Designation: ~~F1798 – 13~~ F1798 – 21

Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants[1]

This standard is issued under the fixed designation F1798; 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 This test method covers the measurement of uniaxial static and fatigue strength, and resistance to loosening of the component interconnection mechanisms of spinal arthrodesis implants.

1.2 The purpose of this test method is to provide a means of mechanically characterizing different designs of spinal implant interconnections. Ultimately, the various components and interconnections should be combined for static and fatigue testing of the spinal implant construct. It is not the intention of this test method to address the analysis of spinal implant constructs or subconstructs or to define levels of performance of spinal implants, as insufficient knowledge is available to predict the consequences of the use of particular spinal implant designs.

1.3 This ~~test method sets out definitions for use in measuring~~ standard defines test methods to measure the strength of ~~component interconnections of spinal implants, possible test methods themselves, and the reporting of~~spinal implant component interconnections and how to report test results.

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

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

1.6 *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

F383 Practice for Static Bend and Torsion Testing of Intramedullary Rods (Withdrawn 1996)[3]

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices ~~and~~ and is 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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

F1582F1717 Terminology Relating to Spinal ImplantsTest Methods for Spinal Implant Constructs in a Vertebrectomy Model

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *active length of longitudinal element*—the span between rigid supports (for example, 50 mm is the active length in Fig. 1, Fig. 2, Fig. 3((a),a), Fig. 3((b),b), and Fig. 4.).

3.1.2 *global coordinate system*—spinal column motion has six degrees of freedom, having translational motion along, and rotational motion about three axes. The axes are labeled anterior-posterior or a-pA-P (X), medial-lateral or transverse (Y), and caudal-cranial or axial (Z). This coordinate system is right handed with +X in the anterior direction, +Y towards the left side of the body, and +Z in the cranial direction. Positive rotations are defined by the right hand rule (see Fig. 5((a)).a)).

3.1.3 *gripping capacity*—the maximum applied load or moment across an interconnection mechanism within the first 1.5 mm of permanent displacement or 5° of permanent rotation between the connected components.

3.1.4 *local coordinate system*—the spine's global coordinate system shall be applied locally at the position of the interconnection. The local direction, z, shall be centered through the longitudinal element of the x-y plane. The local direction, x, shall be defined as parallel to the axis of a screw or back of a hook. The local transverse axis, y, shall be parallel to a transverse element (See(see Fig. 5((b)b) and Fig. 5((c)).c)).

3.1.5 *loosening torque*—the torque required to disconnect the various threaded fasteners that might comprise the implant's interconnection mechanism.of the spinal arthrodesis implant.

3.1.6 *major directions of loading*—directions of the predominant forces and moments (relative to the local axes) to which vertebral connection elements are subjected, (that is, axial load, Fz; A-P load, Fx; axial torsion, Mz; and flexion-extension moment, My).

3.1.6 *maximum run out run-out load/moment*—the maximum load or moment that can be applied to a subassembly where all the tested constructs have withstood 2.5 × 106 cycles without a failure.

3.1.7 *relevant directions of loading*—those directions of loading in which a particular component interconnection is designed to provide resistance to loading. For example, a particular spinal hook may be designed to withstand a positive axial load, A-P load, and flexion-extension moment, but not a negative axial load or axial torsion. Hence, positive axial load, A-P load, and flexion-extension moment are the relevant directions of loading.

