Designation: F2502 – 05

Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants[1]

This standard is issued under the fixed designation F2502; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification and test methods covers a mechanical characterization reference for hydrolytically degradable polymer resin (from this point on referenced as "bioabsorbable") plates and screws for orthopedic internal fixation.

1.2 This specification establishes common terminology to describe the size and other physical characteristics of bioabsorbable implants and performance definitions related to the performance of bioabsorbable devices.

1.3 This specification establishes standard test methods to consistently measure performance-related mechanical characteristics of bioabsorbable devices when tested under defined conditions of pretreatment, temperature, humidity, and testing machine speed.

1.4 This specification may not be appropriate for all bioabsorbable devices. The user is cautioned to consider the appropriateness of the standard in view of the particular bioabsorbable device and its potential application.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

E4 Practices for Force Verification of Testing Machines

E6 Terminology Relating to Methods of Mechanical Testing

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E1823 Terminology Relating to Fatigue and Fracture Testing

F116 Specification for Medical Screwdriver Bits

F382 Specification and Test Method for Metallic Bone Plates

F543 Specification and Test Methods for Metallic Medical Bone Screws

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F1635 Test Method for ***in vitro*** Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants

2.2 *ISO Standards:*[3]

ISO 13781 Poly (L-Lactide) Resins and Fabricated Forms for Surgical Implants—In Vitro Degradation Testing

ISO 14630 Non-Active Surgical Implants—General Requirements

ISO 15814 Copolymers and Blends Based on Polylactide—In Vitro Degradation Testing

3. Terminology

3.1 *Definitions:*

3.1.1 Unless otherwise defined in this specification, the terminology related to mechanical testing that is used in these test methods will be in accordance with the definitions of Terminologies E6 and E1823, and Specifications F382 and F543.

3.2 *General Definitions:*

3.2.1 *bioabsorbable device*—a class of implants that are designed to deteriorate by means of biological resorption once they are implanted into the body.

[1] This specification and test methods is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.2.2 *biological resorption*—process by which degraded biomaterials (that is, products of degradation) are eliminated or incorporated, or both, by means of physiological metabolic routes.

3.2.3 *deterioration (of a bioabsorbable device)*—the action or process that results in a reduction of mass or mechanical performance properties, or both.

3.2.4 *hydrolytically degradable polymer (HDP)*—any polymeric material in which the primary mechanism of chemical degradation in the body is by hydrolysis (water reacting with the polymer resulting in cleavage of the chain).

3.3 *Definitions for Apparatus:*

3.3.1 *data acquisition device*—the data recorder shall be suitable to continuously record torque versus angle of rotation, as well as linear displacement, calibrated in units of Newton-metres for torque and degrees for angle of rotation. The value of torque shall have a resolution of 5 % of torsional yield strength. The angular displacement scale shall have a minimum sensitivity so as to enable an accurate offset measurement capability for a 2° angular displacement (see A1.5.3).

3.3.2 *pilot holes in test block*—pilot holes shall be drilled in the test block for insertion and removal of the test specimen. See Specification F543, Annex 2.

3.3.3 *test block*—the test block shall be fabricated from a uniform material that conforms to Specification F1839. See Specification F543, Annex 2.

3.3.4 *testing fixture*—the torsion testing apparatus that is to be used for applying the required torque to the specimen shall be calibrated for the range of torques and rotational displacements used in the determination. A suitable testing fixture for the torsional yield strength-maximum torque-breaking angle test is illustrated in Fig. A1.1.

3.3.5 *test specimen*—the test specimen shall be a completely fabricated and finished bioabsorbable bone screw.

3.3.6 *torque transducer*—a transducer to translate the applied torque into an electrical signal amenable to continuous recording, calibrated over the range of torques, both in the clockwise and counterclockwise rotation, to be encountered in the test method, shall be provided.

3.3.7 *torsional displacement transducer*—a transducer to translate the angle of twist into an electrical signal amenable to continuous recording, calibrated over the range of angles to be encountered in the test and an accuracy of ±1 % of reading, both in the clockwise and counterclockwise rotation, shall be used.

3.4 *Definitions for Screw Testing:*

3.4.1 *anchor*—a bioabsorbable device or a component of a bioabsorbable device that provides the attachment to the bone.

3.4.2 *bone anchor*—a bioabsorbable device that provides a means to attach soft tissue to bone with a suture.

3.4.3 *insertion depth (mm)*—the linear advancement of the bioabsorbable device into the test block measured relative to its seated position at the test block's surface prior to testing.

3.5 *Definitions for Plate Testing:*

3.5.1 *bone plate*—a device with two or more holes or slots, or both, and a cross section that consists of at least two dimensions (width and thickness), which generally are not the same in magnitude. The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect.

3.5.2 *bone plate length, L (mm)*—the linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. A4.2.

3.5.3 *bone plate thickness, b (mm)*—the linear dimension of the bone plate measured parallel to the screw hole axis as shown in Fig. A4.2. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section.

3.5.4 *bone plate width, w (mm)*—the linear dimension of the bone plate measured perpendicular to both the length and thickness axes as shown in Fig. A4.2.

4. Significance and Use

4.1 Biodegradable devices are expected by intention to deteriorate over time once they are implanted into the body. This makes the removal operation obsolete, which is advantageous especially for pediatrics.

4.2 While the polymer degrades due to hydrolytic reaction with the environment, the mechanical performance of the device also deteriorates. The key to developing effective fracture fixation systems based on biodegradable devices is to provide an adequate level of fixation strength for a time frame that exceeds that expected for fracture healing. Once the fracture is healed, the device can be completely resorbed by the body.

4.3 Generally, biodegradable devices will be tested with similar test methods that are used to evaluate conventional metallic devices. In addition, one has to take into consideration the pre-test conditioning requirements, handling requirements, and time-dependent mechanical property evaluations for biodegradable devices.

