Designation: F3574 – 22

Standard Test Methods for Sacroiliac Joint Fusion Devices[1]

This standard is issued under the fixed designation F3574; 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 cover the materials and methods for the static and dynamic testing of sacroiliac joint (SIJ) fusion device assemblies, SIJ implants designed to promote arthrodesis at the sacroiliac joint.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future nonbiologic SIJ fusion device assemblies. These test methods allow for comparison of SIJ fusion device assemblies intended to be implanted with a trajectory in line with the joint space (in-line implant) or for comparison of SIJ fusion devices intended for implantation across the joint space (transverse implant). These test methods are intended enable the user to compare SIJ fusion device assemblies mechanically and do not purport to provide performance standards for SIJ fusion device assemblies.

1.3 These tests describe 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 SIJ device assemblies.

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

1.5 Some SIJ fusion device assemblies may not be testable in all test configurations.

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

1.7 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Calibration and Verification of Testing Machines

E6 Terminology Relating to Methods of Mechanical Testing

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E1823 Terminology Relating to Fatigue and Fracture Testing

E2309/E2309M Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines

F543 Specification and Test Methods for Metallic Medical Bone Screws

F1582 Terminology Relating to Spinal Implants

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

F2077 Test Methods For Intervertebral Body Fusion Devices

F2193 Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

3. Terminology

3.1 For definitions of terms, refer to Terminologies E6, E1823, and F1582, and the Terminology section in Specifications F543 and F2193.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *axial pullout strength, n*—the maximum tensile force per Annex A2 required to fail or remove a transverse sacroiliac joint fusion implant from a material into which the device has been inserted.

3.2.2 *bending fatigue runout moment (N-m), n*—value of the maximum moment under dynamic cantilever bending per

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are 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.

Annex A2 that can be applied to a transverse sacroiliac joint fusion implant where all the tested specimens have experienced 2 500 000 loading cycles without a failure at a specific R-ratio.

3.2.3 *bending moment arm, L (mm), n*—distance in mm between the point where a transverse sacroiliac joint fusion implant test specimen is gripped (typically the axis of the longitudinal element) and the line of action for the applied force in cantilever bending per Annex A2 prior to any deformation of the assembly.

3.2.4 *bending stiffness, S (N/mm), n*—slope of the initial linear elastic portion of the load versus total displacement curve (slope of Line *Om* in Fig. A1.3) for static cantilever bending of a transverse sacroiliac joint fusion implant.

3.2.5 *bending ultimate moment (N-m), n*—maximum bending moment in static cantilever bending that can be applied to a transverse sacroiliac joint fusion implant test sample; Point *E* in Fig. A1.3.

3.2.6 *bending yield moment (N-m), n*—bending moment in static cantilever bending necessary to produce a 0.2 % offset displacement in the transverse sacroiliac joint fusion implant. If the specimen fractures before the test reaches the 0.2 % offset displacement point, the bending moment shall be defined as the bending moment at fracture.

3.2.7 *coordinate system/axes (in-line implants), n*—three orthogonal axes for an in-line SIJ fusion implant are defined in terms of the joint space and the implant design (Figs. 1-4). The origin of the in-line SIJ coordinate system is located at the geometric center of the device assembly. The X-axis corresponds to the trajectory of the implant. The Y-axis passes tangentially through the joint space. The Z-axis passes normal to the joint space. The XY plane is to bisect the joint space between iliac (lateral) and sacral (medial) surfaces. Force components parallel to the XY plane are shear components of loading. Torsional force is defined to be the component of moment about the Z-axis.

