



Test Methods For Intervertebral Body Fusion Devices¹

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1. Scope

1.1 This test method covers the materials and methods for the static and dynamic testing of intervertebral body fusion device assemblies, spinal implants designed to promote arthrodesis at a given spinal motion segment.

1.2 This test method is intended to provide a basis for the mechanical comparison among past, present, and future non-biologic intervertebral body fusion device assemblies. This test method allows comparison of intervertebral body fusion device assemblies with different intended spinal locations and methods of application to the intradiscal spaces. This test method is intended to enable the user to compare intervertebral body fusion device assemblies mechanically and does not purport to provide performance standards for intervertebral body fusion device assemblies.

1.3 The test method describes static and dynamic tests by specifying force types and specific methods of applying these forces. These tests are designed to allow for the comparative evaluation of intervertebral body fusion device assemblies.

1.4 These tests are designed to characterize the structural integrity of the device and are not intended to test the bone-implant interface.

1.5 This test method does not address expulsion testing of intervertebral body fusion device assemblies (see 1.4).

1.6 Guidelines are established for measuring displacements, determining the yield force or moment, evaluating the stiffness, and strength of the intervertebral body fusion device assemblies.

1.7 Some intervertebral body fusion device assemblies may not be testable in all test configurations.

1.8 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard, with the exception of angular measurements, which may be reported in terms of either degrees or radians.

1.9 *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
- E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
- E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
- E1823 Terminology Relating to Fatigue and Fracture Testing
- E2309 Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines
- F1582 Terminology Relating to Spinal Implants

3. Terminology

3.1 For definition of terms refer to Terminology E6, E1823, and F1582.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *coordinate system/axes, n*—Three orthogonal axes are defined by Terminology F1582. The center of the coordinate system is located at the geometric center of the intervertebral body fusion device assembly. The *XY* plane is to bisect the sagittal plane angle between superior and inferior lines (surfaces) that are intended to simulate the adjacent vertebral end plates. The positive *Z* axis is to be directed superiorly. 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 force is defined to be the component of moment parallel to the *Z* axis.

3.2.2 *crack, n*—an externally visible physical discontinuity in the form of a narrow opening that arises from mechanical forces.

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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.

3.2.3 *fatigue life, n*—the number of cycles, N , that the intervertebral body fusion device assembly can sustain at a particular force or moment before mechanical or functional failure occurs.

3.2.4 *functional failure, n*—permanent deformation that renders the intervertebral body fusion device assembly ineffective or unable to resist force and/or maintain attachment adequately.

3.2.5 *ideal insertion location, n*—the implant location with respect to the simulated inferior and superior vertebral bodies (polyacetal or metal blocks) dictated by the type, design, and manufacturer’s surgical installation instructions.

3.2.6 *intended method of application, n*—intervertebral body fusion device assemblies may contain different types of stabilizing anchors such as threads, spikes, and knurled surfaces. Each type of anchor has an intended method of application or attachment to the spine.

3.2.7 *intended spinal location, n*—the anatomic region of the spine intended for the intervertebral body fusion device assembly. Intervertebral body fusion device assemblies may be designed and developed for specific regions of the spine such as the lumbar, thoracic, and cervical spine. Also, there exists different anatomical potential surgical approaches, which will result in different implant orientation at different levels of the spine.

3.2.8 *intervertebral body fusion device, n*—a structure (biologic or synthetic) that is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodesis of the two adjacent vertebral bodies.

3.2.9 *intradiscal height, n*—the straight-line distance along the Z axis between the unaltered simulated vertebral bodies—minimum height of 4 mm and a maximum height of 18 mm. See Fig. 1.

3.2.10 *force point, n*—the point through which the resultant force on the intervertebral device passes (that is, the geometric center of the superior fixture’s sphere) (Figs. 2-5).

3.2.11 *maximum run out force or moment, n*—the maximum force or moment for a given test that can be applied to an intervertebral body fusion device assembly in which all of the tested constructs have withstood 5 000 000 cycles without functional or mechanical failure.

3.2.12 *mechanical failure, n*—that associated with the onset of a new defect in the material (that is, initiation of fatigue crack).

