



Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants¹

This standard is issued under the fixed designation F 1798; 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.

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

E 4 Practices for Force Verification of Testing Machines

E 6 Terminology Relating to Methods of Mechanical Testing

E 468 Practice for the Presentation of Constant Amplitude Fatigue Test Results from Metallic Materials

E 739 Practice for Statistical Analysis of Linear or Linearized Stress-Life ($S-N$) and Strain-Life ($\epsilon-N$) Fatigue Data

E 1150 Definitions of Terms Relating to Fatigue³

F 383 Practice for Static Bend and Torsion Testing of Intramedullary Rods³

F 1582 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 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, F_z ; A-P load, F_x ; axial torsion, M_z ; and flexion-extension moment, M_y).

³ Withdrawn.

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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.

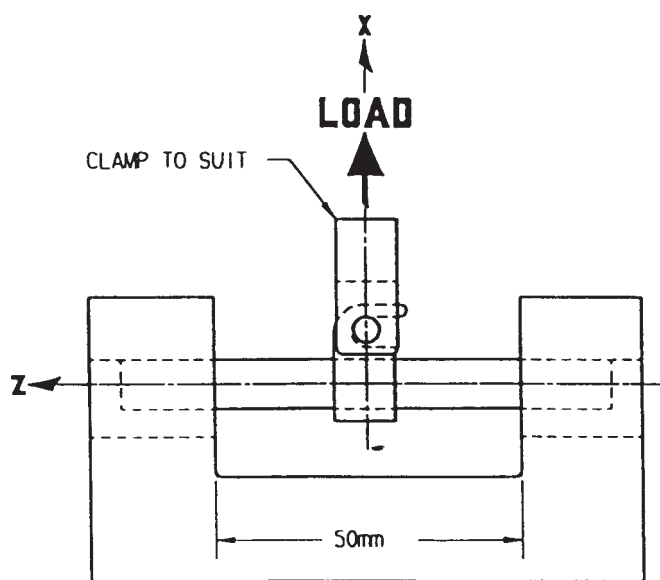


FIG. 1 A-P Test Apparatus for Subassembly

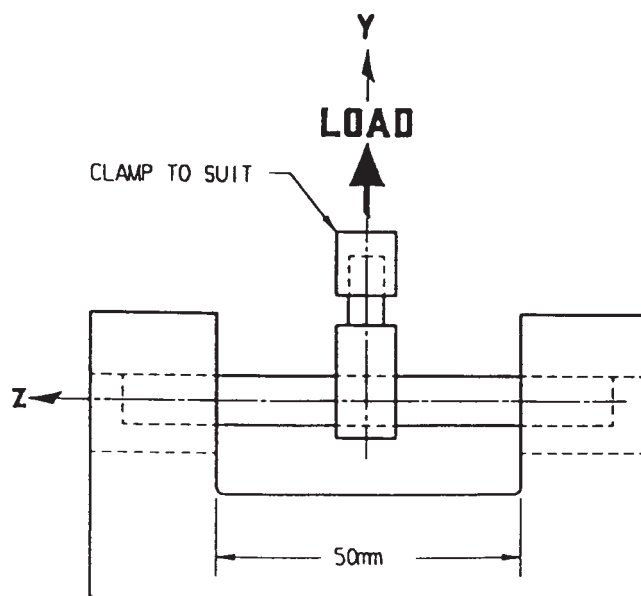


FIG. 2 Transverse Test Apparatus for Subassembly

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 2.5×10^6 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 relevant directions of loading.

3.1.9 *spinal arthrodesis implant*—an implant applied to the spine with the specific 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 insure 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.

