Designation: F2706 – 17

Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model[1]

This standard is issued under the fixed designation F2706; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 These test methods cover the materials and methods for the static and fatigue testing of occipital-cervical and occipital-cervical-thoracic spinal implant assemblies in a vertebrectomy model. The test materials for most combinations of occipital-cervical and occipital-cervical-thoracic spinal implant components can be specific depending on the intended location and intended method of attachment.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future occipital-cervical and occipital-cervical-thoracic spinal implant assemblies. They allow comparison of occipital-cervical and occipital-cervical-thoracic spinal implant constructs with different methods of application to the spine. These test methods are 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 These test methods set out guidelines for load types and methods of applying loads. Methods for three static load types and two fatigue tests for the comparative evaluation of occipital-cervical and occipital-cervical-thoracic spinal implant assemblies are defined.

1.4 These test methods establish guidelines for measuring displacements, determining the yield load, and evaluating the stiffness and strength of occipital-cervical or occipital-cervical-thoracic spinal implant assemblies.

1.5 It may not be possible to test some occipital-cervical and some occipital-cervical-thoracic spinal constructs in all test configurations.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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.*

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Verification of Testing Machines
E6 Terminology Relating to Methods of Mechanical Testing
E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data
E1823 Terminology Relating to Fatigue and Fracture Testing
F1582 Terminology Relating to Spinal Implants
F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
F2077 Test Methods For Intervertebral Body Fusion Devices

3. Terminology

3.1 *Definitions*—For definitions of terms relating to these test methods, see Terminologies E6, F1582, and E1823.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *active length of the longitudinal element, n*—the straight line distance between the centers of rotation of the test blocks.

3.2.2 *block moment arm, n*—the perpendicular to the applied load between the insertion point of an anchor and the axis of the hinge pin.

3.2.3 *compressive or tensile bending stiffness (N/mm), n*—the compressive or tensile bending yield force divided by elastic displacement (see the initial slope of line *BC* in Fig. 1).

3.2.4 *compressive or tensile bending ultimate load (N), n*—the maximum compressive or tensile force in the *X-Z* plane

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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.

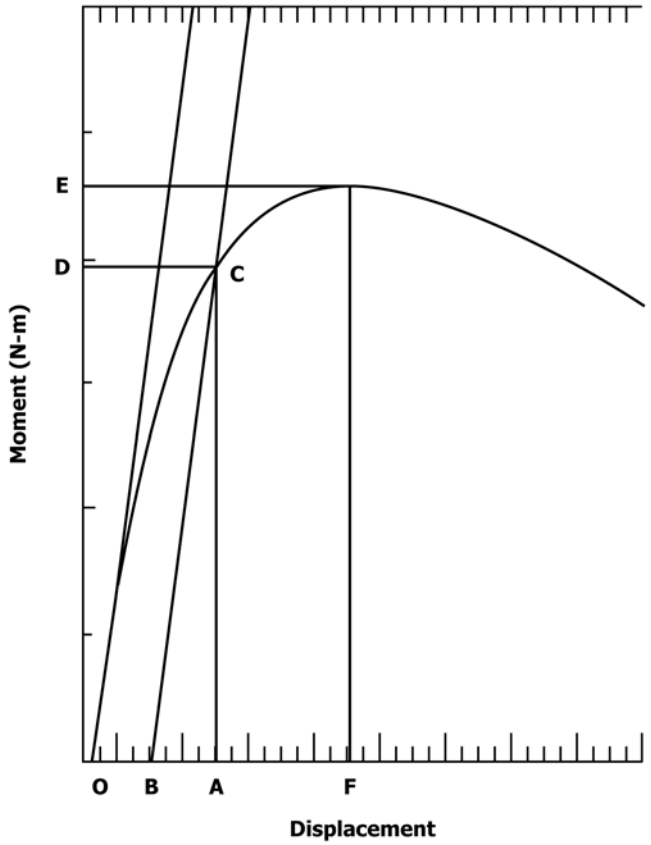


FIG. 1 Typical Load Displacement Curve or Torque Angulation Curve

applied to an occipital-cervical or occipital-cervical-thoracic spinal implant assembly (see the force at Point E in Fig. 1). The ultimate load should be a function of the device and not of the load cell or testing machine.

3.2.5 *compressive or tensile bending yield load (N), n*—the compressive or tensile bending force in the *X-Z* plane necessary to produce a permanent deformation equal to 0.020 times the active length of the longitudinal element (see the force at Point D in Fig. 1).

3.2.6 *coordinate system/axes, n*—three orthogonal axes are defined in Figs. 2 and 3. The anterior-posterior axis is *X* with positive being anterior. The medial-lateral axis is *Y* with left being positive when viewed posteriorly. The superior-inferior axis is *Z* with superior being positive.

3.2.7 *displacement at 2 % offset yield (mm), n*—the displacement of a construct measured via the actuator that produces a permanent deformation equal to 0.020 times the active length of the longitudinal element (distance OA in Fig. 1).

3.2.8 *elastic angular displacement (degrees), n*—the angular displacement at 2 % offset yield (see Point A in Fig. 1) minus the 2 % offset angular displacement (see Point B in Fig. 1) (that is, the distance between Point A and Point B in Fig. 1).

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

3.2.10 *failure, n*—permanent deformation resulting from fracture, plastic deformation, or loosening beyond the ultimate displacement or loosening that renders the occipital-cervical or occipital-cervical-thoracic spinal implant assembly ineffective or unable to adequately resist load.

3.2.11 *fatigue life, n*—the number of loading cycles, *N*, of a specified character that the occipital-cervical or occipital-cervical-thoracic spinal implant assembly sustains before failure of a specified nature occurs (see Terminology E1823).

3.2.12 *hinge pin, n*—the cylindrical rod connecting a test block to a side support. The superior and inferior aspects of the test construct are each secured with a single 9.6-mm diameter pin.

3.2.13 *insertion point of an anchor, n*—the location where the anchor is attached to the test block. The insertion points shown in Figs. 4-7 are to be adhered to, if possible. In situations where the design of the occipital-cervical or occipital-cervical-thoracic spinal implant assembly or the manufacturer's surgical instructions for installation dictate otherwise, the attachment points may deviate from these dimensions.

3.2.14 *intended method of application, n*—occipital-cervical and occipital-cervical-thoracic spinal implant assemblies contain different types of anchors. Each type of anchor has an intended method of application to the spine.

3.2.15 *intended occipital-cervical spinal location, n*—the anatomic region of the spine intended for the application of the

