



Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses¹

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1. Scope

1.1 This guide provides guidance for wear and/or fatigue testing of total disc prostheses under functional and kinematic conditions and, to this end, describes test methods for assessment of the wear or functional characteristics, or both, of total disc prostheses.

1.2 Both lumbar and cervical prostheses are addressed.

1.3 Load and kinematic profiles for lumbar and cervical devices are not identical and, therefore, are addressed separately in the guide.

1.4 Partial disc replacements, such as nucleus replacements or facet joint replacements, are not intended to be addressed.

1.5 Wear is assessed using a weight loss method in a testing medium as defined in this guide.

1.6 This guide does not address any potential failure mode as it relates to the fixation of the implant to its bony interfaces.

1.7 It is the intent of this guide to enable comparison of intervertebral disc (IVD) prostheses with regard to wear and fatigue 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 might not be universally representative.

1.8 Most IVD prostheses primarily fall into two classifications: articulating ball-in-socket type prostheses, and elastomeric or compliant type prostheses. For the former, this guide primarily addresses Mode 1 wear (defined herein); whereas for the latter, this guide addresses potential failure of the prosthesis when the implant is subjected to a range of motion and/or loads that fall within the full range of possible physiologic motions and loads.

1.9 For articulating components, this guide predominantly describes a Mode 1 test. The user is cautioned that other modes

of wear may occur and may have significant influence on the functionality and performance of an articulating IVD prosthesis, and therefore the user should consider the effects of other wear modes on the performance of the prosthesis.

1.10 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures are established. This guide is intended to facilitate uniform methods for testing and reporting of data for total disc replacement prostheses.

1.11 Without a substantial clinical retrieval history of IVD prostheses, actual loading profiles and patterns cannot be delineated at the time of the writing of this guide. It therefore follows that the load and motion conditions specified by this guide do not necessarily accurately reproduce those occurring *in vivo*. Rather, this guide provides useful boundary/endpoint conditions for evaluating prosthesis designs in a functional manner.

1.12 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.

1.13 This guide is not intended to be a performance standard. It is the responsibility of the user of this guide to characterize the safety and effectiveness of the prosthesis under evaluation.

1.14 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

- F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
- F1582 Terminology Relating to Spinal Implants
- F1714 Guide for Gravimetric Wear Assessment of Prosthetic

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Hip Designs in Simulator Devices
 F1877 Practice for Characterization of Particles
 F2077 Test Methods For Intervertebral Body Fusion Devices
 2.2 ISO Standard:³
 ISO 18192-1 Implants for Surgery—Wear of Total Intervertebral Spinal Disc Prostheses—Part 1: Loading and Displacement Parameters for Wear Testing and Corresponding Environmental Conditions for Test

3. Terminology

3.1 All functional and kinematic testing terminology is consistent with the referenced standards (for example, Test Methods F2077, Terminology F1582, and so forth), unless otherwise stated.

3.2 Definitions:

3.2.1 *axial load, n*—the resultant force F_{axial} applied to the superior or inferior fixture-end plate that simulates the *in vivo* load that an IVD prosthesis (original healthy disc) must resist.

3.2.1.1 *Discussion*—Based on a healthy disc, the primary component would be an axial compressive force F_Z in the direction of the negative global Z axis, and it would pass through the origin of the IVD prosthesis. Shear components in the XY plane would be F_X and F_Y . Lateral bending moment M_X and flexion/extension moment M_Y components would be created about the origin when the axial load does not pass through it.

3.2.2 *coordinate system/axes, n*—global XYZ orthogonal axes are defined following a right-handed Cartesian coordinate system in which the XY plane is to bisect the sagittal plane angle between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The global axes are stationary relative to the IVD prostheses' inferior end plate fixture, which, in this guide, is also considered to be stationary with respect to the test machine's frame. Lower case letters, *xyz*, denote a local, moving orthogonal coordinate system attached to the superior end plate fixture with directions initially coincident with those of the global XYZ axes, respectively. The 3-D motion of the superior relative to inferior end plate fixture is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z*, axial rotation; *x*, lateral bending; and *y*, flexion-extension).