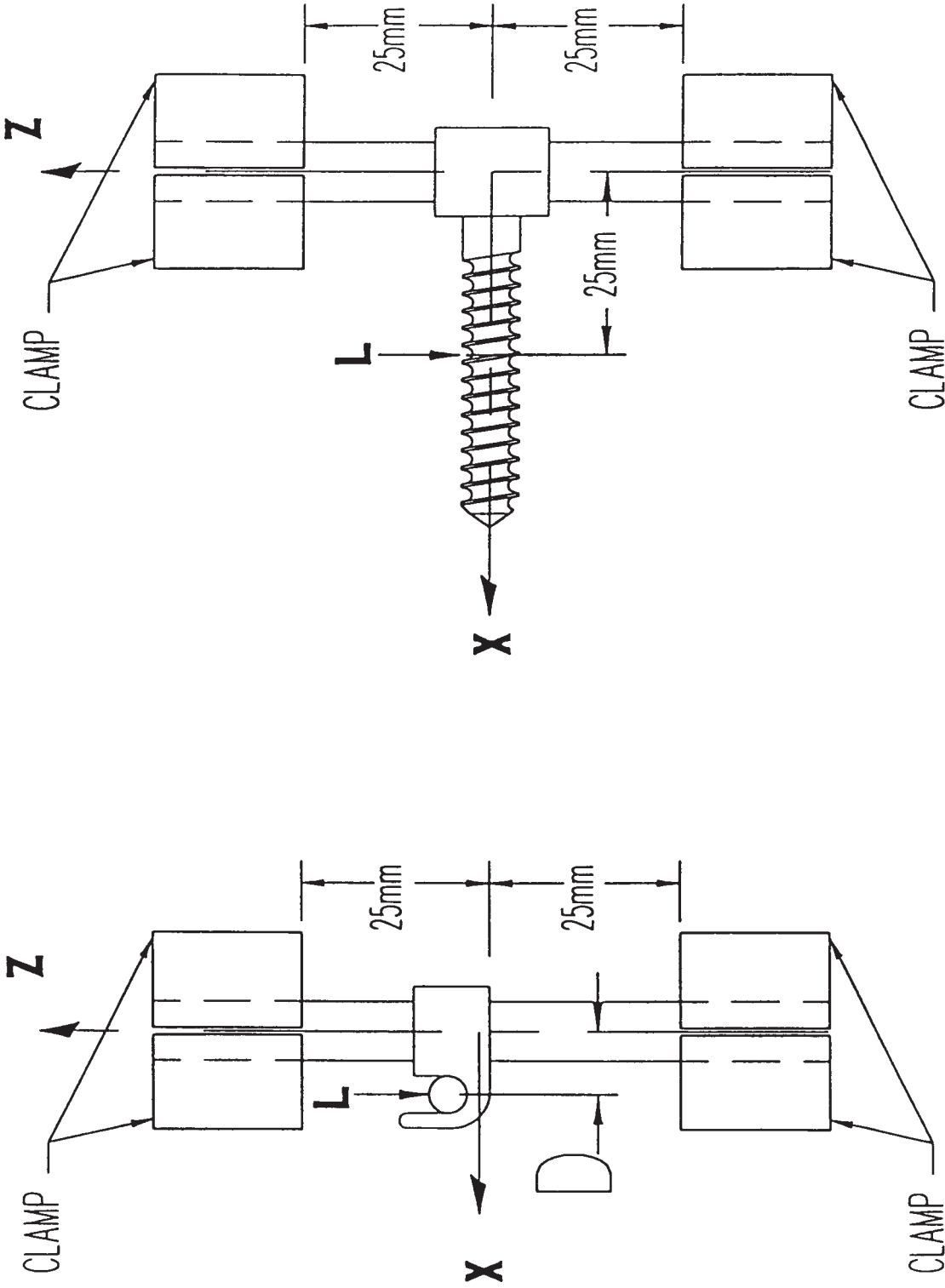
4.3 The interconnections and subassemblies are tested statically in a load to failure mode and also can be tested cyclically to estimate the maximum run out value at 2.5×10^6 cycles.

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 so that comparison between different designs is facilitated. 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 lubrication 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 H₂O), 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 predict *in vivo* performance. However, the results can be used



