Designation: F2694 – 16

Standard Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses[1]

This standard is issued under the fixed designation F2694; 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 practice provides guidance for the functional, kinematic, and wear testing of motion-preserving total facet prostheses for the lumbar spine. These implants are intended to allow motion and lend support to the functional spinal unit(s) through replacement of the natural facets.

1.2 This test method is not intended to address the bone implant interface or the static characteristics of the prosthesis components. Fatigue characteristics are included, but only as a by-product of cyclic wear testing under facet load and thus are not addressed in the typical process of generating a Stress-Life (S-N) characterization.

1.3 Biocompatibility of the materials used in a total facet prosthesis are not addressed in this practice.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4.1 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.

1.5 *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

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

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

F1877 Practice for Characterization of Particles

F2346 Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs

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

3. Terminology

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

3.2 *Definitions of Terms:*

3.2.1 *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. **F2423**

3.2.2 *run out (cycles), n*—maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred. **F2423**

3.3 *Definitions of Terms Specific to This Standard:*

3.3.1 *coordinate systems/axes, n*—global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is parallel to and co-planar with the superior endplate of the inferior vertebral body. The global axes are fixed relative to the inferior vertebral body, which in this practice 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 vertebral body with directions initially coincident with those of the global *XYZ* axes, respectively. The 3D motion of the superior relative to the inferior vertebra is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z* axial rotation, *x* lateral bend, and *y* flexion-extension).

3.3.1.1 *origin, n*—center of the global coordinate system that is located at the posterior medial position on the superior endplate of the inferior vertebral body.

3.3.1.2 *X-axis, n*—positive *X*-axis is to be directed anteriorly relative to the specimen's initial unloaded position.

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

Current edition approved Dec. 1, 2016. Published January 2017. Originally approved in 2007. Last previous edition approved in 2013 as F2694– 07 (2013). DOI: 10.1520/F2694-16.

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

3.3.1.3 *Y-axis, n*—positive *Y*-axis is directed laterally (toward the left) relative to the specimen's initial unloaded position.

3.3.1.4 *Z-axis, n*—positive *Z*-axis is to be directed superiorly relative to the specimen's initial unloaded position.

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

3.3.3 *functional failure, n*—permanent deformation or wear that renders the total facet prosthesis assembly ineffective or unable to perform its intended function.

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

3.3.5 *interval net wear rate WR_i during cycle interval i (g/million cycles), n*—$WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) \cdot 106$; for $i = 1$, $NW_{i-1} = 0$.

3.3.6 *total facet prosthesis, n*—nonbiologic structure intended to restore the support and motion of the natural vertebral facet joint.

3.3.7 *kinematics profile, n*—relative motion between adjacent vertebral bodies that the total facet prosthesis is subjected to while being tested.

3.3.8 *load profile, n*—loading that the device experiences while being tested under a defined kinematics profile or the loading that the total facet prosthesis is subject to if tested in load control.

3.3.9 *radius of rotation, n*—the distance between the center of rotation and the functional position (for example, load-bearing contact point) of the total facet prosthesis, for a given motion (that is, flexion/extension, lateral bending, or axial rotation).

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

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

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

3.3.13 *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.

3.3.14 *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 total facet prosthesis or components of the total facet prosthesis. In the case of a non-articulating, compliant total facet 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).

3.3.15 *facet load, n*—AP directed force (applied in the direction of the global *X*-axis) representing the resultant in the mid-sagittal *XZ* plane applied by the superior vertebra that simulates the *in vivo* AP shear load F_x transmitted from superior to inferior vertebra and resisted by the total facet prosthesis.

4. Summary of Practice

4.1 This practice can be used to describe the function, kinematics, and wear behavior of total facet prostheses subjected to cyclic loading/motion for relatively large numbers of cycles. (For example, various designs of total facet prostheses, as well as the effects of materials, manufacturing techniques and other design variables on one particular design can be studied using this practice.)

