



Designation: F2346 – 05

Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs¹

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

3.1.1 *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.

3.1.2 *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 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

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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.

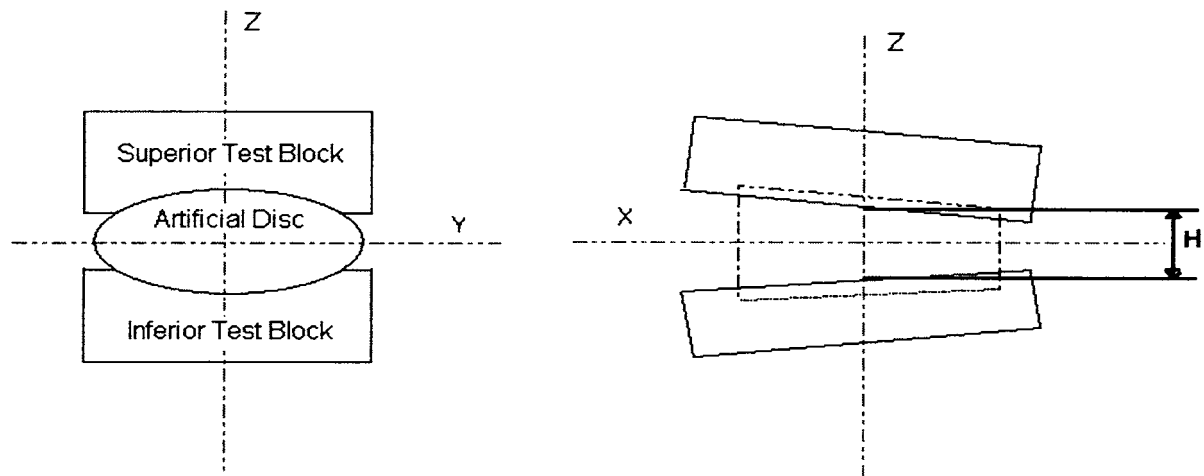


FIG. 1 Intervertebral Height Diagram

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.

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

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

3.1.5 *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.

3.1.6 *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.

3.1.7 *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.

3.1.8 *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 Nissan, M., Gilad, I., “The Cervical and Lumbar Vertebrae—An Anthropometric Model,” *Engineering In Medicine*, 13:3, 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*, 21:4, 1999, pp. 235-239.

3.1.9 *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).

3.1.10 *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.

3.1.11 *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).

3.1.12 *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 $OB = (0.02) (10 \text{ mm}) / (9 \text{ mm}) = 0.022 \text{ radians} = 1.3^\circ$.

3.1.13 *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).

3.1.14 *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.