6a: Hook

6b: Screw

FIG. 3 Flexion-Extension Moment Test Apparatus for Subassembly

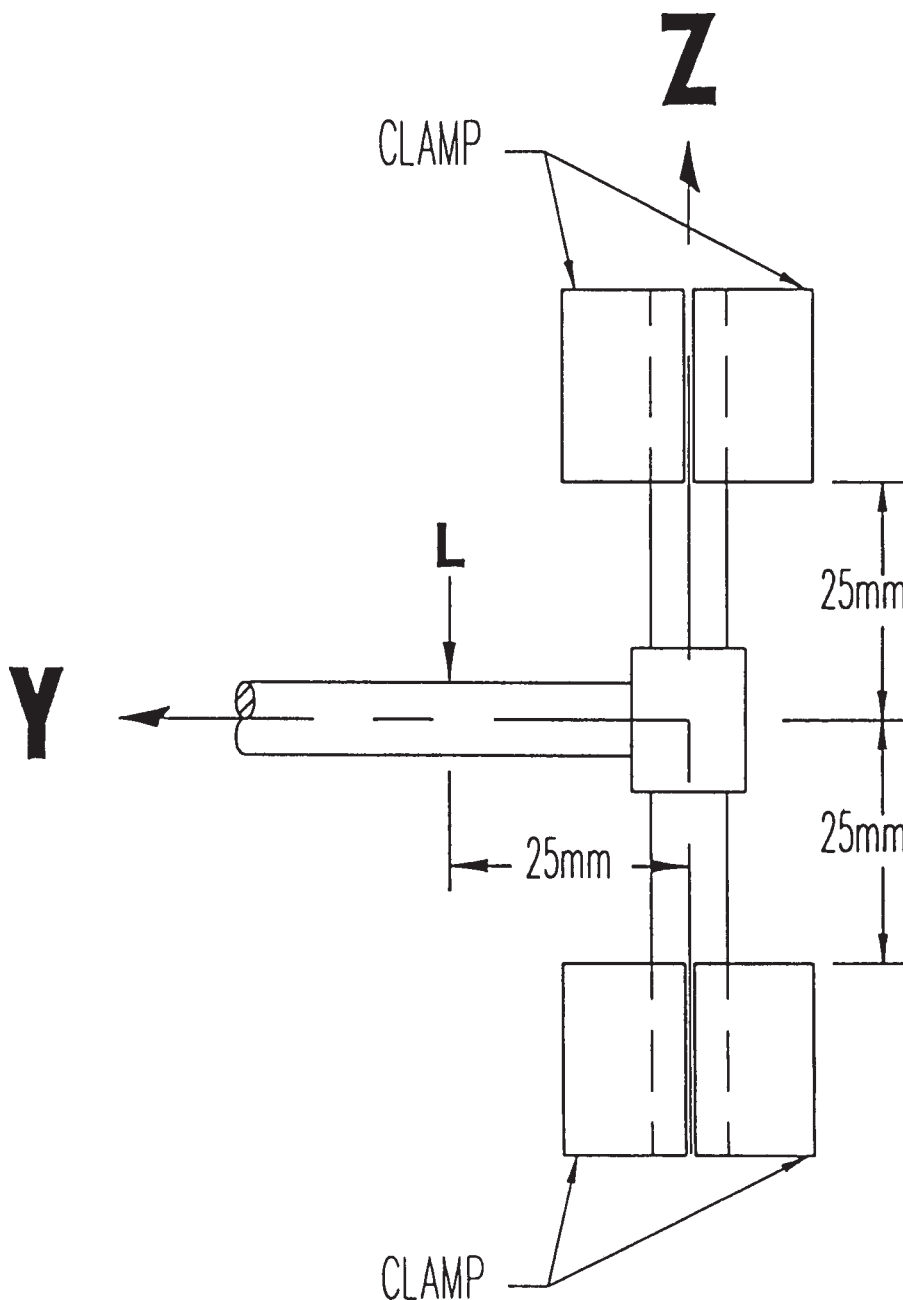


FIG. 4 Transverse Moment Test Apparatus for Subassembly

to compare different component designs in terms of relative mechanical parameters.

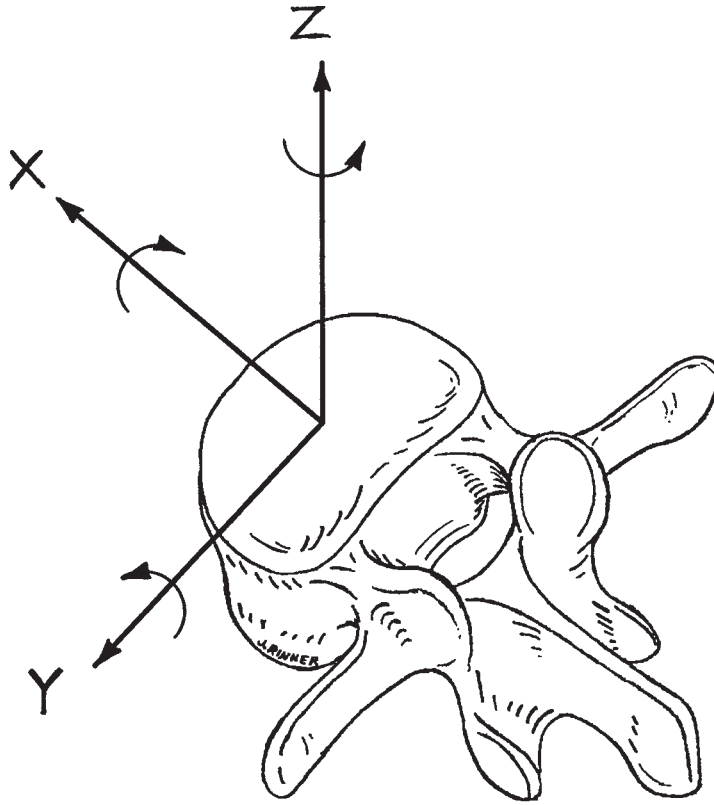
6. Apparatus

6.1 Machines used for the test shall conform to the requirements of Practices E 4.

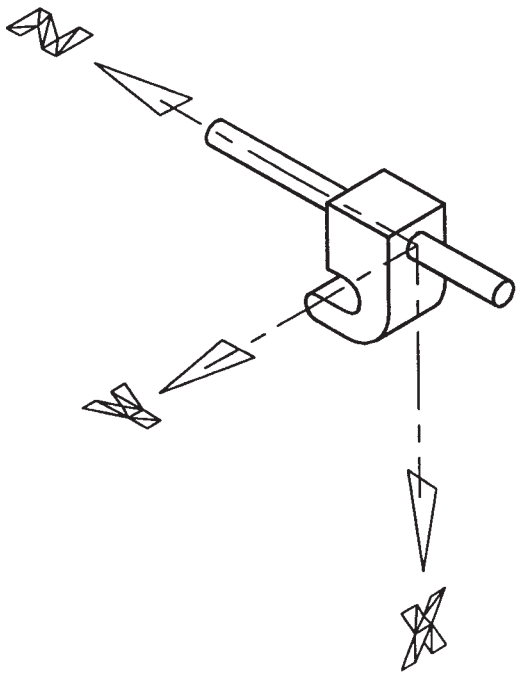
6.2 The apparatus for axial (z) gripping capacity measurements of an interconnection mechanism is depicted in Fig. 7(a). One end of the longitudinal element shall be clamped rigidly, leaving 5 mm exposed between the interconnection mechanism and the test machine base. A section of longitudinal element at least 5 mm shall extend beyond the interconnection linkage and remain unfixed. Axial loads are applied to the interconnection mechanism along the axis of the longitudinal