4.2 This practice is intended to be applicable to total facet prostheses that support and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, and/or polymers may be used in total facet prosthesis design, and it is the goal of this practice to enable a kinematic wear comparison of these devices, regardless of material and type of device.

5. Significance and Use

5.1 *Total Facet Prosthesis Components*—The total facet replacement may comprise a variety of shapes and configurations. Its forms may include, but are not limited to, ball and socket articulating joints, joints having a free-floating or semi-constrained third body, metallic load-bearing surfaces, and spring and dampening mechanisms. Additionally, it may have a unilateral or bilateral design.

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 corrosion-resistant materials, such as acrylic plastic or stainless steel, and shall be 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 total facet 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.

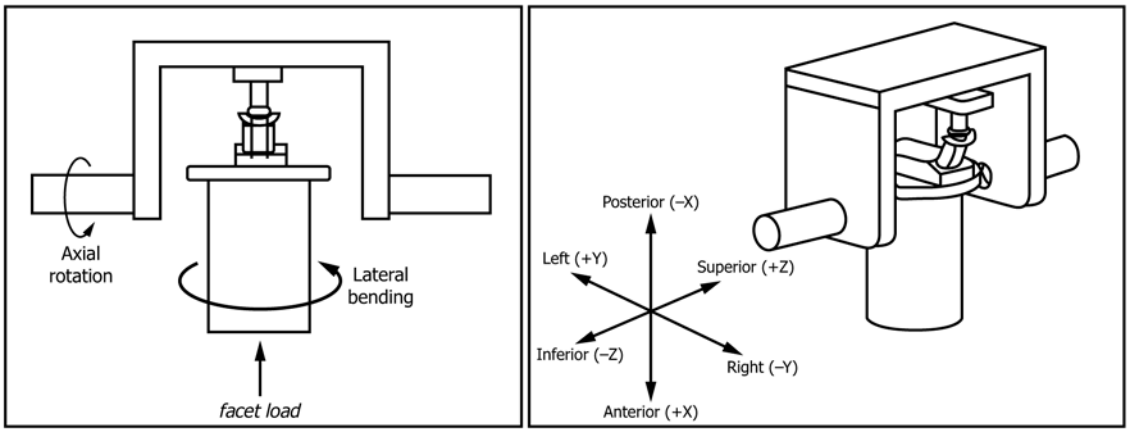
5.2.4 The motion of the superior test fixture (more posterior fixture in Figs. 1 and 2) relative to the inferior testing fixture shall be constrained in three-dimensional space except for the components in the direction of specified test motions/loads.

5.2.5 *Load and Motion:*

5.2.5.1 Facet loads (f_x) are initially applied in the direction of the positive *X*-axis.

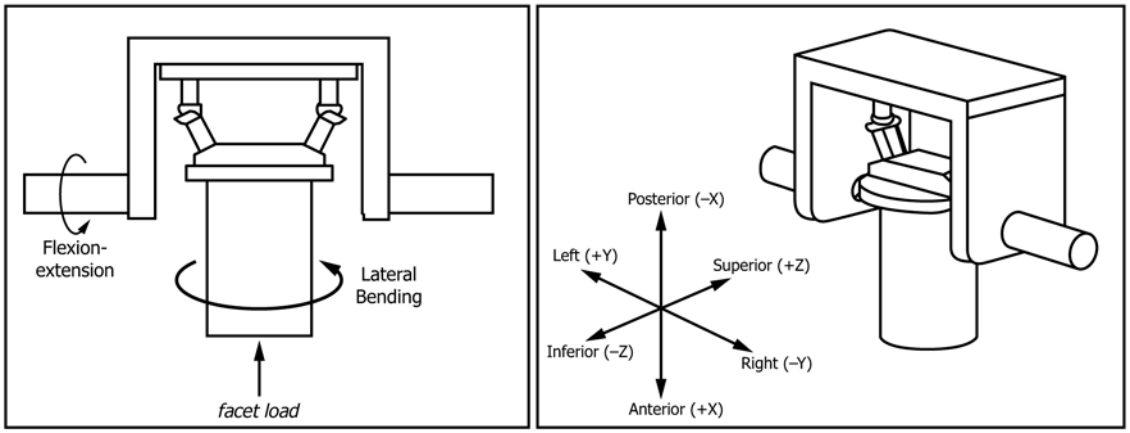
5.2.5.2 Flexion load and motion are positive moment and rotation about the *Y*-axis.

