Designation: F2346 – 05 (Reapproved 2011)

Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs[1]

This standard is issued under the fixed designation F2346; 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 These test methods specify the materials and methods for the static and dynamic testing of artificial intervertebral discs.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future non-biologic artificial intervertebral discs. These test methods allow comparison of artificial intervertebral discs with different intended spinal locations (cervical, thoracic, and lumbar) and methods of application to the intervertebral spaces. These test methods are intended to enable the user to mechanically compare artificial intervertebral discs and do not purport to provide performance standards for artificial intervertebral discs.

1.3 These test methods describe static and dynamic tests by specifying load types and specific methods of applying these loads. These tests are designed to allow for the comparative evaluation of artificial intervertebral discs.

1.4 These test methods do not purport to address all clinically relevant failure modes for artificial intervertebral discs, some of which will be device specific. For example, these test methods do not address the implant's resistance to expulsion or implant wear resistance under expected *in vivo* loads and motions. In addition, the biologic response to wear debris is not addressed in these test methods.

1.5 Requirements are established for measuring displacements, determining the yield load or moment, and evaluating the stiffness of artificial intervertebral discs.

1.6 Some artificial intervertebral discs may not be testable in all test configurations.

1.7 The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in terms of either degrees or radians.

1.8 *The use of this standard may involve the operation of potentially hazardous equipment. 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]

E4 Practices for Force Verification of Testing Machines
E6 Terminology Relating to Methods of Mechanical Testing
E466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
E1823 Terminology Relating to Fatigue and Fracture Testing
F1582 Terminology Relating to Spinal Implants
F2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 All definitions below supersede definitions contained within Terminologies E6, E1823, F1582, and Practices E466, E467.

3.2 *Definitions:*

3.2.1 *artificial intervertebral disc*—a synthetic structure that is permanently implanted in the disc space between two adjacent vertebral bodies to provide spinal column support and allow intervertebral motion.

3.2.2 *coordinate system/axes*—three orthogonal axes are defined by Terminology F1582. The center of the coordinate system is located at the geometric center of the artificial intervertebral disc. Alternative coordinate systems may be used with justification. The *XY*-plane is to bisect the superior and inferior surfaces that are intended to simulate the adjacent

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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.

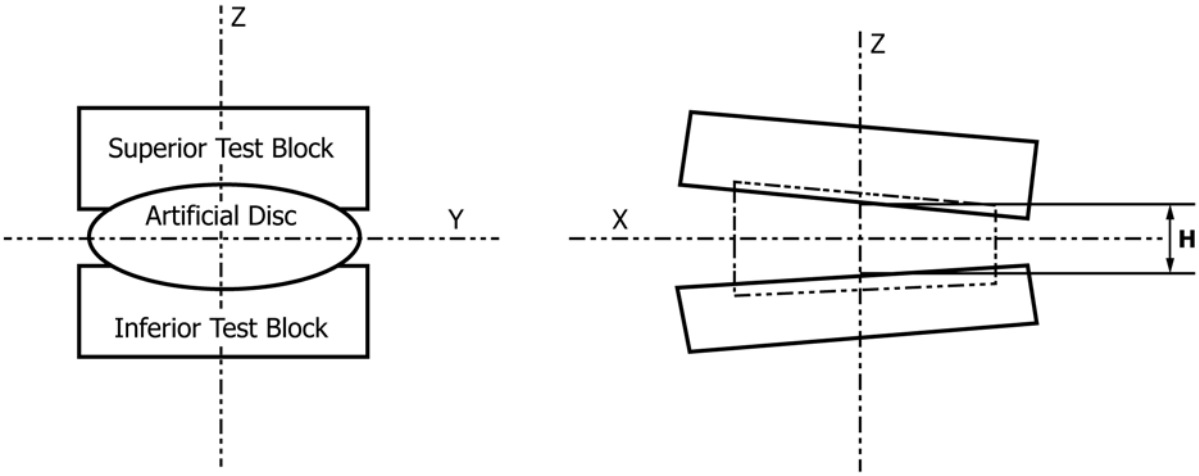


FIG. 1 Intervertebral Height Diagram

vertebral end plates. The positive *Z*-axis is to be directed perpendicular to the bisector of the disc space, oriented in the superior direction. The positive *X*-axis is parallel to the intervertebral space, oriented in the anterior direction and the positive *Y*-axis is parallel to the disc space, oriented in the left direction. Force components parallel to the *XY*-plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z* direction. Torsional load is defined to be the component of moment parallel to the *Z*-axis.

3.2.3 *fatigue life*—the number of cycles, *N*, that the artificial intervertebral disc can sustain at a particular load or moment before functional failure occurs.

3.2.4 *functional failure*—permanent deformation that renders the artificial intervertebral disc ineffective or unable to adequately resist load.

3.2.5 *ideal insertion location*—the location of the artificial disc in the intervertebral space that is suggested in the manufacturer's surgical installation instructions. The ideal insertion location is to be described with respect to the simulated inferior and superior vertebral bodies (polyacetal or metal blocks) and will be dictated by the device design.

3.2.6 *intended method of application*—artificial intervertebral discs may contain different types of features to stabilize the implant-tissue interface such as threads, spikes, and textured surfaces. Each type of feature has an intended method of application or attachment to the spine.

3.2.7 *intended spinal location*—the anatomic region of the spine intended for the artificial intervertebral disc. Artificial intervertebral discs may be designed and developed for specific regions of the spine such as the cervical, thoracic, and lumbar spine. Also, since different surgical approaches may exist, the description of the intended spinal location should include both the indicated spinal levels and the ideal insertion locations within the intervertebral space allowed at each level.

3.2.8 *intervertebral height*—the minimum distance parallel to the *Z*-axis in the *YZ*-plane between the unaltered simulated vertebral bodies: minimum height of 2 mm and maximum height of 16.5 mm.[3,4] See Fig. 1.

