardized due to different intended uses of these types of spinal implants. For example, some devices are intended to resist extension loads while others may be equally balanced in

limiting flexion and extension loading. In this example, different *R* ratios would be required to properly assess the function of the spinal implant. It is therefore incumbent upon the user to select and justify an appropriate *R* ratio or displacement end limits.

9.6.4 *Axial Rotational Fatigue*—Apply a sinusoidal moment load (±*Z*-Axis rotation) to the spinal construct. A constant load ratio of -1 shall be used. If testing in displacement control, displacements shall be maintained via constant sinusoidal displacement amplitude control divided equally between left and right axial rotation.

9.6.5 *Lateral Bending Fatigue*—Apply a sinusoidal moment load (±*X*-Axis rotation) to the spinal construct. The loading should be maintained via a constant sinusoidal load amplitude control. A constant load ratio (*R*) for all tests should be established. For devices that are symmetric about the *X-Z* plane, a constant load ratio of -1 shall be used. If testing in displacement control, displacements shall be maintained via constant sinusoidal displacement amplitude control. For devices that are symmetric, rotation shall be equal in left and right lateral bending. Other displacements may be justified depending on design and intended function of the implant. The end of the test occurs when the spinal construct has a failure or reaches run-out.

9.7 Evaluate at least six specimens to generate a load-cycle or displacement-cycle curve. Establish the maximum run out load or displacement. Suggested maximum forces for initial dynamic tests are 25, 50, and 75 % of the ultimate static force. Continue fatigue testing specimens 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 from the static tests. For example, if the flexion bending ultimate load of the implant is 16 N-m and the user demonstrates run-out at 3 N-m, the 3 N-m is to be considered a run-out value only if the user demonstrates failure of the device below the run out cycle count at a value between the range of 3 N-m and 4.6 N-m. A semi-log fatigue curve of the load versus number of cycles at failure will be plotted.

9.8 The creep behavior of the implant shall be documented by noting the maximum angle reached as a function of cycle count. If testing in displacement control, the stress relaxation behavior of the implant shall be documented by noting the maximum load reached as a function of cycle count.

9.9 If a device ceases to function, the test is terminated. The mechanism of failure and number of cycles at which the functional failure occurred, or was discovered, shall be noted.

9.10 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.

9.11 *Procedure for Static Compression Bending Testing:*

9.11.1 Apply force, *–Fz*, as described in Section 5 of this test method under position control at a rate of no greater than 25 mm/minute until functional or mechanical failure of the spinal construct is obtained.

9.11.2 Record the load displacement curves. Establish the 2 % offset displacement (mm), elastic displacement (mm), compressive bending yield load (N), compressive bending stiffness (N/mm), compressive bending ultimate displacement (mm) and compressive bending ultimate load (N).

9.12 *Procedure for Dynamic Compression Bending Testing:*

9.12.1 Apply force, *Fz* via a sinusoidal waveform as described in Section 5 of this test method under load control. The user of this test method should select the necessary forces to develop a well-defined force-cycle to failure trend comprised of a minimum of six data points. Suggested maximum forces for initial dynamic tests are 25, 50, and 75 % of the ultimate static force. A semi-log fatigue graph of maximum applied force, *F*, versus the number of cycles to failure is to be plotted. Alternatively, the user may apply *Fz* via a sinusoidal wave form under displacement control. The user of the test method should select the necessary displacements to develop a well-defined displacement-cycle curve comprised of a minimum of six data points. The end of the test is defined as functional failure of the construct or the ability to reach run out without functional failure. However, any mechanical failure should be noted at the run out cycle point (for example, crack initiation and crack propagation). The maximum run out force or displacement is to be determined. The precision in establishing the maximum run out force should not deviate more than 10 % of the static ultimate strength of the single level spinal construct.

9.13 The creep behavior (or stress relaxation behavior if testing under displacement control) of the implant shall be documented by noting the maximum displacement reached as a function of cycle count.

9.14 If a device ceases to function, the test is terminated. The mechanism of failure and number of cycles at which the functional failure occurred, or was discovered, shall be noted.