5.2.5.3 Extension load and motion are negative moment and rotation about the *Y*-axis.



NOTE 1—This setup would require two rotational actuators and one translational actuator.

FIG. 1 Diagrams of Possible Test Apparatus for Allowing Simultaneous Lateral Bending and Axial Rotation Motions with Anterior-Posterior Directed Facet Loading



NOTE 1—This setup would require two rotational actuators and one translational actuator

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FIG. 2 Diagrams of Possible Test Apparatus for Allowing Simultaneous Flexion-Extension and Lateral Bending Motions with Anterior-Posterior Directed Facet Loading

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

5.2.5.5 Axial rotation load and motion are positive and negative moments and rotations about the *Z*-axis.

5.2.6 *Frequency*—Test frequency shall be determined and justified by the user of this practice, and shall not exceed 2 Hz without adequate justification ensuring that the applied motion (load) profiles remain within specified tolerances and that the total facet prosthesis's wear and functional characteristics are not significantly affected. See X1.6.

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 testing. In addition, it is recommended that the serum contain a mass fraction of a suitable antibacterial agent to minimize bacterial degradation. Alternate lubricants (other than bovine serum solution) 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 20 mM (7.45 g/L) 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 mediums should be evaluated.

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

6.1.5 The user may wish to reference Test Method F732 for additional guidance on serum preparation.

6.2 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 the selected frequency and resultant localized temperature have on the test results or justify that the effects are insignificant. Refer to X1.5 for further information.

7. Sampling and Test Specimens

7.1 It is suggested that a minimum sample size of six 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, total facet 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 of the device to be tested must be produced using equivalent manufacturing methods as the implantable form of the total facet 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 thus 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 is properly justified and does not interfere with an accurate measurement of the wear and functional characteristics of the device. For example, a ball and socket joint prosthesis having the polished articulation component (that is, functional surfaces or features of the device) and an opposite side that mounts directly to the testing apparatus, may be manufactured, thereby simplifying the fixturing demands.

8.4 The requirements of Guide F1714, Section 5, Specimen Preparation, shall be followed.

9. Procedure

9.1 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.

9.2 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 (see 6.2), or specify and justify if different.

9.3 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 facet load vector as described in Figs. 1 and 2 since it is well known that load can significantly affect fluid absorption.

NOTE 1—The user of this practice may justify not performing control tests in certain circumstances (for example, all-metal components). Before and at all specified time intervals (determined by the user) of the presoak period (defined in Guide F1714), the wear components and soak controls should be removed from the soak bath, cleaned, dried, and weighed three times, in rotation, keeping the same specimen sequence each time. The average of the three weights may be used for the wear calculations. An analytical balance with a sensitivity of ±10 µg shall be used. This degree of sensitivity for weighing is necessary to detect the slight loss in weight of polymers, such as Ultra High Molecular Weight Polyethylene (UHMWPE), which may wear 30 µg or less per million cycles (**1**).[3]

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. Visual, microscopic, profilometric, replication, or other inspection techniques can be used. 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 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 service life expectancy of the total facet 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 of wear particulate 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 total facet prostheses 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. A mechanical failure (for example, considerable wear of the bearing surface) may not necessitate

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

termination of the test since this practice attempts to characterize the time-dependent wear properties of the device. The test shall be terminated if functional failure occurs (for example, gross fracture or a bearing seizes).