3.2.9 *load point*—the point through which the resultant force on the intervertebral device passes; that is, the geometric center of the superior fixture's sphere (see Figs. 2-4).

3.2.10 *maximum run-out load or moment*—the maximum load or moment for a given test that can be applied to an artificial intervertebral disc where all of the tested constructs have withstood 10 000 000 cycles without functional failure.

3.2.11 *mechanical deterioration*—deterioration that is visible to the naked eye and is associated with mechanical damage to the device under test (for example, initiation of fatigue crack or surface wear).

3.2.12 *offset angular displacement*—(distance OB—Fig. 6) offset on the angular displacement axis equal to 2 % of the intervertebral height, *H*, divided by the maximum radius of the implant in the *XY*-plane; for example, for an artificial intervertebral disc with a height of 10 mm and a maximum radius in the *XY*-plane of 9 mm, distance OB = (0.02) (10 mm) / (9 mm) = 0.022 radians = 1.3°.

3.2.13 *offset displacement*—(distance OB—Fig. 6) offset on the linear displacement axis equal to 2 % of the intervertebral height (for example, 0.2 mm for a 10 mm intervertebral height).

3.2.14 *permanent deformation*—the remaining linear or angular displacement (axial—mm, angular—degrees or radians) relative to the initial unloaded condition of the artificial intervertebral disc after the applied load or moment has been removed.

3.2.15 *stiffness* (axial—n/mm, angular—n·mm/degree or n·mm/radian)—the slope of the initial linear portion of the

[3] Nissan, M., Gilad, I., "The Cervical and Lumbar Vertebrae—An Anthropometric Model," *Engineering In Medicine*, Vol 13, No. 3, 1984, pp. 111–114.

[4] Lu, J., Ebraheim, N.A., Yang, H., Rollins, J., and Yeasting, R. A., "Anatomic Bases for Anterior Spinal Surgery: Surgical Anatomy of the Cervical Vertebral Body and Disc Space," *Surg Radiol Anat*, Vol 21, No. 4, 1999, pp. 235–239.

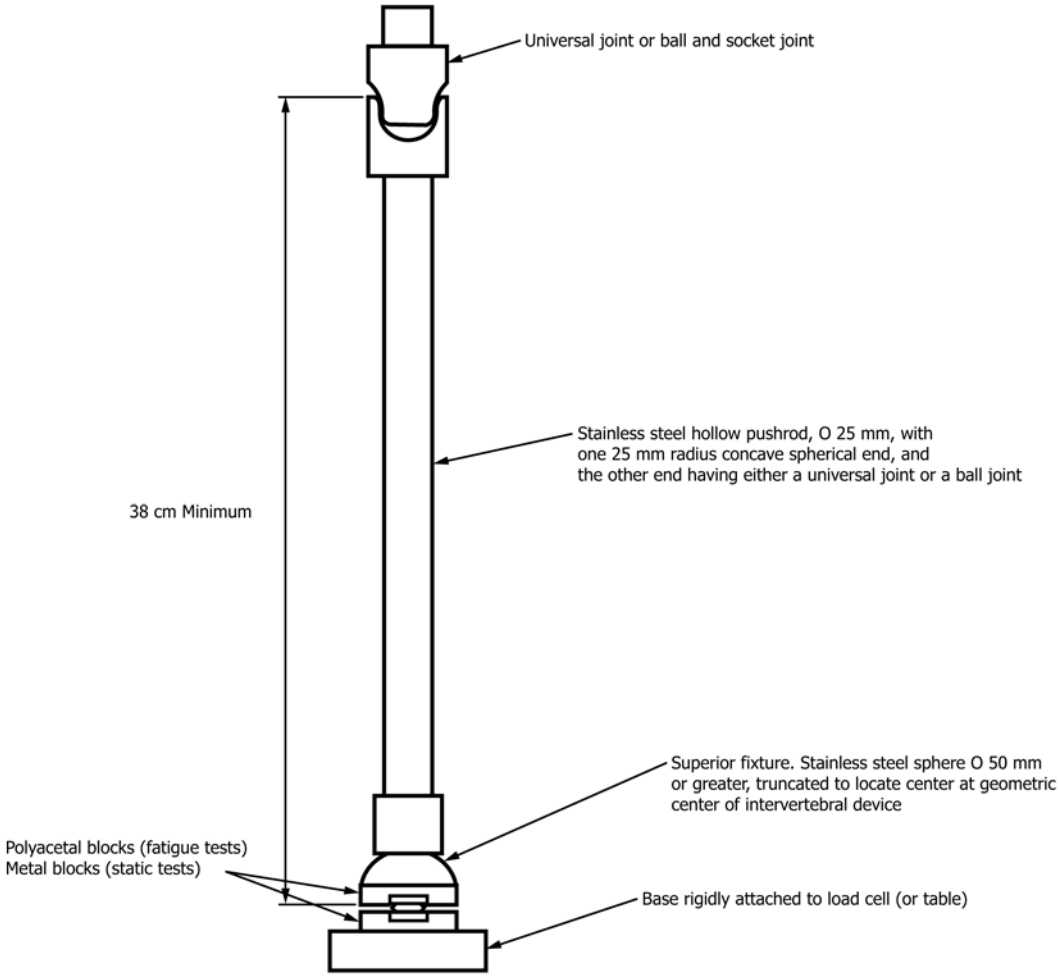


FIG. 2 Compression Testing Configuration

load-displacement curve or the slope of the initial linear portion of the moment-angular displacement curve. This is illustrated as the slope of the line OG in Fig. 6. If the device does not exhibit a linear initial load/displacement curve, the displacement should be reported at 30 %, 60 %, and 90 % of the yield load or moment.

