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Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses[1]

This standard is issued under the fixed designation F2423; 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 guide is intended to provide guidance for the functional, kinematic, and wear testing of total disc prostheses 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 is not intended to 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 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.

1.8 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.

1.9 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, the maximum loads and motions specified in this guide represent a severe and therefore conservative case for testing the wear properties of IVD prostheses. Because of this, a substantially greater rate of wear may be realized than that which may occur during the routine daily activities of a typical patient. It should be noted, however, that a full characterization of a candidate IVD prosthesis should include testing under both typical and extreme conditions.

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.

1.11 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.

1.12 *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.*

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 Hip Designs in Simulator Devices

F1877 Practice for Characterization of Particles

F2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 *Definitions*—All functional and kinematic testing terminology is consistent with the referenced standards, unless otherwise stated.

3.1.1 *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

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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.

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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 fixturing 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).

3.1.1.1 *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). **F1582**

3.1.1.2 *X-axis, n*—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.

3.1.1.3 *Y-axis, n*—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.

3.1.1.4 *Z-axis, n*—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.

3.1.1.5 *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.

3.1.1.6 *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.

3.1.1.7 *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.

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

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

3.1.4 *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.

3.1.5 *interval net volumetric wear rate* VR_i *during cycle interval i (mm³/million cycles)*, *n*—$VR_i = WR_i/\rho$, where ρ = mass density (for example, units of g/mm³) of the wear material.

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

3.1.6.1 *Discussion*—For i = 1, $NW_{i\text{-}1} = 0$.

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

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

3.1.9 *load profile*, *n*—loading that the device experiences while being tested under a defined kinematic profile or the loading that the IVD prosthesis is subject to if tested in load control.

3.1.10 *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.

3.1.11 *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*.

3.1.12 *net volumetric wear* NV_i *of wear specimen (mm³)*, *n*— $NV_i = NW_i/\rho$ at end of cycle interval *i* where ρ = mass density (for example, units of g/mm³) of the wear material.

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

3.1.13.1 *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 *in vivo* physiologic instantaneous center of rotation (COR) 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 initial COR when the preload force does not pass through it.

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

3.1.15 *wear*, *n*—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 IVD prosthesis or components of the IVD prosthesis. Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis.

3.1.15.1 *Discussion*—Note that inferior and superior bone interface components are excluded from this definition; see 5.2.2.

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

3.1.17 *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 describe the function, kinematics, and wear behavior of IVD prostheses subjected to 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 studied using this guide).

4.2 This guide is intended to be applicable to IVD prostheses that support and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, or

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TABLE 1 Test Profiles and Associated Parameters for Cervical IVD Prostheses

Test Profile	Axial Preload, N **(3-5)**	Preferred Displacement Control: Range of Motion (ROM),[A] degree **(4)**	Alternate Load Control: Applied Moment Ranges, Nm **(4)**
Flexion/extension	100	±7.5	±2.0
Lateral bend/ rotation	100	±6	±2.0
		±6	±4.0

[A] 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.

TABLE 2 Test Profiles and Associated Parameters for Lumbar IVD Prostheses

Test Profile	Axial Preload, N **(6)**	Preferred Displacement Control: Range of Motion (ROM), degree	Alternate Load Control: Applied Moments, Nm[A]
Flexion/extension	1200	±7.5[B]	±10
Rotation	1200	±3 **(7,9)**	±10
Lateral bending	1200	±6 **(7,9)**	±12

[A] Approximated based on a review of ROM (p. 111) and average flexibility and stiffness coefficients (p. 47) **(7)**.

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

polymers, or combination thereof, are used in IVD prosthesis design, and it is the goal of this guide to enable a kinematic wear 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 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 kinematic function of the IVD prosthesis, 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 preload 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.

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

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

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

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

5.2.7 *Cycle Counter*—One complete motion 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 may contain 0.2 % sodium azide (or other suitable antibiotic/antimycotic) to minimize bacterial degradation. 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 20m*M* 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 internal heating of the prosthesis 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 wear properties of the prosthesis. If the device experiences localized elevated temperatures, the user must describe the effect that the selected frequency and resultant

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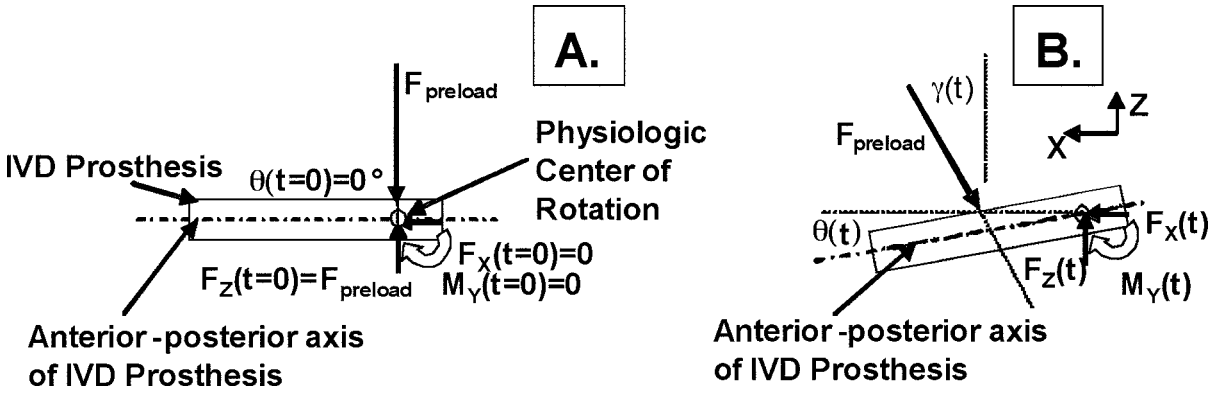

A. Neutral Position (t = 0)
B. Flexed Position Rotated Through Angle θ(t)
γ = Angle of the Preload Relative to the Global Z-Axis

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

localized temperature have on the test results, or justify that the effects are physiologically relevant. Refer to X1.6 for further information.