9.14.1 During dynamic tests, observations of any mechanical failures (for example, cracks) shall be documented with a complete description of the mechanical failure, number of cycles at the initial observation and subsequent changes, if any, in mechanical behavior of the construct. It is recommended that implants be examined for mechanical failure at intervals throughout the dynamic tests. If a crack or other mechanical failure is found, the crack location and cycle count along with the size and description at which it was discovered shall be recorded. At the engineering judgment of the user, the test may be continued following the observation of a mechanical failure to evaluate the ability of the implant to function under the applied forces. If a mechanical failure is detected following a run out, the failure shall be recorded (that is, location, size, and description) at the last cycle count without any detectable cracks. For example, if an implant reached run out and a crack was discovered on the implant upon removal, this crack shall be adequately described, noted, and assigned the previous examination cycle count (for example, 4 000 000 cycles) before a 5 000 000 cycle run out was attained. Functionally, however, this implant would still be considered a run out.

9.14.2 If testing under load control, an *R* value ≥10 (*R* = Min load/Max load) shall be used for the compression bending tests. Unless otherwise justified by intended use and the service life expectancy of the device, for devices intended for non-fusion (that is, to preserve motion), all tests should be

conducted to a run out of 10 000 000 cycles, and 5 000 000 cycles for devices intended for fusion (that is, to inhibit motion) (See Rationale Section, Appendix X1).

9.15 *Procedure for Static Anterior/Posterior Shear Testing:*

9.15.1 Apply force, +*Fx* and/or –*Fx*, as described in Section 5 of this test method under position control at a rate of no greater than 25 mm/minute until functional or mechanical failure of the spinal construct is obtained.

9.15.2 The force displacement curves shall be recorded under positive and negative force application. The yield displacement (mm), stiffness (N/mm), yield force (N), ultimate displacement (mm), and ultimate force (N) are to be established. The user may reference Practices E2309 for assistance in static test yield determination.

9.16 *Procedure for Dynamic Anterior/Posterior Shear Testing:*

9.16.1 Apply force, *Fx* as described in Section 5 of this test method under load control. The user of this test method should select the necessary forces to develop a well-defined force-cycle to failure trend comprised of a minimum of six data points. Suggested maximum forces for initial dynamic tests are 25, 50, and 75 % of the ultimate static force. A semi-log fatigue graph of maximum applied force, *F*, versus the number of cycles to failure is to be plotted. The end of the test is defined as functional failure of the construct or the ability to reach run out without functional failure. However, any mechanical failure should be noted at the run out cycle point (for example, crack initiation and crack propagation). The maximum run out force is to be determined. The precision in establishing the maximum run out force should not deviate by more than 10 % of the static ultimate strength of the single level spinal construct.

9.17 The creep behavior of the implant shall be documented by noting the maximum displacement reached as a function of cycle count.

9.18 If a device ceases to function, the test is terminated. The mechanism of failure and number of cycles at which the functional failure occurred, or was discovered, shall be noted.

9.18.1 During dynamic tests, observations of any mechanical failures (for example, cracks) shall be documented with a complete description of the mechanical failure, number of cycles at the initial observation and subsequent changes, if any, in mechanical behavior of the construct. It is recommended that implants shall be examined for mechanical failure at intervals throughout the dynamic tests. If a crack or other mechanical failure is found, the crack location and cycle count along with the size and description at which it was discovered shall be recorded. At the engineering judgment of the user, the test may be continued following the observation of a mechanical failure to evaluate the ability of the implant to function under the applied forces. If a mechanical failure is detected following a run out, the failure shall be recorded (that is, location, size, and description) at the last cycle count without any detectable cracks. For example, if an implant reached run out and a crack was discovered on the implant upon removal, this crack shall be adequately described and noted and assigned the previous examination cycle count (for example, 4 000 000 cycles) before a 5 000 000 cycle run out was attained. Functionally, however, this implant would still be considered a run out.

9.18.2 An *R* value of –1 shall be used for the anterior/posterior shear tests. Unless otherwise justified by intended use and service life expectancy of the device, for devices intended to preserve motion, all tests should be conducted to a run out of 10 000 000 cycles, and 5 000 000 cycles for devices intended to inhibit motion (see Rationale Section, Appendix X1).