3.2.16 *test block*—the component of the test apparatus for mounting the artificial intervertebral disc in the intended test configuration.

3.2.17 *ultimate displacement* (axial—mm, angular—degrees or radians)—the linear or angular displacement associated with the ultimate load or ultimate moment. This is illustrated as the displacement, OF, in Fig. 6.

3.2.18 *ultimate load or moment* (axial—n, angular—n·mm)—the maximum applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force and moment component parallel to and indicated by load or torque cell) to the artificial intervertebral disc assembly. This is illustrated as point E in Fig. 6.

3.2.19 *yield displacement*—the linear displacement (mm) or angular displacement (degrees or radians) when an artificial intervertebral disc has a permanent deformation equal to the offset displacement or offset angular displacement. This is illustrated as the distance OA in Fig. 6.

3.2.20 *yield load or moment*—the applied load, *F*, or moment, *M*, transmitted by the pushrod (assumed equal to force component parallel to and indicated by load or torque cell) required to produce a permanent deformation equal to the offset displacement or the offset angular displacement. This is illustrated as point D in Fig. 6.

4. Summary of Test Methods

4.1 These test methods are proposed for the mechanical testing of artificial intervertebral discs specific to the cervical, thoracic, and lumbar spine.

4.2 All tests are to be performed on the prosthesis size with the smallest safety factor for the levels indicated for implantation. If this worst-case size cannot be determined using theoretical or experimental methods such as simple stress calculations or finite element analysis, then all available sizes are to be tested and the complete range of results are to be reported.

4.3 Fatigue testing of the artificial intervertebral discs will simulate a motion segment via a gap between two polyacetal

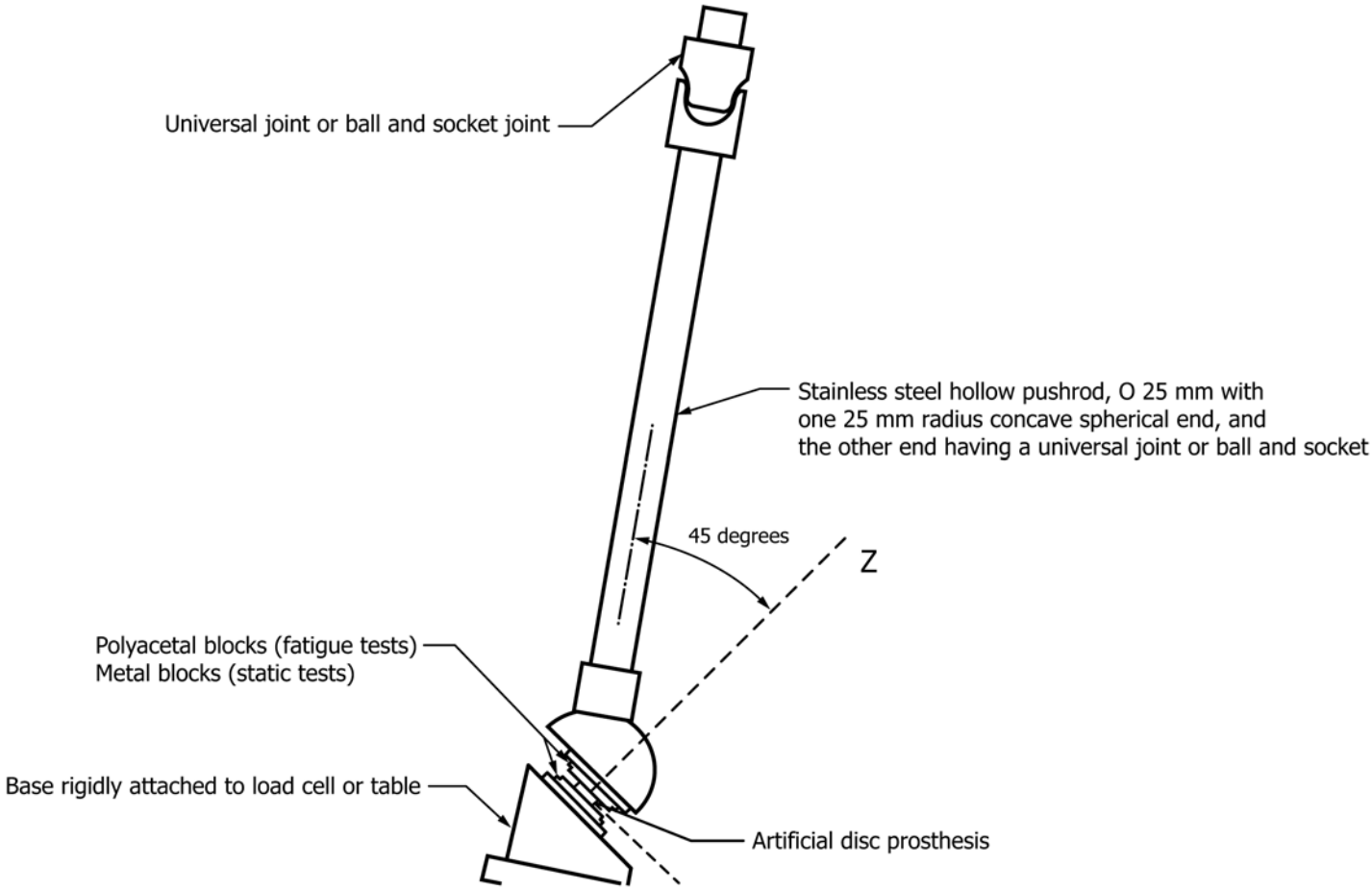


FIG. 3 Compression/Shear Testing Configuration

test blocks. The polyacetal will eliminate the effects of the variability of bone properties and morphology for the fatigue tests. The minimum ultimate tensile strength of the polyacetal blocks shall be no less than 61 MPa.