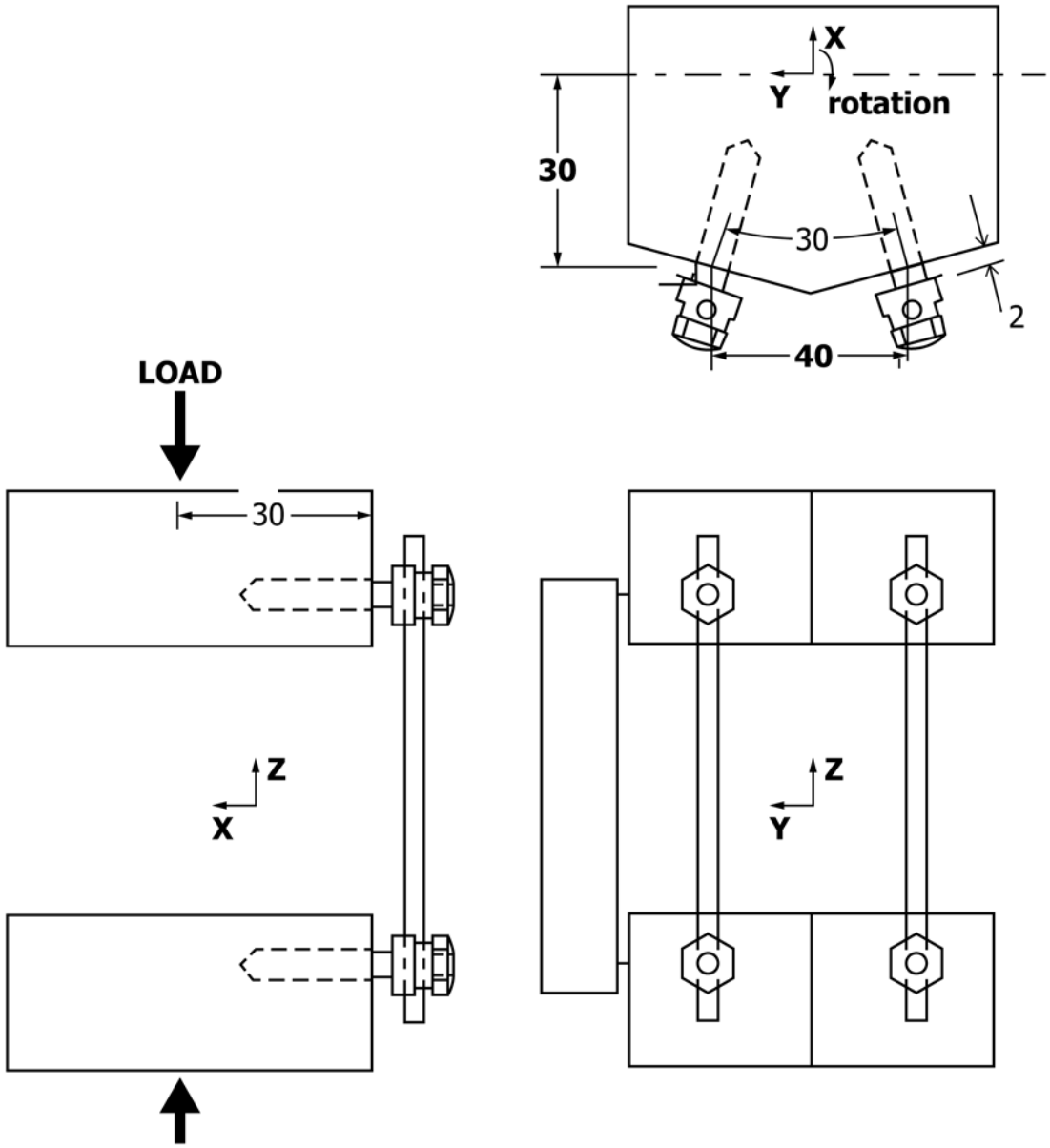


FIG. 2 A Standard Bilateral Construct Containing Screw, Rod and Screw

occipital-cervical spinal implant assembly. Spinal implant assemblies are developed for specific spinal locations such as the posterior occipital-cervical spine.

3.2.16 *intended occipital-cervical-thoracic spinal location, n*—the anatomic region of the spine intended for the application of the occipital-cervical-thoracic spinal implant assembly. Spinal implant assemblies are developed for specific spinal locations such as the posterior occipital-cervical-thoracic spine.

3.2.17 *longitudinal axis offset (mm), n*—distance in the *X* direction between the centerline of the longitudinal element and the insertion point of the anchors on the polyacetal test block.

3.2.18 *longitudinal direction, n*—the initial spatial orientation parallel to the longitudinal element of the occipital-cervical or occipital-cervical-thoracic spinal implant assembly. The longitudinal direction is generally in the superior-inferior direction and therefore, generally parallel to the *Z*-axis.

3.2.19 *maximum runout load, n*—the maximum load that can be applied to an occipital-cervical or occipital-cervical-thoracic spinal implant assembly where all of the tested constructs have withstood 5 000 000 cycles without a failure.

3.2.20 *occipital-cervical spinal implant assembly, n*—a complete occipital-cervical spinal implant configuration as intended for surgical use. An occipital-cervical spinal implant assembly will contain anchors, interconnections, and longitudinal elements and may contain transverse elements (see Figs. 2-7).

3.2.21 *occipital-cervical spinal implant construct, n*—a complete occipital-cervical spinal implant assembly attached to the appropriate test blocks.

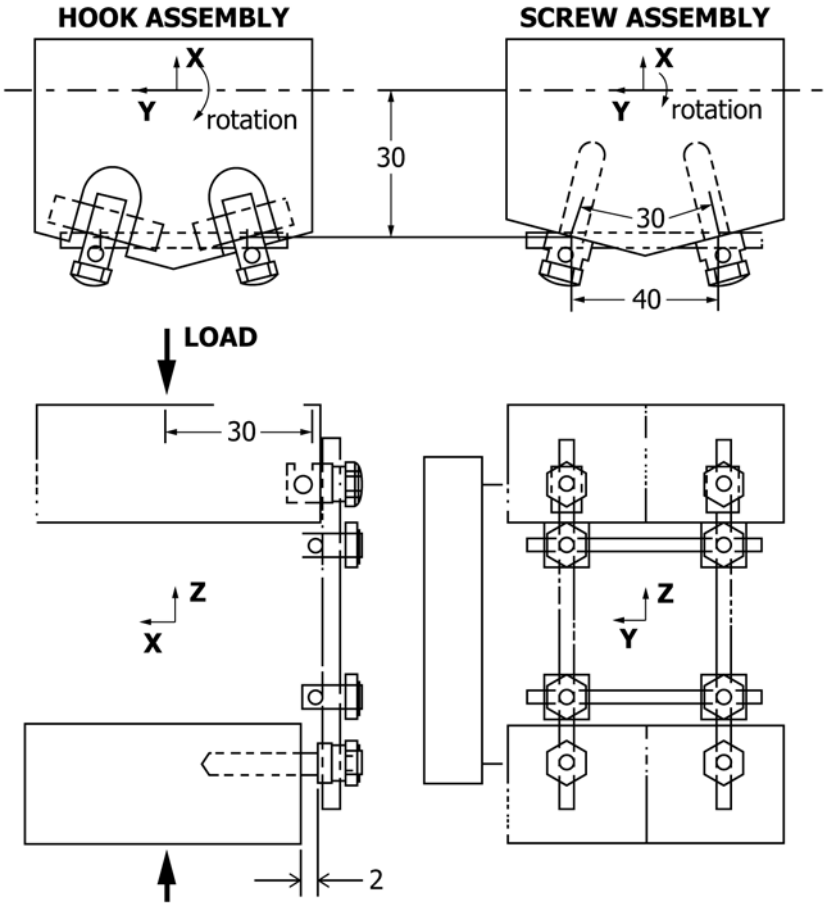


FIG. 3 A Bilateral Hook, Rod, Screw, and Transverse Element Construct

3.2.22 *occipital-cervical-thoracic spinal implant assembly, n*—a complete occipital-cervical-thoracic spinal implant configuration as intended for surgical use. An occipital-cervical-thoracic spinal implant assembly will contain anchors, interconnections, and longitudinal elements and may contain transverse elements (see Figs. 2-7).

3.2.23 *occipital-cervical-thoracic spinal implant construct, n*—a complete occipital-cervical-thoracic spinal implant assembly attached to the appropriate test blocks.

3.2.24 *offset angular displacement at 2 % offset, n*—a permanent angular displacement in the *X-Y* plane measured via the actuator equal to 0.020 times the torsional aspect ratio (for example: 1.95° for 1.70 × 0.02 × 180°/pi) (see Point B in Fig. 1).

3.2.25 *offset displacement (mm), n*—a permanent deformation measured via the actuator 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) (see Point B in Fig. 1).