element via a sleeve (collar) which freely surrounds the longitudinal element. The sleeve (collar) should evenly distribute the load around the interconnection. An alternate method, depicted in Fig. 7(b), applies the load to the longitudinal element and pushes it through the interconnection clamp.

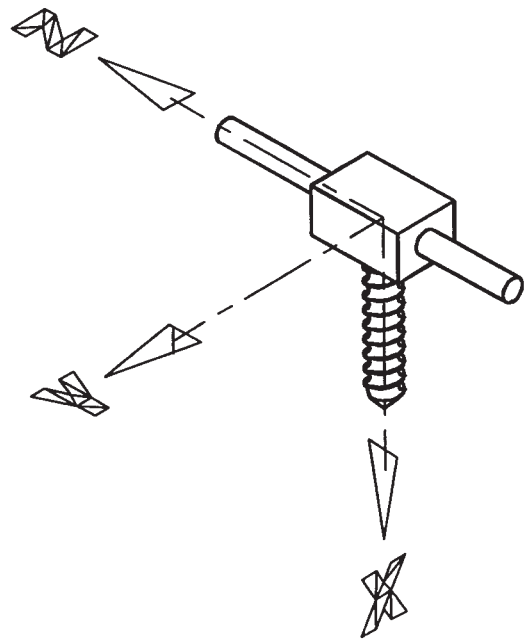
6.3 The apparatus for A-P (x) mechanical property measurements of a subassembly is depicted in Fig. 1. Both ends of the longitudinal element shall be clamped rigidly, with the interconnection centered on a 50 mm section of the longitudinal element. The local origin of the interconnection mechanism shall be centered between the mounts. Loads are applied to the interconnection (perpendicular to the longitudinal element) via a clamp on the hook, screw, or band. The load should be centered through the local x coordinate axis.