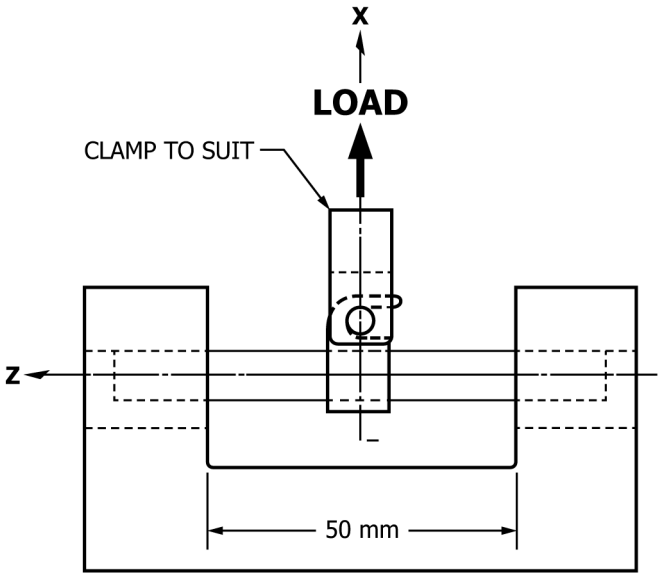


FIG. 1 A-P Test Apparatus for Subassembly

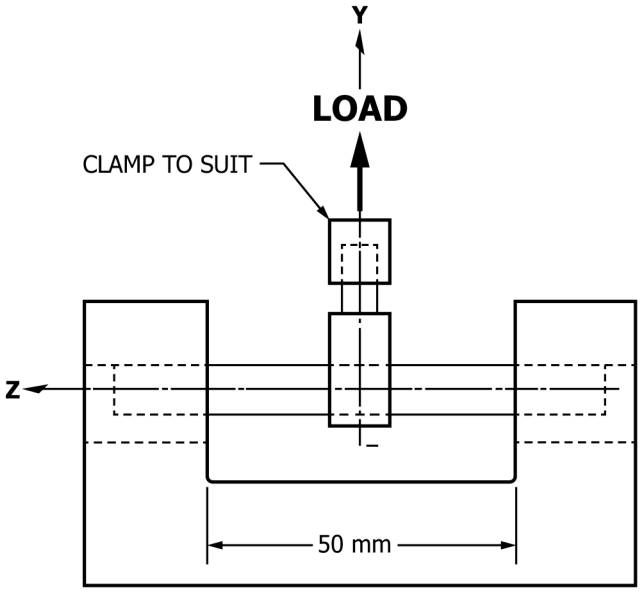


FIG. 2 Transverse Test Apparatus for Subassembly

3.1.8 *spinal arthrodesis implant*—an implant ~~applied to the spine with the intention of providing~~ that provides temporary correction and stability to vertebrae while bony fusion occurs.

3.1.9 *subassembly failure*—permanent deformation resulting from fracture, plastic deformation, loosening, or slippage that renders the subassembly ineffective or unable to adequately resist load.

3.1.10 *subassembly permanent deformation*—the displacement (mm) or angular displacement (degree of the subassembly relative to the unloaded condition) remaining after the applied load moment or torque has been removed. ~~Care must be taken to ensure that the loading fixtures are rigid and do not contribute to the measurement of deflection.~~

3.1.11 *tightening torque*—the specified torque that is applied to the various threaded fasteners ~~that might comprise the implant's interconnection mechanism.~~of the spinal arthrodesis implant during assembly.

3.1.12 *ultimate load/moment of the subassembly*—maximum load or moment applied to a subassembly (see Point E in Fig. 6).

3.1.13 *yield load/moment of the subassembly*—the load or moment required to produce a permanent deformation equal to 0.020 times the active length of the longitudinal element (see Point D in Fig. 6).

4. Summary of Test ~~Methods~~Method

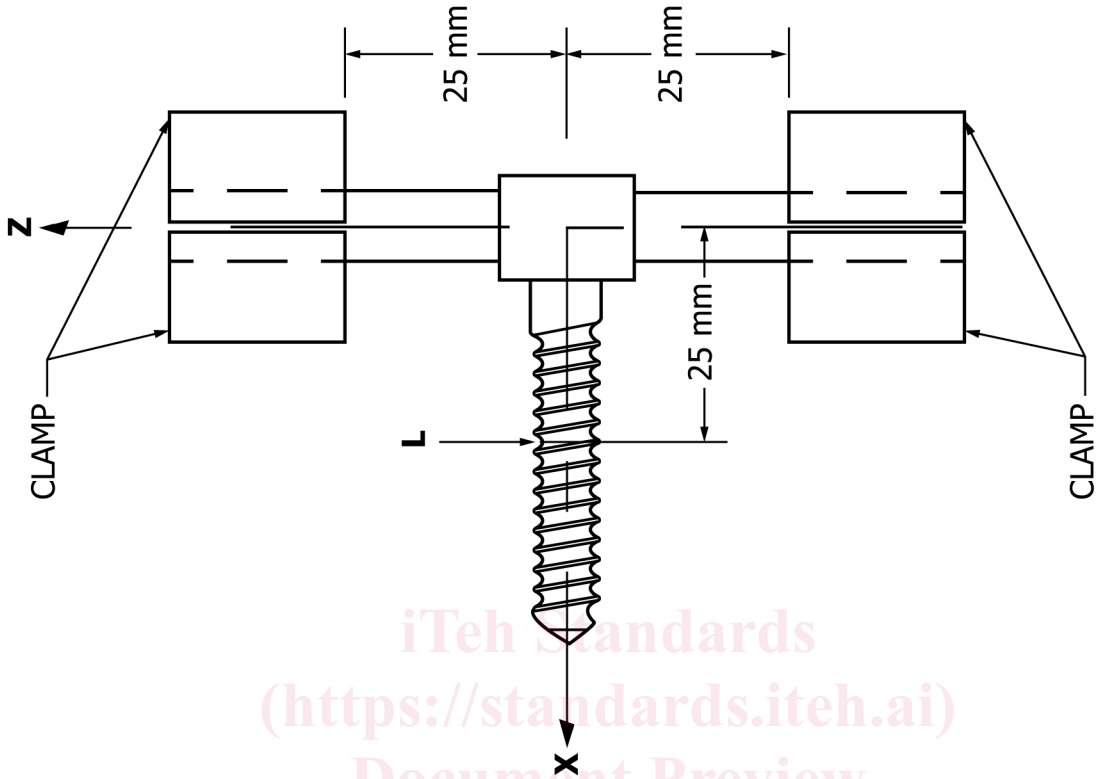
4.1 Vertebral attachment components (for example, hook, screws, bands) and transverse elements must be attached to longitudinal elements (for example, rods, plates) to form spinal implant subassemblies.