4.4 Static testing of the artificial intervertebral discs will simulate a motion segment via a gap between two stainless steel blocks. The minimum tensile yield strength of the blocks shall be no less than 1170 MPa.

4.5 The pushrod shall be manufactured from stainless steel having minimum tensile yield stress of 1170 MPa and be of minimum cross-sectional area that would produce a compressive yield strength of at least 25 000 N.

4.6 Static and dynamic tests will evaluate the artificial intervertebral disc. The user of these test methods must decide which series of tests are applicable to the artificial intervertebral disc in question. The user of these test methods may choose to use all or a selection of the tests described in these test methods for testing a particular artificial intervertebral disc. For example, the torsion test method may not apply to a device that has no mechanical resistance in axial rotation.

5. Significance and Use

5.1 Artificial intervertebral discs are orthopaedic implants that replace degenerated natural intervertebral discs. Their function is to support the anterior column of the spine while allowing motion at the operated level. These test methods outline materials and methods for the characterization of the mechanical performance of different artificial intervertebral discs so that comparisons can be made between different designs.

5.2 These test methods are designed to quantify the static and dynamic characteristics of different designs of artificial intervertebral discs. These tests are conducted *in vitro* in order to allow for analysis of individual disc replacement devices and comparison of the mechanical performance of multiple artificial intervertebral disc designs in a standard model.

5.3 The loads applied to the artificial intervertebral discs may differ from the complex loading seen *in vivo*, and therefore, the results from these tests may not directly predict *in vivo* performance. The results, however, can be used to compare mechanical performance of different artificial intervertebral discs.

5.4 Fatigue tests should be conducted in a 0.9 % saline environmental bath at 37°C at a rate of 2 Hz or less. Other test environments such as a simulated body fluid, a saline drip or mist, distilled water, or other type of lubrication could also be used with adequate justification. Likewise, alternative test frequencies may be used with adequate justification.

