This document is not an ASTM standard and is intended only to provide the user of an ASTM standard an indication of what changes have been made to the previous version. Because it may not be technically possible to adequately depict all changes accurately, ASTM recommends that users consult prior editions as appropriate. In all cases only the current version of the standard as published by ASTM is to be considered the official document.

Designation: ~~F2624 – 07~~ F2624 – 12

Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal ~~Spinal Motion Preserving Implants~~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 ~~is intended to provide test methods for the static, dynamic, and wear testing of extra-discal motion preserving implants. These implants are intended to augment spinal stability without significant tissue removal while allowing motion of the functional spinal unit(s).~~describes methods to assess the static and dynamic properties of single level spinal constructs.

1.2 ~~Wear is assessed~~ An option for assessing wear using a weight loss method and a dimensional analysis ~~for determining wear of components used in extra-discal spinal motion preserving procedures,~~ is given. This method, described herein, is used for the analysis of devices intended for motion preservation, using testing medium as defined in this ~~test method~~ 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 ~~comparison of motion preserving, extra-discal implants~~ single level extra-discal spinal constructs with regard to kinematic, functional, and wear characteristics when tested under the specified conditions. ~~It must be recognized, however, that there are many possible variations in the in vivo conditions. A single laboratory simulation with a fixed set of parameters may not be universally representative.~~

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

~~1.6 This test method prescribes the use of pure angular rotations for assessing the mechanical characteristics of extra-discal motion preserving implants. This test method does not, however, prescribe methods for assessing the mechanical characteristics of the device in translation (for example, anterior/posterior translation), though this type of linear motion may be clinically relevant.~~

1.6 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures ~~are~~be established. This test method is intended to facilitate uniform testing methods and data ~~reporting for extra-discal motion preserving implants.~~ reporting.

1.7 ~~Without a substantial clinical retrieval history of spinal, motion preserving extra-discal implants, actual loading profiles and patterns cannot be delineated at the time of the writing of this test method. It therefore follows that the motion profiles~~ 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 ~~The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.~~ 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] 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. 15, 2007~~Dec. 1, 2012. Published ~~March 2008~~February 2013. Originally approved in 2007. Last previous edition approved in 2007 as F1587 – 07. DOI: ~~10.1520/F2624-07.~~10.1520/F2624-12.

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. United States

~~1.12 *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 and health practices and determine the applicability of regulatory limitations prior to use.*~~

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.

[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.

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ASTM F2624-12
https://standards.iteh.ai/catalog/standards/sist/1b2904d8-3c5a-48df-a25e-5f59d093f37a/astm-f2624-12

