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AMERICAN SOCIETY FOR TESTING AND MATERIALS
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Provisional Standard Test Method for Static and Dynamic Spinal Implants Assembly in a Corpectomy Model[1]

This provisional standard is issued by ASTM in accordance with a special procedure to meet the demand for rapid issuance of specific documents.[2]

1. Scope

1.1 This provisional test method covers the materials and methods for the static and dynamic testing of spinal implant assemblies in a corpectomy model. The test materials for most combinations of spinal implant components can be specific depending on the intended spinal location and intended method of application to the spine.

1.2 This provisional test method is intended to provide a basis for the mechanical comparison among past, present and future spinal implant assemblies. This provisional test method allows comparison of spinal implant constructs with different intended spinal locations and methods of application to the spine. This provisional test method is not intended to define levels of performance, since sufficient knowledge is not available to predict the consequences of the use of a particular device.

1.3 This provisional test method sets out guidelines for load types and methods of applying loads. Methods for four static load types and one dynamic test are defined for the comparative evaluation of spinal implant assemblies.

1.4 This provisional test method establishes guidelines for measuring displacements, determining the yield load, evaluating the stiffness and strength of the spinal implant assembly.

1.5 Some spinal constructs may not be testable in all test configurations.

1.6 The values stated in SI units are to be regarded as standard.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines[2]

E 6 Terminology Relating to Methods of Mechanical Testing[2]

E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process[3]

E 468 Practices for the Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials[2]

E 739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (*ε-N*) Fatigue Data[2]

E 1150 Definitions of Terms Relating to Fatigue[2]

F 648 Specification for Ultra-high-molecular-weight Polyethylene Powder and Fabricated Form for Surgical Implants[4]

3. Terminology

3.1 *Definitions:*

3.1.1 For definitions of terms relating to this provisional test method, see Terminology E 6 and Definitions E 1150.

3.2 *Descriptions of Terms Specific to This Standard:*

3.2.1 *active length of the longitudinal element*—the straight line distance between the center of attachment of the superior anchor and the center of attachment of the inferior anchor.

3.2.2 *angular displacement at 2 % offset yield*—The angular displacement (degrees) when an assembly has a permanent angular displacement in the *x-y* plane equal to 0.020 times the torsional aspect ratio. (See Point A in Fig. 1.)

3.2.3 *anchor*—components that are directly attached to bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs).

3.2.3.1 *band*—a flexible anchor component with a non-circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using knot or similar tying mechanism, forming a locked, closed loop.

3.2.3.2 *bolt*—an anchor component that connects to the bony elements of the spine, pelvis or ribs by means of threads with the lead threads accommodating a nut thus sandwiching the bony elements or implant component between the nut or washer and bolt head or other fixed stop.

3.2.3.3 *hook*—an anchor component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening.

(*1*) *hook blade*—that portion of a spinal hook that is placed under, over or into a bony structure to provide attachment.

(*2*) *hook body*—that portion of a spinal hook that connects the hook blade to the longitudinal element.

3.2.3.4 *post*—a non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element.

3.2.3.5 *screw*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads.

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[1] This provisional test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee on F04.35 on Constructs.

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[2] See Section 13 of the *Regulations Governing ASTM Technical Committees.*

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

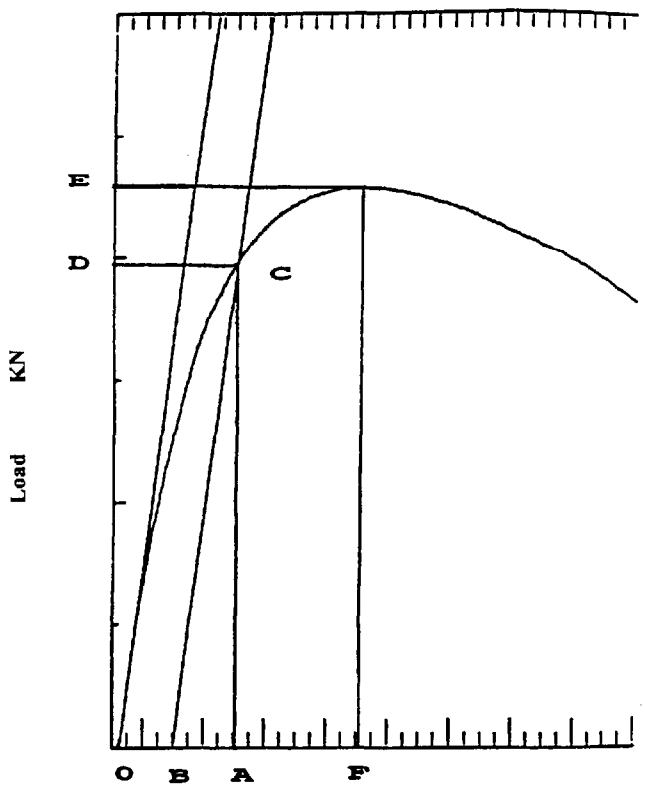


FIG. 1 Displacement

3.2.3.6 *staple*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts.

3.2.3.7 *wire*—a single strand flexible anchor component with a circular cross section that connects to the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts.

3.2.4 *assembly*—a complete implant configuration (not including spine, pelvis, ribs or substitute material) as intended for surgical use.

3.2.5 *bending moment*—the product of the load and the bending moment arm.

3.2.6 *bending moment arm*—the distance in x direction between the insertion point of an anchor and the test block load point. The test loads are transferred through the hinge pins.

3.2.7 *component*—any single element used in an assembly.

3.2.8 *compressive or tensile bending stiffness (N-m/mm)*—The compressive or tensile yield bending moment divided by elastic displacement. (See the slope of line BC in Fig. 1.)

3.2.9 *compressive or tensile bending ultimate strength (N-m)*—The maximum compressive or tensile moment in *x-z* plane that can be applied to a spinal implant assembly. (See the moment at Point E in Fig. 1.)

3.2.10 *compressive or tensile ultimate strength (N)*—the maximum axial compressive or tensile load in *z* direction that can be applied to a spinal implant assembly. (See the load at Point E in Fig. 1.)

3.2.11 *compressive or tensile yield bending moment*—The compressive or tensile bending moment (*N-m*) in *x-z* plane necessary to produce a permanent deformation equal to 0.020 times the active length of the longitudinal element. (See the moment at Point D in Fig. 1.)

3.2.12 *compressive or tensile yield load*—The axial compressive or tensile load (*N*) in *z* direction required to produce a permanent deformation equal to 0.020 times of the active length of the longitudinal element. (See the load at Point D in Fig. 1.)

3.2.13 *construct*—a complete implant configuration attached to and including spine, pelvis, ribs, or substitute material as intended for surgical use.

3.2.14 *coordinate system/axes*—three orthogonal axes are defined in Figs. 1 and 3. The anterior-posterior axis is *x* with positive being anterior. The medial-lateral axis is *y* with left being positive. The superior-inferior axis is *z* with superior being positive.

3.2.15 *displacement at 2 % offset yield*—the displacement (mm) when a construct has a permanent deformation equal to 0.020 times the active length of the longitudinal element. (See Point A in Fig. 1.)

3.2.16 *elastic angular displacement*—the angular displacement (degrees) at 2 % offset yield (Point A in Fig. 1) minus the 2 % offset angular displacement (Point B in Fig. 1). (The distance between Point A and Point B in Fig. 1.)