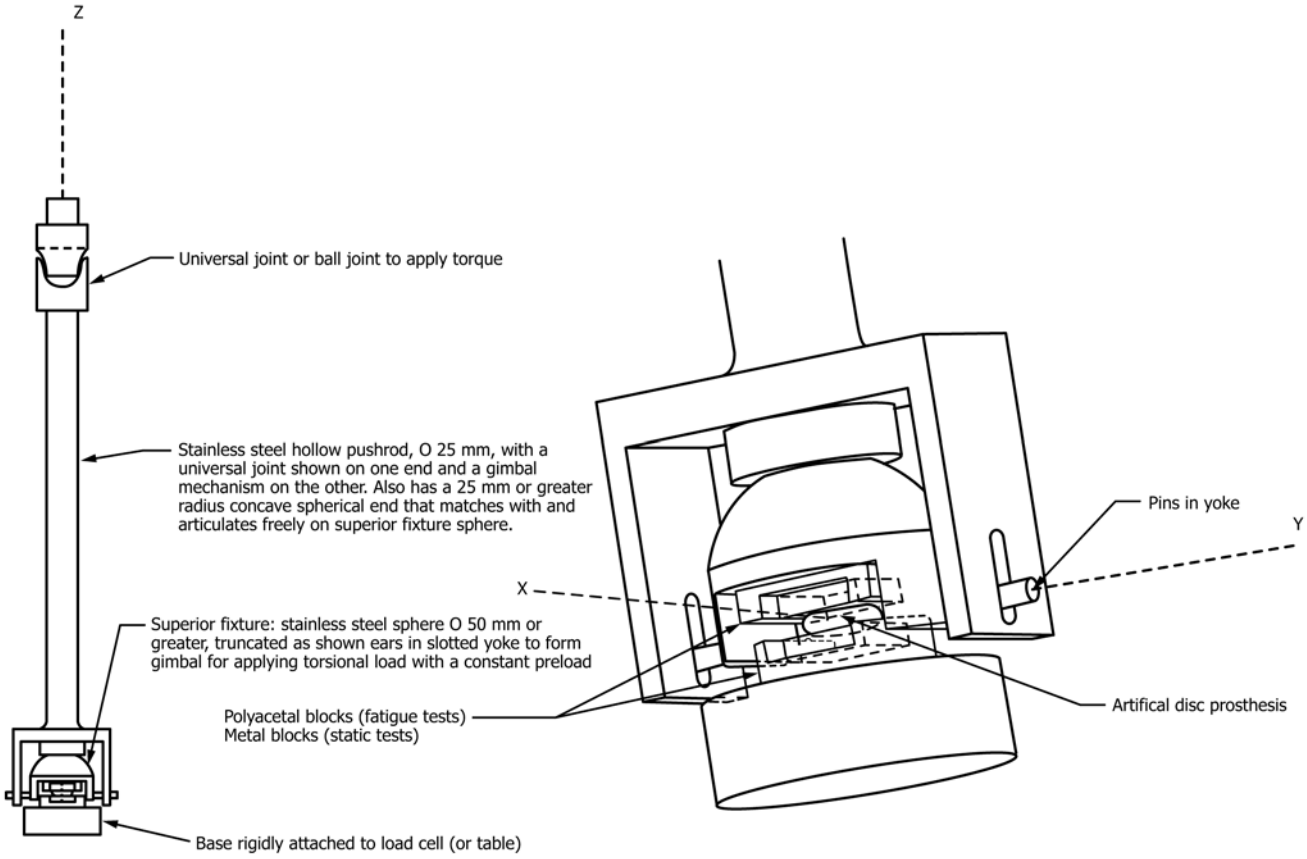


FIG. 4 Torsion Testing Configuration with a Pin-Slot Gimbal

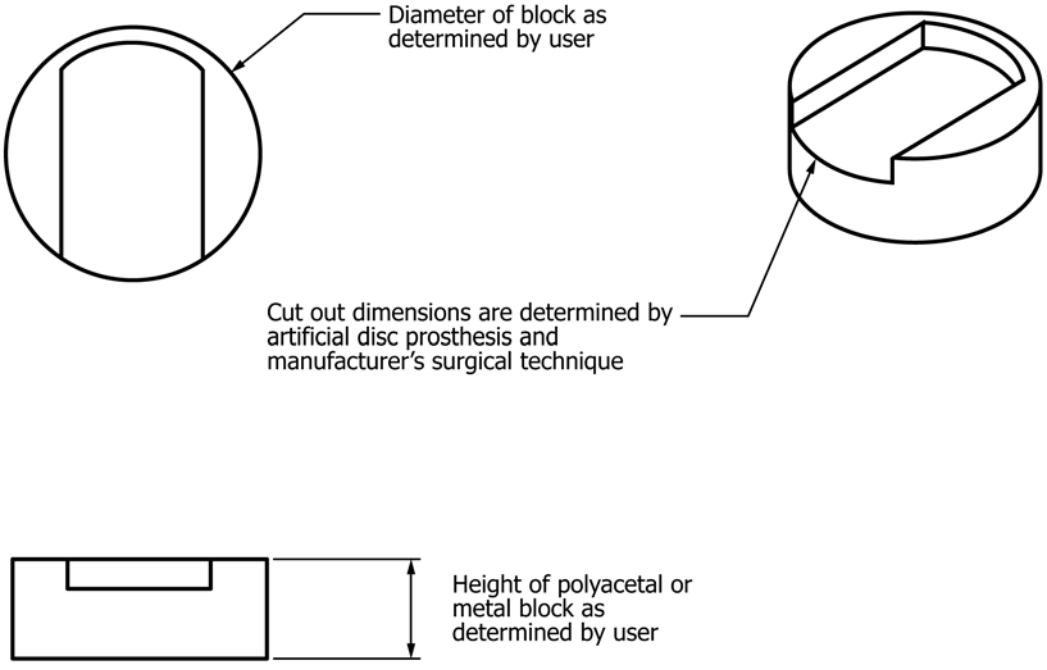


FIG. 5 Polyacetal or Metal Test Block

5.5 It is well known that the failure of materials is dependent upon stress, test frequency, surface treatments, and environmental factors. Therefore, when determining the effect of changing one of these parameters (for example, frequency, material, or environment), all others should be kept constant to facilitate interpretation of the results. In particular, it may be