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

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

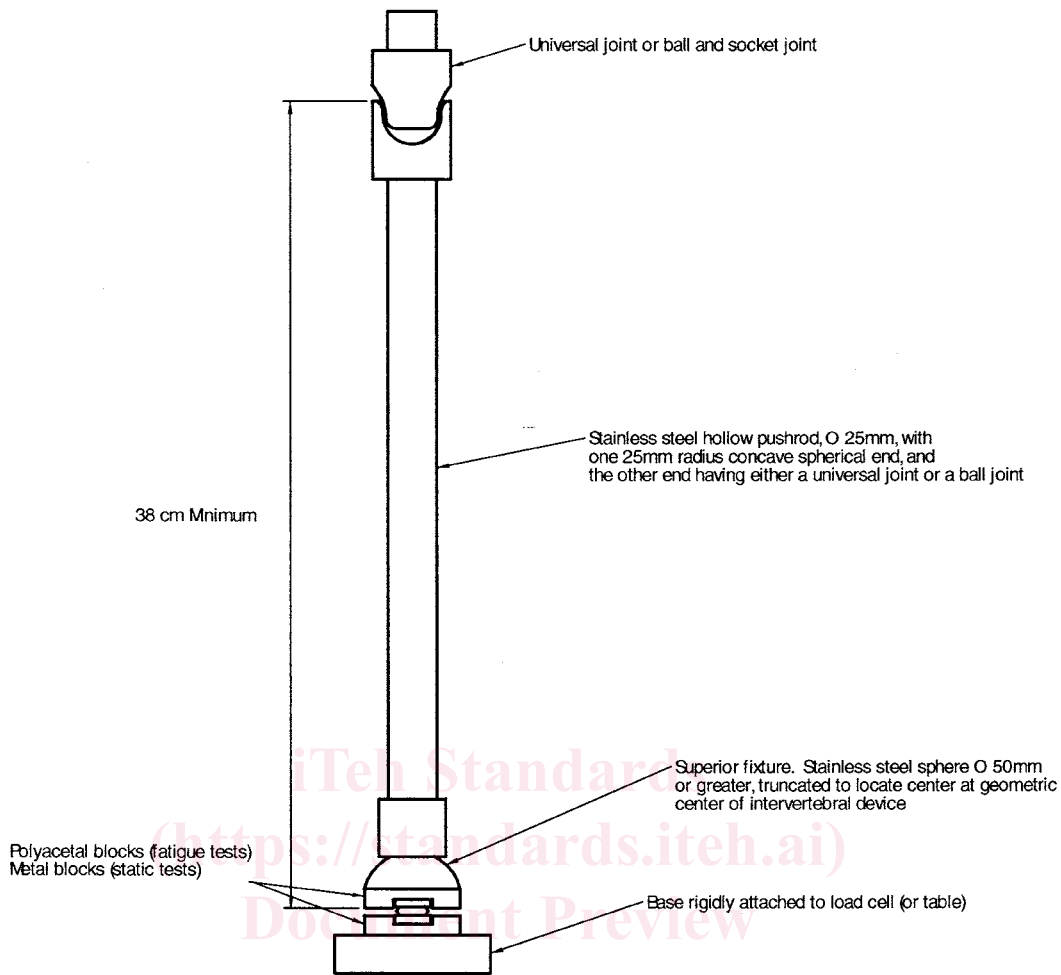


FIG. 2 Compression Testing Configuration

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3.1.17 *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.

3.1.18 *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.

3.1.19 *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.

3.1.20 *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 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.