9.19 *Procedure for Wear Testing:*

9.19.1 Wear may be assessed using the rotational testing apparatus, anterior/posterior shear apparatus, or in compression bending as determined by the user.

9.19.2 As a weight control for the testing, a minimum of two (2) identical soaked control specimens in testing medium (see Section 6.1) shall be used. Note: the user of this test method may justify not performing control tests in certain circumstances (for example, all metal components). Before and at all specified time intervals (determined by the user) of the presoak period (defined in Guide F1714), the wear components and soak controls should be removed from the soak bath, cleaned, dried, and weighed three times, in rotation, keeping the same specimen sequence each time. The average of the three weights may be used for the wear calculations. An analytical balance with a sensitivity of ±10 µg shall be used. This degree of sensitivity for weighing is necessary to detect the slight loss in weight of polymers, such as UHMWPE, which may wear 30 µg or less per million cycles.

9.19.3 Always weigh specimens in the clean, dry condition (see Annex A4 of Guide F1714). Keep the components in a dust-free container and handle with clean tools and/or gloves to prevent contamination that might affect the weight measurement. Weigh each wear and control component three times in rotation to detect random errors in the weighing process.

9.19.4 Record weights, W_0 and S_0 as the initial weights of the wear and soak controls, respectively. Place the loaded soak control specimens in holders in a soak chamber of the testing medium, such that the total surface area exposed to the testing medium is the same as that of the wear components when mounted in the spinal testing apparatus. Maintain the soak chamber temperature at 37 ± 3°C, or specify if different.

9.19.5 For all components—measure the geometry of relevant features prior to starting the test.

9.19.6 Testing medium, temperature and removal periods for weighing components shall be identical for all control and test specimens.

9.19.7 Unless otherwise justified by intended use and life expectancy of the device, for devices intended to preserve motion, all tests should be conducted to a run out of 10 000 000 cycles (see Rationale Section, Appendix X1).

9.19.8 The testing medium shall be collected for subsequent analysis upon the completion of each test for all specimens tested.

9.19.9 Place the device in the spinal testing apparatus as previously described in the "Procedure for Static Tests," add test medium (6.1) and subject the implants to the range of motion (ROM) protocols as indicated. If subjecting the device to the indicated ROM results in loading which would be

deemed physiologically impossible, the user may provide a rationale for an altered ROM for each motion profile.

9.19.9.1 *Flexion/Extension Wear Assessment*—Subject the construct to a sinusoidal waveform of ±7.5° of flexion/extension motion via the application of positive and negative *Y*-Axis rotations. (Note: the user of the test method must determine whether the ROM will be equally divided between flexion and extension or weighted more toward one of the motion directions. The total ROM, however, must equal 15° unless otherwise justified.) Alternatively, the user may test in load control, subjecting the extra-discal device to ±10 N-m of load.

NOTE 6—Approximated based on a review of ROM (p. 111) and average flexibility and stiffness coefficients (p. 47) (**5**).

9.19.9.2 *Rotational Wear Assessment*—Subject the construct to a sinusoidal waveform of ±3° of right axial rotation/left axial rotation motion via the application of positive and negative rotation around the *Z*-axis. Alternatively, the user may test in load control, subjecting the extra-discal device to ±10 N-m of load. See Note 6.

9.19.9.3 *Bending Wear Assessment*—Subject the construct to a sinusoidal waveform of ±6° of right lateral bending/left lateral bending motion via the application of positive and negative rotation around the *X*-axis. Alternatively, the user may test in load control subjecting the extra-discal to ±10 N-m of load. See Note 6.

9.19.10 A new, unused specimen is used to start each test.

9.19.11 The user may perform wear tests in any one of three methods. Note that the user may need to perform tests in more than one of the methods to accurately characterize the extra-discal device. In addition, the user must provide a rationale for the method(s) chosen.

9.19.12 For the first option, specimens used for one motion shall not be used for evaluating device performance in another motion (for example implants used for flexion/extension shall not be used for rotational/torsional testing).

9.19.13 Alternatively, in the second option, the user shall test the same devices for each of the parameters listed. For example, after completing 10 000 000 cycles in flexion/extension, the user shall conduct lateral bend and rotational coupled motions on the same device.