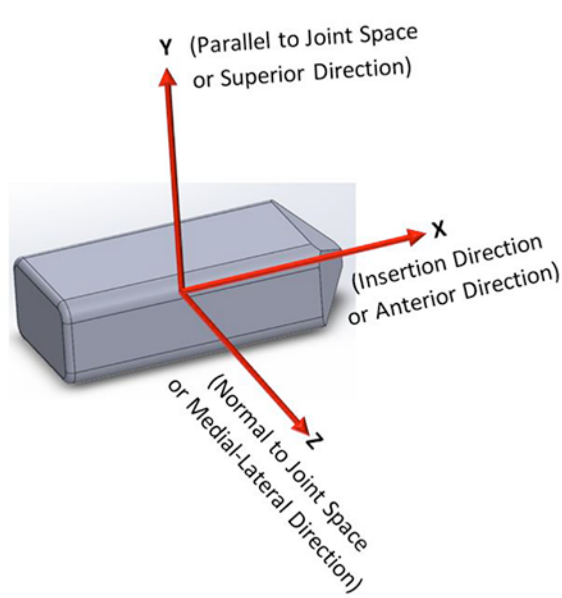


FIG. 1 Orthogonal Coordinate System for Testing of an In-Line SIJ Fusion Implant

3.2.8 *coordinate system/axes (transverse implants), n*—three orthogonal axes for a transverse SIJ fusion implant are defined in terms of the implant design and the joint space (Fig. 5). The origin of the transverse SIJ coordinate system is located at the geometric center of the device assembly. The X-axis corresponds to the long axis of the implant in the direction of trajectory. The Y passes in the superior-inferior direction through a plane parallel to the plane tangential to the joint space. The Z-axis is the resultant axis dependent on the implant trajectory. Torsional force is defined to be the component of moment about the X-axis.

3.2.9 *core diameter, n*—the smallest diameter of the threaded portion of a threaded transverse sacroiliac joint fusion implant measured at the thread root. This is also known as the minor diameter.

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

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

3.2.12 *force point, n*—the point through which the resultant force on the SIJ device passes.

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

3.2.14 *gauge length, n*—the distance between the holding device (for example, a split collet) and the underside of the head for a transverse sacroiliac joint fusion implant in torsional testing.

3.2.15 *grip length, n*—the number of threads held fast in the split collet or holding mechanism during torsional testing of a transverse sacroiliac joint fusion implant.

3.2.16 *ideal insertion location, n*—the implant location with respect to the simulated ilium (lateral) and sacrum (medial) articulating surfaces (bone cement) dictated by the type, design, and manufacturer's surgical installation instructions.

3.2.17 *in-line implant, n*—a device intended to be implanted with a trajectory primarily within the sacroiliac joint space (Figs. 1-4); this kind of device may have integrated fixation (that is, screws, blades) into the sacrum and ilium.

3.2.18 *insertion depth, n*—the length of a transverse sacroiliac joint fusion implant that is inserted into the test block for axial pullout testing.

3.2.19 *intended method of application, n*—SIJ 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 sacral and iliac bones.

3.2.20 *intended SIJ location, n*—the anatomic region of the sacroiliac joint intended for the SIJ fusion device assembly. SIJ fusion device assemblies may be designed and developed for specific anatomical regions such as primarily within the joint space or across the joint space. Also, there exist different

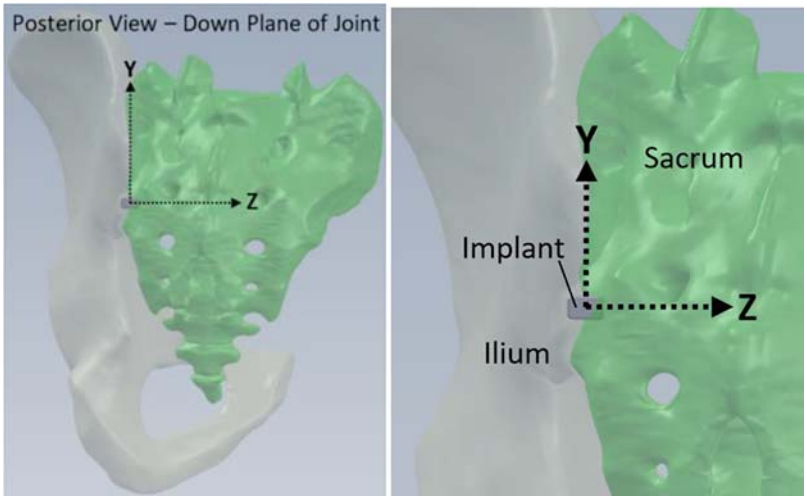


FIG. 2 Orthogonal Coordinate System for In-Line SIJ Fusion Implant Showing Possible Placement Within the SI Joint (posterior perspective)