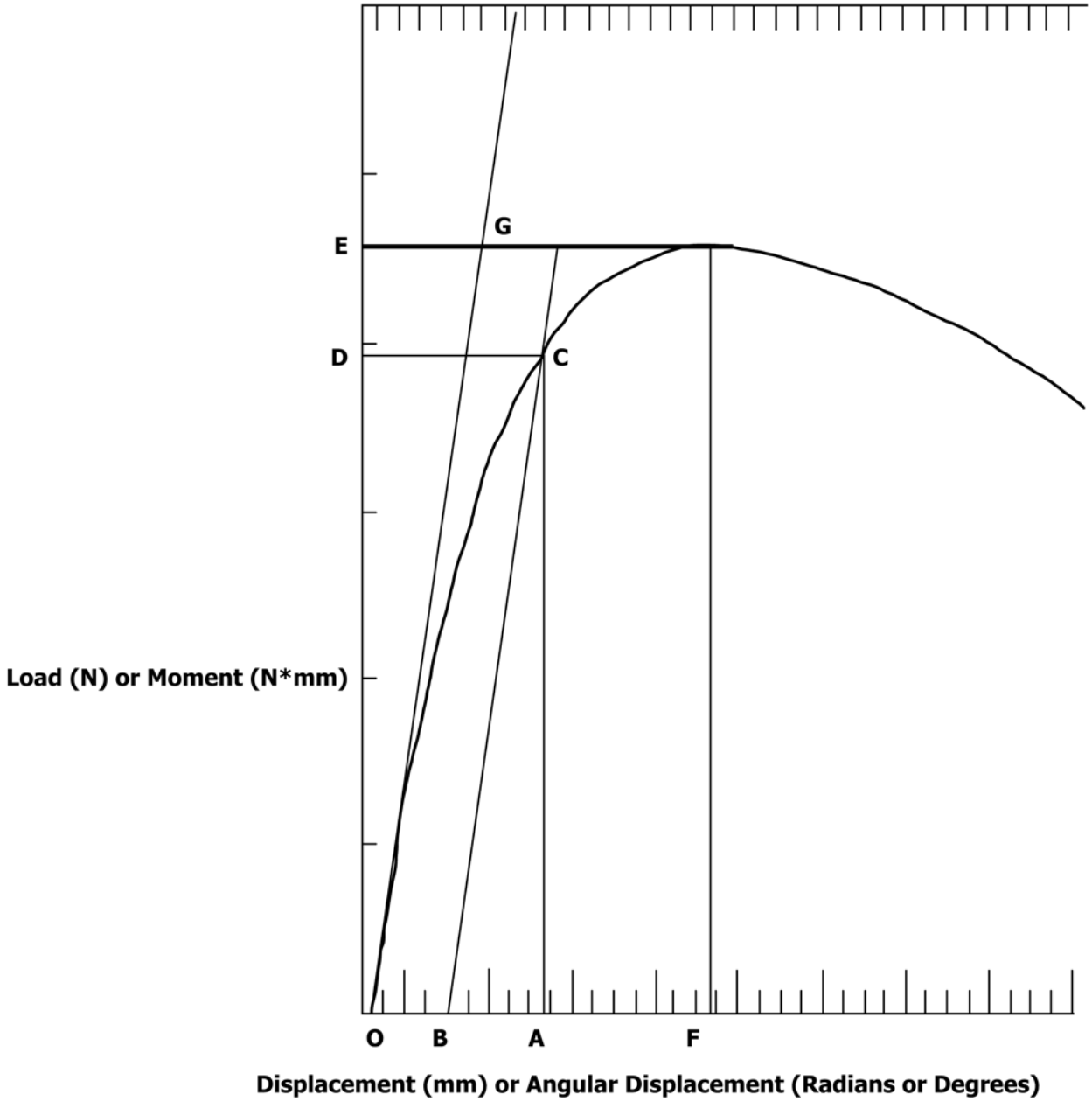


FIG. 6 Typical Load Displacement Curve

necessary to assess the influence of test frequency on device fracture while holding the test environment, implant materials and processing, and implant geometry constant.

6. Apparatus

6.1 Test machines will conform to the requirements of Practices E4.

6.2 The intervertebral height, *H*, shall be determined from vertebral body and disc morphometric data at the intended level of application. Suggested heights are as follows: 4 mm for the cervical spine, 6 mm for the thoracic spine, and 10 mm for the lumbar spine. The intervertebral height should not reach zero prior to the onset of functional failure deterioration. If this occurs, the test is considered a failure. The user of these test methods should select the intervertebral height that is appropriate for the device being tested.

6.3 *Axial Compression Test Apparatus:*

6.3.1 The actuator of the testing machine is connected to the pushrod by a minimal friction ball-and-socket joint or universal joint (that is, unconstrained in bending). The pushrod is connected to the superior fixture by a minimal friction sphere joint (that is, unconstrained in bending and torsion). The hollow pushrod should be of minimal weight so as to be considered a "two force" member.

6.3.2 It thus applies to the artificial intervertebral disc a resultant force directed along the pushrod's axis and located at the center of the superior fixture's sphere joint (the geometric center of the device being tested).

6.3.3 For the fatigue tests, the device is placed between two polyacetal blocks, which are rigidly attached to the metal blocks (Fig. 5).

6.3.4 For the static tests, metal blocks are to be used, which could be incorporated as an integral part of the superior and inferior fixtures. The blocks are to have surfaces that mate geometrically with the intervertebral disc prosthesis similar to how the device is intended to mate with vertebral end plates.

6.3.5 The test apparatus will be assembled such that the *Z*-axis of the intervertebral device is initially coincident with the pushrod's axis and collinear with the axis of the testing machine's actuator and load cell.

6.3.6 The length of the pushrod between the center of the ball-and-socket joint to the center of the spherical surface is to be a minimum of 380 mm. This is required to minimize deviation of the pushrod's axis (direction of applied force, *F*) from that of the test machine's load cell axis. In other words, this is to minimize the error in using and reporting that the force indicated by the load cell F_{ind} is the applied load, *F*, and is equal to the compressive force, F_z, on the artificial intervertebral disc. For example, a 1-mm displacement of the spherical surface's center in the *XY*-plane would produce an angle between axes of 0.15° (10 mm producing 1.5°). Fig. 2 is a schematic of this test set up.

6.3.7 Use of this apparatus for artificial discs that allow flexion/extension or lateral bending may cause the superior fixture to rotate off the test device. In this instance, alternative apparatus that constrains the angle of the superior surface of the test device may be used. For example, analogs to the supporting anatomic structures such as the facet joints, facet capsules, anterior longitudinal ligaments and the posterior longitudinal ligament may be added to prevent the unwanted fixture rotation.

6.4 *Compression-Shear Testing Apparatus:*

6.4.1 The compression-shear test apparatus (Fig. 3), with exception of the inferior fixture, is identical to the axial compression apparatus (Fig. 2). The inferior fixture is to be designed so that the initial position of the intervertebral device's *Z*-axis is rotated +45° about the *Y*-axis. The resultant force, *F*, being applied to the artificial intervertebral disc passes through the center of the superior fixture's spherical surface and is coincident with the pushrod's axis. Thus, a combined compressive load F_z and an anterior shear load F_x is created, which initially are equal in magnitude and pass through the geometric center of the artificial intervertebral disc.

6.4.2 Use of this apparatus for artificial discs that allow flexion/extension may cause the superior fixture to rotate off the test device. In this instance, alternative apparatus that constrains the angle of the superior surface of the test device but still applies a shear-to-compression ratio of one may be used. If alternative fixtures are used, justification of the change with free-body diagrams shall be included in the report. See X1.7 for an example of an alternate test fixture that employs a pair of cables to prevent the unwanted fixture rotation by replicating the tensile properties of the facet capsules.

6.5 *Torsion Testing Apparatus:*

6.5.1 The torsion test apparatus (Fig. 4) is similar to the axial compression test apparatus (Fig. 2) with exception of the pushrod interconnections. The actuator of the testing machine must be connected to the pushrod by a minimal friction (that is, unconstrained in bending) universal joint to be able to transmit torsional moment in addition to axial load. The pushrod is connected to the superior fixture by a spherical gimbal mechanism to apply combined compressive force, *F*, and moment, *M*, with negligible bending moment to the artificial intervertebral disc.

6.5.2 The test apparatus is to be assembled so that the *Z*-axis of the artificial intervertebral disc is initially coincident with the pushrod's axis and collinear with the axis of the testing machine's actuator and load cell. This set-up is designed so that the initially applied load, *F*, and moment, *M*, are equal to the compression force, F_z, and torsional moment, M_z, on the artificial intervertebral disc. An acceptable alternative torsion testing apparatus is illustrated in Fig. 5 of Test Methods F2077.

7. Sampling

7.1 All components in the artificial intervertebral disc shall be previously unused parts only; no implants shall be retested. All implants shall be production quality parts. Any deviations from intended marketed product must be noted in the final report.

