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# 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 an 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

## 3. Terminology

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

3.2 *Definitions:*

3.2.1 *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 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).

3.2.1.1 *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.

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

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

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

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

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

[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.

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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.

3.2.4 *interval net volumetric wear rate $VR_i$ 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.

3.2.5 *interval net wear rate $WR_i$ during cycle interval i (g/million cycles), n*—$WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) \cdot 10^6$; for $i = 1$, $NW_{i-1} = 0$.

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

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

3.2.8 *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.

3.2.9 *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).

3.2.10 *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.

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

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

3.2.13 *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*.

3.2.14 *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.

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

3.2.16 *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).

3.2.17 *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 be 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.

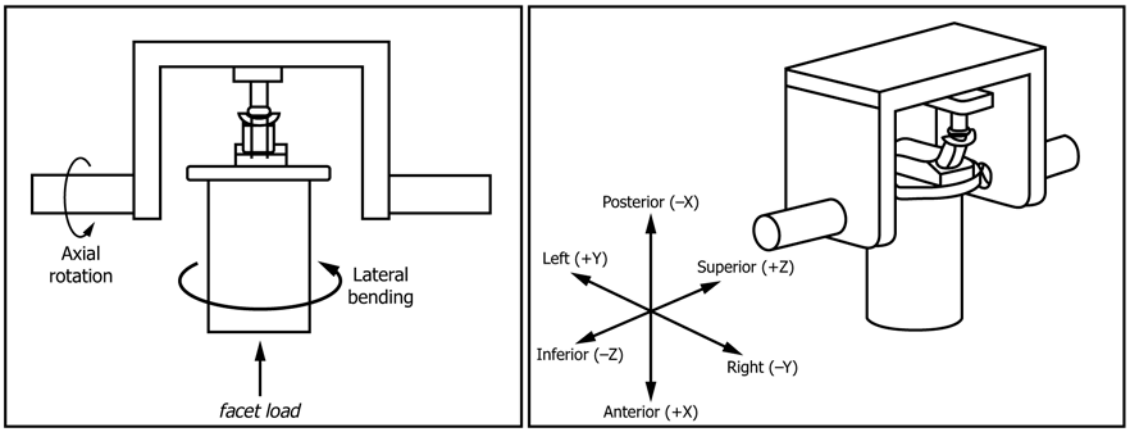
5.2.5 *Load and Motion:*

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.

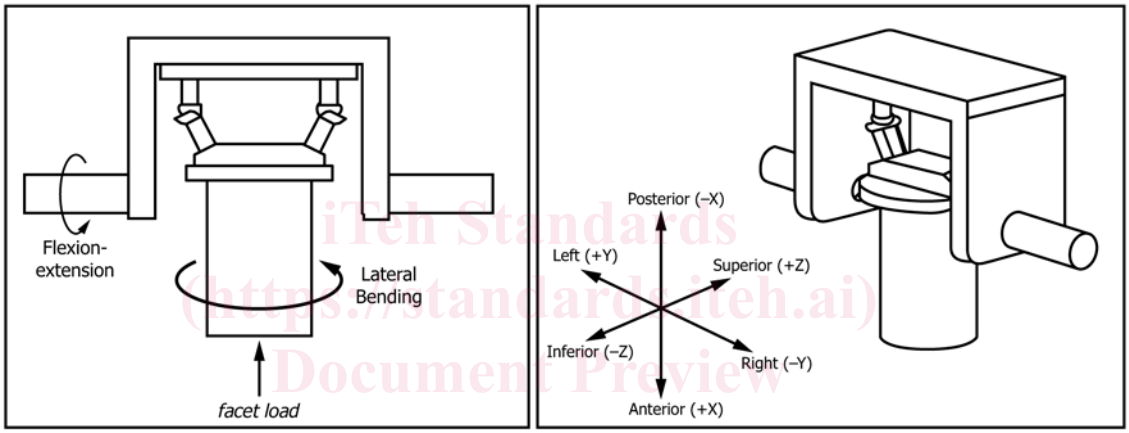
5.2.5.3 Extension load and motion are negative moment and rotation about the *Y*-axis.

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

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

5.2.6 *Frequency*—Test frequency is to 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 contains 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 physiologically relevant. 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 may be manufactured 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, thereby simplifying the fixturing demands.

8.4 The requirements of Guide F1714, Specimen Preparation section, 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 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 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 termination of the test since this practice attempts to characterize the time-dependent wear properties of the device. The

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