3.2.17 *elastic displacement*—The displacement (mm) at 2 % offset yield (Point A in Fig. 1) minus the 2 % offset displacement (Point B in Fig. 1). (The distance between Point A and Point B in Fig. 1.)

3.2.18 *fatigue life*—the number of cycles, *N*, that the spinal implant assembly can sustain at a particular load or moment before initial gross failure occurs.

3.2.19 *gross failure*—permanent deformation resulting

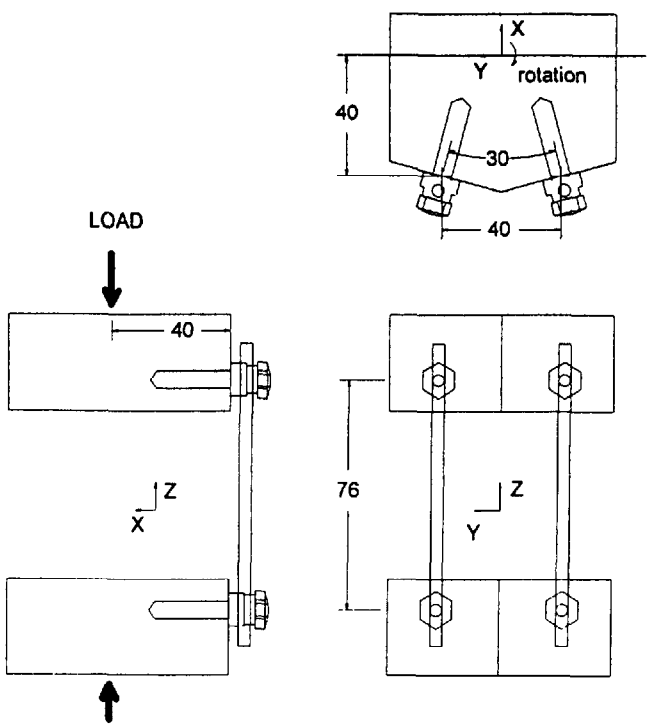


FIG. 2 Standard Bilateral Construct Containing Screw, Rod and Screw

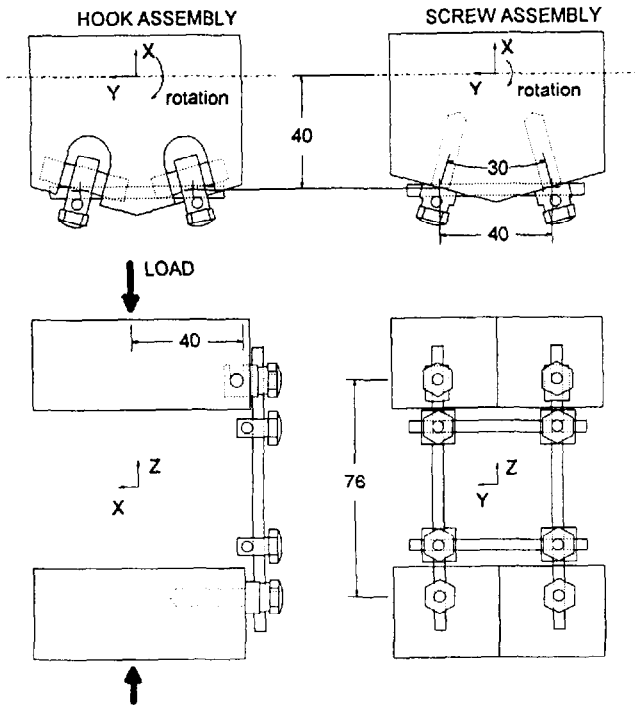
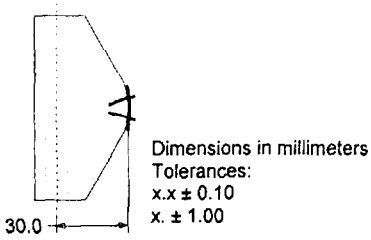


FIG. 3 A Bilateral Hook, Rod, Screw, and Transverse Element Construct

from fracture, plastic deformation beyond the ultimate displacement, or loosening that renders the spinal implant assembly ineffective or unable to adequately resist load.

3.2.20 *insertion point of an anchor*—the location, where the anchor is attached to the test block. The type, design, and manufacturer's surgical instructions for installation will dictate this location (see Figs. 2 through 15).

3.2.21 *intended method of application*—spinal implant assemblies contain different types of anchors. Each type of anchor has an intended method of application to the spine.



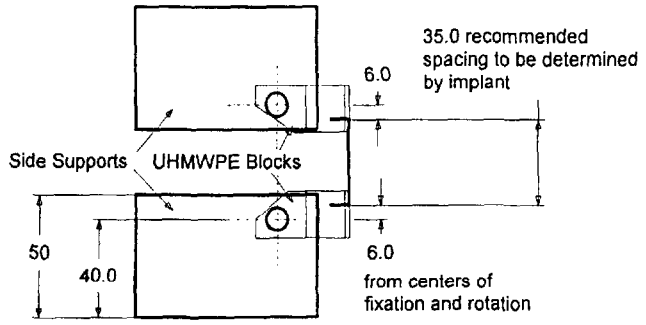


FIG. 4 Cervical Unilateral Construct Test Setup For Screws or Bolts

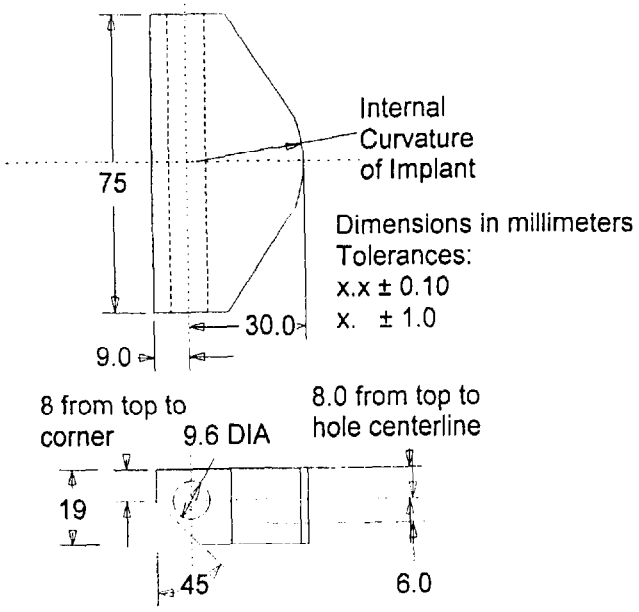
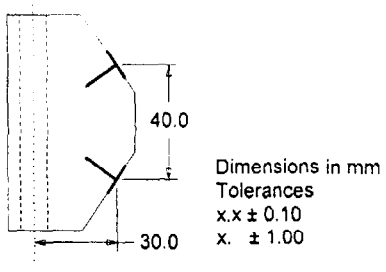


FIG. 5 Cervical Unilateral UHWMPE Block for Screw or Bolts

3.2.22 *intended spinal location*—the anatomic region of the spine intended for the application of the spinal implant assembly. Spinal implant assemblies are developed for specific spinal locations such as the anterior cervical spine or the posterior thoracolumbar, lumbar, and lumbosacral spine.

3.2.23 *interbody spacer*—a structure (biologic or synthetic) to replace (partially or totally) the vertebral body or intervertebral disk(s), or both.