4.2 The interconnections are tested only in the relevant directions of loading by applying loads at specific locations relative to the local coordinate system.

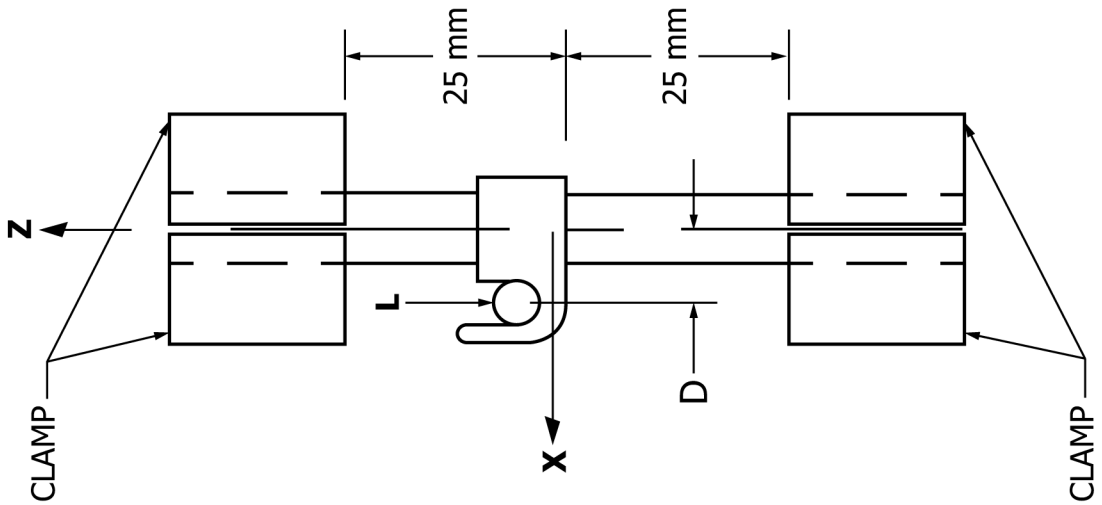
4.3 The interconnections and subassemblies are tested statically in a load-to-failure mode and also can be tested cyclically to estimate the maximum ~~run-out~~ run-out value at 2.5×10^6 cycles.

5. Significance and Use

5.1 Spinal implants are generally composed of several components that, when connected together, form a spinal implant construct. Spinal implant constructs are designed to provide some stability to the spine while arthrodesis takes place. This test method