3.2.2.1 *origin, n*—center of the global coordinate system is located at the initial position of the total disc replacement's instantaneous center of rotation (COR).

3.2.2.1 *Discussion*—Some articulating devices do not have a single center of rotation, but instead have either a mobile center of rotation or multiple distinct centers of rotation, depending on the direction of movement. In this case, the origin should be explicitly defined by the user with a rationale for that definition.

3.2.2.2 *X-axis, n*—positive X-axis is a global fixed axis relative to the test machine's stationary base, and is to be directed anteriorly relative to the specimen's initial unloaded position.

3.2.2.3 *Y-axis, n*—positive Y-axis is a global fixed axis relative to the test machine's stationary base, and is directed laterally relative to the specimen's initial unloaded position.

3.2.2.4 *Z-axis, n*—positive Z-axis is a global fixed axis relative to the test machine's stationary base, and is to be directed superiorly relative to the specimen's initial unloaded position.

3.2.2.5 *x-axis, n*—positive x-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed anteriorly relative to the prosthesis.

3.2.2.6 *y-axis, n*—positive y-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed laterally relative to the prosthesis.

3.2.2.7 *z-axis, n*—positive z-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed superiorly relative to the prosthesis.

3.2.3 *degradation, n*—loss of material or function or material properties as a result of causes other than that associated with wear.

3.2.4 *fluid absorption, n*—fluid absorbed by the device material during testing.

3.2.5 *functional failure, n*—permanent deformation or wear that renders the IVD prosthesis assembly ineffective or unable to 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.

3.2.6 *interval net volumetric wear rate VR_i during cycle interval i ($\text{mm}^3/\text{million cycles}$), n — $VR_i = WR_i/\rho$, where ρ = mass density (for example, units of g/mm^3) of the wear material.*

3.2.7 *interval net wear rate WR_i during cycle interval i ($\text{g}/\text{million cycles}$), n — $WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) \times 10^6$.*

3.2.7.1 *Discussion*—For $i = 1$, $NW_{i-1} = 0$.

3.2.8 *intervertebral disc (IVD) prosthesis, n*—nonbiologic structure intended to restore the support and motion or a portion thereof between adjacent vertebral bodies.

3.2.9 *kinematic profile, n*—relative motion between adjacent vertebral bodies that the IVD prosthesis is subjected to while being tested.

3.2.10 *limit, n*—a significant change in stiffness during a given motion, indicating the implant has reached its designed endpoint in range of motion.

3.2.11 *load profile, n*—loading that the device experiences while being tested under an applied kinematic profile or the loading that the IVD prosthesis is subjected to if tested in load control.

3.2.12 *mechanical failure, n*—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 Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

3.2.13 Wear modes (1)⁴ for articulating type designs:

3.2.13.1 Mode 1 refers to the articulation between two primary bearing surfaces only.

3.2.13.2 Mode 2 occurs whenever a primary surface articulates directly against a secondary, nonbearing surface.

3.2.13.3 Mode 3 occurs when the two primary bearing surfaces are still articulating together, but third-body particles have become entrapped between them.

3.2.13.4 Mode 4 refers to any contact and motion occurring between two secondary, nonbearing surfaces.

3.2.14 *net wear NW_i of wear specimen (g)*, n — $NW_i = (W_0 - W_i) + (S_i - S_0)$; loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval i .

3.2.15 *net volumetric wear NV_i of wear specimen (mm^3)*, n — $NV_i = NW_i / \rho$ at end of cycle interval i where ρ = mass density (for example, units of g/mm^3) of the wear material.

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

3.2.17 *wear*, n —progressive loss of material from the device(s) as a result of relative motion at the surfaces as measured by the change in mass of the IVD prosthesis or components of the IVD prosthesis.

3.2.17.1 *Discussion*—Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis. Note that inferior and superior bone interface components are excluded from this definition; see 5.2.2.

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

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

4. Significance and Use

4.1 This guide can be used to determine the fatigue and wear behavior of IVD prostheses subjected to functional and kinematic cyclic loading/motion for relatively large numbers of cycles (for example, various designs of IVD prostheses, as well as the effects of materials, manufacturing techniques and other design variables on one particular design can be determined using this guide).