3.2.24 *interconnection*—The mechanical interface or connection mechanism between at least two components or between components and bony elements of the spine, pelvis, or ribs.



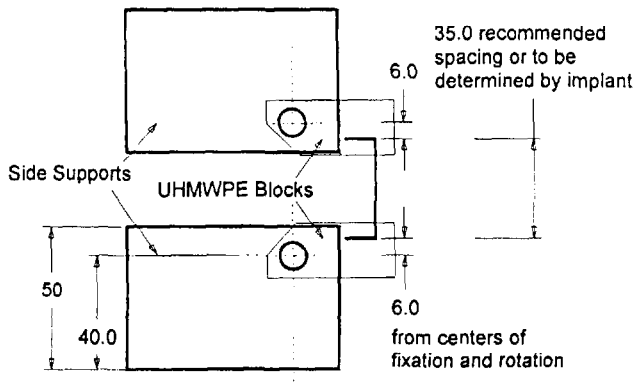


FIG. 6 Cervical Bilateral Construct Test Setup For Screws or Bolts

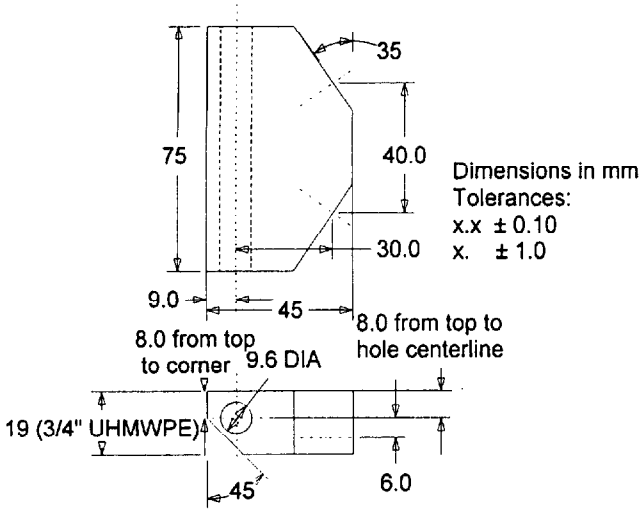


FIG. 7 Cervical Bilateral UHMWPE Block For Screws or Bolts

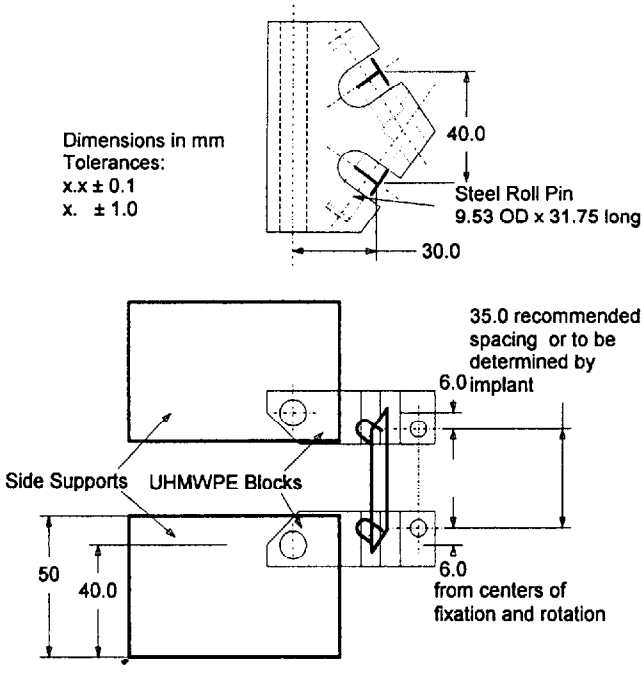


FIG. 8 Cervical Bilateral Construct Test Setup For Hooks, Cables, or Wires

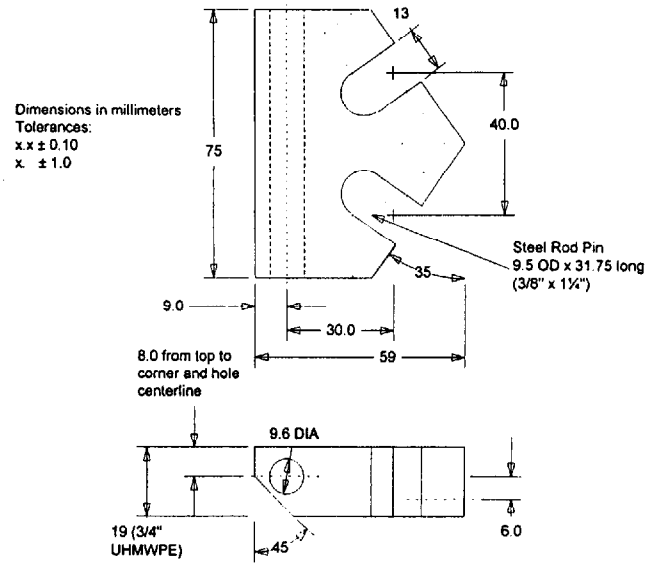


FIG. 9 Cervical Bilateral UHMWPE Block For Hooks, Cables, Wires

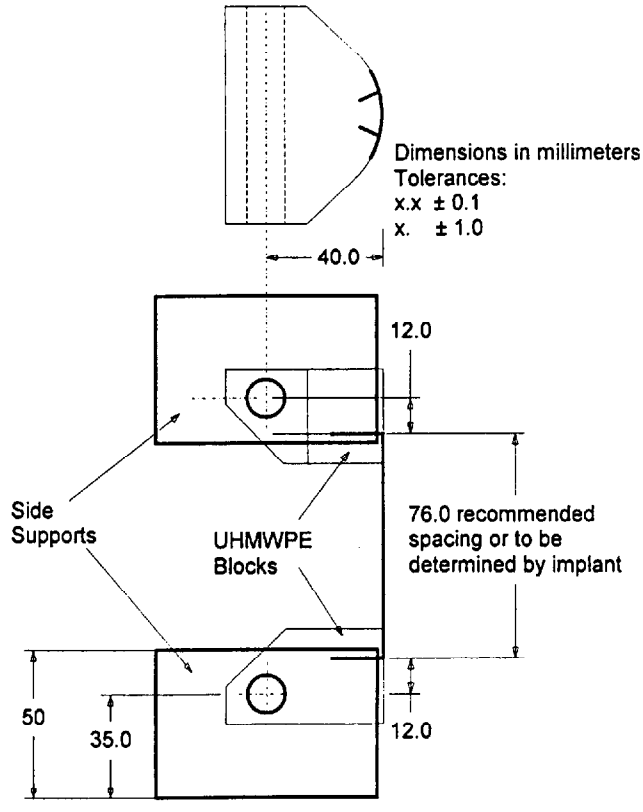


FIG. 10 Lumbar Unilateral UHMWPE Block For Screws or Bolts

3.2.24.1 *bolt interconnection*—an interconnection having an implant component sandwiched between two nuts or between a nut and fixed stop.

3.2.24.2 *clamp*—an interconnection component whose mechanism to secure the longitudinal element is through a squeezing action, for example, crimps wedges, set screws.

3.2.24.3 *screw interconnection*—An interconnection having an implant component sandwiched between the screw head (or screw thread) and bony element or other implant components.