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

9.10 *Tests:*

9.10.1 A facet load shall be an applied compressive force through the total facet prosthesis (f_x). The specific methodology for fixturing and applying the facet load will dictate the resultant load and bending moment the device will be subjected to throughout the motion profile.

9.10.2 The facet load for all testing shall be applied with the use of a mechanism that can apply a constant magnitude of 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 facet load. The user may also wish to consider the use of a cyclic facet load for the testing as a cyclic loading profile may drastically change the amount of lubricant on relevant features of the prosthesis and thus significantly alter the wear properties of the prosthesis. If a cyclic axial facet load is employed, minimum and maximum facet loads shall be 50 % and 150 % respectively of the facet loads listed in Table 1 unless otherwise justified.

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

9.10.3 *Total Facet Prostheses Tests:*

9.10.3.1 Table 1 lists the test profiles and associated parameters for testing total facet 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 strive for identifying and then using test conditions that would produce the worst-case, clinically relevant 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 section X1.3 for further comments):

(1) The user may test the same device under the single motion parameters defined in Table 1 (i.e., 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. By 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 alternate method in which all of the simple motions are combined in one test may also be employed. Note that each simple motion in this combined motion test must complete at least 10 000 000 cycles.

9.10.3.2 For all coupled motions, the user must determine and justify the phase angle used between the motions.

9.10.3.3 The sequence of motions shall be determined and justified by the user of this practice. It should be noted, however, that the sequence of motion can affect the wear properties of the total facet 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 total facet prosthesis.

9.10.4 Regardless of the selected test method, ROM and facet load data shall be recorded during the test.

9.10.5 If a device ceases to function (for example, a bearing surface wears through, a 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.

9.10.6 Displacement control angular motions shall be controlled with an accuracy of ±0.5º.

9.10.7 Load control moments and forces shall be controlled to ±5 % of the maximum value for the complete motion cycle.

9.11 At the indicated inspection interval, remove the wear and soak components, wash, rinse, and dry 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 procedures. 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

TABLE 1 Test Profiles and Associated Parameters for Total Facet Prostheses

Test Profile	Facet Load, N (2-6)	Displacement Control: Range of Motion (ROM), degrees	Load Control: Applied Moments, Nm[A]	Radius of Rotation, mm
Flexion/Extension	400[B]	15º total motion[C,D]	±10	44.3[E]
Rotation	400[B]	±3 (6, 7)	±10[D]	52.1[E]
Lateral Bending	400[B]	±6[D] (6, 7)	±10	27.5[E]

[A] Approximated based on a review of ROM (p. 111) and average flexibility and stiffness coefficients (p. 47) (8) as done for Test Methods F2346.
[B] This load represents combined loading for two facets (see X1.7). In the scenario where an unilateral prosthesis is used to replace the two natural facets, the combined load should be applied in its entirety. In a bilateral design it may be distributed between the two facets.
[C] Depending on device design, the balance of ROM should be appropriate and justified to the expected ROM in a clinical situation (9).
[D] Preferred test modes for each motion (see 9.10.1).
[E] Approximate distance to natural facet location based on location of a fixed center of rotation (COR) at the anterior third of the disc and centralized in the medial-lateral direction (see X1.8).

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 filtration methods. Submicron filters (0.2 μm or below) are suggested; though, ultimately, the material type of the wear particles and their size distribution will dictate the methods used. Note that several stages of filtration may be necessary to isolate the different particles of interest effectively.

9.16.2 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 3.3.12 and definitions for S_i and W_i in 3.3.10 and 3.3.11, respectively. Calculate the interval net wear rate WR_i during cycle interval i using the equation in 3.3.5.

10.2 *Conversion to Volumetric Wear*—Convert net wear NW_i to net volumetric wear NV_i using the equation in 3.3.13 and interval net wear rate WR_i to interval net volumetric wear rate VR_i using the equation in 3.3.4. This is recommended for comparison of wear between different materials or material grades (UHMWPE wear versus cobalt-chromium alloy 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 3for 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 any articulating surface shall be characterized by profilometry, photomicrography, replication, or other applicable techniques and included within the report.