3.2.26 *permanent deformation, n*—the displacement (mm) or angular displacement (degree) of the occipital-cervical or occipital-cervical-thoracic spinal implant construct relative to the initial unloaded condition as measured via the actuator after the applied load, moment, or torque has been removed.

3.2.27 *test block, n*—the component of the test apparatus for mounting the occipital-cervical or occipital-cervical-thoracic spinal implant assembly. A specific design of test block is required for each intended spinal location and intended method of application. Figs. 5-7 describe the recommended designs for the test blocks; however, alternate designs can be used as long as equivalent performance is demonstrated.

3.2.28 *test block load point, n*—the location on the test block at which the resultant load is transmitted from the test apparatus.

3.2.29 *tightening torque, n*—the specified torque that is applied to the various threaded fasteners of the occipital-cervical or occipital-cervical-thoracic spinal implant assembly.

3.2.30 *torsional aspect ratio, n*—the active length of the longitudinal element divided by the distance from the center of rotation to the insertion point of an anchor on the cervical block (for example: in Fig. 2, 1.70 for a 76-mm active length, $X = 40$ mm and $Y = 40/2$ mm).

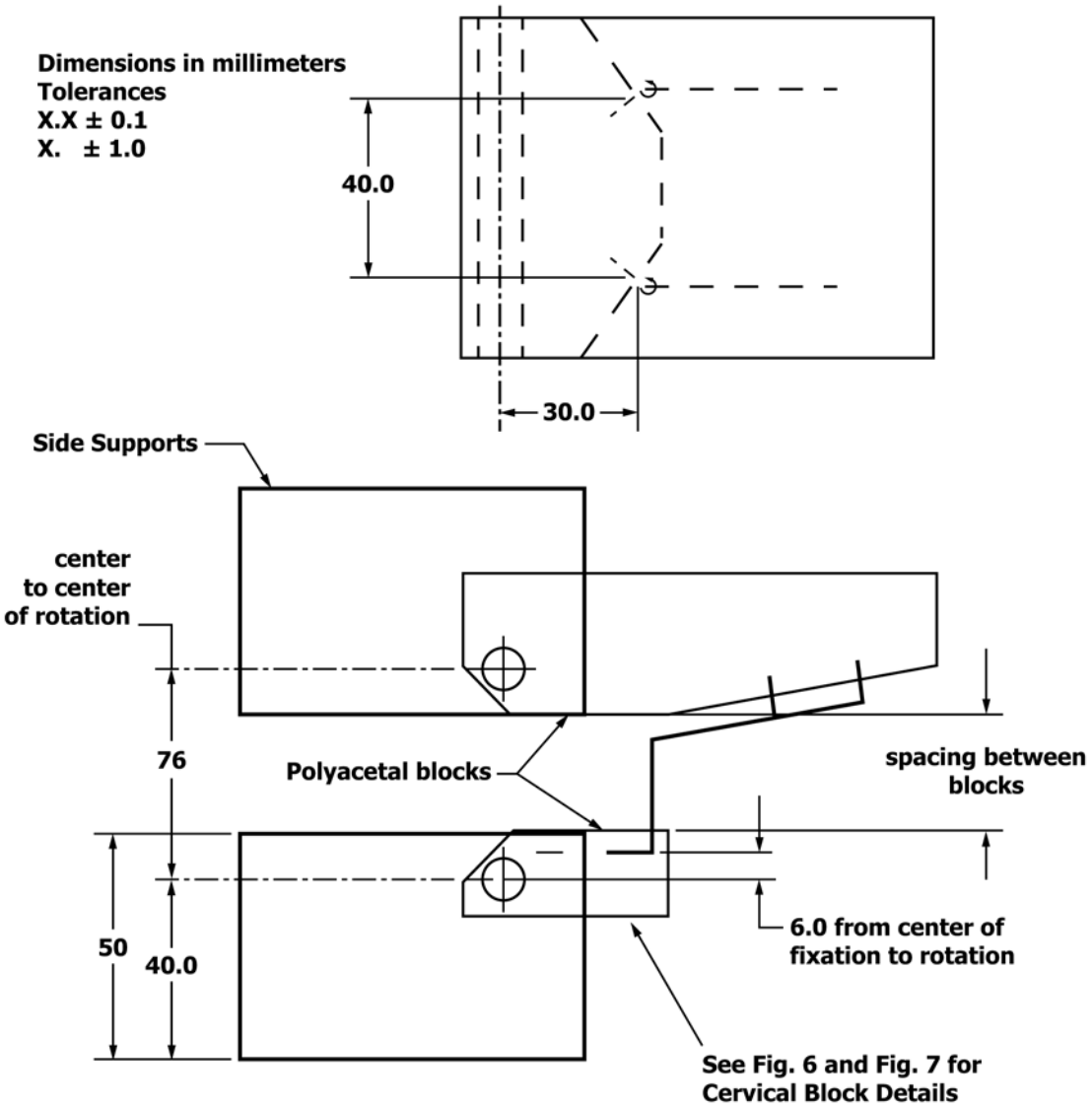


FIG. 4 Occipital-Cervical Bilateral Construct Test Setup for Occipital Screws or Bolts

$$A = \frac{L}{D} = \frac{L}{(x^2+y^2)^{1/2}} \quad (1)$$

where:

L = active length of longitudinal element,
D = distance to insertion point,
x = x distance to insertion point, and
y = y distance to insertion point.

3.2.31 *torsional stiffness (N-m/degree), n*—the yield torque (N-m) divided by elastic angular displacement (degrees) (the initial slope of line *BC* in Fig. 1).

3.2.32 *torsional ultimate load (N-m), n*—the maximum torque in the *X-Y* plane applied to an occipital-cervical or occipital-cervical-thoracic spinal implant assembly (the torque at Point E in Fig. 1). The ultimate torque should be a function of the device and not of the load cell or testing machine.

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

3.2.34 *yield displacement (distance OA—Fig. 6), n*—the displacement (mm) or angular displacement (deg) when an assembly has a permanent deformation equal to the offset displacement or the offset angular displacement.

3.2.35 *yield torque (N-m), n*—the torque in the *X-Y* plane required to produce a permanent displacement of 0.020 times the torsional aspect ratio (the torque at Point D in Fig. 1).

3.2.36 *zero displacement intercept (mm), n*—the intersection of the straight line section of the load-displacement curve and the zero load axis (the zero displacement reference Point 0 in Fig. 1).

4. Summary of Test Methods

4.1 Similar test methods are proposed for the mechanical evaluation of all occipital-cervical and occipital-cervical-thoracic spinal implant assemblies (see Fig. 4).

4.2 A vertebrectomy model is used for the evaluation of both occipital-cervical and occipital-cervical-thoracic systems.

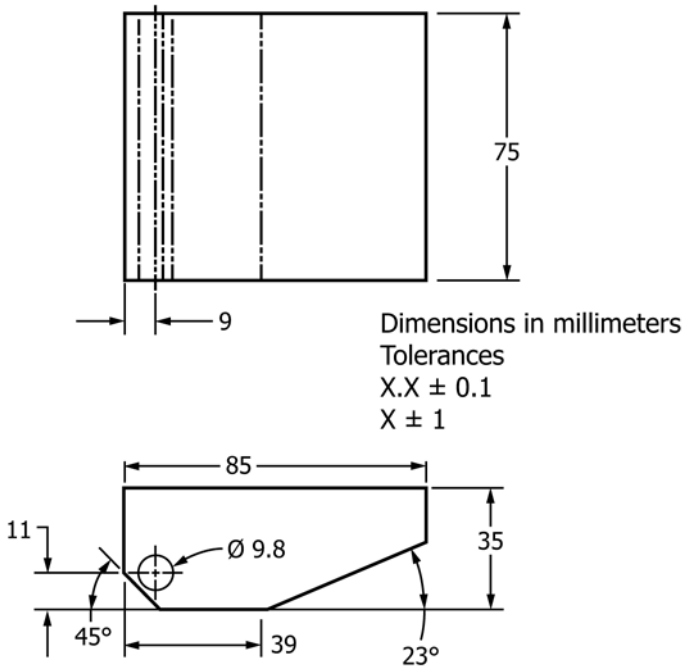


FIG. 5 Occipital Bilateral Polyacetal Block for Occipital Screws or Bolts

The spinal hardware is attached at the superior and inferior aspects to polyacetal homopolymer (polyacetal) test blocks separated by a large gap. The polyacetal homopolymer used to manufacture the test blocks should have a tensile breaking strength no less than 61 MPa. The use of polyacetal test blocks (see Figs. 5-8) eliminates the effects of the variability of bone geometry and material properties associated with cadaveric testing. Alternate designs of test blocks may be used as long as equivalent performance is demonstrated.