3.2.24.4 *sleeve interconnection*—an interconnection in which an implant component passes through any opening that limits motion in one or more planes.

3.2.25 *Interface*—one of the two mating surfaces, lines or points of contact within an interconnection between two components, between any component and bone, or between two bony elements.

3.2.26 *longitudinal direction*—the initial spatial orientation parallel to the longitudinal element of the spinal implant assembly. The longitudinal direction is generally in the superior-inferior direction and therefore, generally parallel to the *z* axis.

3.2.27 *longitudinal element*—a component whose long axis is parallel, or nearly so, to the long axis of the spine.

3.2.27.1 *cable*—a multi-strand, flexible longitudinal ele-

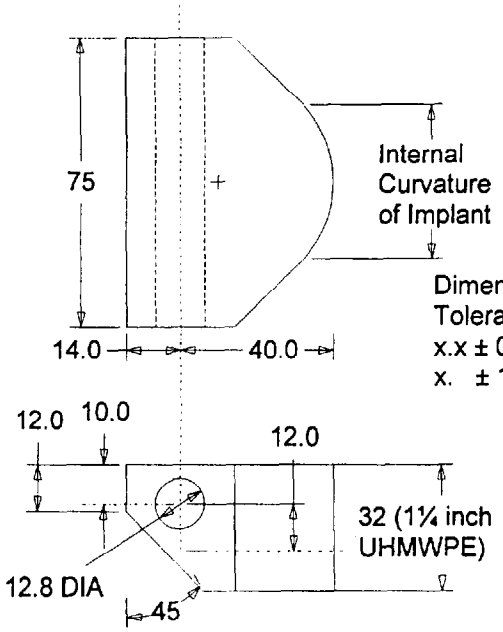


FIG. 11 Lumber Unilateral UHMWPE Block For Screws or Bolts

ment designed primarily to resist axial tension loading.

3.2.27.2 *hybrid longitudinal element*—a longitudinal element consisting of two or more types of longitudinal elements of different size or cross-section manufactured into a single element.

3.2.27.3 *plate*—a longitudinal element asymmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion.

3.2.27.4 *rod*—a longitudinal element symmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion.

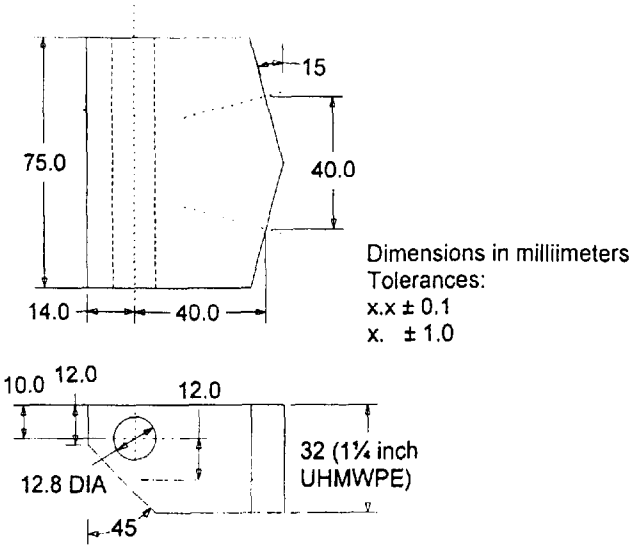


FIG. 13 Lumber Bilateral UHMWPE Block For Screws or Bolts

3.2.28 *maximum run out load or moment*—The maximum load or moment that can be applied to a spinal implant assembly where all of the tested constructs have withstood 5 000 000 cycles without a gross failure.

3.2.29 *motion segment*—two adjacent vertebrae, the intervening disc, and the associated ligamentous structures.

3.2.30 *permanent deformation*—the displacement (mm) of the spinal implant assembly relative to the unloaded condition remaining after the applied load has been removed.