9.19.14 The final option is a method in which all of the simple motions are combined in one test. Note that each simple motion in this combined motion test must complete at least 10 000 000 cycles.

9.19.15 Compression bending wear assessment: subject the construct to sinusoidal loads according to 9.13.

9.19.16 Anterior-posterior shear wear assessment: subject the construct to sinusoidal loads according to 9.17.

TABLE 2 Wear Test Profiles and Associated Parameters

Test Profile	Displacement Control: Range of Motion (ROM), degree	Load Control: Moments, Nm
Flexion/Extension	± 7.5	± 10
Axial Rotation	± 3	± 10
Bending	± 6	± 10

9.19.17 For all wear tests, devices shall be visually analyzed at least once per 1 000 000 cycles with mechanical failures noted. Note, however, that the device being tested shall not be removed and/or disassembled for this visual inspection. A mechanical failure (for example, considerable wear of the bearing surface or at the connection of multiple components) may not necessitate termination of the test since this test method attempts to characterize the time-dependent wear properties of the device. The test shall be terminated if functional failure occurs (for example gross fracture or a device seizes).

9.19.18 If a device ceases to function, the test is terminated. The mechanism of failure and number of cycles at which the functional failure occurred, or was discovered, shall be noted.

9.19.19 At the completion of the test, remove the tested and soaked components, wash, rinse, and dry concurrently, in accordance with the procedure in Annex A4 of Guide F1714. It is important that both the tested and soaked components be treated identically to ensure that they have the same exposure to the wash, rinse, and drying fluids. This will provide the most accurate correction for fluid absorption by the tested specimens.

9.19.20 After rinsing and drying, weigh the tested components and soak controls (±10 µg).

9.19.21 Thoroughly rinse the tested chambers and component surfaces with distilled water.

9.19.22 Inspect the components of the device and note their condition. Visual, microscopic, or other inspection techniques can be used. Care must be taken, however, that the implant components do not become contaminated or damaged by any substance or technique that might affect the subsequent wear properties. If contamination occurs, thoroughly reclean the specimens prior to restarting the test.

9.19.23 The testing medium shall be replaced at the appropriate testing intervals (the minimum being once every million cycles).

9.19.24 *Gathering of Particulate:*

9.19.24.1 At a minimum, once per 1 000 000 cycles, representative particles should be isolated from the testing medium with appropriate filtration methods. Submicron filters (0.2 µm or below) are suggested; though, ultimately, the material type of the wear particles and their size distribution will dictate the methods used. Note that several stages of filtration may be necessary to isolate the different particles of interest effectively.

9.19.24.2 The particulate debris should be analyzed as appropriate. The user may wish to reference Practices F1877 and F561 for further information regarding particle characterization and/or debris isolation.

10. Calculation or Interpretation of Wear Results

10.1 *Correcting for Fluid Absorption:*

10.1.1 Calculate the net wear NW_i at the end of each cycle interval i using the equation in 3.2.16 and definitions for W_i and S_i in 3.2.27and 3.2.26, respectively. Calculate the interval net wear rate WR_i during cycle interval i using the equation in 3.2.11.

10.2 *Conversion to Volumetric Wear:*

10.2.1 Convert net wear NW_i to volumetric wear NV_i using the equation in 3.2.15 and interval net wear rate WR_i to interval net volumetric wear rate VR_i using the equation in 3.2.10. This is recommended for comparison of wear between different materials or material grades (polymer versus metallic, for example). The accuracy of this calculation is dependent on the material being reasonably homogeneous, that is, having a constant density with wear depth. Report the density value used in this conversion. See Section 3 for details.

11. Report

11.1 Provide materials traceability information for all components used, such as part and lot numbers of finished parts or material grades, batch numbers, manufacturing certifications, processing variables and any other pertinent manufacturing/material information.

11.2 All pretest bulk material properties characterizations shall be provided (for example, molecular weight average, range and distributions, percent crystallinity, density, degree of oxidation).