4.2 This guide is intended to be applicable to IVD prostheses that support load and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, or polymers, or combination thereof, are used in IVD prosthesis, and it is the goal of this guide to enable a kinematic wear and/or fatigue comparison of these devices, regardless of material and type of device.

5. Apparatus

5.1 *Total Disc Prosthesis Components*—The total disc replacement may comprise a variety of shapes and configurations. Some known forms include ball-and-socket articulating

TABLE 1 Test Profiles and Associated Parameters for Cervical IVD Prostheses

Test Profile	Axial Load, N (2-4)	Preferred Displacement Control: Range of Motion (ROM), ⁴ degree (3)	Alternate Load Control: Applied Moment Ranges, Nm (3)
Flexion/extension	100	±7.5	±2.0
Lateral bend/rotation	100	±6	±2.0
		±6	±4.0

⁴ The user of the guide must determine whether the ROM will be equally divided between flexion and extension or weighted more toward one of the motion directions.

joints, biconcave joints having a free-floating or semi-constrained third body, metallic endplates bonded to elastomer cores, and single-axis hinge joints.

5.2 Spinal Testing Apparatus:

5.2.1 *Test Chambers*—In case of a multispecimen machine, each chamber shall be isolated to prevent cross-contamination of the test specimens. The chamber shall be made entirely of noncorrosive components, such as acrylic plastic or stainless steel, and shall be easily removable from the machine for thorough cleaning between tests.

5.2.2 *Component Clamping/Fixturing*—Since the purpose of the test is to characterize the wear and/or fatigue properties of the IVD prosthesis under functional and kinematic conditions, 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, prostheses having complicated superior and inferior 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.

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

5.2.4 The motion of the superior test fixture relative to the inferior testing fixture shall be unconstrained in three-dimensional space except for the components in the direction of specified test motions/loads.

5.2.5 *Load and Motion (components in Table 1 and Table 2):*

5.2.5.1 An axial load is to be a compressive load applied in the direction of the negative Z-axis. Deviations from this as the IVD moves from its initial position are to be reported as shear components F_x , F_y , and moments M_x and M_y .

5.2.5.2 Flexion load and motion are positive moment, M_y , and rotation about the y-axis, respectively.

5.2.5.3 Extension load and motion are negative moment, M_y , and rotation about the y-axis, respectively.

5.2.5.4 Lateral bend load and motion are positive and negative moments, M_x , and rotations about the x-axis, respectively.

5.2.5.5 Torsional load and motion are positive and negative moments, M_z and rotations about the z-axis, respectively.

5.2.6 *Frequency*—Test frequency is to be determined and justified by the user of this guide, and shall not exceed 2 Hz without adequate justification ensuring that the applied motion (load) profiles remain within specified tolerances and that the

⁴ The boldface numbers in parentheses refer to the list of references at the end of this standard.

TABLE 2 Test Profiles and Associated Parameters for Lumbar IVD Prostheses

Test Profile	Axial Load, N (5)	Cyclic Axial Load, N (min–max) (6)	Preferred Displacement Control: Range of Motion (ROM), degree	Alternate Load Control: Applied Moments, Nm ^A
Flexion/extension	1200	(900 – 1850)	±7.5 ^B	±10
Rotation	1200	(900 – 1850)	±3 (5,7)	±10
Lateral bending	1200	(900 – 1850)	±6 (5,7)	±12

^A Approximated based on a review of ROM (p. 111) and average flexibility and stiffness coefficients (p. 47) (6).

^B Depending on the device design, the balance of ROM should be appropriate to the expected ROM in a clinical situation (8).

IVD prosthesis' wear and functional characteristics are not significantly affected. See 6.1.5.

5.2.7 Cycle Counter—One complete cycle is the entire range from starting position through the range of motion (or load when in load control) and returning to the starting position (load). Cycles are to be counted using an automated counting device.

6. Reagents and Materials

6.1 Testing Medium:

6.1.1 A solution containing bovine serum diluted to a protein concentration of 20 g/L in deionized water shall be used as the testing medium.

6.1.2 To retard bacterial degradation, freeze and store the serum until needed for test. 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.

