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

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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]

F 561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F 1582 Terminology Relating to Spinal Implants

F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices

F 1877 Practice for Characterization of Particles

F 2077 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 are stationary relative to the IVD prostheses' inferior end plate

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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.

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). **F 1582**

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*—$WR_i = ((NW_i - NW_{i-1})/(\text{number of cycles in interval } i)) * 10^6$.

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

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

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 ±6	±2.0 ±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