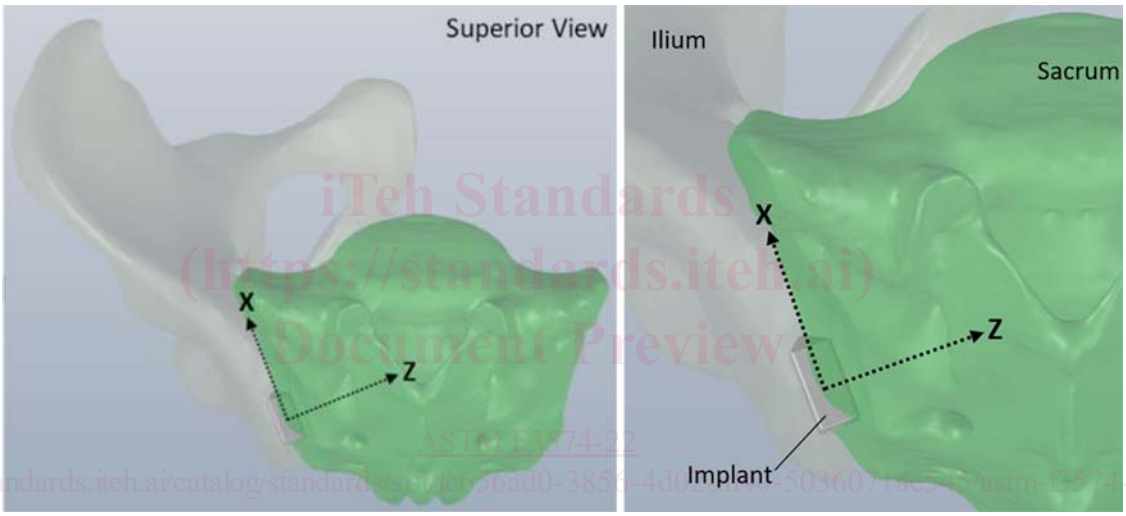


FIG. 3 Orthogonal Coordinate System for In-Line SIJ Fusion Implant Showing Possible Placement Within the SI Joint (superior perspective)

surgical approaches relative to anatomy, which result in different implant orientations.

3.2.21 *intra-joint space (G), n*—the gap between the sacrum and ilium; the straight-line distance along the Z-axis between the unaltered simulated articulating surfaces. The intra-joint space for testing of in-line implants will be 4 mm.

3.2.21.1 *Discussion*—Stallmeyer and Zoarski[3] reported that the sacroiliac joint space is usually between 0.5 mm and 4 mm along a posteromedial-to-anterolateral plane.

3.2.22 *maximum runout force or moment, n*—the maximum force or moment for a given test that can be applied to an SIJ fusion device assembly in which all the tested constructs have withstood 2 500 000 cycles without functional or mechanical failure.

3.2.23 *maximum torque, n*—the largest value of torque recorded during the period of rotation before transverse sacroiliac joint fusion implant failure when tested in accordance with Annex A2.

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

3.2.25 *offset angular displacement, n*—distance *OB* in Fig. A1.3; offset on the angular displacement axis equal to 10 % of intra-joint space (*G*), divided by the outside diameter or width of the in-line implant (maximum dimension of implant in the YZ plane) (for example, for the 4 mm intra-joint space and a 10 mm (medial-lateral dimension) wide in-line fusion device assembly, distance *OB* = (4 mm / 10 mm)*(0.1)*(180°/π) = 2.3°).

3.2.26 *offset displacement, n*—distance *OB* in Fig. A1.3; offset on the displacement axis equal to 2 % of the intra-joint space (for example, 0.08 mm for the 4 mm gap).

[3] Stallmeyer, M. and Zoarski, G. H., "Sacroiliac Joint Injection," in *Image-Guided Spine Interventions*, Johnson, B. A., Staats, P. S., Wetzel, F. T. and Matthis, J. M., Eds., New York, Springer, 2004, pp. 234–244.