11.4 All relevant geometric measurements of the total facet 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 the 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 shall be clearly stated in the report.

11.6 *Loading Conditions:*

11.6.1 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 3D components of the resultant facet load from the specified AP force in the mid sagital *XZ* plane.

11.6.2 The user should report the method (that is, hydraulic/pneumatic cylinders or other method) as well as the testing apparatus used to apply the facet load and kinematic/load profile to the total facet prosthesis. A diagram or picture of the testing setup 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.

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

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

11.7 *Wear Rates:*

11.7.1 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 (mm^3/million cycles) of each specimen as a function of total test cycles at the end of the 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 multi-sample tests have been conducted over the same cycle intervals, include in the table the average and standard deviation of the data in each sample interval. If the sample intervals are not identical for all test samples of multi-sample tests, regression analysis should be used to fit an equation as a function of the total cycles along with determination of 95 % confidence interval lines. Plot these in the corresponding graph. The method used shall be justified, described, and the limitations identified in the report.

11.7.2 Report the test duration in cycles.

11.7.3 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 and/or crack initiation site. Any wear or loosening of the assembly shall be described. Any other noteworthy observations should be included.

11.7.4 Report the following information for the particulate debris:

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

11.7.4.2 Methods used to digest and separate the particles.

12. Precision and Bias

12.1 *Precision*—Data establishing the precision of this test method has not yet been obtained.

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

13. Keywords

13.1 dynamic test; facet arthroplasty; posterior instrumentation; spinal implants; static test; wear assessment; weight loss method

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR TEST METHODS

X1.1 Total facet prostheses may be manufactured in a variety of sizes, materials, and shapes with various design features. The purpose of this practice is to allow for a consistent, repeatable comparison of different total facet prosthesis designs through a series of mechanical tests.

X1.2 The spinal implants that fall into the category of total facet prostheses are intended for facet replacement. All of the implants may reside on the posterior aspect of the adjacent vertebral bodies. This practice will allow for comparison of these devices since the methods and loading configuration remain consistent regardless of method of application. Biologic replacements are excluded from the scope of this practice since biologic structures that share the *in vivo* loads vary among designs, making total facet test methods inappropriate.

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 bending, and axial rotation. These motions may occur independently or be coupled in some fashion. 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 clinically relevant "worst case" wear rate would be the one(s) specified in this practice. It is generally accepted for many material combinations that coupled motion profiles have been observed to accelerate wear of some materials compared to single-axis profiles. However, in certain materials such as metal-on-metal or ceramic-on-ceramic, linear "simple" motions may produce the "worst case" wear conditions. Since the "worst case" wear rate is dependent on the material and motion profile, 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 total facet prosthetic devices. However, no claim can be made relative to assuring that these tests will produce the highest rate of wear. Use of these profiles will, however, serve as a common starting base to compare wear rates of different total facet prosthetic devices and their materials. As experience is gained in testing total facet prosthetic devices or knowledge becomes available indicating that other profiles would produce greater wear rates or both, the user of this practice is encourage to define, use, and report on other potentially more detrimental motion/load profiles.

X1.4 Since one purpose of a total facet prosthesis is the long-term restoration of function, run out has been defined as 10 000 000 cycles. As justification for this runout cycle count, flexion/extension is expected to be the dominant loading condition influencing the wear performance of the facets. While estimates of the number of significant bends (flexion/extension) a person makes per year vary, a conservative estimate is 125 000 bends/year, which equates to 1.25 million significant bends in ten years (**10**). 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 total facet prosthesis. Therefore, if appropriate and justified, the user may choose to define a lower run out cycle count that is more applicable for the device being tested and the clinical setting in which the device will be used.