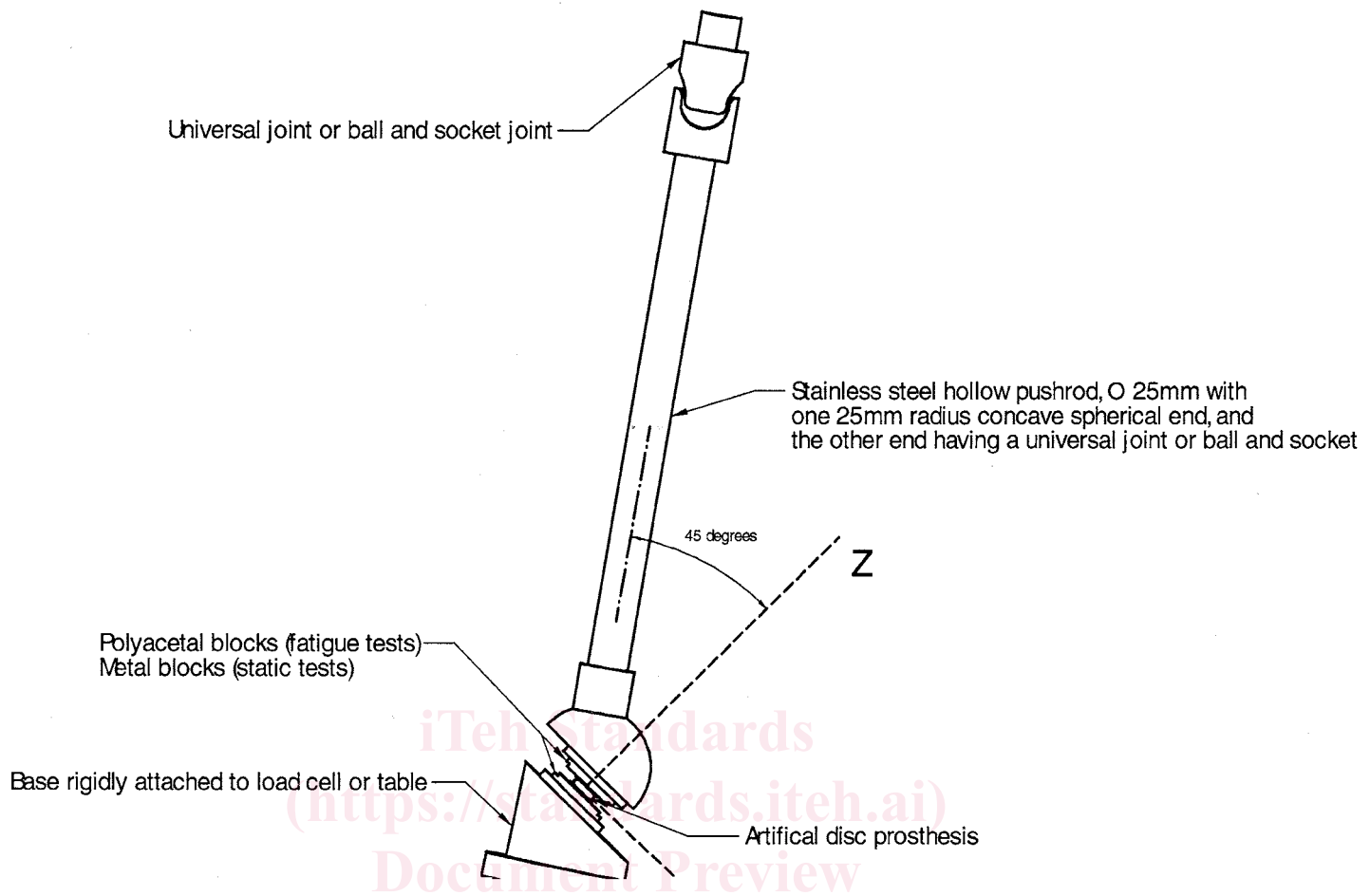


FIG. 3 Compression/Shear Testing Configuration

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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.

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 necessary to assess the influence of test frequency on device