6.1.3 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the 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 affect the friction and wear properties strongly, particularly of polyethylene/ceramic combinations. The addition of EDTA to other testing media should be evaluated.

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

6.1.5 The user is cautioned that the non-stop articulation typically used in wear simulations may cause the bearing surfaces and/or the contacting lubricant to become substantially hotter than will occur *in vivo*, that is, when motions typically are interrupted periodically (9-11). The maximum temperatures reached may depend on a number of factors including but not limited to joint friction, material hysteresis, conductivity of the device-fixtured materials, design, and test frequency. Under such conditions, there can be non-physiological thermal damage to the bearing materials and/or the lubricant (for example, degradation of lubricating proteins.) This can, in turn, increase the friction, further increasing the

temperatures above those that will occur *in vivo* in the vast majority of situations. It is recommended, therefore, that the test be closely monitored for evidence of excessively high temperatures and corrective measures taken if needed. These can include running the test at a lower frequency, stopping the test periodically to allow the bearing and lubricant to cool, and cooling the lubricant bath by, for example, circulating it through a cooling apparatus.

7. Sampling and Test Specimens

7.1 It is suggested that a minimum sample size of five be used for each kinematic/load profile. However, note 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.

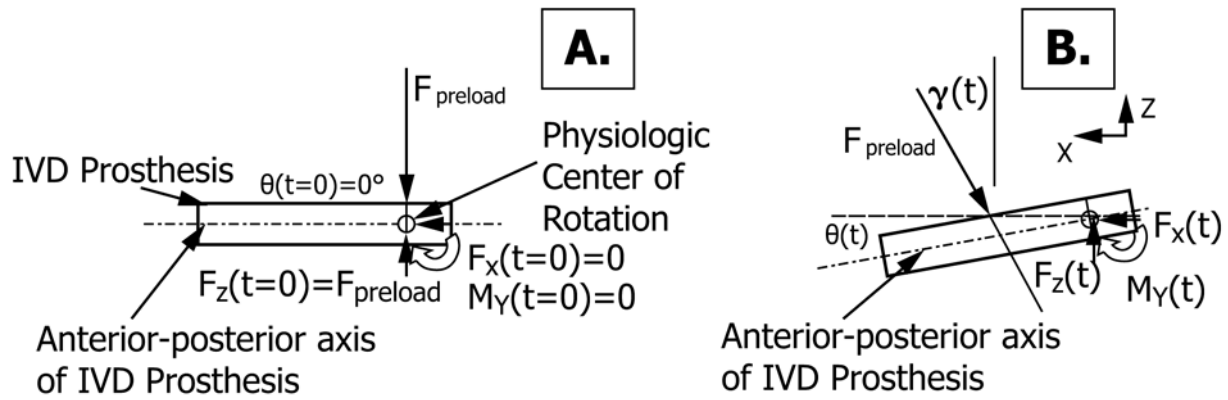
7.2 The test assemblies (that is, IVD prosthesis components in the tested configuration) shall be labeled so they can be traced, and must be kept in a clean environment to avoid contamination. The test assembly can be disassembled to facilitate examination of surface conditions.

8. Preparation of Apparatus

8.1 As closely as practical, the functional portion (components permitting motion between vertebral bodies) of the device to be tested must be produced using equivalent manufacturing methods as the implantable form of the IVD prosthesis, including sterilization.

8.2 It is permissible to exclude nonfunctional features that may interfere with obtaining wear/fatigue 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, thereby, produce an unwanted mixture of functional and nonfunctional component wear particles (see 5.2.2).

8.3 It is permissible to make entirely different bone-implant interface components (that is, superior and inferior surfaces) provided that the modification does not substantially alter the wear and functional characteristics of the device. For example, a ball-and-socket joint prosthesis may be manufactured having the polished articulation component (that is, functional surfaces or features of the device) and an opposite side that



A. Neutral Position ($t = 0$)
 B. Flexed Position Rotated Through Angle $\theta(t)$
 γ = Angle of the Axial Load Relative to the Global Z-Axis

FIG. 1 2-D (XZ Plane Only) Loading Diagrams Showing F_{load} and its resultant Reaction Force-Moment Components Shown Acting at the Initial Physiologic Center of Rotation of the IVD Prostheses

mounts directly to the testing apparatus, thereby simplifying the fixturing demands.