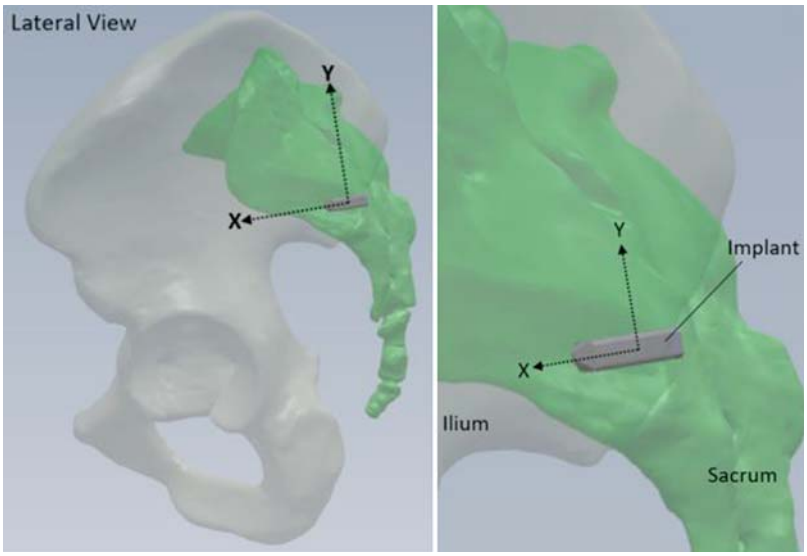
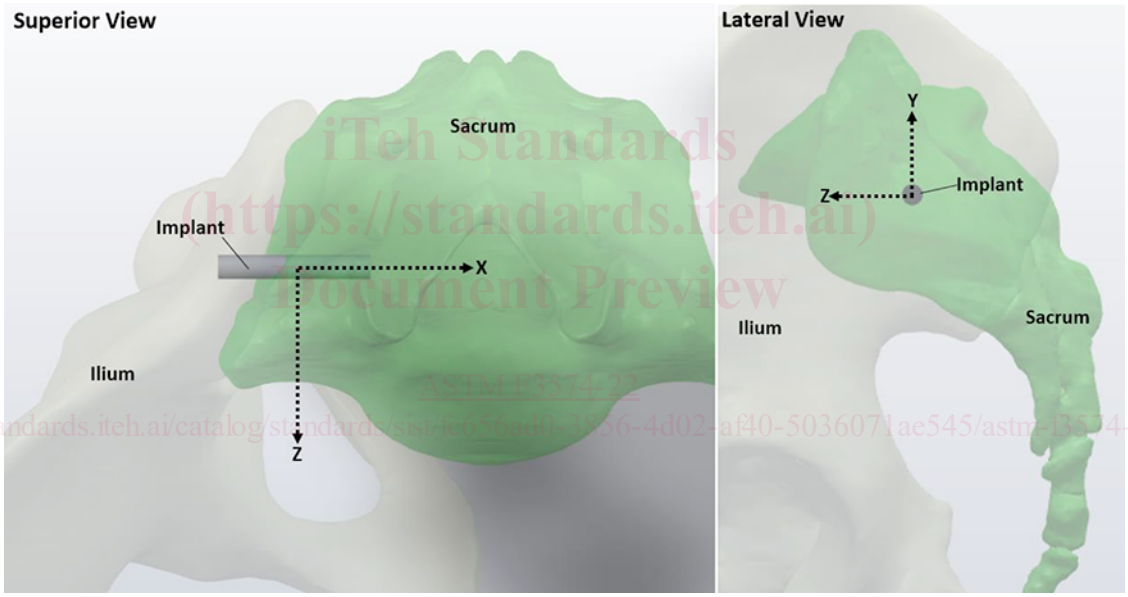


FIG. 4 Orthogonal Coordinate System for In-Line SIJ Fusion Implant Showing Possible Placement Within the SI Joint (lateral perspective)



NOTE 1—Sacroiliac joint fusion screws are typically implanted in pairs or in sets of three.

FIG. 5 Orthogonal Coordinate System for Transverse SIJ Fusion Implant Showing Possible Placement Within the SI Joint (the example shown has a lateral approach, but the surgical approach for transverse implants may be lateral or posterior)

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

3.2.28 *pilot hole, n*—the hole drilled into the bone (or test block) into which a transverse sacroiliac joint fusion implant tip is inserted. The pilot hole is normally slightly larger than implant's core diameter.