6b: Screw



6a: Hook

FIG. 3 Flexion-Extension Moment Test Apparatus for Subassembly

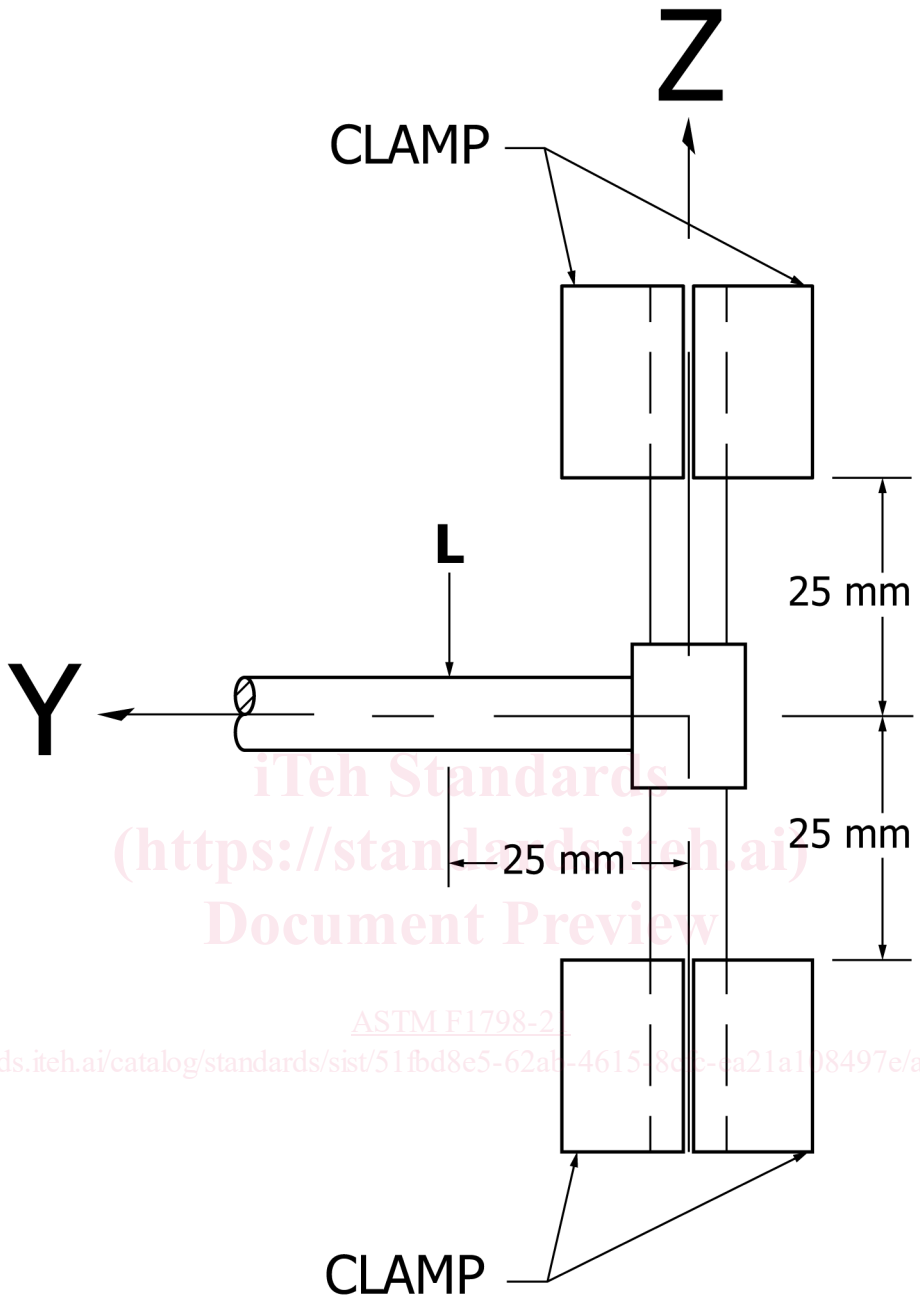
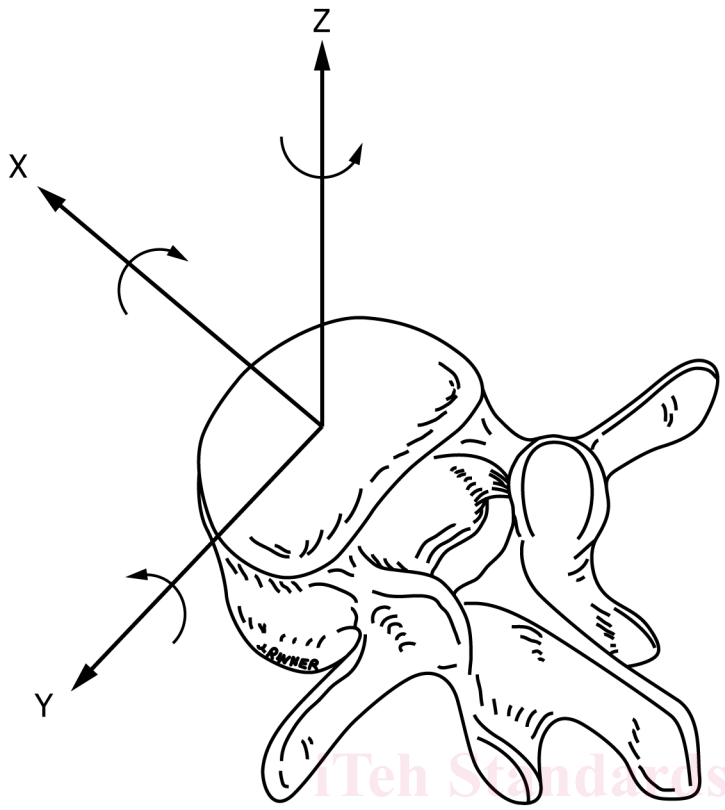