8.4 The requirements of Guide F1714, Specimen Preparation section, shall be followed.

9. Procedure

9.1 As a weight control for the testing, a minimum of two identical loaded soak control specimens in testing medium (see 6.1) shall be used. In other words, the loaded soak control specimen must be loaded statically with the same axial load vector as described in Fig. 1 since it is well known that load can significantly affect fluid absorption.

NOTE 1—The user of this guide may justify not performing soak 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 $\pm 10 \mu\text{g}$ or less shall be used. This degree of sensitivity for weighing is necessary to detect the slight loss in weight of highly wear-resistant bearing materials (12).

9.2 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 or gloves or both to prevent contamination that might affect the weight measurement.

9.3 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 $37 \pm 3^\circ\text{C}$, or specify if different.

9.4 For all components, measure the geometry of relevant functional surfaces or features before starting the test. For example, articulating joints should have measurements of the bearing area. Prostheses having bonded polymer cores should have measurements of the external geometry such as starting

circumference (to calculate changes caused by equatorial bulging) and prosthesis height.

9.5 The limits of the ROM of the prosthesis in flexion/extension, left and right lateral bending, and left and right axial torsion shall be determined prior to the start of wear testing. If the device has no limit in a given direction, this should be noted in lieu of the limit.

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

9.7 Unless otherwise justified by intended use and life expectancy of the IVD prosthesis, all tests should be conducted to a run out of 10 000 000 cycles (see Appendix X1).

9.8 The testing medium shall be collected for subsequent analysis at least once every one million cycles.

9.9 Place the prostheses in the spinal testing apparatus, add testing medium, and subject the IVD prosthesis to each of the tests as listed in 9.11. The prostheses shall be visually analyzed at a minimum once per 1 000 000 cycles, with mechanical failures noted. A mechanical failure (for example, considerable wear of the bearing surface) may not necessitate termination of the test since this guide 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 the bearing seizes).

9.10 A new, unused specimen shall be used to start each test series according to 9.11.5 and 9.11.6.

9.11 Tests:

9.11.1 Tests should be conducted under displacement control. Load control may also be used with adequate justification.

9.11.2 An axial load (initial axial load) is to be an axially applied compressive force parallel to the global Z direction through the *in vivo* physiologic instantaneous center of rotation of the IVD prosthesis (that is, the expected initial center of rotation of the IVD prosthesis when implanted *in vivo* (see X1.5). If the design of the prosthesis presents no distinct center

of rotation, such as with elastomeric designs or devices with mobile or multiple centers of rotation, then the axial load should pass through the *XY* plane balance point, such that the axial load produces no rotation prior to the initiation of applied motions. The specific methodology for fixturing and applying the axial load will dictate the resultant shear load, F_x , axial load, F_z , and rotational moment, M , the device will be subject to throughout the motion profile. (F_x , F_z , and M , are shown in Fig. 1 acting at the physiologic center of rotation of the IVD prosthesis.) θ is the rotation angle (that is, flexion/extension angle) of the prosthesis in flexion/extension motion, and γ is angle of the axial load relative to the global *Z*-axis. See Cripton et al (13) for a discussion of the effects of various axial load fixturing configurations.

9.11.3 Loading diagrams, along with their reaction forces acting on the physiologic center of rotation of the IVD prosthesis in the neutral position ($t = 0$) and flexed position that describe the axial load configuration are given in Fig. 1.

9.11.4 The axial load for all testing is to be applied with the use of a mechanism that can apply a desired load profile ($\pm 5\%$) throughout the ranges of motion that the test rig will undergo during testing. Pneumatic or hydraulic cylinders, by virtue of their ability to apply a nearly constant force but allow movement of the actuator, are examples of devices that would be appropriate for use to apply the axial load. Alternatively, the user may consider the use of a cyclic, sinusoidal axial load for lumbar IVD testing, as a cyclic loading profile may drastically change the amount of lubricant present between the bearing surfaces for articulating components and thus significantly alter the wear properties of the prosthesis. Unless otherwise justified, follow the recommendations for cyclic axial load parameters listed in Table 2.