3.2.29 *sacroiliac joint (SIJ) fusion device, n*—a structure (biologic or synthetic) that is placed in or across the joint space to provide support for eventual arthrodesis of the joint.

3.2.30 *stiffness (N/mm or N*mm/degree (radian)), n*—slope of Line *Om* in Fig. A1.3 or slope of Line *OA* in Fig. A2.5; 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.

3.2.31 *test block, n*—the component of the test apparatus for mounting the SIJ fusion device assembly for the intended test configuration.

3.2.32 *torsional yield strength (N-m), n*—the point at which the transverse sacroiliac joint fusion implant reaches its proportional limit when tested in accordance with Annex A2. This will be determined by the offset method. A 2° offset value shall be used.

3.2.33 *transverse implant, n*—a device intended to be implanted with a trajectory across the sacroiliac joint by being implanted first into the iliac or sacral bone, subsequently through the joint space, and finally into the opposite (sacral or iliac bone) (Fig. 5); this type of device may be implanted from a lateral approach or a posterior approach, but will be inserted through one of the articulating bones and extend into the other articulating bone. A screw design is common for transverse implants. Note: sacroiliac joint fusion screws are typically implanted in pairs or in sets of three.

3.2.34 *ultimate displacement (mm or degrees or radians), n*—displacement *OF* in Fig. A1.3; the displacement associated with the ultimate force or ultimate moment.

3.2.35 *ultimate force or moment (N or N*mm), n*—point *E* in Fig. A1.3; the maximum applied force, *F*, transmitted by the test frame actuator or the applied moment, *M*, that can be applied during testing of a SIJ fusion device assembly.

3.2.36 *yield displacement, n*—distance *OA* in Fig. A1.3; the displacement (mm) or angular displacement (deg) when an SIJ fusion device assembly has a permanent deformation equal to the offset displacement or the offset angular displacement.

3.2.37 *yield force or moment (N or N*mm), n*—point *C* in Fig. A1.3 or Point *b* in Fig. A2.5; the applied force, *F*, transmitted by actuator, or the applied moment, *M*, required to produce a permanent deformation equal to the offset displacement or to the offset angular displacement.

4. Significance and Use

4.1 The function of the SIJ fusion device assembly is to stabilize the SIJ to facilitate arthrodesis of the motion segment. This test method outlines materials and methods for the characterization and evaluation of the mechanical performance of different SIJ fusion device assemblies so that comparisons can be made between different designs.

4.2 These test methods are designed to quantify the static and dynamic characteristics of different designs of SIJ fusion device assemblies. These tests are conducted in vitro to allow for analysis and comparison of the mechanical performance of SIJ fusion device assemblies to specific force modalities.

4.3 The forces applied to the SIJ fusion device assemblies during the tests described herein 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 SIJ fusion device assemblies.

4.4 Since the environment may affect the dynamic performance of SIJ fusion device assemblies, dynamic testing in a saline environment may be considered for implants with wearing surfaces or with movable components or for implants with components that are temperature dependent. Fatigue tests should first be conducted in air (at ambient temperature) for comparison purposes since the environmental effects could be significant. If a simulated in vivo environment is necessary, the investigator should consider testing in a saline environmental bath at 37 °C (for example, 0.9 g NaCl per 100 mL water). A simulated body fluid, a saline drip or mist, distilled water, or other type of lubrication at 37 °C could also be used with adequate justification.

4.5 If the devices are known to be temperature and environment dependent, testing should be conducted in physiologic solution as described in 4.4. Devices that require physiologic solution for testing should be tested in the same type of solution for comparison purposes.

4.6 The location within the simulated joint space and position of the SIJ fusion device assembly with respect to the loading axis will be dependent upon the design, the manufacturer's recommendation, or the surgeon's preferred method for implant placement.

4.7 It is well known that 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 must be kept constant to facilitate interpretation of results.

5. Keywords

5.1 dynamic test methods; sacroiliac joint (SIJ) fusion device; SIJ implants; static test methods

ANNEXES

(Mandatory Information)

A1. TEST METHODS FOR IN-LINE SACROILIAC FUSION IMPLANTS

A1.1 Summary of Test Methods

A1.1.1 These test methods are proposed for the mechanical testing of SIJ fusion device assemblies intended as posterior trajectory for implantation within the joint space (in-line implants). The test method for SIJ fusion device assemblies intended to cross the joint space (transverse implants) is described in Annex A2. These tests are designed to characterize the structural integrity of the device and are not intended to test the bone-implant interface.