7.2 Each pair of polyacetal blocks and each pair of metal blocks may be reused if undamaged.

7.3 The test devices shall be labeled and shall be maintained according to good laboratory practices. The test assembly can be disassembled to facilitate examination of surface conditions. Test fixtures are exempt from archiving and may be reused.

7.4 All static tests should have a minimum of five test samples.

7.5 The user of these test methods should select the necessary loads to generate a well-defined maximum load-cycle to failure plot and to establish the maximum runout load. This plot must be comprised of at least six data points with a minimum of two run-out points.

8. Procedure for Static Tests

8.1 While recording load and displacement, perform a load-control static axial compression test to at least 1200 N on the metal test fixtures without the test device. A solid steel test block with the same external geometry as the test device should be used in place of the intervertebral disc to protect the test fixtures. Repeat the test in shear to a load of at least 1200 N while recording load and displacement. Repeat test in torsion to a torque of at least 3.5 Nm while recording torque and angular displacement.

8.2 The artificial intervertebral disc is then inserted between the two prepared metal blocks having the appropriate matching geometry of the artificial intervertebral disc (Fig. 5).

8.3 The load, *F*, and moment, M_z, are to be applied as described in Section 6 in position control at a rate no greater than 25 mm/min or 60 degrees/min (1.05 radians/min) until functional failure of the artificial intervertebral disc is obtained.

8.4 Physiological compressive preloads of 100, 300, and 500 N for cervical, thoracic, and lumbar artificial intervertebral

discs respectively are required for the static torsion test to ensure that the device under test remains engaged with the test blocks during testing. Other loads may be used with adequate justification.

8.5 Load and displacement or moment and angle data shall be recorded.

9. Procedure for Dynamic Tests

9.1 An artificial intervertebral disc is to be inserted between two prepared polyacetal blocks having the appropriate matching geometry of the artificial intervertebral disc (Fig. 5). The initial intervertebral height, *H*, shall be constant for all tests for an artificial intervertebral disc of a given size.

9.2 Load, *F*, and moment, *M*, are to be applied as described in Section 6 in load control. The varying load as determined by suitable dynamic verification should be maintained at all times to within ±2 % of the largest moment or compressive force used. The user of these test methods should select the necessary loads to develop a well-defined load-cycle to failure plot comprised of a minimum of 6 data points, two of which must be runout points. Suggested maximum loads for initial dynamic tests are 25 %, 50 % and 75 % of the maximum load applied during static testing. The end of the test is defined as functional failure of the construct or attainment of 10 000 000 cycles without functional failure. However, any mechanical deterioration should be noted at the 10 000 000-cycle point (for example, surface wear, crack initiation, crack propagation, and so forth).

9.3 An *R*-value of 10 shall be used for the axial compression and compression-shear tests, and an *R*-value of -1 shall be used for the torsional testing.

9.4 The frequency of the dynamic test shall be determined by the user of these test methods and recorded (see X1.6).

9.5 The intervertebral disc height shall be recorded approximately once every two million cycles during the fatigue tests.

10. Analysis

10.1 *Static Test Analyses:*

10.1.1 Using a least-squares best fit linear approximation, determine the slope of the load-displacement curve between 500 and 1000 N for the solid steel test device. This value is reported as the axial fixture stiffness, K_f. Repeat this calculation for the shear test and torsion test for the region between 500 and 1000 N and 1 and 3 Nm, respectively.

10.1.2 Calculate and report the device axial and torsional stiffness as follows:

$$K_d = \frac{K_s}{\left(1 - \frac{K_s}{K_f}\right)} \quad (1)$$

where:

K_f = fixture stiffness (N/mm or N·mm/deg) determined in 10.1.1,

K_s = system stiffness of device and fixtures (N/mm or N·mm/deg) in the linear region of the load-displacement curve, and

K_d = device stiffness (N/mm or N·mm/deg).

Repeat this calculation for each compression test sample and for each torsion test sample.

10.1.3 The yield displacement (axial—mm, angular—degrees or radians), stiffness (axial—N/mm, angular—N·mm/degree or N·mm/radian), yield load or moment (axial—N, angular—N·mm), ultimate displacement (axial—mm, angular—degrees or radians), and ultimate load or moment (axial—N, angular—N·mm) are to be established where applicable (for example, it may not be possible to establish the yield load for nonlinear load-displacement curves using the methods described). Use the offset methods for calculating yield loads and moments as defined in 3.2 and illustrated in Fig. 6. Likewise, select the ultimate loads and moments as defined in 3.2 and illustrated in Fig. 6.

10.2 *Dynamic Test Analyses:*

10.2.1 A regression analysis of the load or moment versus number of cycles to failure data should be reported per Practice E468. A semi-log fatigue graph of maximum applied load, *F*, or moment, M_z, versus the number of cycles to failure is to be plotted and a regression analysis shall be conducted on the load or moment versus number of cycles to failure data.

10.2.2 The maximum runout load is to be determined. The precision in establishing the maximum runout load should not deviate more than 10 % of the ultimate failure load or moment of the artificial intervertebral disc.

11. Report

11.1 The report shall specify the artificial intervertebral disc components, the artificial intervertebral disc, the intended spinal location, and the numbers of specimens tested. Any pertinent information about the components such as name, design, manufacturer, material, part number, lot number, and size shall also be reported. All information necessary to reproduce the assembly shall also be included.

11.2 Exact loading configurations for the testing apparatus shall be included. All deviations (with adequate justification) from the recommended test procedures shall be reported, and all relevant testing parameters, such as test environment, shall be reported. Rationale for testing configurations not utilized shall also be reported.