NOTE 2—If a cyclic axial, sinusoidal load is applied, the user must determine and justify the phase angle used between the axial load and the applied motions.

9.11.5 Cervical IVD Prostheses Tests:

9.11.5.1 Table 1 lists the test profiles and associated parameters for testing cervical spine IVD prostheses. Note that if the maximum ROM of the IVD prosthesis (that is, without impingement of non-bearing surfaces) is less than that stipulated in Table 1, the user is to test the device to 90 % of the ROM of the device as determined in 9.5, to ensure that the device remains in Mode 1 (that is, no Mode 4 impingement). There are two options open to the user for testing the prosthesis as described in this section; however, justification for the chosen methodology must be provided. As with all device testing, the user is reminded that the selected test methods should provide the most rigor and enable the most accurate characterization of the device as possible (that is, strive for identifying and then using test conditions that would produce the worst case of Mode 1 wear that the device may experience *in vivo*).

(1) 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.

(2) Alternatively, all of the simple motions may be combined in one test in lieu of testing each device sequentially

under each test profile as stated in 9.11.5.1 unless *in vivo* wear data suggests other wear patterns (for example, linear simple motion wear), or the device is constrained in such a way that combined motion is not possible, or the user provides a rationale for other motion conditions being more relevant. The user should consider applicable phasing between motions (14). (See X1.3 for further comments).

NOTE 3—Each simple motion in this combined motion test must complete at least 10 000 000 cycles.

9.11.5.2 The user must determine the phasing when motions are combined. For guidance in selecting appropriate phasing, the user should reference Paré et al (14) for a discussion on the effects of phasing on the performance of articulating IVD prostheses.

NOTE 4—The user may also wish to reference ISO 18192–1 for a discussion on alternative methods for applying phasing when testing IVD prostheses.

9.11.5.3 The sequence of motions shall be determined and justified by the user of this testing guide. It should be noted, however, that the sequence of motion can affect the wear properties of the IVD prosthesis, and therefore, the user may wish to consider the use of different sequences to analyze their ensuing effect on the wear properties of the IVD prosthesis.

9.11.6 Lumbar IVD Prostheses Tests:

9.11.6.1 Table 2 lists the test profiles and associated parameters for testing lumbar spine IVD prostheses. Note that if the designed ROM of the IVD prosthesis is less than that stipulated in Table 2, the user is to test the device to 90 % ROM of the device as determined in 9.5. There are several options open to the user for testing the prosthesis as described in this section; however, justification for the chosen methodology must be provided. As with all device testing, the user is reminded that the selected test methods should provide the most rigor and enable the most accurate characterization of the device as possible (that is, strive for identifying and then using test conditions that would produce the worst case of Mode 1 wear that the device may experience *in vivo*).

(1) The user may test the same device under the single motion parameters defined in Table 2 (that is, the user shall test the device in flexion/extension loading for 10 000 000 cycles, followed by lateral bend testing for 10 000 000 cycles on the same device and finally rotational testing for 10 000 000 cycles on the same device).

(2) The user may wish to perform a test in which the device is tested following one of the prescribed single motions followed by a coupled test (on the same device) for the remaining two motions. As way of example, the user may wish to test the device in flexion/extension for 10 000 000 cycles and then perform a coupled test of lateral bending and rotation on the same device (10 000 000 cycles for each motion).

(3) An alternative method in which all of the simple motions are combined in one test may also be employed unless *in vivo* wear data suggests other wear patterns (for example, linear simple motion wear), the device is constrained in such a way that combined motion is not possible, or the user provides a rationale for other motion conditions being more relevant. Note that each simple motion in this combined motion test must complete at least 10 000 000 cycles.

9.11.6.2 The user must determine the phasing when motions are combined. For guidance in selecting appropriate phasing, the user should reference Paré et al (14) for a discussion on the effects of phasing on the performance of articulating IVD prostheses.

9.11.6.3 The sequence of motions shall be determined and justified by the user of this testing guide. It should be noted, however, that the sequence of motions can affect the wear properties of the IVD prosthesis, and therefore, the user may wish to consider the use of different sequences to analyze their effect on the wear properties of the IVD prosthesis.