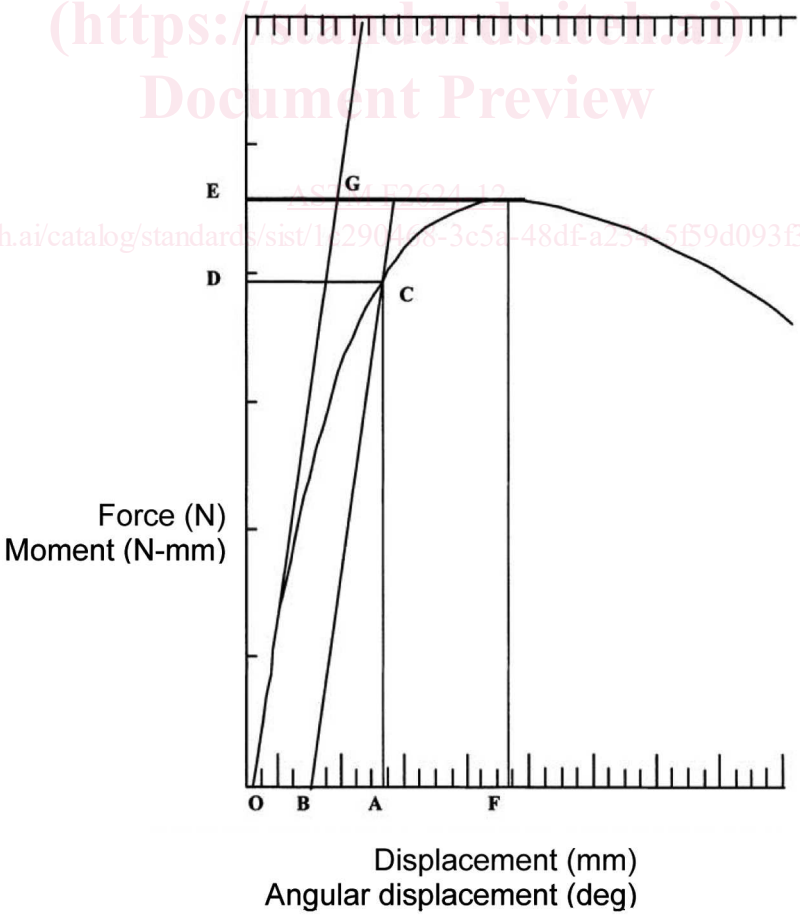


FIG. 1 ~~3-D View of Extra-Discal Motion Preserving Implants in One Representative Testing Configuration~~Typical Force Displacement Curve

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~~ 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~~ axis is to be directed superiorly. Force components parallel to the *XY* ~~-plane~~ plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z* ~~-direction.~~ 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 ~~*extra-discal motion preserving device or implant*—~~*elastic displacement (mm or degrees)*—~~a non-biologic structure, which lies entirely outside the intervertebral disc space and is intended to at least~~the displacement at 2 % offset yield (see Point A in Fig. 1~~partially support the motion/load~~) minus the 2 % offset displacement (see Point B in Fig. 1~~between adjacent vertebral bodies. In this test~~). (The distance between Point A and Point B in Fig. 1~~method, this definition does not include facet arthroplasty devices.~~.)

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 ~~extra-discal motion preserving~~ 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.

~~3.2.7 *functional spinal unit (FSU)*—two adjacent vertebrae, including the intervertebral disc, and all adjoining ligaments between them, specifically excluding all other connective tissues such as muscles (Ref (1)).~~[3]

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:*~~
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* ~~*(g/million*~~*(mg/million cycles)*:

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

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

3.2.12 *kinematic profile*—the relative motion between adjacent vertebral bodies that the ~~extra-discal motion preserving~~ spinal device is subjected to while being ~~tested.~~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:*~~

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 ~~*origin—*~~*permanent deformation—*the ~~center of the coordinate system is located at the center of rotation of the testing fixture.~~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.

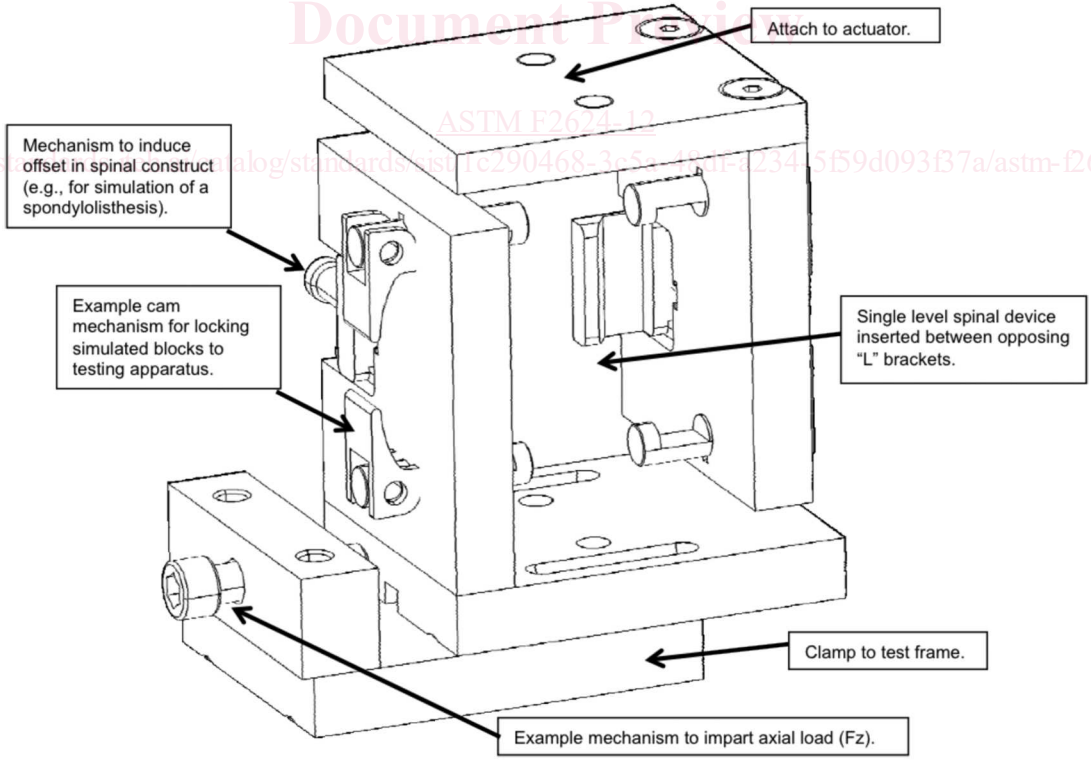
3.2.19 *single level spinal construct*—a non-biologic structure, which lies entirely outside the intervertebral disc space, intended to support the full or partial load between adjacent vertebral bodies. In this test method, this definition does not include facet arthroplasty devices.