11.3 Report the method of sterilization, sterilization test dates, and sterilization expiration dates. In case of sterilization using gamma radiation, report the time and storage conditions (for example, air, inert gas, vacuum, and so forth) between fabrication and irradiation, the atmosphere irradiation, the total gamma dose and dose rate, and the duration and condition of storage between sterilization and the beginning of the test, since each of these may affect the amount of oxidative degradation during or after the radiation sterilization process. If sterilization information is not available, this must be clearly stated in the report.

11.4 Adequate details of the testing apparatus and test methods employed shall be included. All deviations (with adequate justification) from the recommended test procedures shall be reported along with all relevant testing parameters.

11.5 Rationale for not using any of the testing configurations specified in this test method shall be reported.

11.6 All relevant geometric measurements of the spinal device throughout the duration of the test shall be reported.

11.7 For the static flexion and static extension tests, provide all load–angular displacement plots, and report the establish the displacement (degrees) at 2 % offset displacement, elastic angular displacement (degrees), extension bending yield force (N-m), and extension bending stiffness (N-m/degree). If the device does not have linear elastic characteristics, record only the ultimate displacement (degrees) and ultimate load (N-m)., or if the device does not have linear elastic characteristics, report only the flexion/extension bending ultimate displacement (degrees) and flexion/extension bending ultimate load (N-m).

11.8 For the static torsion test, provide all load–angular displacement plots, and report the 2 % offset yield, elastic angular displacement (degrees), yield torque (N-m), and torsional stiffness (N-m/degree), or for devices, which do not exhibit linear elastic behavior, simply report the torque at 10º rotation.

11.9 For the static lateral bending tests, provide all load–angular displacement plots, and report the elastic angular displacement (degrees), bending yield load (N-m), compressive bending stiffness (N-m/degree).

11.10 Report the yield displacement (mm), stiffness (N/mm), yield force (N), ultimate displacement (mm), and ultimate force (N) in anterior/posterior shear tests.

11.11 Report the offset displacement (mm), elastic displacement (mm), compressive bending yield load (N), compressive bending stiffness (N/mm), compressive bending ultimate displacement (mm) and compressive bending ultimate load (N) for all compression bending tests.

11.12 Provide all load-cycle plots for all fatigue tests.

11.13 Report the creep behavior for the fatigue testing by plotting the maximum angle reached as a function of cycle count. The values shall be reported at log cycle scale (for example, 1, 10, 100, 1 000, 10 000, 100 000, 1 000 000, 10 000 000).

11.14 Report motion profiles for the wear testing.

11.15 Report the test duration in cycles for the wear testing.

11.16 For each motion profile used in wear testing, include a table with data for the net volumetric wear NV_i (mm^3) and interval net volumetric wear rate VR_i (mm^3/ million cycles) of each specimen as a function of total test cycles at end of test interval *i*. Plot all of the NV_i data points on one graph, and the VR_i data points on another to graphically display trends. If multi-sample tests have been conducted over the same cycle intervals, include in the table the average and standard deviation of the data in each sample interval. If the sample intervals are not identical for all test samples of multi-sample tests, regression analysis should be used to fit an equation as a function of the total cycles along with determination of 95 % confidence interval lines. Plot these in the corresponding graph. The method used is to be justified, described and the limitations identified in the report.

11.17 Report the following information for the particulate debris generated in the wear testing (see Practice F1877 for further information):

11.17.1 The source of the particles and materials and methods for generation.

11.17.2 Methods utilized to digest and separate the particles.

11.18 All initial and secondary failures, modes of failure, and deformations of components shall be reported for the device. Failures (mechanical and functional) should be described completely including a description of the failure and/or crack initiation site. Any wear or loosening of the assembly must be described. Any other noteworthy observations should be included.

11.19 Report all data acquisition filtering methods used during the testing (whether continuously, periodically or intermittently).

12. Precision and Bias

12.1 *Precision*—Data establishing the precision of this test method has not yet been obtained but will be available within five years.

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

13. Keywords

13.1 posterior instrumentation; spinal implant; wear assessment; weight loss method

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR TEST METHODS

X1.1 Single level spinal constructs are manufactured in a variety of sizes, materials and shapes with various design features. The purpose of this test method is to allow for a consistent, repeatable comparison of different single level motion preserving devices through a series of mechanical tests.