A1.1.2 The implant is to be positioned in the test setup within test blocks with device-matched pockets such that the sacral and iliac sides of the implant are rigidly held and such that there is an intra-joint space of 4 mm to simulate the joint space (Figs. A1.1 and A1.2) which shall be held within test fixtures attached to the test frame table top and actuator. Material selection for test blocks should be according to the test block recommendations per Test Methods F2077.

A1.1.2.1 If stability cannot be maintained between the device and the test blocks during testing, the use of a potting medium in place of test blocks should be considered. Polymethyl methylcrylate (PMMA) is recommended as a potting medium; alternative potting materials such as metal-filled epoxies may be considered if a stronger potting material is necessary. The potting medium should have a modulus of elasticity between 2500 MPa and 6000 MPa. The potting medium should have a minimum thickness of 5 mm between the implant and the test fixtures on all sides of the implant. Note: testing data for devices assembled in test blocks might not be comparable to testing data for devices assembled in a potting medium.

A1.1.3 Static and fatigue testing of the SIJ fusion device assemblies will simulate a motion segment via a gap between the sacral and iliac sides of the implant.

A1.1.4 The test fixtures holding the test blocks and implant (or potted specimen) shall be manufactured from stainless steel or other suitably rigid material.

A1.1.5 Static and dynamic tests will evaluate the SIJ fusion device assembly. The user of this test method must decide which series of tests are applicable to the to the SIJ fusion device assembly in question. The user of this test method may choose to use all or a section of the tests described in this test method for testing a particular SIJ fusion device assembly.

A1.2 Significance and Use

A1.2.1 The function of the SIJ fusion device assembly is to support the SIJ joint space to facilitate arthrodesis of the motion segment. These test methods outline materials and methods for the characterization and evaluation of the mechanical performance of different SIJ fusion device assemblies so that comparisons in shear strength or torsional strength can be made between different designs.

A1.2.2 These test methods are designed to quantify the static and dynamic characteristics of different designs of SIJ