4.3 Three static mechanical tests and two dynamic tests will evaluate the occipital-cervical or occipital-cervical-thoracic spinal implant assemblies. The three static mechanical tests are compression bending, tensile bending, and torsion. The dynamic tests are compression bending fatigue and torsion fatigue.

4.4 A specific clinical indication generally requires a specific occipital-cervical or occipital-cervical-thoracic spinal implant assembly. Occipital-cervical and occipital-cervical-thoracic spinal implant assemblies will be evaluated with test configurations that simulate the clinical requirements for the intended spinal location. The intended spinal location is the posterior surface of the occipital-cervical or occipital-cervical-thoracic spine (see Fig. 4). The block moment arm for a test configuration depends on the intended spinal location. The block moment arm of the occipital-cervical or occipital-cervical-thoracic spine configuration (see Fig. 4) varies depending on the occipital attachment components, but should be no less than the block moment arm specified in the cervical spine configuration. The cervical spine configuration (see Figs. 6 and 7) specifies the block moment arm.

4.5 The intended method of application of the occipital-cervical or occipital-cervical-thoracic spinal implant assembly may vary for specific anatomic regions and clinical indications. Occipital-cervical and occipital-cervical-thoracic spinal implant assemblies contain different types of anchors. Each type of anchor has an intended method of application to the spine. For example, one assembly may include screws and rods (see Fig. 2), while another assembly may contain screws, hooks, rods, and transverse elements (see Fig. 3). The block moment arm of a test configuration will be independent of the intended method of application of a spinal implant assembly, thereby allowing the user to compare devices for a given load. However, it should be noted that the same load on different implant assemblies will result in different loading on the implants as a function of implant design. The user should take this into account when evaluating the performance of a device.

5. Significance and Use

5.1 Occipital-cervical and occipital-cervical-thoracic spinal implants are generally composed of several components which, when connected together, form either an occipital-cervical spinal implant assembly or an occipital-cervical-thoracic spinal implant assembly. Occipital-cervical and occipital-cervical-thoracic spinal implant assemblies are designed to provide some stability to the spine during the process of arthrodesis. These test methods outline standard materials and methods for the evaluation of different spinal implant assemblies to facilitate comparisons between different designs.

5.2 These test methods are used to quantify the static and dynamic mechanical characteristics of different designs of occipital-cervical and occipital-cervical-thoracic 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 occipital-cervical and occipital-cervical-thoracic spine.

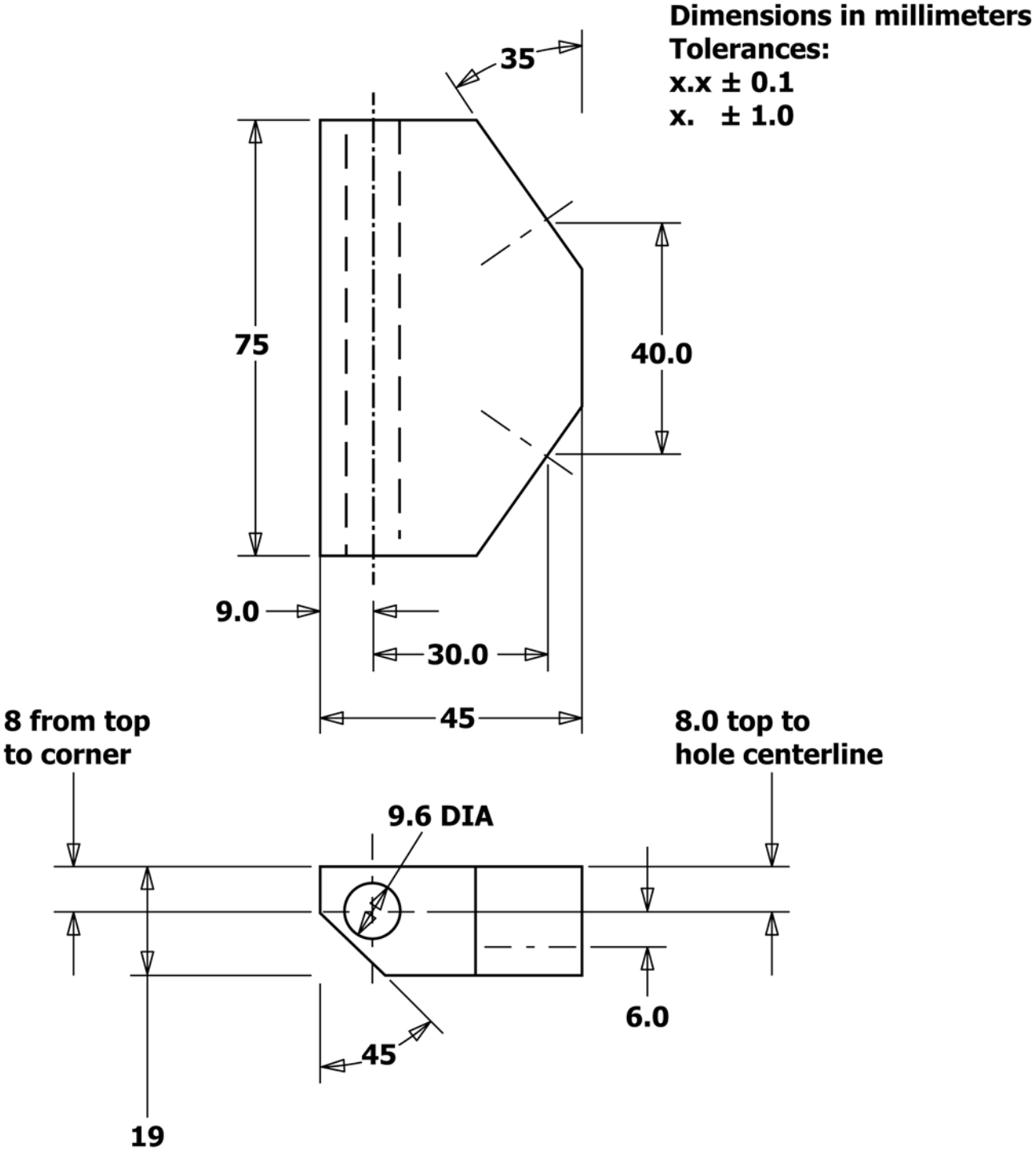


FIG. 6 Cervical Bilateral Polyacetal Block for Screws or Bolts

5.3 The loads applied to the spinal implant assemblies *in vivo* will, in general, differ from the loading configurations used in these test methods. 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 the 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. The maximum recommended frequency for this type of cyclic testing should be 5 Hz.