FIG. 4 Transverse Moment Test Apparatus for Subassembly

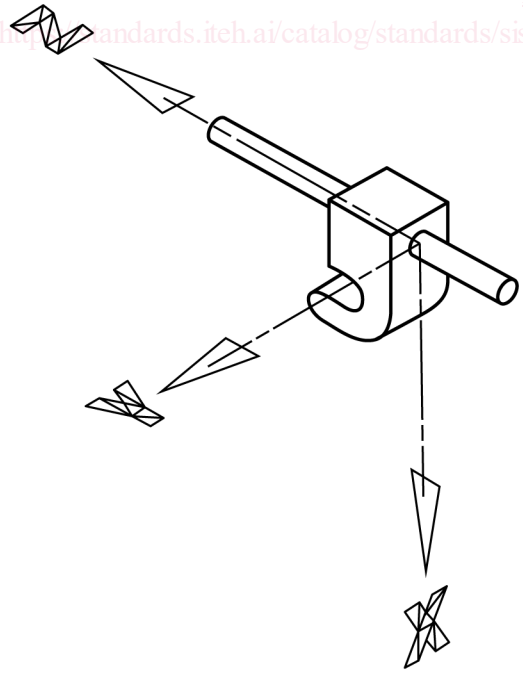
outlines standardized evaluations of different interconnection mechanisms to facilitate comparison between different designs. Comparisons must be made cautiously and with careful analysis, taking into account the effects that design differences can have on the loading configurations.

5.2 This test method is used to quantify the static and fatigue properties of different implant interconnection designs. The mechanical tests are conducted *in vitro* using simplified, unidirectional loads and moments. Fatigue testing in a simulated body fluid or saline may have a fretting, corrosive, or lubricating effect on the interconnection and thereby affect the relative performance of tested devices. Hence, the test environment, whether a simulated body fluid, saline (~~9g~~(9 g NaCl per 1000 mL H_2O), with a saline drip, or dry, is an important characteristic of the test and must be reported accurately.

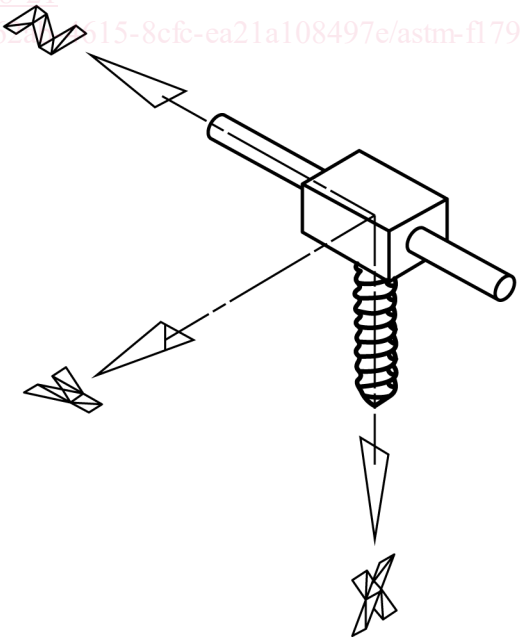
5.3 The loading of spinal implant constructs *in vivo* will, in general, differ from the loading configurations used in this test method. The results obtained here cannot be used directly to predict *in vivo* performance. However, the results can be used to compare different component designs in terms of relative mechanical parameters.