5a: Global Coordinate System



5b: Local Coordinate System- Hook



5c: Local Coordinate System -Screw

FIG. 5 Coordinate System

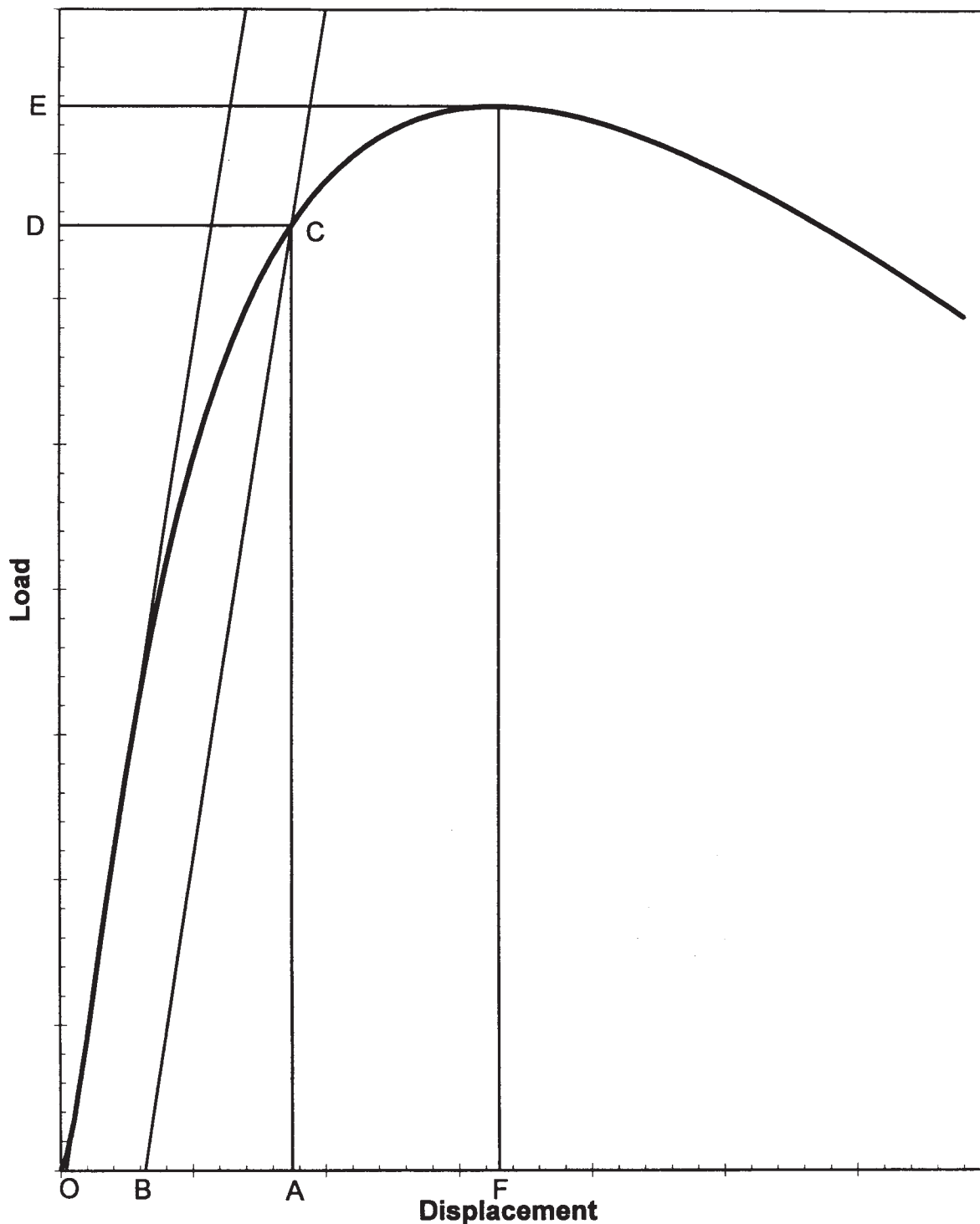
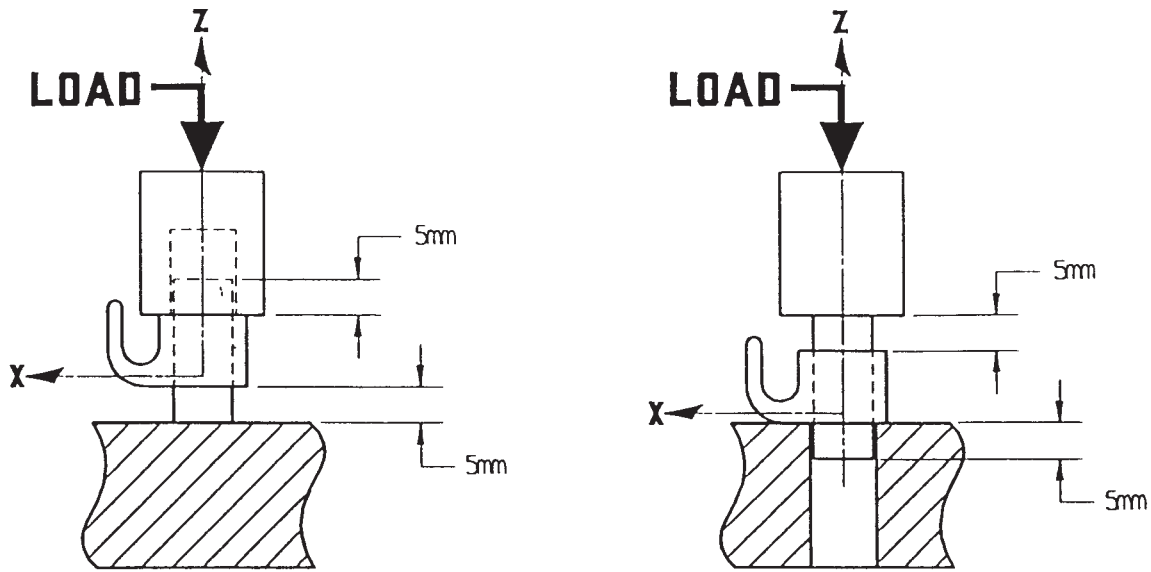


FIG. 6 Load/Displacement Curve

6.4 The apparatus for transverse (y) mechanical property measurements of a subassembly is depicted in Fig. 2. Both ends of the longitudinal element shall be clamped rigidly, with the interconnection centered on a 50 mm section of the longitudinal element. The local origin of the interconnection mechanism shall be centered between the mounts. Loads are applied to the interconnection (perpendicular to the longitudinal element) via a clamp on the transverse connector. The load should be centered through the local y coordinate axis.

6.5 The apparatus for flexion-extension moment (My) mechanical property measurements of a subassembly is depicted in Fig. 3. Both ends of the longitudinal element shall be clamped rigidly, with the interconnection centered on a 50 mm section of the longitudinal element. The local origin of the interconnection mechanism shall be centered between the mounts. Loads are applied to the interconnection (parallel to the longitudinal element). For spinal hooks, the load shall be applied via a cylinder set in the hook notch, Fig. 3(a). For other



7a: Load Applied to Sleeve

7b: Load Applied to Longitudinal Element

FIG. 7 Axial Gripping Capacity Test Apparatus

elements (screws) the load shall be applied 25 mm from the local z axis, Fig. 3(b).