11.3 The report of the static mechanical testing shall include a complete description of all functional failures, modes of failure, signs of mechanical deterioration, and permanent deformation of the artificial intervertebral disc or test apparatus. The static mechanical test report shall include the following:

11.3.1 All load-displacement curves are to be included in an appendix. These curves should illustrate the pertinent static data. All static test data, including the mean and standard deviation will be reported for yield displacement (axial—mm, angular—degrees or radians), yield load or moment (axial—N, angular—N·mm), stiffness (axial—N/mm, angular—N·mm/degree or N·mm/radian), ultimate displacement (axial—mm, angular—degrees or radians), and ultimate load or moment (axial—N or angular—N·mm).

11.4 The report on the dynamic testing shall include the following:

11.4.1 Details regarding fatigue test specimens, procedures, and results shall be reported in accordance with Practice E468. The highest load level at which two or more specimens endured 10 000 000 cycles and no functional failure were observed should be denoted as the maximum runout load or moment.

11.4.2 All mechanical damage including initial and secondary failures, permanent deformations, wear, or loosening of components should be reported for the artificial intervertebral disc. In addition, the testing environment (medium and temperature) and intervertebral height as a function of load level and cycle count should be reported. Any other noteworthy observations such as the ability of the device to perform a range of motion activity should be included.

12. Precision and Bias

12.1 *Precision*—Data establishing the precision of these test methods have not yet been obtained.

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

13. Keywords

13.1 artificial intervertebral disc; dynamic test methods; spinal implants; static test methods

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Artificial intervertebral discs are manufactured in a variety of sizes, materials, and shapes with various design features. The purpose of these test methods is to allow for a consistent, repeatable comparison of different artificial intervertebral discs through a series of mechanical tests.

X1.2 All of the spinal implants that fall into the category of artificial intervertebral discs are intended for the purpose of disc replacement. All of the implants may reside in the disc space with varied orientations and methods of fixation to the adjacent vertebral bodies. These test methods will allow for comparison of these devices since the methods and loading configuration remains consistent regardless of method of application. Biologic disc replacements and nucleus replacements are excluded from the scope of these test methods since biologic structures that share the *in vivo* loads vary among designs, making total disc test methods inappropriate.

X1.3 The proposed test configurations are based on anatomical dimensions.

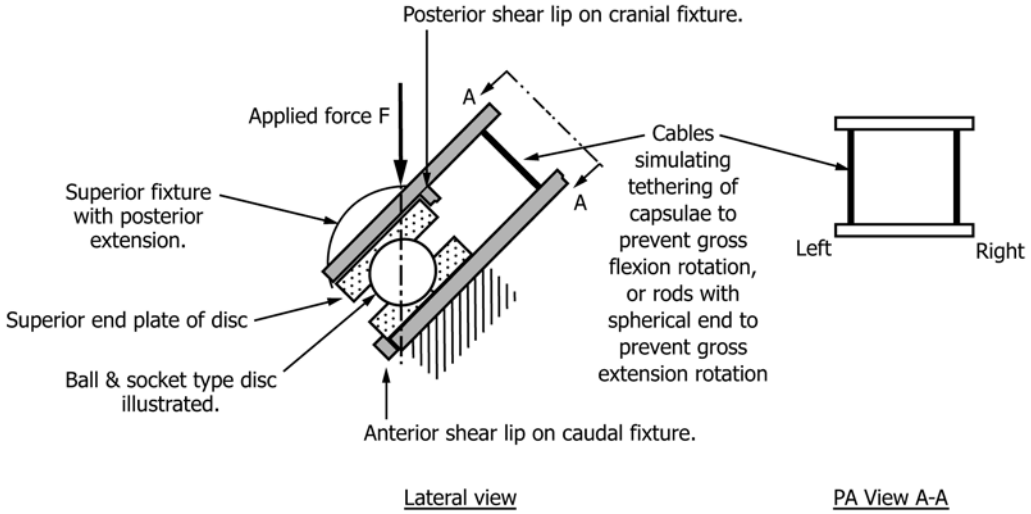
X1.4 Polyacetal blocks are used to simulate the mechanical properties of the vertebral bodies in dynamic testing. Metallic blocks are used for the static testing of artificial intervertebral discs so that the stiffness measurements reflect that of the intervertebral device itself.

X1.5 Since one purpose of an artificial intervertebral disc is long-term restoration of function, the maximum runout load or moment at 10 000 000 cycles is to be determined. This may not be the endurance limit for some designs, but it has been selected to establish a practical *in vitro* test duration. The maximum runout load or moment should be compared to expected clinical loads. The runout cycle count of 10 000 000 cycles has been selected to establish the endurance limit of most designs. It may be desirable to acquire fatigue data for certain intervertebral disc designs beyond 10 000 000 cycles.

X1.6 Frequencies over 10 Hz may result in heating and subsequent softening of the test blocks or a change in behavior of the device under test due to the temperature rise. Since this phenomenon is device and environment specific, the user of these test methods is left to discern an appropriate cyclic frequency. For reference, the physiologic range of frequencies is noted to be typically between 0.1 and 8.0 Hz.

X1.7 In the case where it is desired to perform compression/shear tests for an intervertebral disc prosthesis that does not allow use of the fixture illustrated in Fig. 3, alternatives are allowed with justification. One example is illustrated in Fig. X1.1.

X1.8 The purpose of these test methods is to allow for the comparison of different artificial intervertebral discs and does not attempt to dictate performance standards for these types of devices since *in vivo* spinal loading is complex, variable, and dependent on the level of patient activity.



NOTE 1—A) Simulated tethering by capsulae required to stabilize superior fixture-endplate fixation rotation
NOTE 2—B) Shear lips to transfer shear load to disc if interface between disc endplates and fixtures is insufficient

FIG. X1.1 Schematic of Compression-Shear Testing Apparatus