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).

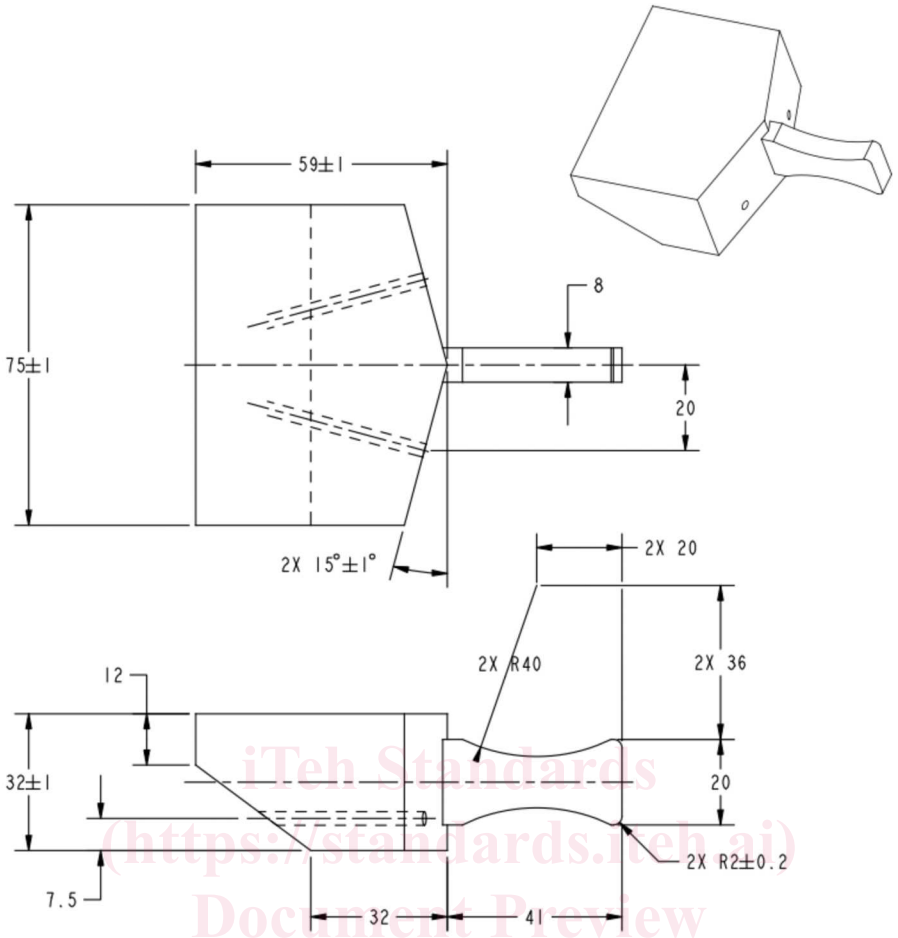
3.2.22 *torsional aspect ratio*—the active length of the longitudinal element divided by the distance from the center of rotation to the insertion point of an anchor (for example: 0.78 for a 35 mm active length, *X* = 40 mm and *Y* = 40/2 mm).

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ASTM F2624-12
https://standards.iteh.ai/catalog/standards/sist/c290468-3e5a-4df-1234-5f59d093f37a/astm-f2624-12



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 ~~Extra-Discal Motion-Preserving Implants in One Representative Testing Configuration~~Rotational Testing Apparatus



NOTE 1—All dimensions are in mm.

FIG. 3 Simulated Vertebral Body Testing Block

iTeh Standards (https://standards.iteh.ai) Document Preview
ASTM F2624-12
https://standards.iteh.ai/catalog/standards/sist/1c290468-3c5a-48df-a234-5f59d093f37a/astm-f2624-12

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 ~~a~~ non-articulating, compliant ~~device,~~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~~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 ~~*X-axis—ultimate load (N or N-m)—*~~the positive(Point E—Fig. 1)—the ~~X~~maximum applied~~-axis is~~ force, ~~*aF,* 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.~~transmitted by the actuator that can be applied to the spinal construct.