6.6 The apparatus for transverse moment (M_x) mechanical property measurements of a subassembly is depicted in Fig. 4. As in the previous test, 6.5, both ends of the longitudinal element shall be clamped rigidly, with the interconnection centered on a 50 mm section of the longitudinal element. The local origin of the interconnection mechanism shall be centered between the mounts. Loads are applied to the interconnection (parallel to the longitudinal element), 25 mm from the z axis.

6.7 The apparatus for axial torque (M_z) gripping capacity measurements of an interconnection mechanism is depicted in Fig. 8(a) and is similar to that described in 6.2 with the exception that the axial torque is applied via notches in the sleeve that surrounds the longitudinal element. An alternative method is to hold the interconnection rigidly and apply the torsional force to the longitudinal element as shown in Fig. 8(b). A third alternative is to apply the torque via a force applied to a moment arm as shown in Fig. 8(c), but this alternative may introduce an additional variable of bending of the anchor component. In any case, care must be taken to evaluate and minimize the affect of the torsional properties of the longitudinal element on the results.

7. Sampling

7.1 The samples tested shall be previously unused parts only, and shall not be re-tested.

7.2 The test constructs shall be labeled and maintained according to good laboratory practice.

7.3 Static tests of mechanical properties should have a minimum sample size of five.

7.4 Fatigue tests for determining the maximum run out load or moment of a subassembly at 2.5×10^6 cycles shall utilize a

run down, half-interval approach⁴ with one specimen per run down interval or half-interval and three consecutive specimens showing run out to 2.5×10^6 cycles. Alternative methods for determining the starting point of the fatigue curve are the run-up method or choosing 75 % of the ultimate static load or moment.

8. Procedure for Measuring Static Mechanical Properties

8.1 Measure the tightening torques for any set screws or nuts which are incorporated into the interconnection linkage.

8.2 Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.3 The recommended maximum rate for applying a load is 20 N/s (or 25 mm/min) and is 25 N-m/min (or 25 °/min) for applying a moment or torque. Since rate is machine and software dependent, it may be necessary to run the tests slower to achieve accurate data.

8.4 Static A-P load (F_x), transverse load (F_y), axial gripping capacity (F_z), and transverse moment (M_x), flexion-extension moment (M_y), and axial torque (M_z) shall be measured using the apparatus described in 6.1-6.7.

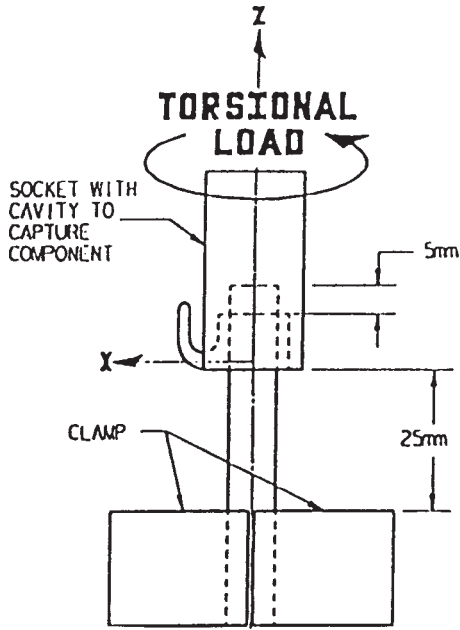
8.5 Loads and moments in only the relevant directions of loading need be measured.

8.6 After each load or moment measurement, loosening torque shall be measured (if applicable).

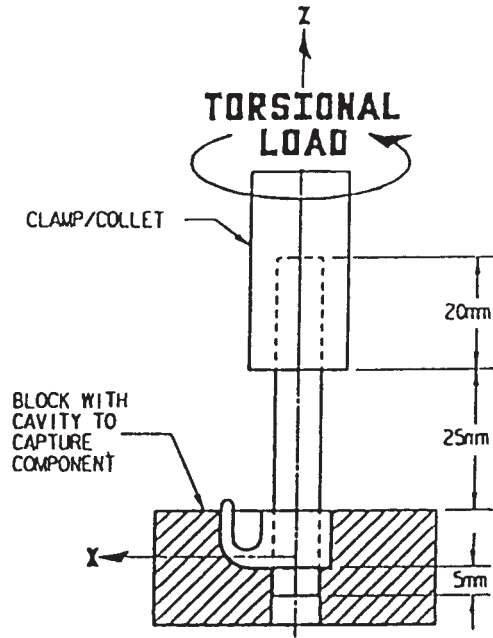
9. Procedure for the Measurement of Fatigue Run Out