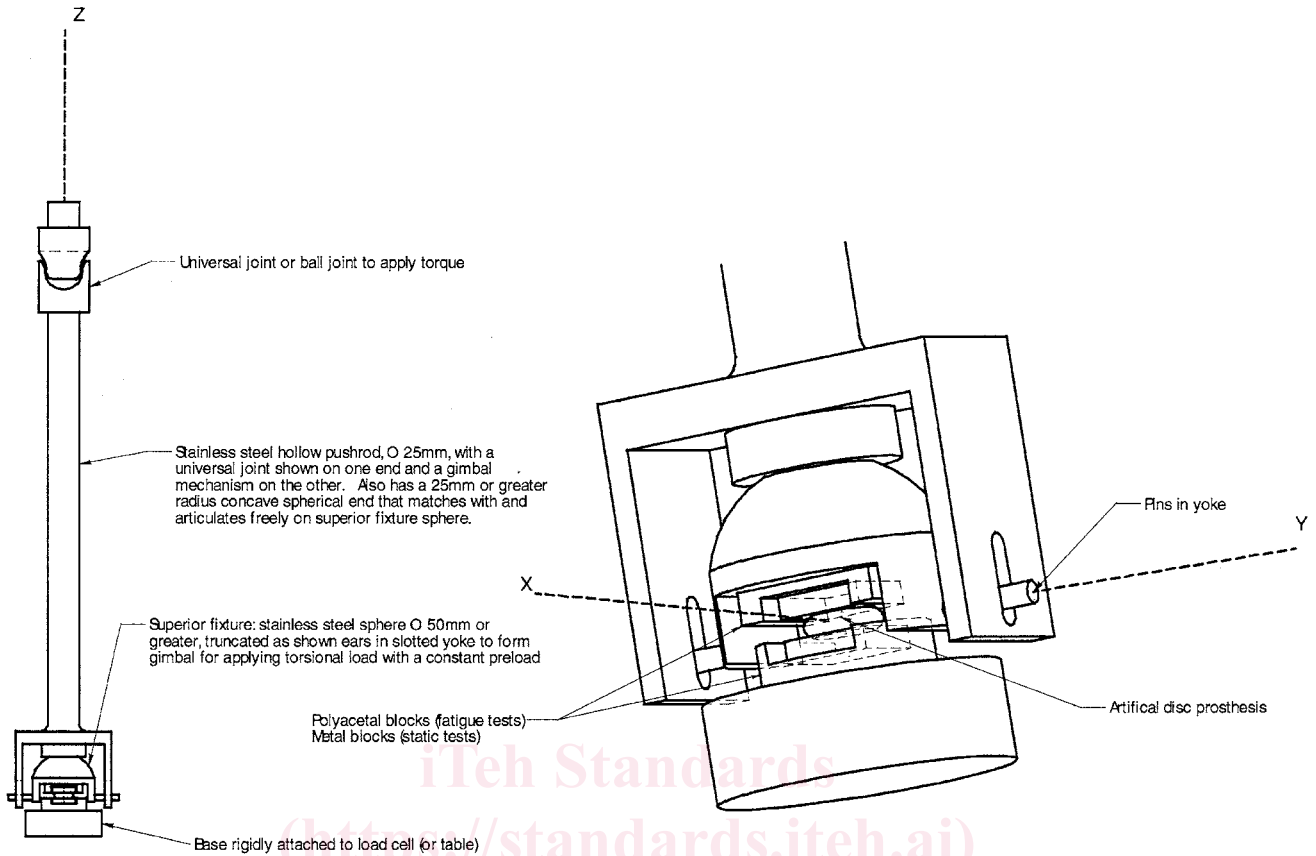


FIG. 4 Torsion Testing Configuration with a Pin-Slot Gimbal

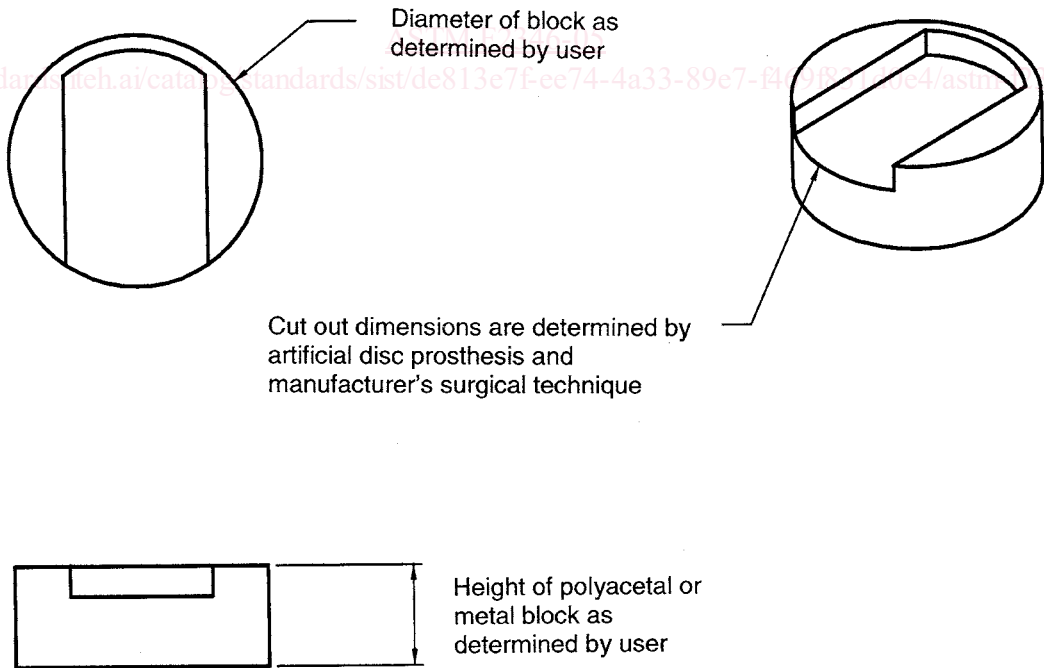