9.11.6.4 If the device is intended for use in situations in which the facet joints are compromised, selection and justification for the amount of rotation should be provided.

9.11.7 Regardless of the selected test method, ROM data shall be recorded during the test.

9.11.8 If a device ceases to function (for example, the bearing surface has worn through, the bearing seizes, or a polymer core cracks or separates from a metal endplate), the test shall be terminated. The mechanism of failure and number of cycles at which the functional failure occurred, or was discovered, shall be noted.

9.11.9 Angular motions shall be controlled with an accuracy of $\pm 0.5^\circ$.

9.11.10 Applied moments shall be controlled to $\pm 5\%$ of the maximum moment value for the complete motion cycle when tested in load control.

9.12 At the indicated inspection interval (once every million cycles at a minimum), remove the wear and soak components, wash, rinse, and dry concurrently, in accordance with the procedure in Annex A4 of Guide F1714. It is important that both the wear and soak 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 wear specimens.

9.13 After rinsing and drying, weigh the wear components and soak controls.

9.14 Thoroughly rinse the wear chambers and component surfaces with distilled water.

9.15 Inspect the bearing surfaces of the components and note the characteristics of the wear process. Visual, microscopic, profilometric, replication, or other inspection techniques can be used. Geometric measurements of relevant features should also be taken. Care must be taken, however, that the surfaces 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 before restarting the wear test.

9.16 Replace the wear components and soak controls in fresh testing medium and continue wear cycling.

9.17 *Gathering of Particulate:*

9.17.1 At appropriate intervals, representative particles should be isolated from the testing medium with appropriate extraction 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 effectively isolate the different particles of interest.

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

10. Calculation

10.1 *Correcting for Fluid Absorption*—Calculate the net wear NW_i at the end of each cycle interval i using the equation in 3.2.14 and definitions for S_i and W_i in 3.2.18 and 3.2.19, respectively. Calculate the interval net wear rate WR_i during cycle interval i using the equation in 3.2.7.

10.2 *Conversion to Volumetric Wear*—Convert net wear NW_i to volumetric wear NV_i using the equation in 3.2.6 and interval net wear rate WR_i to interval net volumetric wear rate VR_i using the equation in 3.2.6. This is recommended for comparison of wear between different materials or material grades (UHMWPE wear versus cobalt-chromium-molybdenum wear, 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, and degree of oxidation).

11.3 The surface finish as measured at the appropriate testing interval shall be included in the report.

11.4 All relevant geometric measurements of the IVD prosthesis throughout the duration of the test shall be reported.

11.5 Report the date and method of sterilization. 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 during irradiation, the total gamma dose and dose rate, 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.

11.6 Report the limits of the ROM in flexion/extension, lateral bending, and axial rotation of the prosthesis.

11.7 *Loading Conditions:*

11.7.1 Report the motion profile and the associated applied moments M_x , M_y , and M_z that resulted when using position control. When using load control, report the load profile and the associated angular motion of superior relative to inferior end plate rotations that resulted in terms of Eulerian angles.

Report the maximum deviation of the 3-D components of the resultant axial load from the specified axial load through the initial COR.

11.7.2 The user should report the method (that is, hydraulic/pneumatic cylinders or other method) as well as the testing apparatus used to apply the axial load and kinematic profile to the IVD prosthesis. A diagram of the testing set-up indicating all loading and boundary conditions should also be included. All deviations (with adequate justification) from the recommended test procedures shall be reported, along with all relevant testing parameters.

11.7.3 The rationale for not using any of the testing configurations specified in this test method shall be reported.

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

11.8 Wear Rates:

11.8.1 For each motion/load profile used, include a table with data for the net volumetric wear NV_i (mm^3) and interval net volumetric wear rate VR_i ($\text{mm}^3/\text{million cycles}$) 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 display trends graphically. If multisample 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 multisample 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.

11.8.2 Report the test duration in cycles.

11.8.3 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 or crack initiation site, or both. Any wear or loosening of the assembly must be described. Any other noteworthy observations should be included.