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

3.2.31 ~~*Z-axis—yield force—*~~the positive(Point D—Fig. 1)—the ~~Z~~applied force,~~-axis is~~*F,* ~~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.~~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, dynamic,~~ static and ~~wear~~dynamic characteristics of different designs of ~~extra-discal motion preserving implants~~ 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 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 ~~This test method is intended to be applicable for extra-discal motion preserving implants. These implants augment the motion/load bearing characteristics between adjacent vertebral bodies, and thereby fully or partially support and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, or~~ Implants may be designed using a variety of materials (for example, ceramics, metals, polymers, or combinations ~~thereof are used in implant design,~~ 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 ~~extra-discal motion preserving~~ 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,~~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,~~ 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,~~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 ~~spinal motion preserving~~ device/construct from wear centers created by the testing fixtures.

5.2.3 ~~For all testing, the actuator of the testing machine is connected to the superior testing block.~~ 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 ~~of the test is~~ may be to characterize the wear properties of the ~~extra-discal motion preserving~~ spinal device, the method for mounting components in the test chamber shall not compromise

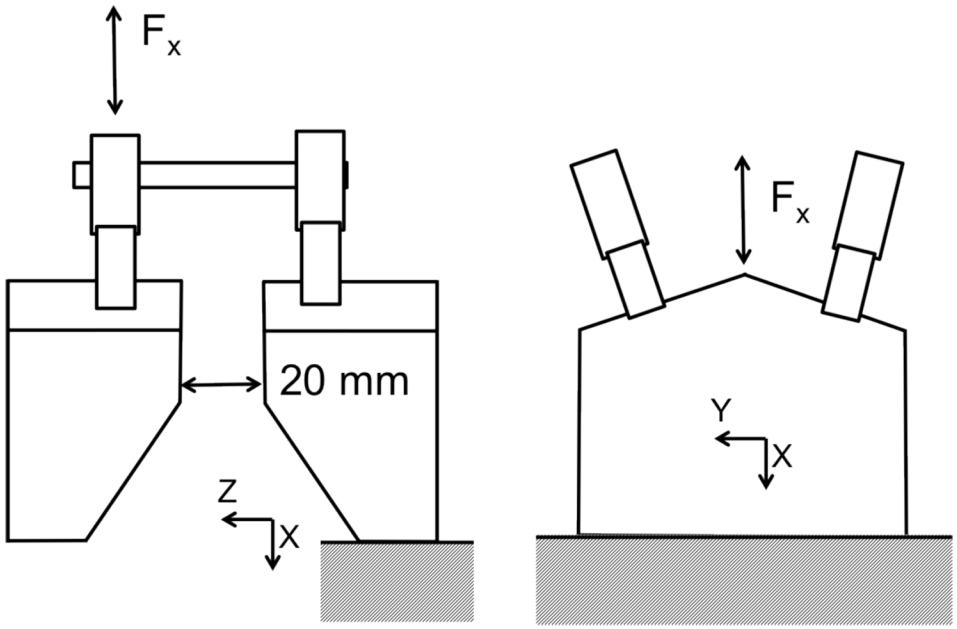


FIG. 4 Schematic of Anterior/Posterior Shear Testing Apparatus

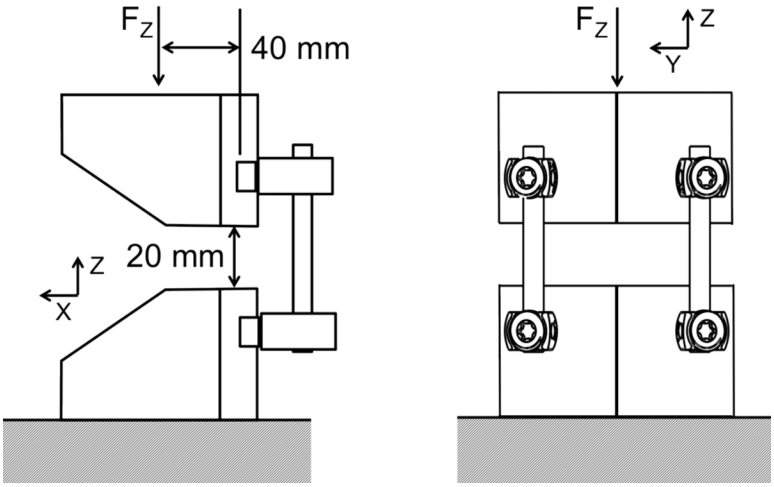


FIG. 5 Schematic of Single Level Compression Bending Test

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

iTeh Standards (https://standards.iteh.ai) Document Preview
ASTM F2624-12
https://standards.iteh.ai/catalog/standards/sist/1c290468-3c5a-48df-a234-5f59d093f37a/astm-f2624-12

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.

