Designation: F1798 – 97(Reapproved 2008)

Standard Guide 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 guide 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 guide 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 guide 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 guide sets out definitions for use in measuring the strength of component interconnections of spinal implants, possible test methods themselves, and the reporting of 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 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

F383 Practice for Static Bend and Torsion Testing of Intramedullary Rods (Withdrawn 1996)[3]

F1582 Terminology Relating to Spinal Implants

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*), Fig. 3(*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-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*)).

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 Fig. 5(*b*) and Fig. 5(*c*)).

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

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).

[1] This guide is under the jurisdiction of ASTM Committee F04 onMedical and Surgical Materials and Devices.

Current edition approved Dec. 1, 2008. Published December 2008. Originally approved in 1997. Last previous edition approved in 2003 as F1798 – 97(2003). DOI: 10.1520/F1798-97R08.

[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.

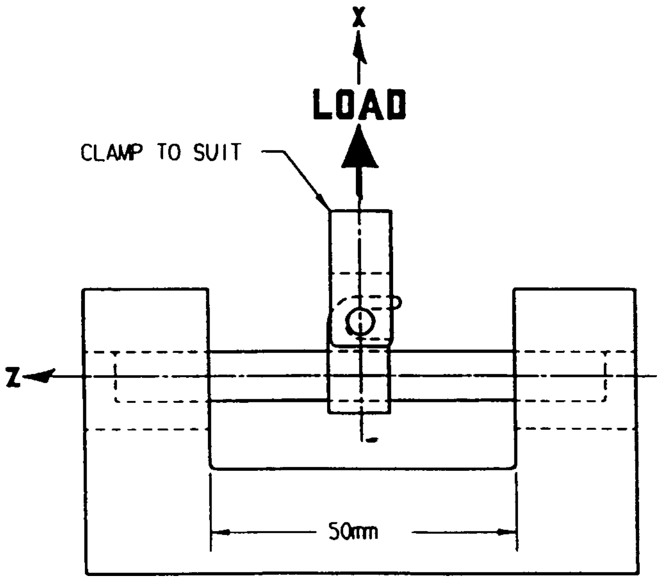

FIG. 1 A-P Test Apparatus for Subassembly

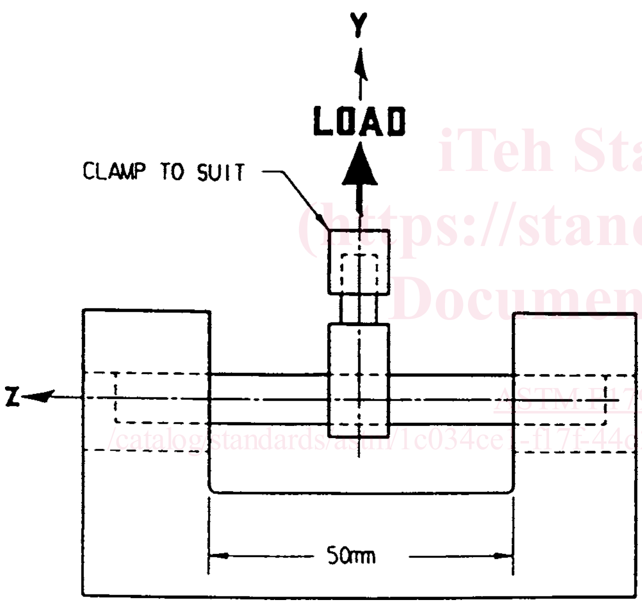

FIG. 2 Transverse Test Apparatus for Subassembly

3.1.7 *maximum 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.

3.1.8 *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.

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

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

3.1.11 *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.

3.1.12 *tightening torque*—the specified torque that is applied to the various threaded fasteners that might comprise the implant's interconnection mechanism.

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

3.1.14 *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

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 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 guide 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 guide 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 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 guide. The results obtained here cannot be used directly to