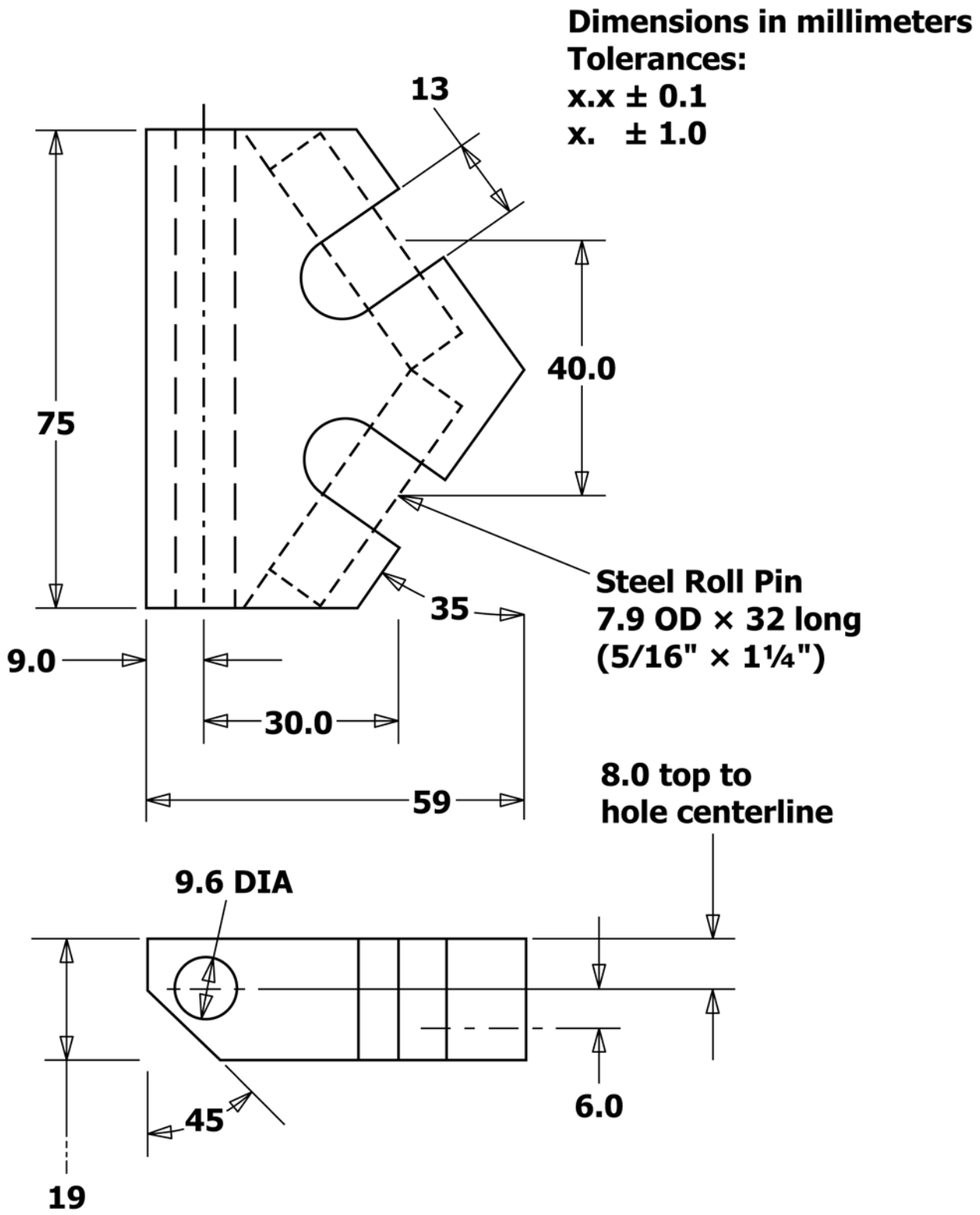
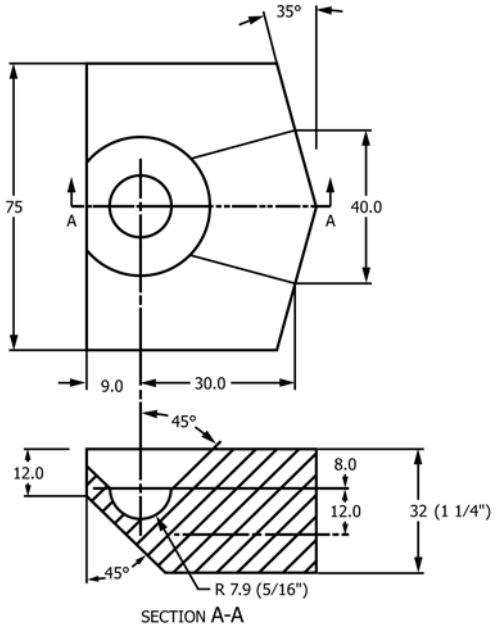


FIG. 7 Cervical Bilateral Polyacetal Block for Hooks, Cables, Wires

5.5 The location of the longitudinal elements is determined by the intended *in vivo* location of the anchors. The perpendicular distance to the load direction between the axis of a hinge pin and the anchor's attachment points to a polyacetal block is independent of anchor-type for the cervical block, but dependent on the design for the occipital test block. The distance between the polyacetal block and the center of the longitudinal element is a function of the design of the implant.



Representative of how Figs. 2-7 can be modified to allow for unconstrained motion.

FIG. 8 Alternate Lumbar Bilateral Polyacetal Block for Screws and Bolts

6. Apparatus

6.1 Test machines shall conform to the requirements of Practices E4.

6.2 The test apparatus allows multiple loading regimes to be applied to all forms of occipital-cervical and occipital-cervical-thoracic spinal implant assemblies. Two pair of side supports are mounted on the test machine (see Fig. 4). 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 bending, tension bending and fatigue tests. Polyacetal blocks are connected to the side supports via hinge pins, as one possible test method, to facilitate comparison to constructs tested as in Test Methods F1717. However, it is recommended that unconstrained motion be used as is specified in Test Methods F2077 and is summarized as follows:

6.2.1 Sphere joint superior-inferior blocks joint blocks, made of polyacetal, are shown in Fig. 8. A 12.7 mm (½ in.) diameter spherical socket is shown to maintain the 12 mm longitudinal distance that was used for the pinned block in Fig. 6. Spherical blocks are limited to conducting compression-flexion tests.

6.2.2 A spherical gimbal superior block with push rod system similar to that used in Test Methods F2077 could be used as an alternative to perform unconstrained torsion, compression-flexion tests, and tensile-extension tests. See Figure 4, Torsion Testing Configuration With Pin-Slot Gimbal in Test Methods F2077.

6.2.3 All testing will simulate a vertebrectomy model via a large gap between the two polyacetal blocks. Select the appropriate design of the polyacetal blocks (see Figs. 2-7 and Figures 2 and 4 of Test Methods F2077) to facilitate testing of the spinal implant assembly in a manner that simulates the specific clinical indication at the intended spinal location.

6.2.4 Regardless of what testing method is employed, all polyacetal screws are to be inserted 2 mm short of the depth they would be inserted *in vivo*. In other words, the screws are to be inserted to the point at which they would just come in contact with the vertebra (that is, polyacetal blocks) and then backed out 2 mm. Alternatively, insertion points for screws may be counterbored at a minimum of 300 % of the diameter of the screw (depth of 2 mm) used to purchase the polyacetal. Both methods effectively prevent biasing the test toward any particular design due to a buttressing effect of the screw against the polyacetal, which could effectively stress shield the implant from failure that might be experienced *in vivo*.