5.2.6 The ~~extra-discal motion preserving~~ 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). ~~The~~ It is suggested that the simulated spinous process ~~is to~~ be made from ~~304 series~~ stainless steel (minimum ultimate tensile strength ~~shall be no less than~~ of 500 MPa). ~~See~~Other ~~Note 1.~~ 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 ~~more~~ accurately characterize the mechanical performance of the extra-discal ~~motion preserving~~ 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 ~~The~~ If a simulated spinous process ~~must~~ is used, the entire simulated vertebral body (Fig. 3~~be manufactured in such a way as to be rigidly attached to the polyacetal homopolymer block. Modifications~~) 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 ~~is expected~~ between the implant and the spinous ~~process,~~ 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*—~~Fig. 1 and~~ 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 ~~are of an extra-discal motion preserving implant attached to simulated vertebral bodies (~~depicts an example testing fixture for testing the spinal construct in flexion/extension.~~Fig. 3) and testing fixtures.~~ 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.

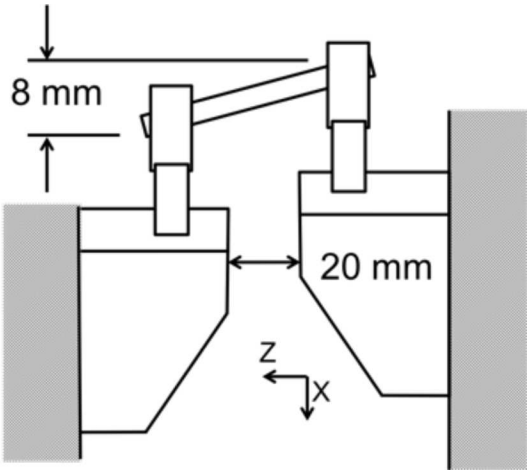
5.2.12.3 Extension loads/motions are generated by negative rotation about the *Y*-axis.

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.

[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

5.2.12.7 *Center of Rotation (COR)*—See the Appendix (~~X1.6~~X1.7) for a discussion on the COR. Since the COR will vary ~~in accordance with~~ 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:*~~ *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 and~~ 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 are not significantly affected.~~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).

6.1.2 If the device does not have articulating surfaces or surfaces that move relative to one another, ~~then a solution containing 0.9 % saline shall be used as the testing medium.~~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 ~~If the device contains articulating surfaces, or surfaces that move relative to one another, the device shall be tested in a~~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 ~~bovine~~ serum ~~diluted to~~ at a ~~protein~~ concentration of 20 ~~g/L in deionized water. The user should reference Guide~~mM to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been ~~F2423 for more information on the use of serum in the testing medium.~~ 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.

~~6.1.2.1 To retard bacterial degradation, freeze and store the serum until needed. In addition, the testing medium should contain suitable antibiotics or antimycotics, or both, to prevent bacterial and fungal growth, respectively. Penicillin-streptomycin (0.15 % per volume) and amphotericin B (0.25 % per volume) are recommended. Note that, if possible, the user should avoid using sodium azide (0.2 % per volume) as an antimicrobial reagent, due to its chemical toxicity.~~

~~6.1.2.2 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the testing medium containing serum at a concentration of 20mM 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 ~~dynamic/wear~~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, ~~extra-discal implant~~ 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 ~~or hydration, or both,~~ 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.~~ 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 ~~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.~~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.

~~9.2.1 Mount the extra-discal motion preserving device to the polyacetal homopolymer blocks (Fig. 1, Fig. 2, and Fig. 3). Install the anchors in accordance with the manufacturer's instructions. Note that modifications to the blocks may be required to adapt the test blocks to the extra-discal motion preserving device.~~

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 ~~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 (F_Z) when the implants are in the neutral position.~~*Rotational Testing Apparatus—*

~~NOTE 2—Note the rationale for a 300 N axial load. Assuming an approximate 1000 N load (based on intradiscal pressure measurements made by A. Nachemson (**2**, **3**)) 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.~~

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.~~ 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.