3.2.13 *offset angular displacement, n*—(Distance OB—Fig. 6)—offset on the angular displacement axis equal to 10 % of the intradiscal height, H , divided by the outside diameter or height of the implant (maximum dimension of implant in XZ plane if not cylindrical) (for example, for a 10-mm intradiscal height and 16-mm intervertebral body fusion device assembly, distance $OB = 10 \text{ mm}/16 \text{ mm} (0.10)(180^\circ)/\pi = 3.6^\circ$).

3.2.14 *offset displacement, n*—(Distance OB—Fig. 6)—offset on the displacement axis equal to 2 % of the intradiscal height (that is, 0.2 mm for a 10-mm intradiscal height).

3.2.15 *permanent deformation, n*—the remaining displacement (mm or degrees or radians) relative to the initial unloaded condition of the intervertebral body fusion device assembly after the applied force has been removed.

3.2.16 *stiffness (N/mm or N*mm/Degree (Radian)) (The Slope of Line OG—Fig. 6), n*—the slope of the initial linear portion of the force-displacement curve or the slope of the initial linear portion of the moment—angular displacement curve.

3.2.17 *test block, n*—the component of the test apparatus for mounting the intervertebral body fusion device assembly for the intended test configuration.

3.2.18 *ultimate displacement (mm or degrees or radians) (Displacement OF—Fig. 6), n*—the displacement associated with the ultimate force or ultimate moment.

3.2.19 *ultimate force or moment (N or N*mm) (Point E—Fig. 6), n*—the maximum applied force, F , transmitted by the pushrod (assumed equal to force component parallel to and indicated by load cell), or the applied moment about the Z axis that can be applied to an intervertebral body fusion device assembly.

3.2.20 *yield displacement (Distance OA—Fig. 6), n*—the displacement (mm) or angular displacement (deg) when an interbody fusion device assembly has a permanent deformation equal to the offset displacement or the offset angular displacement.