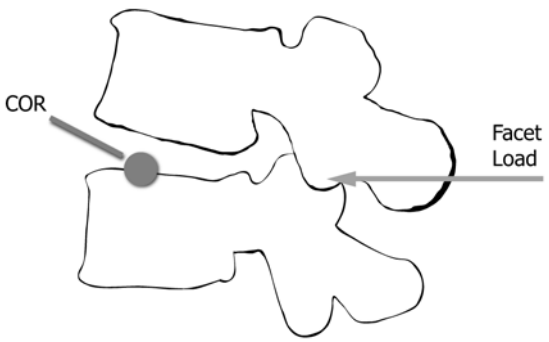
X1.5 Testing the prosthesis using constraints on 3D motions other than specified in this practice (which are intended to simulate conditions expected after *in vivo* implantation) could produce different wear results. Thus, use of different constraints must be justified with respect to those occurring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

X1.6 Section 6.1.4 stipulates that the testing medium shall be maintained at 37 ± 3°C. Note that, while this will be the temperature of the surrounding tissues *in vivo*, it is possible that the implant surfaces will exceed the temperature range of the testing medium 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 the lubricating properties of the fluid in contact with the implant surfaces, the goal of the practice is 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 ± 3°C. If frequencies greater than 2 Hz are used, care should be taken that running the wear test at this high frequency does not adversely 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 as one means of removing excess frictional heat.

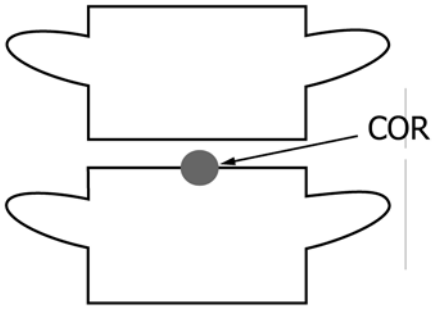
X1.7 Loading of the facets is a complicated action which has received relatively little attention, in comparison to the disc. While load values in the literature vary from moments of no load to loads as high as 600N, it is more appropriate in wear testing to apply a typical load representing activities of daily living. Specifically, Shirazi-Adl (**6**) demonstrated that contact forces on each facet were approximately 200N when a compressive load was placed on the spine with a coupled extension moment.

X1.8 While reports of the center of rotation are variable throughout the literature (and throughout the motions of the functional spinal unit (FSU)), for simplicity of testing it is positioned at a fixed location at the anterior third of (and on) the superior endplate of the inferior vertebral body and centralized medio-laterally (Figs. X1.1-X1.3). Morphologic data was compiled to quantify the radius of rotation for all motions and a two standard deviation method was used to ensure representation of the majority of the population. This fixed center of rotation allows for simpler combined motion testing, while still representing realistic radii of rotation. To calculate the flexion-extension radius of rotation values, two thirds of the anterior-posterior measurement of the vertebral body (**11**) is added to the anterior-posterior length of the pedicle (**12**). Additionally, while the center of rotation for lateral bending has been reported to be as far away from the facet as the opposite lateral edge of the vertebral body, it is represented in this practice as being centralized medio-laterally, for simplicity of test setup. As such, the interfacet distance is calculated as the interpedicular distance at the posterior aspect of the pedicle utilizing the canal width (**11**) plus the pedicle width (**13**) and accounting for the pedicle angle (**12**, **13**). Half of this interfacet distance is thus equal to the lateral bending radius of rotation. To calculate the radius of rotation for axial rotation, the sum of the squares may be calculated from the lateral bending and flexion extension rotational radii. The resultant measurements to be used for the rotational radii are listed in Table 1 (see 9.10.3).