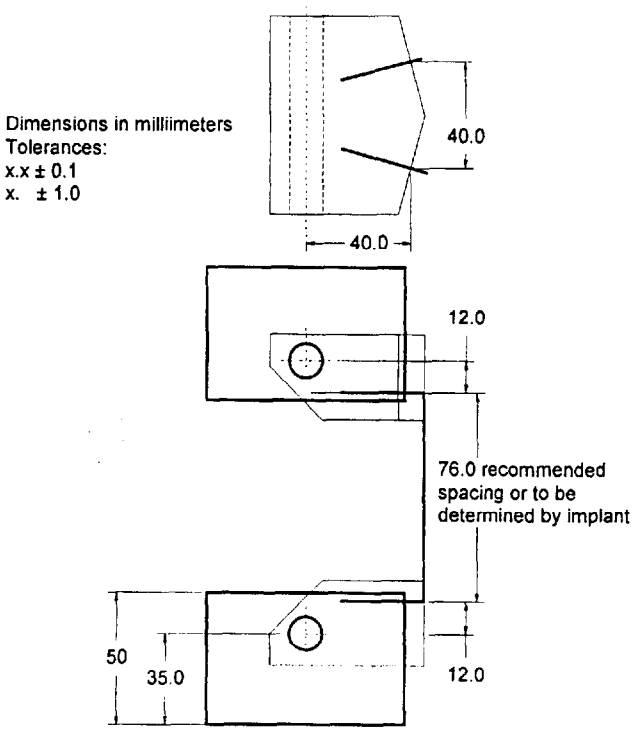


FIG. 12 Lumber Bilateral Construct Test Setup For Screws

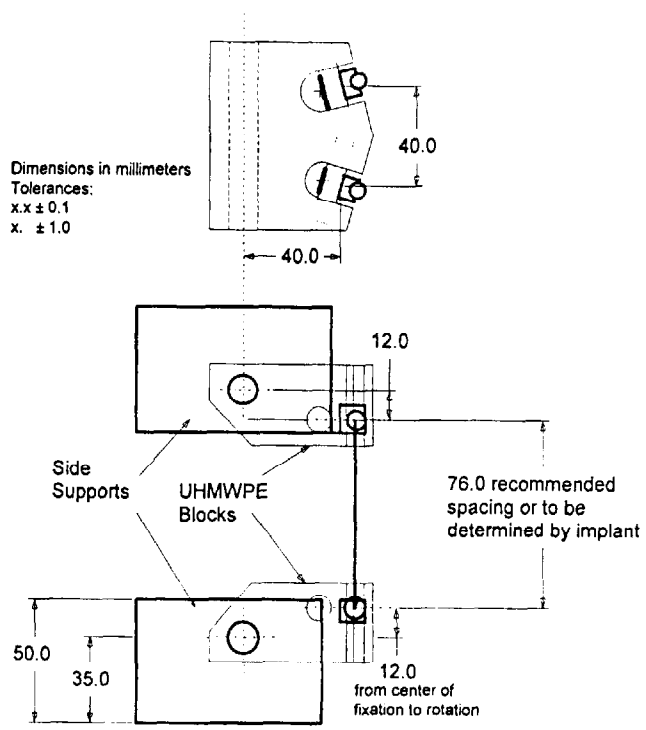


FIG. 14 Lumber Bilateral Construct Test Setup For Hooks, Cables, or Wires

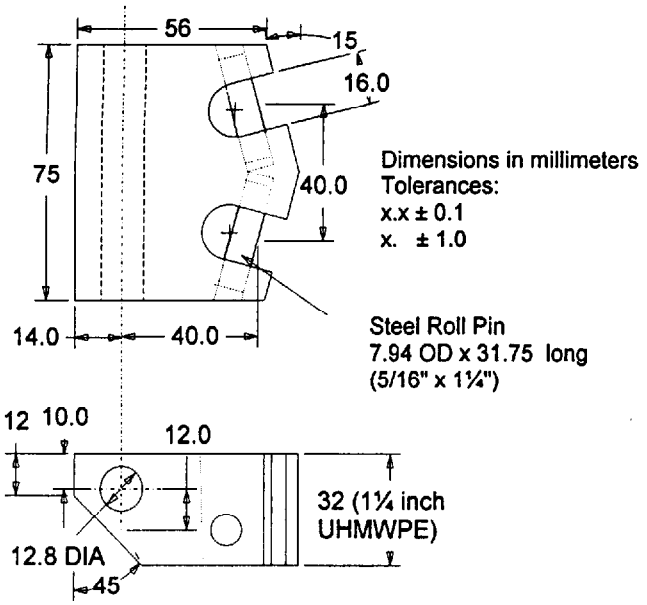


FIG. 15 Modified Lumber Bilateral UHMWPE Block For Hooks, Cables, or Wires

3.2.31 *spinal implant assembly*—a complete spinal implant configuration as intended for surgical use. A spinal implant assembly will contain anchors, interconnections and longitudinal elements and may contain transverse elements (see Figs. 4, 6, 8, 10, 12, and 14).

3.2.32 *stiffness (N/mm)*—The compressive or tensile yield load divided by elastic displacement. (The slope of line BC in Fig. 1.)

3.2.33 *subassembly*—any portion of an implant assembly that is comprised of two or more components.

3.2.34 *subconstruct*—any portion of an implant construct that is comprised of two or more components including spine, pelvis, ribs or substitute structure.

3.2.35 *test block*—the component of the test apparatus for mounting the spinal implant assembly. A specific design of test block is required for each intended spinal location and intended method of application. (See Figs. 5, 6, 9, 11, 13, and 15.)

3.2.36 *test block load point*—the location on the test block that transmits load from the test apparatus.

3.2.37 *tightening torque*—the specified torque that is applied to the various threaded fasteners of the spinal implant assembly.

3.2.38 *torsional aspect ratio*—the active length of the longitudinal element divided by the distance from the center of rotation to the insertion point of an anchor (For example: 1.70 for a 76 mm active length, x = 40 mm and y = 40/2 mm).

3.2.39 *torsional stiffness (N-m/degree)*—the yield torque (N-m) divided by elastic angular displacement (degree). (The slope of line BC in Fig. 1.)

3.2.40 *torsional ultimate strength (N-m)*—the maximum torque in x-y plane that can be applied to a spinal implant assembly. (The torque at Point E in Fig. 1.)

3.2.41 *transverse elements*—a component or subassembly that links longitudinal members together.

3.2.42 *two percent (2 %) offset angular displacement*—a permanent angular displacement in the x-y plane equal to 0.020 times the torsional aspect ratio (For example: 1.95° for 1.70 × 0.02 × 180°/pi). (Point B in Fig. 1.)

3.2.43 *two percent (2 %) offset displacement*—a permanent deformation equal to 0.020 times the active length of the longitudinal element (For example: 1.52 mm for a 76 mm active length of the longitudinal element or 0.70 mm for 35 mm). (Point B in Fig. 1.)

3.2.44 *ultimate displacement (mm)*—the displacement associated with the ultimate load, ultimate bending moment, or ultimate torque. (The displacement at Point F in Fig. 1.)

3.2.45 *vertebral span*—the number of vertebra that are spanned by the longitudinal element, including the vertebrae containing anchor components.

3.2.46 *yield torque*—the torque in x-y plane (N-m) required to produce a permanent displacement of 0.020 times of the active length of the longitudinal element. (The torque at Point D in Fig. 1.)

4. Summary of Provisional Test Methods

4.1 Similar test methods are proposed for the mechanical evaluation of cervical spinal implant assemblies (see Figs. 4, 6, and 8) and thoracolumbar, lumbar, and lumbosacral spinal implant assemblies (see Figs. 10, 12, and 14).

4.2 Testing of the spinal implant assemblies will simulate a corpectomy model via a large gap between two ultra high molecular weight polyethylene (UHMWPE (see Specification F 648)) test blocks. The UHMWPE test blocks (see Figs. 3, 5, 7, 9, 11, and 13) will eliminate the effects of the variability of bone properties and morphometry.

4.3 Four static mechanical tests and one dynamic test will evaluate the spinal implant assemblies. The four static mechanical tests are axial compression, compression bending, tensile bending, and torsion. The dynamic test is a compression bending fatigue.

4.4 A specific clinical indication generally requires a specific spinal implant assembly. Spinal implant assemblies will be evaluated with test configurations which simulate the clinical requirements for the intended spinal location. The intended spinal locations are both anterior (see Fig. 4) and posterior (see Figs. 6 and 8) surfaces of the cervical spine or both anterior (see Fig. 10) and posterior (see Figs. 12 and 14) surfaces of the thoracolumbar, lumbar, and lumbosacral spine. The bending moment arm for a test configuration depends on the intended spinal location. The cervical spine configurations specific to the cervical spine have one bending moment arm and the thoracolumbar, lumbar, and lumbosacral spine has a different bending moment arm.

4.5 The intended method of application of the spinal implant assembly may vary for specific anatomic regions and clinical indications. Spinal implant assemblies contain different types of anchors. Each type of anchor has an intended method of application to the spine. One assembly may include anterior vertebral body screws and rods (see Fig. 2), while another assembly may contain posterior sacral screws, hooks, rods, and rodlinks (see Fig. 3). The bending moment arm of a test configuration will be independent of the intended method of application of a spinal implant assembly, therefore the test data for different intended method of application may be compared.

5. Significance and Use

5.1 Spinal implants are generally composed of several components which, when connected together, form a spinal implant assembly. Spinal implant assemblies are designed to provide some stability to the spine while arthrodesis takes place. This provisional test method outlines standard materials and methods for the evaluation of different spinal implant assemblies, so that comparison between different designs may be facilitated.

5.2 This provisional test method is used to quantify the static and dynamic mechanical characteristics of different designs of spinal implant assemblies. The mechanical tests are conducted *in vitro* using simplified load schemes and do not attempt to mimic the complex loads of the spine.

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

5.4 Fatigue testing in a simulated body fluid or saline may cause fretting, corrosion or lubricate the interconnections and thereby affect the relative performance of tested devices. This test should be initially performed dry (ambient room conditions) for consistency. The effect of environment may be significant. Repeating all or part of these test methods in simulated body fluid, saline (9 g NaCl per 1000 mL water), a saline drip, water, or a lubricant should be considered.

5.5 The location of the longitudinal elements is determined by where the anchors are clinically placed against bony structures. The distance in the x direction (moment arm) between the axis of a hinge pin and the anchors' attachment points to a UHMWPE block is independent of the type of anchor. The distance between the anchors' attachment point to the UHMWPE block and the center of the longitudinal element is a function of the interface design between the screw, hook, wire, cable, etc. and the rod, plate, etc.