6.3 The design of the occipital polyacetal blocks causes the plane through the occipital implant assemblies to be angled at 23° from the *X-Y* plane. (This angle from the *X-Y* plane to the occiput is the average occipitocervical neutral position angle as determined from human radiological data, n=15.)[3] The design of the cervical polyacetal 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 polyacetal block with the inferior polyacetal block. The center axis of each hinge pin should be perpendicular (±0.5°) to and aligned (±0.5 mm) with the load axis of the test machine. Center the test apparatus in the test machine such that the line through the mid-point (0, 0, Z1) of the inferior hinge pin's axis and the mid-point (0, 0, Z2) of the superior hinge pin's axis is collinear within ±0.1 mm of the load and rotational axis of the test machine's actuator. Or, in the case of spherical joint or pin-slot gimbal mechanism, the points (0, 0, Z1) and (0, 0, Z2) are to be collinear (±0.1 mm) with the test machine's actuator.

6.4 Alternative designs of test blocks may be used as long as equivalence is demonstrated. The solid polyacetal test blocks may be replaced with metal blocks with polyacetal inserts of appropriate size. Any surface or component of the occipital-cervical or occipital-cervical-thoracic spinal assembly which would contact the solid polyacetal should also contact an appropriate thickness of the polyacetal. If screws are used to mount the spinal construct to the test blocks, then the screws shall be placed into polyacetal inserts in the alternate design of test block. The diameter of the polyacetal inserts shall be equal to or greater than three times the diameter of the screws.

6.5 If the locations of the superior anchors, inferior anchors, or both sets of anchors are dictated by the longitudinal element and are at different *Z* locations (a diagonal), then the set of anchors should be centered above and below the standard location such that they maintain the average *Z* location. If the anchors are secured into slots in the longitudinal element, then they should be centrally placed in the slots and not at either end to produce a worst case scenario.

6.6 Different spinal implant assemblies have different intended methods of application to the polyacetal blocks. The locations of the longitudinal elements are determined by the design of anchors and interconnections. The load capacity of

[3] Personal correspondence with John Kirkpatrick, M.D., September 21, 2007.

the spinal construct is a function of the designs of the interconnections, anchors, and longitudinal elements but should not be a function of the test apparatus, hence the addition of the 2 mm offset or counterbore when attaching the construct to the blocks (see 6.2).

6.7 The hinge pin in the test configuration allows the same test apparatus to be used for the static compression bending test, static tensile bending test, and static torsion test as well as the compression bending fatigue test. The polyacetal blocks are allowed to rotate around the *Y*-axis of the hinge pin during the compression bending, tensile bending, and fatigue tests.

6.8 If a superior spherical joint is used, the test configuration allows the same test apparatus to be used for the static compression bending test and the compression bending fatigue test. The polyacetal blocks are free to rotate around the *Y*-axis, *Z*-axis, and *X*-axis during the compression bending static and fatigue tests.

6.9 If a pin-slot gimbal mechanism is used (Figure 4, Test Methods F2077), the test configuration allows the same test apparatus to be used for the static compression bending test, static tensile bending test, and static torsion test as well as the compression bending fatigue test. The polyacetal blocks are free to rotate around the *Y*-axis of the hinge pin, *Z*-axis, and *X*-axis during the compression bending, tensile bending, and fatigue tests.

6.10 Modified bilateral polyacetal blocks (see Figs. 4 and 5) have been developed for testing occipital components (see Fig. 5).

6.11 Modified bilateral polyacetal blocks (see Fig. 7) have been developed for testing hooks, wires, or cables. Steel roll pins are placed into the modified blocks such that the outer surfaces of the roll pins are parallel to the front surfaces of the standard bilateral polyacetal block (see Fig. 7). Hooks, wires, and cables are not fully constrained (semi-rigid) fixation devices because they cannot transfer bending moments in the three axes. The combination of the rotation of the modified polyacetal block 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 polyacetal block shall not rotate. Eliminate a degree of freedom by inhibiting rotation about the *Y*-axis.

6.12 The relative cephalad/caudad location of the hinge pin with respect to the anchor insertion point is intentionally selected to minimize variation of the block moment arm. Orient the test blocks such that the hinge pins are internal to the anchors during the tension bending test. Flip each polyacetal block over for the compression bending, torsion, and fatigue tests such that the hinge pins are external to the anchors. (See Figs. 4-7.)

6.13 The recommended active length of the longitudinal element of the occipital-cervical or occipital-cervical-thoracic spinal implant system is 76 mm as described in ASTM STP 1431.[4] (See Note 1.) Alternative configurations such as a 196 mm occipital-cervical-thoracic construct with the inferior block fixed, rather than free to rotate, can be used with justification. The active length should be constant for all constructs used in comparative testing. In all cases, selection of attachment method (hooks, screws, etc.) at all points on the construct should match the configuration expected in the worst-case construct indicated for use. For example, constructs that are indicated for screw fixation to the thoracic spine should be tested with screws, rather than hooks, at the inferior test block.

NOTE 1—The 76 mm is defined as the *z* distance from hinge pin to hinge pin instead of the *z* distance from the occipital attachment point to the cervical attachment point, thereby providing a fixed distance for all implant assemblies.

6.14 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 occipital-cervical or occipital-cervical-thoracic spinal implant assembly shall be previously unused parts. Implants shall not be retested.

7.2 Use the polyacetal test blocks for only one test. When alternate designs of test blocks are used, then all polyacetal inserts should be replaced after each test. Alternate designs of test blocks which include steel roll pins (see Fig. 7) should replace the steel roll pins and polyacetal inserts for the hinge after each test.

7.3 The test assemblies shall be labeled so they can be traced, and shall be kept in a clean environment to avoid contamination. Do not disassemble the test construct after testing unless disassembly is necessary to evaluate failure surfaces, interconnections, corrosion, or loosening surfaces. Photograph the construct prior to disassembly.

7.4 All static tests should have a minimum of six samples. Each of the test samples should be fabricated, inspected, and sterilized in the same fashion as the product intended for clinical release. Examination of each load-displacement curve may reveal a laxity in the fixture. After the laxity has been removed, then the initial linear portion of the curve will define the straight-line section of the load-displacement curves. The intersection of the straight-line section and zero load axis is the zero load displacement (Point 0).

8. Procedure

8.1 *Procedure for Static Tests*—Evaluate only the load parameters in the relevant direction.

8.1.1 *Static Compression Bending Test:*

[4] Slivka, M. A., Serhan, H., Selvitelli, D. M., and Torres K., "Gauge Length and Mobility of Test Blocks Strongly Affect the Strength and Stiffness of Posterior Occipito-Cervico-Thoracic Corpectomy Constructs," Spinal Implants: Are We Evaluating Them Appropriately?, ASTM STP 1431, M. N. Melkerson, S. L. Griffith, and J. S. Kirkpatrick, Eds., ASTM International, West Conshohocken, PA, 2002.

8.1.1.1 Select the appropriate polyacetal blocks for the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as previously described.

8.1.1.2 Install the anchors according to the manufacturer's instructions. If a modified bilateral polyacetal block is used, place an aluminum spacer block between the modified polyacetal 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 occipital-cervical or occipital-cervical-thoracic spinal implant assembly requires two sets of modified bilateral polyacetal blocks and aluminum spacer blocks, then it is equivalent to an axial compression test.

8.1.1.3 If using hinge pins, place polyacetal 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, and so forth). Secure polyacetal blocks with hinge pins. If a modified bilateral polyacetal block is used to test hooks, wires, or cables, place it superiorly. If using a spherical joint or pin-slot gimbal mechanism, align the testing actuator as indicated in Fig. 8.

8.1.1.4 Complete the occipital-cervical or occipital-cervical-thoracic spinal implant assembly in a standard construct (see Figs. 4-8) or a hybrid construct (see Fig. 3). Set the active length of the longitudinal element. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.1.5 Load the test apparatus at a rate up to a maximum of 25 mm/min.