5a: Global Coordinate System



5b: Local Coordinate System- Hook



5c: Local Coordinate System-Screw

FIG. 5 Coordinate System

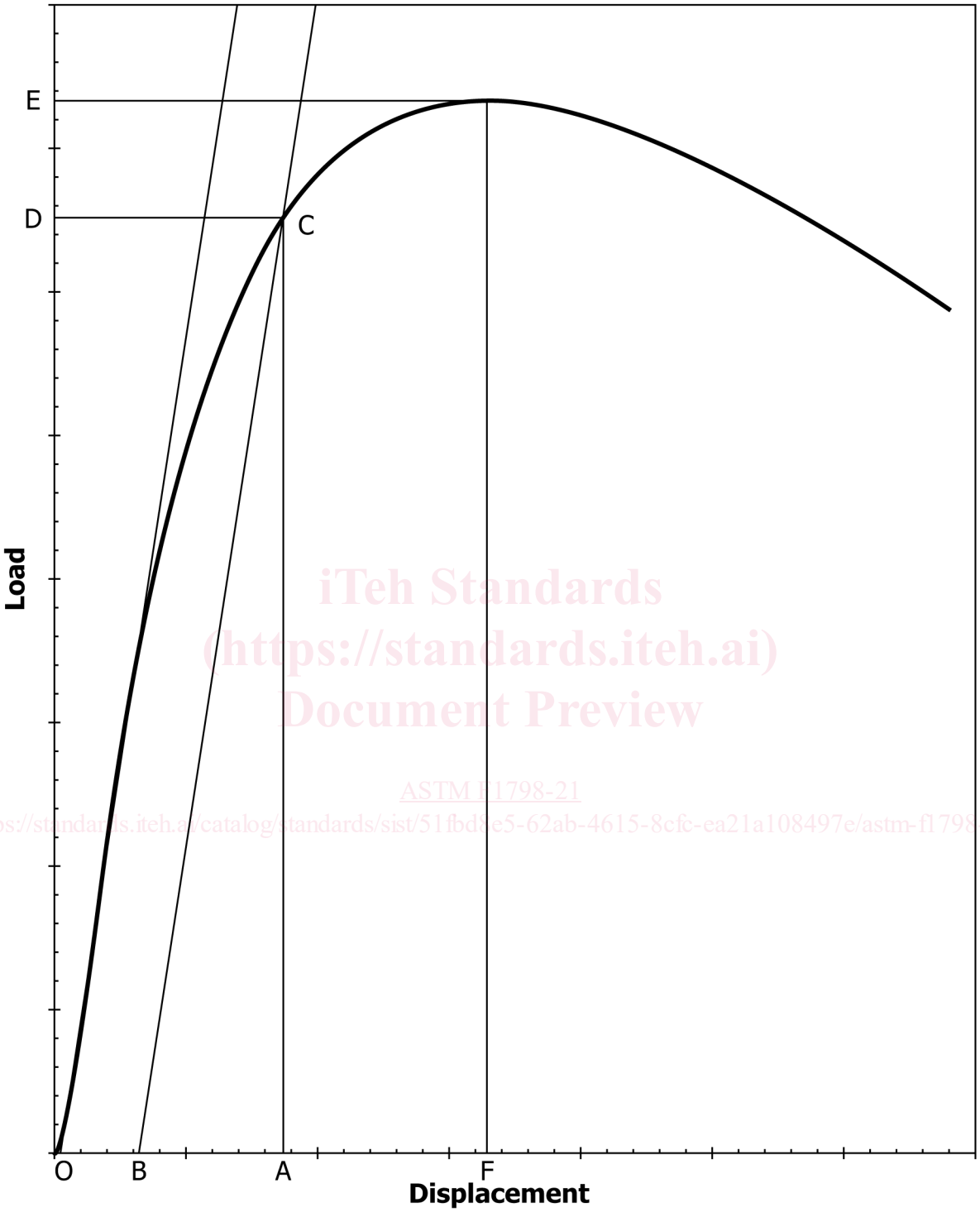


FIG. 6 Load/Displacement Curve

6. Apparatus

6.1 Machines used for the test shall conform to the requirements of Practices E4.

6.2 The apparatus for axial (z) gripping capacity measurements of an interconnection mechanism is depicted in Fig. 7~~((a).a)~~. One