FIG. 5 Polyacetal or Metal Test Block

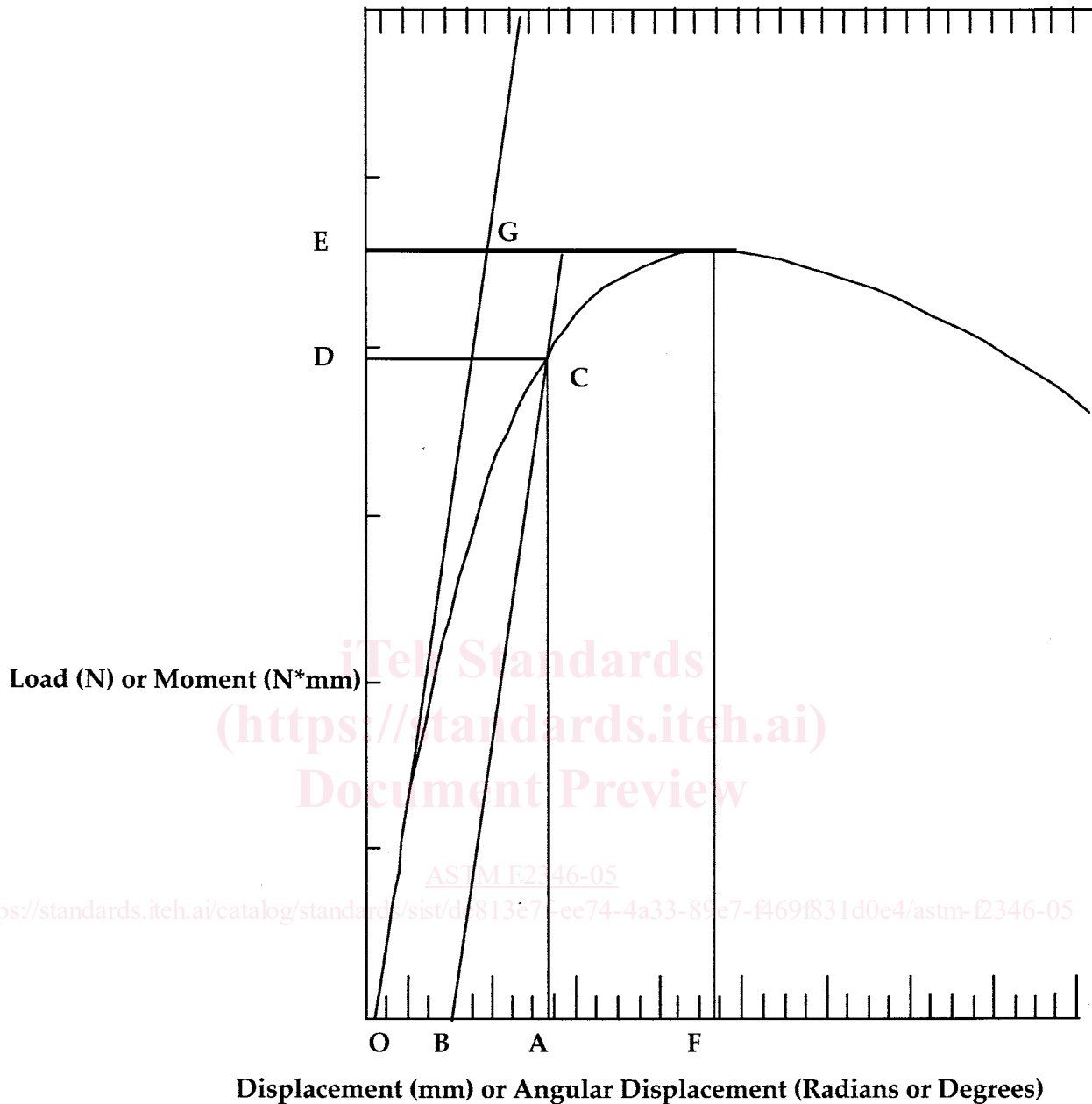


FIG. 6 Typical Load Displacement Curve

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