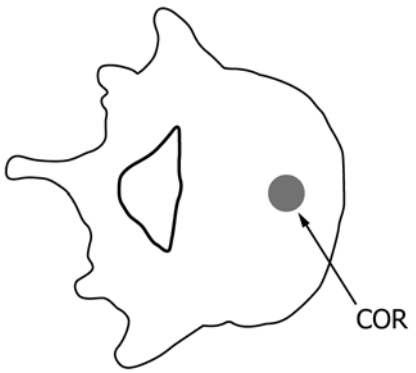
NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.1 Sagittal View of a Single FSU Demonstrating the Position of the Center of Rotation (COR) in the *XZ* Plane



NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.2 AnteroPosterior View of a Single FSU Demonstrating the Position of the COR in the *YZ* Plane



NOTE 1—The center is located at the anterior third of the inferior vertebral body's endplate.

FIG. X1.3 Axial View of a Single FSU Demonstrating the Position of the COR in the *XY* Plane

REFERENCES

(1) McKellop, H., Clarke, I. C., Markolf, K. L., and Amstutz, H. C., "Wear Characteristics of UHMW Polyethylene: A Method for Accurately Measuring Extremely Low Wear Rates," *J Biomed Mater Res*., Vol 12, No. 6, 1978, pp. 895–927.

(2) Lorenz, M., Patwardhan, A., and Vanderby, R., "Load-Bearing Characteristics of Lumbar Facets in Normal and Surgically Altered Spinal Segments," *Spine* , Vol 8, No. 2, 1983, pp. 122–130.

(3) Kong, Goel, and Gilbertson, "Prediction of Biomechanical Parameters in the Lumbar Spine During Static Sagittal Plane Lifting," *Journal of Biomechanical Engineering*, Vol 120, No. 273, 1998, pp. 273–280.

(4) Yang and King, "Mechanism of Facet Load Transmission as a Hypothesis for Low-Back Pain," *Spine*, Vol 9, No. 6, 1984, pp. 557–565.

(5) Young, Goel, Weinstein, and Tae-Hong, "Effect of Disc Degeneration at One Level on the Adjacent Level in Axial Mode," *Spine*, Vol 16, No. 3, 1991, pp. 331–335.

(6) Shirazi-Adl and Drouin, "Load-Bearing Role of Facets in a Lumbar Segment under Sagittal Plane Loadings," *Journal of Biomechanics*, Vol 20, No. 6, 1987, pp. 601–613.

(7) Pearcy, M. J. and Tibrewal, S. B., "Axial Rotation and Lateral Bending in the Normal Lumbar Spine Measured by Three-Dimensional Radiography," *Spine*, Vol 9, No. 6, 1984. pp. 582–587.

(8) *Clinical Biomechanics of the Spine*, A. A. White and M. M. Panjabi, Eds., J.B. Lippincott, Philadelphia, 1990.

(9) Pearcy, M., Portek, I., and Shepherd, J., "Three-Dimensional X-Ray Analysis of Normal Movement in the Lumbar Spine," *Spine*, Vol 9, No. 3, 1984, pp. 294–297.

(10) Hedman, T. P., Kostuik, J. P., Fernie, G. R., and Hellier, W. G., "Design of an Intervertebral Disc Prosthesis," *Spine*, Vol 16, No. 6, Suppl., 1991, pp. S256–S260.

(11) Panjabi, M. M., Goel, V., Oxland, T., Takata, K., Duranceau, J., Krag, M., and Price, M., "Human Lumbar Vertebrae: Quantitative Three-Dimensional Anatomy," *Spine*, Vol 17, No. 3, 1992, pp. 229–306.

(12) Krag, M., Weaver, D., Beynnon, B., and Haugh, L., "Morphometry of the Thoracic and Lumbar Spine Related to Transpedicular Screw Placement for Surgical Spinal Fixation," *Spine*, Vol 13, No. 1, 1988, pp. 27–32.

(13) Wolf, A., Shoham, M., Michael, S., and Modhe, R., "Morphometric Study of the Human Lumbar Spine for Operation-Workspace Specifications," *Spine*, Vol 26, No. 22, 2001, pp 2472–2477.