6. Apparatus

6.1 Test machines will conform to the requirements of Practice E 4.

6.2 The test apparatus allows multiple loading regimes to be applied to all forms of spinal implant assemblies. Two pair of side supports are mounted on the test machine (see Figs. 2, 4, 6, 8, 10, and 12). One pair of side supports attach to the actuator and the second to the load cell. A mounting plate for one of the sets of side support plates should be free to rotate about the Z axis for the compression, compression bending, tension bending, and fatigue tests. UHMWPE blocks are connected to the side supports via hinge pins. All testing will simulate a corpectomy model via a large gap between the two UHMWPE blocks. Select the appropriate design of the UHMWPE blocks (see Figs. 3, 5, 7, 9, 11, and 13) to facilitate testing of the spinal implant assembly in a manner that simulates the specific clinical indication at the intended spinal location.

6.3 The design of the UHMWPE blocks causes the plane through the spinal implant assemblies to be parallel to the plane (the y-z plane) through the axes of the hinge pins. Align the superior side supports and UHMWPE block with the inferior side supports and UHMWPE block such that the centerlines of their hinge pins are in the same y-z plane and have similar y positions. Center the test apparatus in the test machine such that the line through the mid-point (0, 0, zl) of inferior hinge pin's axis and the mid-point (0, 0, z2) of superior hinge pin's axis is collinear with the load and rotational axis of the test machine's actuator. Align the test configuration to within ± 0.10 mm of the load line axis of the test machine.

6.4 The distance in the x direction between the axis of a hinge pin and the anchors' attachment point is the bending moment arm. Spinal implant assemblies are designed for two intended spinal locations having two unique bending moment arms. The two intended spinal locations are the cervical spinal implant system (see Figs. 4, 6, and 8) and the thoracolumbar, lumbar and lumbosacral spinal implant system (see Figs. 10, 12, and 14). The test configurations for the cervical spinal implant system have a bending moment arm equal to 30.0 millimeters. The thoracolumbar, lumbar, and lumbosacral test configurations have a 40 mm bending moment arm.

6.5 The UHMWPE blocks are designed to provide similar bending moment arms regardless of the anchor being tested. Different spinal implant assembly have different intended methods of application to the UHMWPE blocks. The locations of the longitudinal elements are determined by the design of anchors and interconnections. The bending moment arm seen by the longitudinal element is a function of the designs of the interconnections anchors and longitudinal members.

6.6 The hinge pin in the test configuration allows the same test apparatus to be used for the static axial compression test, static compression bending test, static tensile bending test and static torsion test as well as the compression bending fatigue test. The UHMWPE blocks are allowed to rotate around the y-axis of the hinge pin during the compression bending, tensile bending and fatigue tests. Since only an axial force should be generated during the compression test, place aluminum blocks between the UHMWPE blocks and the base plates to stop any rotation around the hinge pin. The total clearance between an aluminum block, an UHMWPE block and a base plate will not exceed 0.10 mm.

6.7 Modified bilateral UHMWPE blocks (see Figs. 8, 9, 14, and 15) have been developed for testing hooks, wires or cables. Place steel roll pins into the modified blocks such that the outer surfaces of the roll pins are parallel to the front surfaces of the standard bilateral UHMWPE block (see Figs. 6, 7, 12, and 13). Hooks, wires, and cables are not fully constrained (semi-rigid) fixation devices because they can not transfer bending moments in all three axes. The combination of the rotation of modified UHMWPE block on hinge pin and the rotation of the hooks, wires, or cables around the steel roll pins means that the test configuration would be a mechanism. Therefore, the testing of hooks, wires and cables necessitates that the modified UHMWPE block must not rotate. Place an aluminum block between the modified UHMWPE block and the base plate to stop rotation around the hinge pin and eliminate a degree of freedom in a similar manner as the axial compression test.

6.8 The relative location (x direction versus z direction) between the hinge pin and the insertion point of an anchor

produces minimal variation in the moment arm. The variation in the moment arm is dependent on the direction of rotation of the UHMWPE blocks. The variation is minimized by having the hinge pins in the UHMWPE blocks rotate past the anchors as the test progresses. Position the hinge pins internal to the anchors during the tension bending test (not shown). Position the hinge pins external to the anchors during the compression bending, torsion and fatigue tests (see Figs. 4, 6, 8, 10, 12, and 14). The compression test is not influenced by the relative position of the hinge pins and anchors, however, use the same arrangement as the compression bending, torsion and fatigue tests (see Figs. 4, 6, 8, 10, 12, and 14).

6.9 The thoracolumbar, lumbar, and lumbosacral test apparatus has a recommended active length of the longitudinal element equal to 76.0 mm and based on the work of Cunningham, et al[5]. The recommended active length of the longitudinal element for the cervical spinal implant system is 35.0 mm. If the longitudinal element has fixed spacings and the recommended active length can not be achieved, then select the longitudinal element that is nearest the recommended active length. The active length should be constant for all constructs used in comparative testing.

6.10 The testing machine and the apparatus used in the static axial compression, static compression bending, static tension bending, and compression bending fatigue tests applies load in the *z* direction without constraining rotation in the *x-y* plane. The hinge pin in the apparatus allows rotation in the *x-z* plane during the static compression bending, static tension bending, and compression bending fatigue tests. The aluminum block in the apparatus prevents rotation in the *x-z* plane during the static compression tests. The compression bending fatigue test will use the same test configuration as compressive bending.

6.11 The testing machine or the apparatus used in the static torsion test applies torque about the *z* axis without constraining displacement in the *z* direction. The aluminum blocks are placed in the apparatus to prevent rotation in the *x-z* plane during the static torsion tests.

7. Sampling

7.1 All components in the spinal implant assembly shall be previously unused parts only, and shall not be retested.

7.2 Use the UHMWPE (Specification F 648) test blocks for only one test. Blocks should not be reused for testing.

7.3 Label and maintain the test constructs according to good laboratory practice. Do not disassemble the test construct after testing unless disassembly is necessary to evaluate failure surfaces or interconnections. Prior to disassembly photograph the construct.

7.4 All static tests should have a minimum of five samples. Determine the minimum samples size as outlined in Practice E 122.

7.5 The results of the fatigue testing will provide a curve of cyclical compression bending load versus the number of cycles at failure. The moment is the load multiplied by 30.0 mm for cervical spinal implant systems (see Figs. 4, 6, and 8). The moment is the load multiplied by 40.0 mm for thoracolumbar, lumbar, and lumbosacral spinal implant systems (see Figs. 10, 12, and 14). The initial fatigue loads will be 75, 50, and 25 % of the compression bending strength as determined in the static compression bending test. If a specimen does not fail by 5 000 000 cycles, then discontinue testing of that component. An initial sample size equal to two specimens is necessary at each load or moment. The final sample size is recommended by Practice E 739. Establish the maximum run out load or moment (all constructs complete of 5 000 000 cycles). The precision in establishing the value for the maximum run out load or moment should be less than 10 % of the compression bending strength. Conduct a regression analysis on the load or moment versus number of cycles to failure data.

8. Procedures

8.1 *Procedure for Static Tests:*

8.1.1 *Static Axial Compression Test:*

8.1.1.1 Select the appropriate UHMWPE blocks for the spinal implant assembly. Use unilateral UHMWPE blocks (see Figs. 5 and 11) for singular longitudinal element constructs. Use bilateral UHMWPE blocks (see Figs. 7 and 13) during the testing of screws, bolts etc. Use modified bilateral UHMWPE blocks (see Figs. 9 and 15) during the testing of hooks, wires, or cables.