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

8.1.2 *Static Tension Bending Test:*

8.1.2.1 Select the appropriate polyacetal blocks for the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as previously described.

8.1.2.2 Install the anchors according to the manufacturer's instructions. If a modified bilateral polyacetal block is used, place an aluminum spacer block between the modified polyacetal 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 occipital-cervical or occipital-cervical-thoracic spinal implant assembly requires two sets of modified bilateral polyacetal blocks and aluminum spacer blocks, then it is equivalent to an axial tension test.

8.1.2.3 If using hinge pins, place polyacetal 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, and so forth). Secure the polyacetal blocks with hinge pins. If a modified bilateral polyacetal block is used to test hooks, wires, or cables, place it superiorly. If using a spherical joint or pin-slot gimbal mechanism, align the testing actuator as indicated by Fig. 8.

8.1.2.4 Complete the spinal implant assembly as appropriate for the intended use and intended application (see Figs. 4-8). Set the active length of the longitudinal element for the intended occipital-cervical or occipital-cervical-thoracic spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.2.5 Load the test apparatus up to a maximum rate of 25 mm/min.

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

8.1.3 *Static Torsional Test:*

8.1.3.1 Select the appropriate polyacetal blocks for the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as previously described.

8.1.3.2 Install the anchors according to the manufacturer's instructions. If the occipital-cervical or occipital-cervical-thoracic spinal implant assembly contains only hooks, wires, or cables then the system may not be able to resist torsional moments and need not be tested; however, this should be verified by testing.

8.1.3.3 If using hinge pins, place the polyacetal blocks in the test apparatus such that the positions of the hinge pins are external to the anchors (that is, the hinge pin in the superior block is more superior than the screw, hook, and so forth, and the hinge pin in the inferior block is more inferior than the screw, hook, and so forth). Secure the polyacetal blocks with hinge pins. If only one modified bilateral polyacetal block is used to test hooks, wires, or cables, place it superiorly. Attach the polyacetal blocks to the side supports via hinge pins. Place the aluminum blocks between the polyacetal blocks and the base plates to stop rotation around the hinge pin. If using the pin-slot gimbal apparatus (Figure 4, Test Methods F2077), align the testing actuator as indicated in Fig. 8.

8.1.3.4 Complete the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as appropriate for the intended use and intended application (see Figs. 4-8). Set the active length of the longitudinal element for the intended occipital-cervical or occipital-cervical-thoracic spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.1.3.5 Load the test apparatus at a maximum rate up to 60°/min. An axial load of approximately zero (N) should be maintained during testing.

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

8.2 *Procedure for Dynamic Tests*—Evaluate only the load parameters in the relevant direction. The following is noted for the fatigue testing: the suggested initial fatigue loads should be 75, 50, and 25 % of the compression bending ultimate strength as determined in the static compression bending test. If a specimen does not fail by 5 000 000 cycles, then testing of that component should be considered runout. The final sample size is recommended by Practice E739. The differences between the maximum runout load and a load that results in a failed construct should be less than 10 % of the compression bending ultimate strength.

8.2.1 *Dynamic Compression Bending Test:*

8.2.1.1 Select the appropriate polyacetal blocks for the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as previously described. Use bilateral polyacetal blocks (see Fig. 5, Fig. 6, and/or Fig. 8) for the testing of screws, bolts, and so forth. Use modified bilateral polyacetal blocks (see Fig. 7) for the testing of hooks, wires, or cables.

8.2.1.2 Install the anchors according to the manufacturer's instructions. If one modified bilateral polyacetal block for hooks, wires, cables, and so forth, is used, stop rotation about the hinge pin or *Y*-axis. The extra degree of freedom is eliminated in a manner similar to the axial compression test. If the occipital-cervical or occipital-cervical-thoracic spinal implant assembly requires two sets of modified bilateral polyacetal blocks and aluminum spacer blocks, then the testing mode becomes an axial compression fatigue test.

8.2.1.3 If using hinge pins, place the polyacetal blocks in the test apparatus such that the positions of the hinge pins are external to the anchors (that is, 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, and so forth). Secure the polyacetal blocks with hinge pins. If only one modified bilateral polyacetal block is used to test hooks, wires, cables, and so forth, place it superiorly. If using a spherical joint or pin-slot gimbal mechanism, align the testing actuator as indicated in Fig. 8.

8.2.1.4 Complete the occipital-cervical or occipital-cervical-thoracic spinal implant assembly in a standard construct (Fig. 4, Fig. 5, Fig. 6, Fig. 7, and/or Fig. 8) or a hybrid construct (Fig. 3). Set the active length of the longitudinal element. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.2.1.5 The fatigue test applies a sinusoidal load to the spinal construct. The loading should be maintained by controlling load amplitude. A constant load ratio (R) for all tests should be established and should be equal to or greater than 10:

$$R = \frac{minimum\ load}{maximum\ load} \geq 10 \quad (2)$$

Example: if the minimum load = –200 *N* and the maximum load = –10 *N*, then $R = 20$. The maximum cycle rate for the fatigue test is five cycles per second. The end of the test occurs when the spinal construct has a failure or reaches runout.

8.2.1.6 The user of these test methods should select the necessary loads to develop a well-defined load-cycle to failure plot comprised of a minimum of 6 data points, two of which shall be runout points. Establish the maximum runout load (no specimens fail before 5 000 000 cycles). Continue fatigue testing specimens until the difference between a load in which a construct has failed and the maximum runout load is no greater than 10 % of the compression bending ultimate load. A semi-log fatigue curve of the compression bending load versus number of cycles at failure shall be plotted.

8.2.1.7 Note the initial and secondary failures, modes of failure, and deformations of components prior to removing the occipital-cervical or occipital-cervical-thoracic spinal construct from the test apparatus. Evaluate all surface changes.

8.2.2 *Dynamic Torsion Test:*

8.2.2.1 Select the appropriate polyacetal blocks for the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as previously described. Use bilateral polyacetal blocks (see Figs. 5 and 6) for the testing of screws, bolts, and so forth. Use modified bilateral polyacetal blocks (see Fig. 7) for the testing of hooks, wires, or cables.

8.2.2.2 Install the anchors according to the manufacturer's instructions. If the occipital-cervical or occipital-cervical-thoracic spinal implant assembly contains only hooks, wires, or cables, then the system may not be able to resist torsional moments and need not be tested; however, this should be verified by testing.

8.2.2.3 If using hinge pins, place the polyacetal blocks in the test apparatus such that the positions of the hinge pins are external to the anchors (that is, 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, and so forth). Secure the polyacetal blocks with hinge pins. If only one modified bilateral polyacetal block is used to test hooks, wires, cables, and so forth, place it superiorly. Attach the polyacetal blocks to the side supports via hinge pins. Place the aluminum blocks between the polyacetal blocks and the base plates to stop rotation around the hinge pin. If using a pin-slot gimbal mechanism, align the testing actuator as indicated in Fig. 8.

8.2.2.4 Complete the occipital-cervical or occipital-cervical-thoracic spinal implant assembly as appropriate for the intended use and intended application (see Figs. 4-8). Set the active length of the longitudinal element for the intended occipital-cervical or occipital-cervical-thoracic spinal location. Apply all tightening, crimping, or locking mechanisms as specified by the manufacturer.

8.2.2.5 Apply a fully-reversed sinusoidal load to the spinal construct. The loading should be maintained by controlling torque amplitude. A constant load ratio (R) for all tests should be established and should be equal to –1. Example: if the minimum torque = –1 Nm and the maximum load = +1 Nm then $R = -1$. The maximum cycle rate for the fatigue test shall be five cycles per second. The end of the test occurs when the spinal construct has a failure or reaches runout.