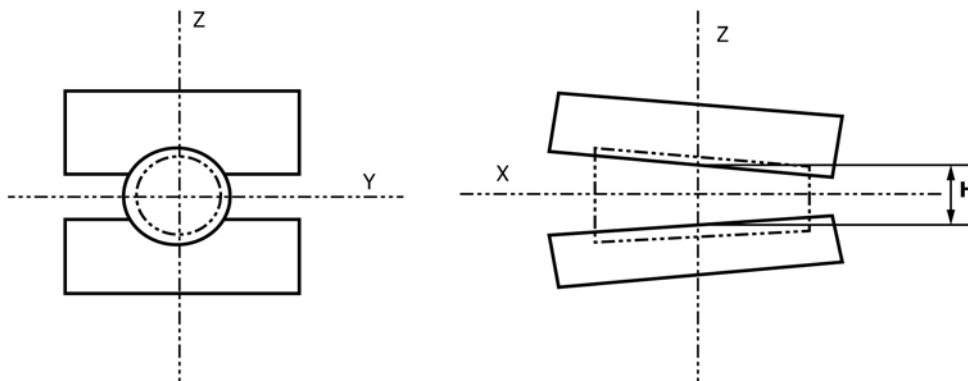


FIG. 1 Intradiscal Height Diagram

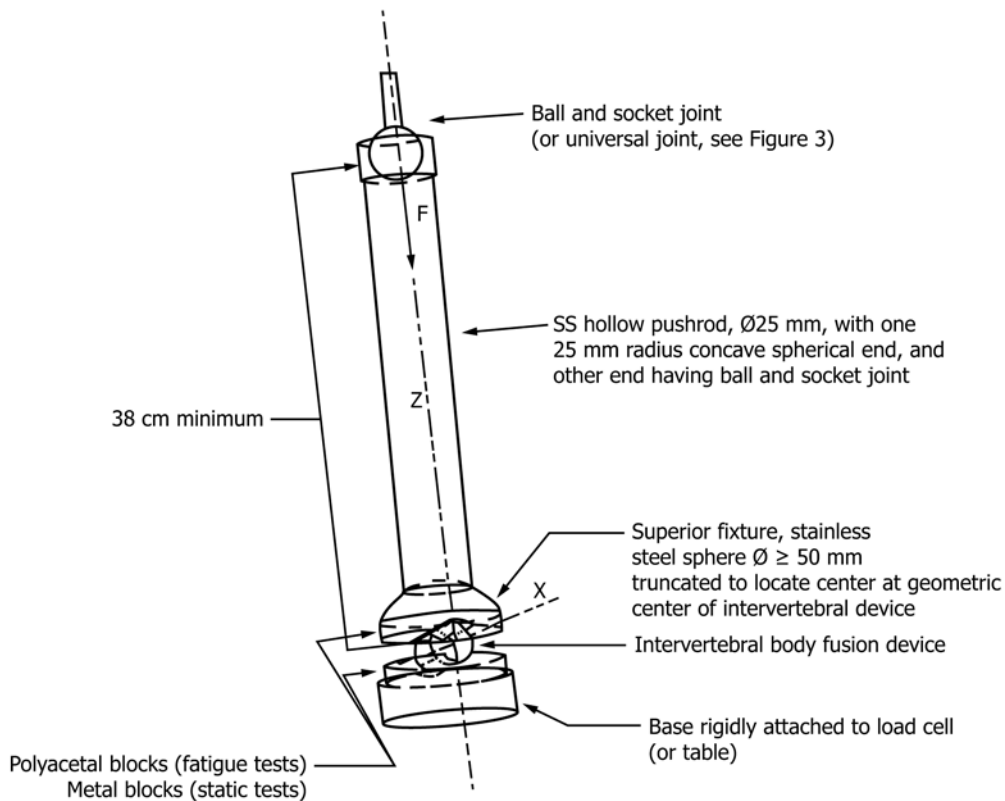


FIG. 2 Compression Testing Configuration

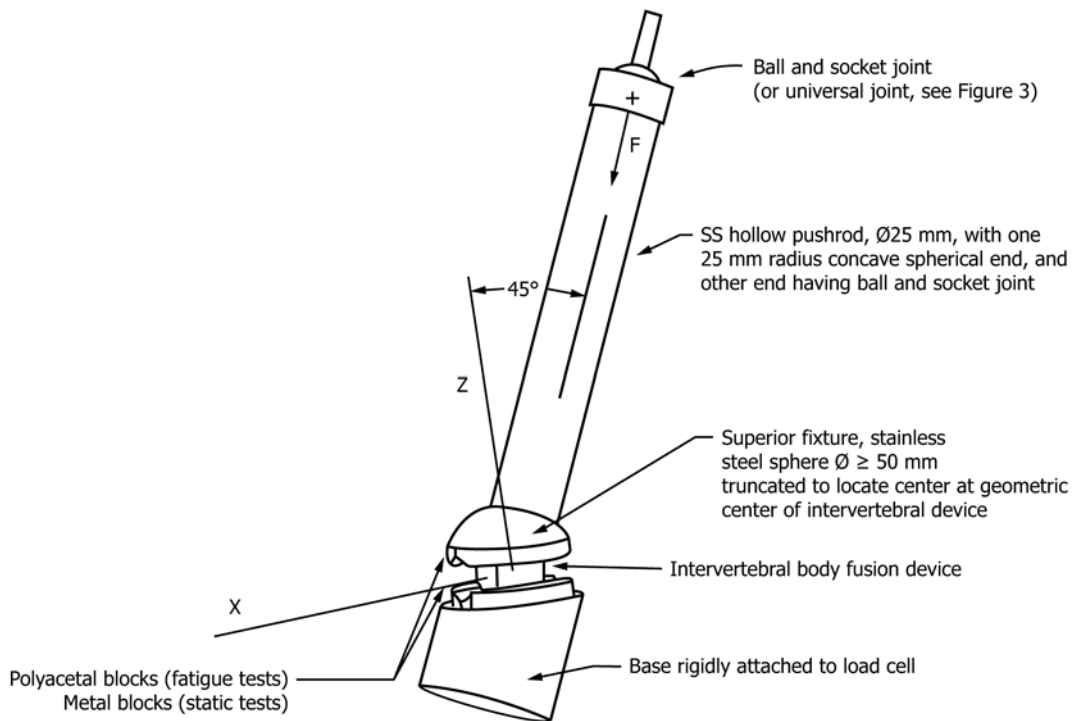


FIG. 3 Compression-Shear Testing Configuration

3.2.21 yield force or moment (Point D—Fig. 6), n —the applied force, F , transmitted by the pushrod (assumed equal to force component parallel to and indicated by load cell), or the

applied moment about the Z axis required to produce a permanent deformation equal to the offset displacement or the offset angular displacement.