8.1.1.2 Fix anchors to the UHMWPE blocks according to the manufacturer's instructions.

8.1.1.3 Position UHMWPE blocks in the test apparatus such that the hinge pins lie external to the anchors in the *xz* plane. The hinge pin in the superior block is more superior than the screw, hook, etc. and the hinge pin in the inferior block lies inferior to the anchor. Secure UHMWPE blocks with hinge pins. Place the aluminum blocks between the UHMWPE blocks and the base plates to stop rotation around the hinge pin.

8.1.1.4 Complete the spinal implant assembly in a standard construct (see Figs. 4, 6, 8, 10, 12, and 14) or a hybrid construct (see Fig. 3). Apply all tightening, crimping or locking mechanisms as specified by the manufacturer.

8.1.1.5 Load the test apparatus at a rate equal to 25 mm per minute.

8.1.1.6 Record the load displacement curves. Establish the displacement at 2 % offset yield (mm), elastic displacement (mm), compressive yield load (N), stiffness (N/mm), ultimate displacement (mm), and compressive ultimate strength (N).

8.1.1.7 Only the load parameters in the relevant direction need be evaluated.

8.1.2 *Static Compression Bending Test:*

8.1.2.1 Select the appropriate UHMWPE blocks for the spinal implant assembly as previously described.

8.1.2.2 Install the anchors according to the manufacturer's instructions. If one modified bilateral UHMWPE block is used then place an aluminum spacer block between the modified UHMWPE block and the base plate to stop rotation around the hinge pin. A degree of freedom is eliminated in a similar manner to the axial compression test. If the spinal implant assembly requires two sets of modified bilateral UHMWPE blocks and aluminum spacer blocks,

[5] Cunningham, B.W., Sefer, J.O., Shono, Y., and McAfee, P.C., "Static and Cyclical Biomechanical Analysis of Pedicle Screw Spinal Constructs," *Spine*, Vol. 18, No. 12, pp. 1677-1688.

then the test is equivalent to an axial compression test and need not be repeated.

8.1.2.3 Place UHMWPE blocks into the test apparatus such that the position of the hinge pins are external to the anchors (the hinge pin in the superior block is more superior than the screw, hook, etc.). Secure UHMWPE blocks with hinge pins. If one modified bilateral UHMWPE block is used to test hooks, wires, or cables then place it superiorly.

8.1.2.4 Complete the spinal implant assembly in a standard construct (see Figs. 4, 6, 8, 10, 12, and 14) or a hybrid construct (see Fig. 3). Set the active length of the longitudinal element for the intended spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.2.5 Load the test apparatus at a rate equal to 25 mm per minute.

8.1.2.6 Record the load displacement curves. Establish the displacement at 2 % offset yield (mm), elastic displacement (mm), compressive bending yield load (N), compressive bending yield moment (N-m), compressive bending stiffness (N-m/mm), compressive bending ultimate displacement (mm), and compressive bending ultimate strength (N-m).

8.1.2.7 Evaluate only the load parameters in the relevant direction.

8.1.3 *Static Tension Bending Test:*

8.1.3.1 Select the appropriate UHMWPE blocks for the spinal implant assembly as previously described.

8.1.3.2 Install the anchors according to the manufacturer's instructions. If one modified bilateral UHMWPE block is used then place an aluminum spacer block between the modified UHMWPE block and the base plate to stop rotation around the hinge pin. A degree of freedom is eliminated in a similar manner to the axial compression test. If the spinal implant assembly requires two sets of modified bilateral UHMWPE blocks and aluminum spacer blocks, then the test is equivalent to an axial tension test.

8.1.3.3 Place UHMWPE blocks into the test apparatus such that the position of the hinge pins are internal to the anchors (the hinge pin in the superior block is more inferior than the screw, hook, etc.). Secure UHMWPE blocks with hinge pins. If one modified bilateral UHMWPE block is used to test hooks, wires, or cables then place it superiorly.

8.1.3.4 Complete the spinal implant assembly in a standard construct (see Figs. 4, 6, 8, 10, 12, and 14 except the UHMWPE block are inverted) or a hybrid construct (see Fig. 2 except the UHMWPE block are inverted). Set the active length of the longitudinal element for the intended spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.3.5 Load the test apparatus at a rate equal to 25 mm per minute.

8.1.3.6 Record the load displacement curves. Establish the displacement at 2 % offset yield (mm), elastic displacement (mm), tensile bending yield load (N), tensile bending yield moment (N-m), tensile bending stiffness (N-m/mm), tensile bending ultimate displacement (mm), and tensile bending ultimate strength (N-m).

8.1.3.7 Evaluate only the load parameters in the relevant direction.

8.1.4 *Static Torsional Test:*

8.1.4.1 Select the appropriate UHMWPE blocks for the spinal implant assembly as previously described.

8.1.4.2 Install the anchors according to the manufacturer's instructions. If the spinal implant assembly contains only hooks, then the system will not be able to resist torsional moments and need not be tested.

8.1.4.3 Place UHMWPE blocks in the test apparatus such that the position of the hinge pins is external to the anchors. The hinge pin in the superior block is more superior than the screw, hook etc. and the hinge pin in the inferior block is more inferior than the screw, hook etc. Secure UHMWPE blocks with hinge pins. If only one modified bilateral UHMWPE block is used to test hooks, wires, or cables, then place it superiorly. Attach UHMWPE blocks to the side supports via hinge pins. Place the aluminum blocks between the UHMWPE blocks and the base plates to stop rotation around the hinge pin.

8.1.4.4 Complete the spinal implant assembly in a standard construct (see Figs. 4, 6, 8, 10, 12, and 14) or a hybrid construct (see Fig. 3). Set the active length of the longitudinal element for the intended spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.4.5 Load the test apparatus at a rate equal to 60° per minute.

8.1.4.6 Record the load displacement curves. Determine the angular displacement at 2 % offset yield (degrees), elastic angular displacement (degrees), yield torque (N-m), torsional stiffness (N-m/degree).

8.1.4.7 Evaluate only the load parameters in the relevant direction.

8.2 *Procedure for Dynamic Testing:*

8.2.1 Select the appropriate UHMWPE blocks for the spinal implant assembly. Use unilateral UHMWPE blocks (see Figs. 5 and 11) for singular longitudinal element constructs. Use bilateral UHMWPE block (see Figs. 7 and 13) for the testing of screws, bolts, etc. Use modified bilateral UHMWPE block (see Figs. 9 and 15) for the testing of hooks, wires, or cables.

8.2.2 Install the anchors according to the manufacturer's instructions. If one modified bilateral UHMWPE block for hooks, wires, cables, etc. is used, then place an aluminum spacer block between the modified UHMWPE block and the base plate to stop rotation about the hinge pin. The extra degree of freedom is eliminated in a manner similar to the axial compression test. If the spinal implant assembly requires two sets of modified bilateral UHMWPE blocks and aluminum spacer blocks, then the test is an axial compression fatigue test.

8.2.3 Place UHMWPE blocks in the test apparatus such that the position of the hinge pins is external to the anchors. The hinge pin in the superior block is more superior than the anchor and the hinge pin in the inferior block is more inferior than the screw, hook etc. Secure UHMWPE blocks with hinge pins. If only one modified bilateral UHMWPE block is used to test hooks, wires, cables, etc., then place it superiorly.