8.2.2.6 The user of these test methods should select the necessary loads to develop a well-defined load-cycle to failure plot comprised of a minimum of 6 data points, two of which must be runout points (no specimens fail before 5 000 000 cycles). Continue fatigue testing specimens until the difference between a load in which a construct has failed and the maximum runout load is no greater than 10 % of the yield torque determined in 8.1.3.6. A semi-log fatigue curve of the torque load versus number of cycles at failure shall be plotted.

8.2.2.7 Note the initial and secondary failures, modes of failure, and deformations of components prior to removing the occipital-cervical or occipital-cervical-thoracic spinal construct from the test apparatus. Evaluate all surface changes.

9. Report

9.1 The report should specify the occipital-cervical or occipital-cervical-thoracic spinal implant components, the occipital-cervical or occipital-cervical-thoracic spinal implant assembly, and the number of specimens tested. Describe all relevant information about the components including name, lot number, manufacturer, material, part number, sterilization

method, and so forth. Also include any specific information necessary to produce the assembly, including the tightening torque.

9.2 Include an illustration of the exact loading configurations, including diagrams of the polyacetal blocks, which were used for testing. Describe the similarities and differences to relevant figures contained herein. Report and provide justification for the active length. Report the longitudinal axis offset for all attachment points. Note any deviations from the recommended test procedure. State the rate of loading. Provide justification for the loading rate if any of the structural components under test are not metallic.

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

9.3.1 Load-displacement curves for all static compression bending tests. 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 stiffness (N/mm), compressive bending ultimate displacement (mm), and compressive bending ultimate load (N).

9.3.2 Load-displacement curves 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 stiffness (N/mm), tensile bending ultimate displacement (mm), and tensile bending ultimate load (N).

9.3.3 Torque-angular displacement curves for all 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), and torsional stiffness (N-m/degree).

9.4 The report of the dynamic mechanical testing shall provide the following:

9.4.1 The fatigue test environment, load wave form, and test frequency. State the final sample sizes and load or torque versus number of cycles at failure for all fatigue tests. State the load or torque levels for the specimens enduring 5 000 000 cycles and the maximum runout load or torque. Report the constant load ratio (R).

9.4.2 All initial and secondary failures, modes of failure and deformations of components for the occipital-cervical or occipital-cervical-thoracic 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 all surface changes, any fretting of interfaces or loosening of interconnections. Include pictures of failure surfaces and surface texturing from fretting.

9.4.3 A semi-log fatigue curve of the load or torque versus number of cycles at failure. Indicate specimens that have not failed before 5 000 000 cycles.

9.4.4 A regression analysis of the load or torque versus number of cycles for only failed constructs.

10. Precision and Bias

10.1 *Precision*—It is not practical to specify the precision of the procedures in these test methods because of the wide variety in design of the components to be tested.

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

11. Keywords

11.1 fatigue test methods; occipital-cervical spinal implant assembly; occipital-cervical spinal implant construct; occipital-cervical-thoracic spinal implant assembly; occipital-cervical-thoracic spinal implant construct; static test methods; vertebrectomy model

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Occipital-cervical and occipital-cervical-thoracic spinal implant assemblies contain many different component designs and can be assembled into a wide variety of configurations and combinations for different clinical indications, dependent on the clinical requirements, intended clinical location, and intended method of application. The purpose of these test methods 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 An occipital-cervical or occipital-cervical-thoracic spinal implant assembly contains groups of components necessary for specific clinical indications. These test methods contain test configurations for the evaluation of spinal implant assemblies that simulate the clinical requirements for an intended clinical location and method of application. These systems include occipital screws, pedicle screws, hooks, rods, and transverse interconnections. Fig. 2 is an example of a standard test configuration. The hybrid test configuration seen in Fig. 3 would normally be applied posteriorly and contains screws, hooks, rods, and transverse interconnections. The user should also be aware that when conducting tests of constructs featuring transverse interconnections, the results may be sensitive to the number of interconnections used. Users may wish

to refer to ASTM STP 1431[5] which demonstrates this occurrence in some cases.

X1.3 An occipital-cervical or occipital-cervical-thoracic spinal implant construct installed in the test apparatus will simultaneously evaluate all components within the assembly in the worst case test configuration (vertebrectomy model). A vertebrectomy is assumed to be a worst case scenario because all loads are transferred from the fixture and are transmitted only through the implant assembly. All proposed test configurations are based on anatomical dimensions. Some asymmetric test assemblies may not be applicable to these test methods. In these cases, the hinge pin might be replaced with a spherical ball loading mechanism, described herein.

X1.4 These test methods cover the static and cyclic evaluation of occipital-cervical and occipital-cervical-thoracic spinal implant assemblies. The purpose of occipital-cervical and occipital-cervical-thoracic spinal implants is to provide short term stability while arthrodesis takes place. These test methods do not address the long term mechanical stability of spinal implants, nor do they address implants that do not lead to spinal fusion. The fatigue testing in these test methods establish the maximum runout load where all of the tested constructs have withstood 5 000 000 cycles without a failure. 5 000 000 cycles represents the number of loading cycles a specimen might experience within two years based on moderate activity ([sim]7000 cycles per day).

X1.5 Uniaxial torque and combination axial and bending loading are applied in these test methods. Numerous combinations of multiaxial loading conditions *in vivo* have not yet been fully defined. These test methods outline a series of simplistic static and dynamic loading conditions and do not attempt to mimic the complex loading patterns in the spine. In this regard, the current pin fixtures that are prescribed act as an external fixator, in addition to the internal spinal constructs being tested. Since similar external fixation constraints do not exist clinically, test results using the pin fixtures may not mimic *in vivo* clinical 3D biomechanical characteristics (particularly for example: asymmetrical constructs, some loads such as torsion, and the stability/instability of the implant construct to those components of relative motion constrained by the fixtures). Because of this, the user is encouraged to consider applicable failure modes and evaluate the implant construct in clinically relevant externally unconstrained relative motion conditions. See 6.2, 6.8, and 6.9.

X1.6 The influence of simulated body fluid or saline may affect the relative performance of tested devices. The test methods 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 investigators may consider additional evaluations in simulated body fluid, saline, water, or lubricants to address environmental factors. It should be noted that corrosive fatigue testing may be influenced by the cycle rate, therefore the maximum cycle rate should be reduced.

X1.7 The variation in the block moment arm for the static and fatigue bending tests is a function of the relative location (*X*-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 polyacetal blocks. The variation in the block moment arm for the occipital-cervical test configuration range between ±2 % for a 29-mm displacement or 27° rotation of each block.

X1.8 Reporting the compression or tensile bending moments and the bending moments versus numbers of cycles at failure may be a better indicator of the mechanical characteristics of these assemblies, though the user is cautioned in interpreting the results if plotted in this manner due to possible confusion regarding the moment arm. The block moment arms are constants per these test methods. The block moment arm is 30.0 mm for all cervical blocks and is variable depending on the design of the implant for occipital attachment. However, the moment arm at the longitudinal element can vary from one spinal assembly to another. The moment arm at the longitudinal element is the sum of the block moment arm and the *X*-distance from the insertion point of an anchor to the longitudinal element (that is, longitudinal axis offset).

X1.9 These test methods are not intended to allow direct comparison between the *in vitro* results and clinical results.

X1.10 These test methods are not intended to define performance levels of occipital-cervical or occipital-cervical-thoracic spinal implants as insufficient knowledge is available to predict the consequence of the use of particular spinal implant design and assemblies.

[5] Spinal Implants: Are We Evaluating Them Appropriately? ASTM STP 1431, ASTM International, 2003.