X1.2 This test method may be used for rigid fixation devices or devices which are intended to preserve motion of the functional spinal unit.

X1.3 Motion of the superior relative to the inferior vertebra in a "normal" *in vivo* functional spinal segment is three dimensional with predominant components being: axial translation, flexion/extension, lateral bend, and axial rotation. These motions may occur independently or be coupled in some fashion. For this test method, a similar approach to that of Test Methods F1717 was taken, which is an analysis of the implants in single axis motions, with options for coupling motions for wear testing. This approach was primarily selected due to the nature of extra-discal motion preserving devices; most of these implants are constructed with the use of compliant materials to allow for motion and not with articulating surfaces. However, for articulating surfaces, it should be noted that with many material combinations, coupled motion profiles result in wear acceleration compared to single axis profiles. Because of potential wear acceleration, if the device being tested utilizes articulating surfaces, the user should consider coupled motion tests in addition to or in lieu of the single axis motions specified in this test method. (The user should reference F2423 for a more thorough discussion of this topic.) No claim can be made relative to assuring that any of the tests specified in this test method will produce the "worst" rate of wear. However, use of these profiles will serve as a common starting base to compare wear rates of different devices and their materials. As experience is gained in testing devices and/or knowledge becomes available indicating that other profiles/coupled profiles would produce greater wear rates, the user of this test method is encouraged to define, use and report on other potentially more detrimental motion/load profiles.

X1.4 The run out cycle count for devices intended for fusion (that is, motion inhibiting) has been defined as 5 000 000 cycles (see Test Methods F1717). The run out cycle count for devices that are intended for non-fusion (that is, motion preservation) in this test method has been defined as 10 000 000 cycles. This run out cycle count has been chosen based on the ROM profiles in this test method, which represent significant physiologic bends and motions in the wear testing of these devices. Flexion/extension is expected to be the dominant loading condition influencing the wear performance of the disc, and while estimates vary on the number of significant bends (flexion/extension) a person makes per year, a conservative estimate is 125 000 bends/year (**6**), which equates to 1.25 million significant bends in ten years. 10 000 000 cycles would therefore be estimated to correspond to 80 years' worth of significant bends. In another study, Morlock and colleagues measured the number of significant bends (that is, greater than 80º trunk flexion) that nurses perform in an hour (**7**). According to the data presented in this study, 98 % of the population would perform less than 34.4 significant bends in one hour. Extrapolating this number, assuming an 8-hour work day and working 7 days per week, yields 275.2 significant bends per day, or 100 448 bends per year, which is remarkably close to that estimated by Hedman and colleagues. From these data, 10 000 000 cycles would correspond to approximately 100 years worth of significant bends. However, it should be noted 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 this type of spinal stability augmentation type device. Therefore, if appropriate and justified, the user may choose to define a lower or higher run out cycle count which is more applicable for the device being tested and the clinical setting in which the device will be used.

X1.5 Extra-discal spinal devices may also be intended to function in combination with intra-discal devices. These combinations may be for the purpose of motion preservation or they may be intended for rigid or semi-rigid fixation. In these cases, static, dynamic, and wear testing of the devices separately and together should be considered to investigate the failure modes under all relevant loading modes in isolated and combined conditions. The fixtures should be modified so that the location and motion of the extra-discal and intra-discal devices are simulated by the test fixtures under worst case conditions. It may also be necessary to make the intra-discal device the pivot point of the fixtures and apply load/displacement by the test machine about this point to produce the intended motion/loading of the implants. Typical dimensions of the lumbar spine are shown as guidance in developing fixtures (Fig. X1.1). These dimensions are based on cadaveric measurements reported in the literature (Wolf, 2001 (**1**); Chaynes, 2001 (**2**)).