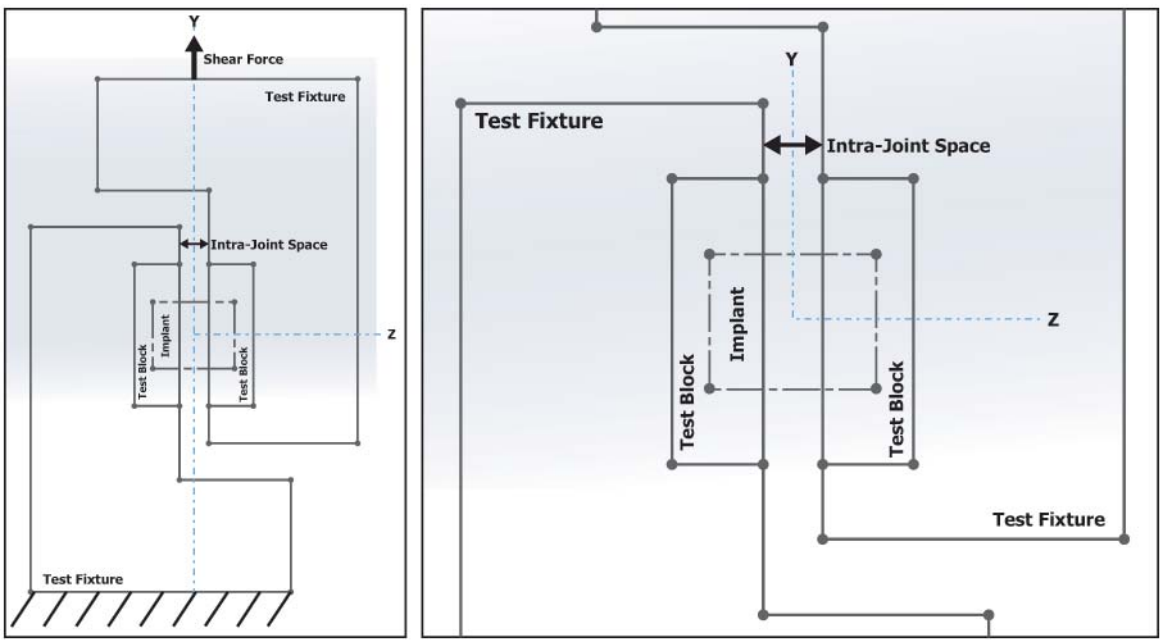


FIG. A1.1 Test Configuration for Shear

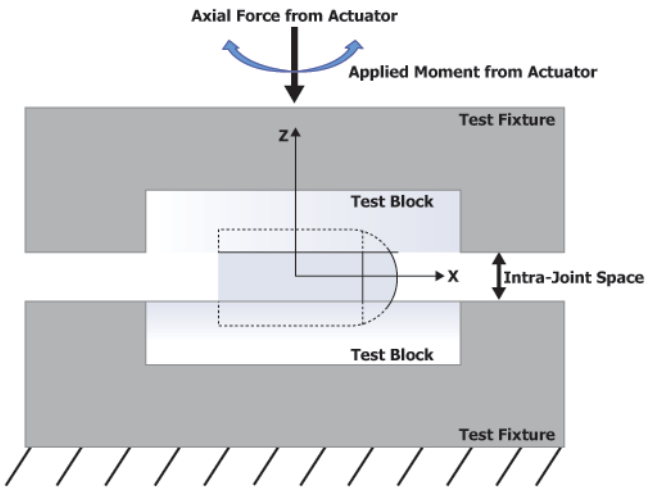


FIG. A1.2 Test Configuration for Torsion

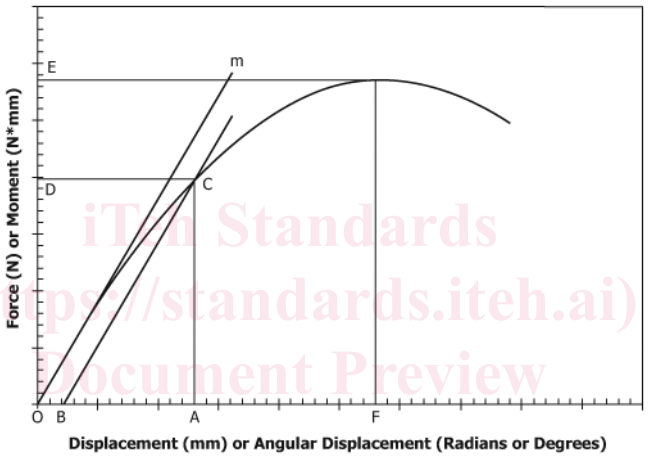


FIG. A1.3 Typical Force-Displacement Curve

fusion device assemblies implanted within the joint space. These tests are conducted in vitro to allow for analysis and comparison of the mechanical performance of SIJ fusion device assemblies to specific force modalities.

A1.2.3 The forces applied to the in-line SIJ fusion device assemblies 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 SIJ fusion device assemblies.

A1.2.4 Since the environment may affect the dynamic performance of SIJ fusion device assemblies, dynamic testing in a saline environment may be considered for implants with wearing surfaces or with movable components or for implants with components that are temperature dependent. Fatigue tests should first be conducted in air (at ambient temperature) for comparison purposes since the environmental effects could be significant. If a simulated in vivo environment is necessary, the investigator should consider testing in a saline environmental bath at 37 °C (for example, 0.9 g NaCl per 100 mL water). A simulated body fluid, a saline drip or mist, distilled water, or other type of lubrication at 37 °C could also be used with adequate justification.

A1.2.4.1 If the devices are known to be temperature and environment dependent, testing should be conducted in physiologic solution as described in A1.2.4. Devices that require physiologic solution for testing should be tested in the same type of solution for comparison purposes.

A1.2.5 The location within the simulated joint space and position of the SIJ fusion device assembly with respect to the loading axis will be dependent upon the design, the manufacturer's recommendation, or the surgeon's preferred method for implant placement.

A1.2.6 It is well known that 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 must be kept constant to facilitate interpretation of results.