11.8.4 Report the following information for the particulate debris:

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

11.8.4.2 Methods used to digest and separate the particles.

11.8.4.3 Method used to characterize the morphology of the particles.

12. Keywords

12.1 intervertebral disc prosthesis; IVD; spinal implants; wear assessment; weight loss method

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR TEST METHODS

X1.1 Artificial intervertebral discs (IVD prostheses) are manufactured in a variety of sizes, materials, and shapes with various design features. The purpose of this guide is to allow for a consistent, repeatable comparison of different artificial IVD prostheses through a series of wear and/or fatigue tests.

X1.2 All of the spinal implants that fall into the category of artificial IVD prostheses are intended for the purpose of disc replacement. All of the implants may reside in the disc space, with varied orientations and methods of fixation to the adjacent vertebral bodies. This guide will allow for comparison of these devices, since the methods and loading configuration remain consistent regardless of method of application. Biologic disc replacements and nucleus replacements are excluded from the scope of this guide.

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. There may be predominant *in vivo* coupled motion profiles; however, if they exist, they are currently unknown. Ideally, the *in vivo* motion profile(s) that would produce the “worst case” wear rate would be the one(s) specified in this guide. Compared to

single-axis motion, coupled motion profiles can cause more rapid wear with some bearing materials (for example, polyethylene) but less rapid wear with others (for example, metal-on-metal bearings) (15). Therefore, since “worst case” wear rate is material- and motion-profile dependent, and there is no known predominant coupled *in vivo* motion profile(s), three different testing options are given as the initial tests to be conducted on lumbar IVD prosthetic devices with one single-axis “simple” motion and one coupled motion/load recommended as the initial tests to be conducted on cervical IVD prosthetic devices. In this light, no claim can be made relative to ensuring that any of the prescribed tests will produce the “worst” rate of wear. Use of these profiles will, hopefully, serve as a common starting base to compare wear rates of different IVD prosthetic devices and their materials. Until further experience is gained in testing IVD prosthetic devices or knowledge becomes available indicating that other profiles are more physiologically relevant, the user of this guide is encouraged to define, use, and report on other potentially more detrimental or relevant motion/load profiles.

X1.4 Since one purpose of an artificial IVD is long-term restoration of function, runout has been defined as 10 000 000 cycles. As justification for this runout cycle count, flexion/extension is expected to be the dominant motion condition

influencing the wear performance of the disc. While estimates vary on the number of significant bends (flexion/extension) a person makes per year, a conservative (in terms of severity or worst case) estimate is 125 000 bends/year, which equates to 1.25 million significant bends in ten years (16). Therefore, 10 000 000 cycles would correspond to 80 years worth of significant bends. However, note that there has been much debate on what should be defined as a realistic target lifetime for *in vitro* testing, target clinical lifetime, and the minimum acceptable clinical lifetime for the artificial disc replacement. Therefore, if appropriate and justified, the user may choose to define a lower runout cycle count that is more applicable for the device being tested and the clinical setting in which the device will be used.

X1.5 Testing the IVD prosthesis using constraints on 3-D motion other than specified in this guide (which are intended to simulate conditions expected after *in vivo* implantation) could potentially produce different wear results. Thus, use of different constraints must be justified with respect to those occurring *in vivo* after implantation, or that doing so produces only insignificant differences in wear results.

X1.6 Paragraph 6.1.5 stipulates that the testing medium shall be maintained at $37 \pm 3^\circ\text{C}$. Note that while this will be the temperature of the surrounding tissues *in vivo*, it is possible that the temperature of the implant surfaces will be substantially higher than that of the testing medium, as a result of frictional heat that is generated during movement. Since the temperature of the implant surfaces may affect their physical properties, including wear resistance, as well as affecting the lubricating properties of the fluid in contact with the implant surfaces, the goal of the guide should be to ensure that the implant surface temperatures that occur in the wear machine are reasonably close to those that occur *in vivo*, which may or may not be $37 \pm 3^\circ\text{C}$. Particularly, if frequencies greater than 1 Hz are used, care should be taken that running the wear test at this high frequency does not seriously overheat the materials or the lubricating fluid (for example, serum) or both. 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, or the specimens directly, as means of removing excess frictional heat.

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