9.1 Measure the tightening torques for any set screws or nuts that are incorporated into the connection linkage.

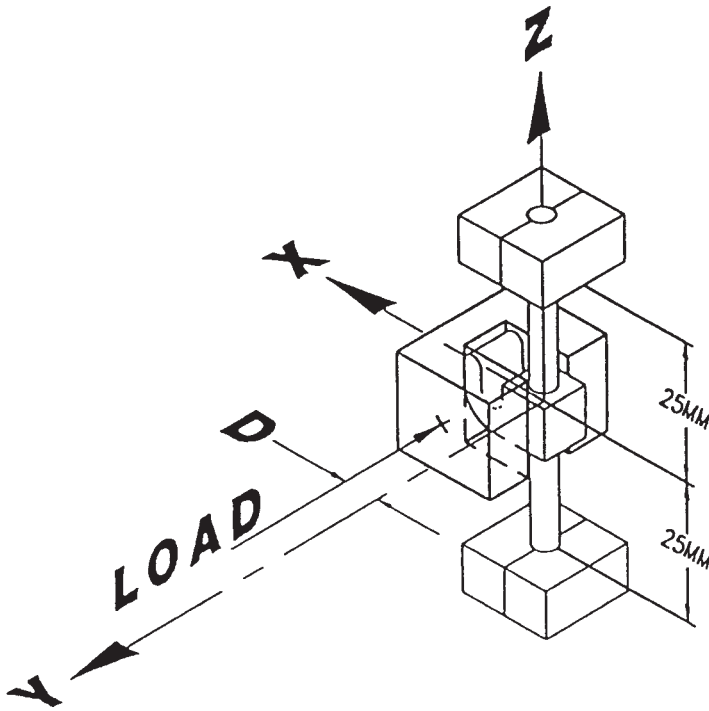
⁴ See "Optimal Stress Amplitude Selection in Estimating Median Fatigue Limits Using Small Samples", Little, R.E., ed., *J. of Testing and Evaluation*, ASTM, 1990, pp. 115-122.



8a: Torsional Load Applied to Sleeve



8b: Torsional Load Applied to Longitudinal Element



8c: Load Applied Via Moment Arm to Sleeve

FIG. 8 Axial Torque Gripping Capacity Test Apparatus

9.2 Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

9.3 The maximum frequency of cyclic loading is not specified but shall be measured and reported.

9.4 All fatigue loading should be sinusoidal, accomplished via continuous load amplitude control, rather than in a controlled deflection manner.

9.5 A-P fatigue run out (F_x), transverse fatigue run out (F_y), axial fatigue run out (F_z), transverse moment fatigue run out (M_x), flexion extension moment fatigue run out (M_y), axial torsional fatigue run out (M_z), if considered relevant, shall be determined using the apparatus described in 6.1-6.7.

9.6 In each relevant loading direction, apply a continuous amplitude cyclical load to an interconnection subassembly specimen. If a failure occurs prior to 2.5×10^6 , decrease the load and test the second specimen in the same manner. This run down is continued at equal intervals until a load amplitude is reached at which no failure occurs before 2.5×10^6 cycles. At this point, the load is increased or decreased by half-intervals until three consecutive specimens run out to 2.5×10^6 cycles. Alternative methods for determining the starting point of the fatigue curve are the run-up method, where a single test specimen is progressively retested at higher loads until it eventually fails, or choosing 75 % of the ultimate static load.

9.7 A similar procedure, as described in 9.6, is used for moments. Fatigue run out in only the relevant directions of loading need be measured.

9.7.1 By definition, some components are generally designed to withstand only fluctuating (0 to value) loads in the axial, A-P, and flexion-extension moment directions, hence fatigue loading of hooks (or other unidirectionally loaded components) shall be fluctuating for cyclic loading in the axial (z), A-P (x), and flexion-extension moment (My) measurements, but shall be completely reversed ($+/-$ value) for the axial torsion measurement. To facilitate the application of fluctuating loads, and eliminate the problems associated with controlling loads close to zero, fluctuating loads may be applied with a minimum load ratio, R , of 10 where:

$$R = \frac{\text{minimum load} = -L}{\text{maximum load} \geq -0.10L} \quad (1)$$

For example, a fluctuating load between -200 N and -10 N would be an acceptable fluctuating load with $R=20$. It is essential that the ratio should remain constant for all similar tests.

9.7.2 Other spinal components must withstand some degree of reversed loading. Hence, mechanical properties shall be determined using completely reversed loading in all major directions of loading for these components. The maximum load ratio in completely reversed loading should be -1.00 .

9.8 After each fatigue test, loosening torque shall be measured (if applicable). A baseline loosening torque, measured prior to any cyclic loading, should also be established prior to the fatigue tests.