8.2.4 Complete the spinal implant assembly in a standard construct (see Figs. 4, 6, 8, 10, 12, and 14) or a hybrid construct (see Fig. 2). Set the active length of the longitudinal element for the intended spinal location. Apply all tight-

ening, crimping, or locking mechanisms as specified by the manufacturer.

8.2.5 The fatigue test applies a sinusoidal compressive bending load to the spinal implant assemblies. Control the loading via a constant sinusoidal load amplitude control. The maximum cycle rate is five cycles per second for the fatigue test. The end of the test is when the spinal construct has a gross failure.

8.2.6 The initial fatigue loads will be 75, 50, and 25 % of the compression bending strength as determined in the static compression bending test. One load level should have specimens that do not fail before 5 000 000 cycles. The load determined as the maximum run out load or moment should not deviate more 10 % of the level of the compression bending strength. A semi-log fatigue curve of the compression bending load or moment versus number of cycles at failure will be plotted.

8.2.7 Evaluate only the load parameters in the relevant direction.

9. Report

9.1 The report should specify the spinal implant components, the spinal implant assembly, the intended spinal location and the numbers of specimens tested. Describe all available information about the components including name, design, manufacturer, the material, the part number, etc. Also include any specific information necessary to produce the assembly including the tightening torque.

9.2 Include the illustration of the exact loading configurations. Describe the similarities and differences to relevant figures contained herein. Report the active length. Report the bending moment arm and the distance in the x direction between the centerline of the longitudinal element and the insertion point of the anchors on the UHMWPE blocks. Outline any deviations from the recommended test procedure. State the rate of loading.

9.3 The report of the static mechanical testing shall include a complete description of all fatigues, modes of failure, deformations of the spinal implant assembly, or test apparatus. Include any noticeable fretting or surface texturing. The static mechanical test report shall include:

9.3.1 Show a typical load-displacement curve for the static axial compression test. Report all static axial compression test data, the mean and standard deviation for displacement at 2 % offset yield (mm), elastic displacement (mm), compressive yield load (N), stiffness (N/mm), ultimate displacement (mm), and compressive ultimate strength (N).

9.3.2 Show a typical load-displacement curve for a static compression bending test. Report all static compression bending test data, the mean and standard deviation for the displacement at 2 % offset yield (mm), elastic displacement (mm), compressive bending yield load (N), compressive bending yield moment (N-m), compressive bending stiffness (N-m/mm), compressive bending ultimate displacement (mm) and compressive bending ultimate strength (N-m).

9.3.3 Show a typical load-displacement curve for the static tension bending test. Report all static tension bending test data, the mean and standard deviation for the displacement at 2 % offset yield (mm), elastic displacement (mm), tensile bending yield load (N), tensile bending yield moment (N-m), tensile bending stiffness (N-m/mm), tensile bending ultimate displacement (mm), and tensile bending ultimate strength (N-m).

9.3.4 Show a typical load-displacement curve for the static torsional test. Report all static torsional test data, the mean, and standard deviation for the angular displacement at 2 % offset yield (degrees), elastic angular displacement (degrees), yield torque (N-m), torsional stiffness (N-m/degree).

9.4 The report of the dynamic mechanical testing shall include:

9.4.1 State the final sample sizes and load versus number of cycles at failure for the fatigue test. State the load levels for the specimen enduring 5 000 000 cycles and the maximum run out load or moment.

9.4.2 Report all initial and secondary failures, modes of failure and deformations of components for the spinal implant assembly and the test apparatus. Fatigue failures should include a description of the failure initiation site, propagation zone, and ultimate failure zone. Describe any fretting of interfaces or loosening of interconnections. Include pictures of failure surfaces and surface texturing from fretting.

9.4.3 Plot a semi-log fatigue curve of the compression bending load or moment versus number of cycles at failure. Indicate specimen that have not failed before 5 000 000 cycles.

9.4.4 Report a regression analysis of the load or moment versus number of cycles to failure data.

10. Precision and Bias

10.1 *Precision*—It is not practical to specify the precision of the procedure in this provisional test method because of the wide variance in design of the components to be tested.

10.2 *Bias*—No statement can be made as to bias of this provisional test method since no acceptable reference values are available, nor can they be obtained because of the destructive nature of the tests.

11. Keywords

11.1 dynamic test methods; corpectomy model; spinal implant assembly; spinal implant construct; static test method

APPENDIX

(Nonmandatory Information)

X1. Rationale

X1.1 Spinal implant assemblies contain many different component designs can be assembled into a wide variety of configurations and combination for different clinical indications dependent on the clinical requirements, intended clinical location and intended method of application. The purpose of this provisional test method is to provide the framework for a comprehensive series of mechanical tests that can be used to compare different implant designs in a consistent manner.

X1.2 A spinal implant assembly contains groups of components necessary for specific clinical indications. This provisional test method contains test configurations for the evaluation of spinal implant assemblies that simulate the clinical requirements for an intended clinical location and method of application. Some designs of thoracolumbar, lumbar and lumbosacral spine system are intended for both anterior and posterior attachment. These systems include anterior vertebral body/sacral screws, hooks, rods, and rodlinks. Figure 2 is an example of a standard test configuration (see Figs. 6 or 12) that simulates a common clinical group of components normally applied to the anterior surface of a vertebral body. The hybrid test configuration seen in Fig. 3 would normally be applied posteriorly and contains sacral screws, hooks, rods and rodlinks.

X1.3 A spinal implant assembly installed in the test apparatus will simultaneously evaluate all components within the assembly in the worst case test configuration (corpectomy model). A corpectomy model is assumed to be the worst case scenerio because all loads are transferred from the fixtures and transmitted only through the implant construct. All proposed test configurations are based on anatomical dimensions.

X1.4 This provisional test method covers the static and dynamic evaluation of spinal implant assemblies. The purpose of spinal implants is to provide short term stability while arthrodesis takes place. This provisional test method does not address the long term mechanical stability of spinal implants, nor does it address implants that do not lead to spinal fusion.

X1.5 Uniaxial loading, uniaxial torque and combination loading and bending moments are applied in this provisional test method. Numerous combinations of multiaxial loading conditions *in vivo* have not yet been fully defined. This provisional test method outlines a series of simplistic static and dynamic loading conditions and does not attempt to mimic the complex loading patterns in the spine.

X1.6 The influence of simulated body fluid or saline may affect the relative performance of tested devices. The tests outlined here should be performed dry (ambient room conditions) to eliminate unwanted complexity resulting from environmental factors. This will reduce the variability of the results. Individual investigator may consider addition evaluations in simulated body fluid, saline, water, or lubricants to address environmental factors.

X1.7 The variation in the moment arm for the static and dynamic bending tests is a function of the relative location (x direction versus z direction) between the hinge pin and the insertion point of the anchor. The variation in the relative location is dependent on the direction of rotation (tension or compression) and arrangement of the UHMWPE blocks. The variation in the moment arm for the thoracolumbar, lumbar and lumbosacral test configuration ranges between ± 3 % for a 44 mm displacement or 37° rotation of each block. The moment arm variations for the cervical test configuration range between ± 2 % for a 27 mm displacement or 27° rotation of each block.

X1.8 This provisional test method is not intended to define performance levels of spinal implants as insufficient knowledge is available to predict the consequence of the use of particular spinal implant design and assemblies.