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 The functional portion (components producing 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/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 fabricate entirely different bone-implant interface components (that is, superior and inferior surfaces) provided that the modification does not interfere with an accurate measurement of 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, the functional surfaces or features of the device) and an opposite side that 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 with the same preload as is applied to the wear test specimens, since it is well known that load can significantly affect fluid absorption.

NOTE 1—The user of this guide 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 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 (**1**).[3]

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. Weigh each wear and control component three times in rotation to detect random errors in the weighing process.

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 ± 3°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

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

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

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

9.6 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).

9.7 The testing medium shall be collected for subsequent analysis at least once every one million cycles, and shall be replaced with fresh testing medium.

9.8 Place the prostheses in the spinal testing apparatus, add testing medium, and subject the IVD prosthesis to each of the tests as listed in 9.10. The prostheses shall be visually analyzed at a minimum once per 1 000 000 cycles, with mechanical failures noted (see Note 2). 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).

NOTE 2—The user may choose to analyze the specimen more frequently than recommended by the guide.

9.9 A new, unused specimen shall be used to start each test series according to 9.10.6 and 9.10.7.

9.10 *Tests*:

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

9.10.2 The preload (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). The specific methodology for fixturing and applying the preload will dictate the resultant shear load, F_X, axial load, F_Z, and bending 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 preload force relative to the global Z-axis. See Cripton et al **(2)** for a discussion of the effects of various preload fixturing configurations. (Also, see X1.7 for further comments and information about preload configurations.)

9.10.3 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 preload configuration are given in Fig. 1.

9.10.4 An example of a specific method and fixture design for achieving the preload configuration depicted in Fig. 1 is described in Appendix X1.

9.10.5 A constant preload for all testing is to be applied with the use of a mechanism that can apply a constant magnitude force (±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 preload force. Note that the application of a constant preload to a spine arthroplasty during wear testing may lead to unrealistically high wear due, in part, to depletion of the lubricant between the bearing surfaces. Alternatively, the user may apply a cyclic preload, since this may drastically affect the lubrication and, thereby, the rate of wear of the prosthesis. If a cyclic axial preload is employed, minimum and maximum axial preloads shall be 50 % and 150 % respectively of the axial preloads listed in Tables 1 and 2 unless otherwise justified.

NOTE 3—If a cyclic axial preload is applied, the user must determine and justify the phase angle used between the axial preload and the other applied motions.

9.10.6 *Cervical IVD Prostheses Tests*:

9.10.6.1 Table 1 lists the test profiles and associated parameters for testing cervical spine IVD prostheses. 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.

9.10.6.2 An alternate method in which all of the simple motions are combined in one test may be used in lieu of testing each device sequentially under each test profile as stated in 9.10.6.1. Note that each component motion in this combined motion test must complete at least 10 000 000 cycles.

9.10.6.3 For all coupled motions, the user must report and justify the phase angle used between the motions.

9.10.6.4 The sequence of motions shall be determined and justified by the user of this 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 testing under different sequences to analyze their effect on the wear properties of the IVD prosthesis.

9.10.7 *Lumbar IVD Prostheses Tests*:

9.10.7.1 Table 2 lists the test profiles and associated parameters for testing lumbar spine IVD prostheses. 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 wear that the device may experience *in vivo*). To this end, the user may wish to test according to more than one of the following options (see X1.3 for further comments):

(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).

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(3) An alternate method in which all of the component motions are combined in one test may also be employed. Note that each component motion in this combined motion test must complete at least 10 000 000 cycles.

9.10.7.2 For all coupled motions, the user must report and justify the phase angle used between the motions.

9.10.7.3 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.

9.10.7.4 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.

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

9.10.9 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.

9.10.10 Angular motions shall be controlled with an accuracy of ±0.5°.

9.10.11 Applied moments shall be controlled to ±5 % of the maximum moment value for the complete motion cycle when tested in load control.

9.11 At the indicated inspection interval, 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.

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

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

9.14 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.

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

9.16 *Gathering of Particulate*:

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

9.16.2 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 3.1.11 and definitions for S_i and W_i in 3.1.16 and 3.1.17, respectively. Calculate the interval net wear rate WR_i during cycle interval i using the equation in 3.1.6.

10.2 *Conversion to Volumetric Wear*—Convert net wear NW_i to volumetric wear NV_i using the equation in 3.1.5 and interval net wear rate WR_i to interval net volumetric wear rate VR_i using the equation in 3.1.5. 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 of both counterfaces shall be characterized by profilometry, photomicrography, replication, or other applicable techniques and included within 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 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.

11.6 *Loading Conditions*:

11.6.1 Report the motion profile, load, frequency, and phase angles 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

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