10. Report

10.1 The report of the test results shall include the following:

10.1.1 Description of the tested implant components, including the numbers of specimens tested, the manufacturer, the part number, the lot number, and the engineering drawings, if applicable,

10.1.2 The exact loading configuration, reflecting the similarity (and any differences) to the relevant figures contained herein. Include all dimensions. If several implant designs are to be compared, use as similar as possible testing configuration on all implants,

10.1.3 Any deviations from the recommended test procedures,

10.1.4 Means and standard deviations of tightening torques,

10.1.5 The ultimate load/moment, yield load/moment, or gripping capacity values for each test performed, along with means, standard deviations and all load-deflection curves. An indication shall be made whether measurable permanent deformation or gross failure occurred,

10.1.6 A description of any fretting or surface corrosion that is noticeable to the unaided eye in both the assembled and disassembled conditions,

10.1.7 *Environment*—If the test was not conducted in air, describe the test fluid, including temperature, Ph, and ionic concentration, of the solution. State how the solution was applied (for example, drip, immersion). This applies not only to the test itself, but also the conditions during tightening of the interconnections,

10.1.8 A description of any failures or deformations occurring in the testing apparatus or implant construct other than at the interconnection mechanism being tested,

10.1.9 Rate of loading,

10.1.10 A description of the loads applied (fluctuating or completely reversed) using R =minimum load/maximum load,

10.1.11 Plots of load or moment versus number of cycles to failure for each loading direction on a semi-log scale (load, or moment, on the linear axis) showing the order in which the specimens were tested and whether each specimen was run out or failed,

10.1.12 Report the maximum run out load/moment of the interconnection at 2.5×10^6 cycles for each relevant load or moment direction, and

10.1.13 Means and standard deviations of loosening torques.

11. Precision and Bias

11.1 *Precision*—It is not practical to specify the precision of the procedure in this guide because of the wide variance in design of the components to be tested.

11.2 *Bias*—No statement can be made as to the bias of this procedure since no acceptable reference values are available, nor can they be obtained in that this test is a destructive test.

12. Rationale

12.1 This guide covers the evaluation of unidirectional static and fatigue, strength and resistance to loosening of the component interconnection mechanisms of spinal arthrodesis implants. Even though spinal implants may reside in the body for many years, their purpose is to provide short term stability while arthrodesis (bone fusion) takes place. Hence, this guide does not address the long term mechanical stability of spinal

implants, nor does it address surgical procedures using implants that do not lead to spinal fusion (for example, artificial discs).

12.2 This guide outlines basic evaluations of the interconnection mechanisms that may be found in spinal arthrodesis implants. It does not address all aspects of spinal surgery nor does it address every unique aspect of particular implant designs. The purpose of this guide is to provide a basic framework of tests which can be used to compare different implant designs in a consistent manner.

12.3 Uniaxial loads and moments are applied in this guide, as multiaxial loading conditions *in vivo* are not yet fully defined. The methods outlined here are considered minimum test conditions, and more sophisticated tests are encouraged.

12.4 The choice of 1.5 mm and 5° as the defined limits of gripping capacity are large compared to other standards (for example, Practice F 383; 0.13 mm and 1°). There are many ways to define failure. The choice of these arbitrary deflections are admittedly large to ensure ease of measurement from load-deflection curves.

12.5 In developing this guide, significant debate revolved around the question of whether to test in saline, in a simulated body fluid, or in air. Because it was impossible to define a fluid that exactly simulates the *in vivo* environment and because implants must be compared to one another until performance standards are defined, the test environment is left to the individual investigator.

12.6 In fatigue testing of spinal components (for example, pedicle screws), there is some history of researchers building bilevel constructs of two screws spanned by a rod or plate that is then cyclically loaded through plastic “pucks”. From a practical standpoint, such a test should be considered similar to the loading configurations suggested here in Fig. 3. However, it should be noted that when testing bilevel constructs, the specified determination of measurable permanent deformation is altered by a factor of two. This guide describes tests that seek to determine performance of the interconnection mechanism

alone. The bilevel test determines overall performance of the implant (for example, pedicle screw root fatigue strength). Based on various goals, individual investigators may seek to address both issues with a single test.

12.7 The question of the degree of fluctuating or completely reversed loading seen by various spinal implants is yet to be answered. Hence, the issue of whether to apply fluctuating or completely reversed loading is left to the investigator, until *in vivo* data can be generated.

12.8 In fatigue testing, load is the independent variable. The investigator is referred to Footnote 4 for a more complete description using small numbers of samples to estimate fatigue strength. Furthermore, the cycle rate is not specified since it is dependent on the test machine and the specimen. However, a recommended maximum is 16 Hz.

12.9 Depending on the intent of the investigator, different numbers of specimens may be necessary to establish a meaningful sample size. Hence, this guide does not set a specific number of specimens to be tested statistically.

12.10 It is not the intention of this guide 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.

12.11 The estimated number of cycles seen *in vivo* in a twelve month period, which can be considered the approximate average time until fusion, ranges from 1 to 2.5 million cycles. Doubling the 2.5 million cycles to 5 million provides a factor of safety, but substantially increases the cost of testing without providing additional meaningful data. Even if a failure is noted in the 2.5 to 5 million cycle range, it generally occurs in the horizontal run out portion of the curve, and does not significantly affect the curve itself. Therefore, 2.5 million cycles was chosen as the cyclic run out limit.

13. Keywords

13.1 gripping capacity; interconnection; run out; spinal arthrodesis implant; subassembly

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