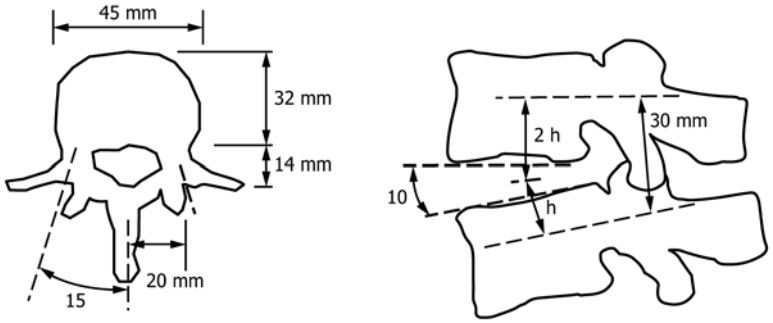


FIG. X1.1 Representative Morphological Data of Human Vertebrae (Wolf, 2001 (1) and Chaynes, 2001 (2))

X1.6 Section 6.1.5 stipulates that the testing medium shall be maintained at 37 ± 3°C. It is important to note that, while this will be the temperature of the surrounding tissues *in vivo*, it is possible that the implant surfaces will exceed the temperature range of the testing medium due to frictional heat that is generated during movement. Since the temperature of the device surfaces may affect their physical properties, including wear resistance, as well as affecting the lubricating properties of the fluid in contact with the device surfaces, the goal of the test method should be to ensure that the device surface temperatures that occur in the wear machine are reasonably close to those that occur *in vivo*, which may or may not be 37 ± 3°C. If frequencies greater than 2 Hz are used, care should be taken that running the wear test at this high frequency does not seriously overheat the materials and/or the lubricating fluid (for example, serum). If it is necessary (and a proper rationale is provided) to run at such a high frequency, the user should consider cooling the test lubricant as one means of removing excess frictional heat.

X1.7 A recent article by Zhao et al. 2005 (**8**) evaluates the COR of functional spinal units in the lumbar spine. This study simulated degeneration in a functional spinal unit by performing a creep test to dehydrate the disc. Once dehydrated, the authors recorded vertebral motions under specified ranges of motion and calculated the COR relative to the geometric center of rotation. Significant differences were noted comparing the simulated degeneration to the "healthy" functional spinal unit. For flexion/extension motion, the COR of a dehydrated disc relative to the geometric center of the simulated disc is estimated to be positioned 1 mm posteriorly and 24 mm inferiorly during flexion and 3 mm posteriorly and 18 mm inferiorly during extension. If one were not to use the degenerated COR, approximate expected values under flexion and extension motion, relative to the geometric center of the disc, would be a shift of 3 mm posteriorly and 30 mm inferiorly and 0.3 mm posteriorly and 21 mm inferiorly, respectively.

REFERENCES

(1) Wolf, A., Shoham, M., Michael, S., and Moshe, R., "Morphometric study of the human lumbar spine for operation-workspace specifications," *Spine*, Vol 26, 2001, pp. 2472–2477.

(2) Chaynes, P., Sol, J.C., Vaysse, P., Becue, J., and Lagarrigue, J., "Vertebral pedicle anatomy in relation to pedicle screw fixation: a cadaver study," *Surg Radiol Anat.*, Vol 23, 2001, pp. 85–90.

(3) Amonoo-Kuofi, H. S., "Morphometric Changes in the Heights and Anteroposterior Diameters of the Lumbar Intervertebral Discs with Age," *Journal of Anatamoy*, Vol 175, 1991, pp. 159–168.

(4) Gilad, I., and Nissan, M., "A Study of Vertebra and Disc Geometric Relations of the Human Cervical and Lumbar Spine," *Spine*, Vol 11, No. 2, 1986, pp. 154–157.

(5) White, A. A., Panjabi, M. M., *Clinical Biomechanics of the Spine*, 2nd Ed., J. B. Lippincott, Philadelphia, PA, 1990.

(6) 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.

(7) Morlock, M. M., Bonin, V., Deuretzbacher, G., Muller, G., Honl, M., and Schneider, E., "Determination of the *in vivo* Loading of the Lumbar Spine with a New Approach Directly at the Workplace—First Results for Nurses," *Clinical Biomechanics (Bristol, Avon)*, Vol 15, No. 8, 2000, pp. 549–558.

(8) Zhao, F., Pollintine, P., Hole, B. D., Dolan, P., and Adams, M. A., "Discogenic Origins of Spinal Instability," *Spine*, Vol 30, No. 23, 2005, pp. 2621–2630.