5. Materials and Manufacture

5.1 Bioabsorbable devices may be fabricated from one of the following materials:

5.1.1 *l*-lactide, *d*-lactide, *d,l*-lactide, glycolide, or other known hydrolytically degradable polymer resins or copolymers. (See ISO 13781, ISO 15814, Test Method F1635, and Specification F1925.)

5.2 The manufacturer is responsible to ensure that materials used to manufacture bioabsorbable implants are suitable for implanting into the body. Methods to evaluate a material's suitability are described in ISO 14630.

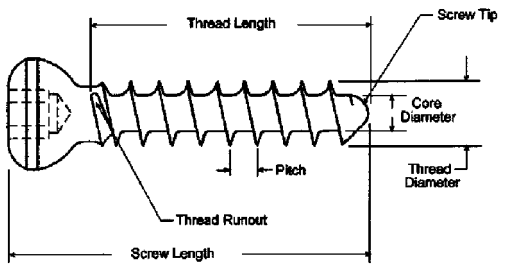

FIG. 1 Screw Parameters

5.3 All bioabsorbable devices made of materials that have an ASTM committee F04 or D20 standard designation or an ISO designation shall meet those requirements given in the ASTM standards.

5.4 *Soaking Solution*—A phosphate buffered saline (PBS) solution shall be used. The pH of the solution shall be maintained at 7.4 ± 0.2 (see Test Method F1635, Section X1.3). The pH should be monitored frequently and, if need be, the solution should be changed periodically in order to maintain the pH within the acceptable limits.

5.4.1 Other physiologic solutions may be substituted provided the solution is properly buffered. An anti-microbial additive should be used to inhibit the growth of microorganisms in the solution during the test period. The investigator must demonstrate that the chosen antimicrobial does not affect the degradation rate (see X1.3).

5.5 *Sample Container*—A self enclosed container capable of holding the test sample and the solution (see X1.4). Multiple samples may be stored in the same container provided that suitable sample separation is maintained to allow fluid access to each sample surface and to preclude sample to sample contact. Each container must be sealable against solution loss due to evaporation.

5.6 *Constant Temperature Bath or Oven*—An aqueous bath or heated air oven capable of maintaining the samples and containers at physiologic temperatures (37 ± 2°C) for the specified testing periods.

5.7 *pH Meter*—A pH metering device sensitive in the physiological range (pH 6 to pH 8) with a precision of 0.02 or better.

5.8 *Balance*—A calibrated weighing device capable of measuring the weight of a sample to a precision of 0.1 % of its initial weight.

6. Conditioning

6.1 *Conditioning*—Condition the test specimens in a suitable solution (for example, PBS solution) and temperature until it is time to be tested. Remove from solution and wipe off excess. The specimens must be tested within 1 h of rinsing (see Test Method F1635). In addition to conditioning the test specimen in suitable solutions, if the test specimen is intended for use in a loaded physiological condition, it may be important to address the additional influence of conditioning static or fatigue loads, or both, on the deterioration of the test specimen. Conditioning loads should be chosen that are representative of anticipated physiological conditions.

6.1.1 *Test Conditions*—Conduct tests at 23 ± 2ºC (73.4 ± 3.6ºF) and 50 ± 5 % relative humidity, unless otherwise specified. (Remove from solution, wipe excess, and test within 1 h of removal.)

7. Care and Handling

7.1 Bioabsorbable devices should be cared for and handled in accordance with Practice F565, as appropriate.

8. Performance Requirements

8.1 Factors considered being important, but for which values and test methods have not been established, are shear strength of the head of a screw, shear strength of the threaded region of a screw, and enzymatically degradable polymer resins.

9. Driving Instruments

9.1 Specification F116 provides related dimensional information for several types of medical screwdrivers.

10. General Requirements and Performance Considerations

10.1 The following properties may be important when determining the suitability of a screw for a particular application. However, the test methods referenced as follows may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the test methods in view of the devices being tested and their potential application.

10.1.1 *Offset Yield Strength* is the stress at which the stress-strain curve departs from linearity by a specified percent of deformation (offset).

10.1.2 *Torsional Strength* is an important parameter to prevent screw breakage during insertion. The torsional strength shall be determined using the test methods described in Annex A1.

10.1.3 *Axial Pullout Strength* is an important parameter if the screw is subjected to axial tensile forces, or if the screw is fixed into poor quality or osteoporotic bone. The pullout strength may be determined using the test methods described in Annex A3.

10.1.4 *Insertion Torque* is an important parameter to avoid failure of the screw during insertion and to ensure that the screw may be easily inserted by the surgeon. The insertion torque should be much less than the torsional yield strength of the screw as well as that of the appropriate screwdriver bit. The insertion torque may be determined using the test methods described in Annex A2.

10.1.5 *Geometric Considerations*—Bone plates that are intended to be used with bone screws shall have design features (screw holes or slots) that conform or appropriately fit the corresponding bone screw.

10.1.6 *Bending Properties*—Critical characteristics of bone plates for orthopedic applications since the bone plate provides the primary means of stabilizing the bone fragments. Additionally, the bending stiffness of the bone plate may directly affect the rate and ability of healing.

10.1.6.1 The relevant bending properties (bending stiffness, bending structural stiffness, and bending strength) shall be determined using the standard test method of Annex A4.

11. Keywords

11.1 bend testing; bone plates; bone screw; dimensions; insertion; pullout; shear; torsion

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR DETERMINING THE TORSIONAL PROPERTIES OF BIOABSORBABLE BONE SCREWS

A1.1 Scope

A1.1.1 This test method describes methods for torsion testing in order to determine intrinsic and structural properties of bioabsorbable bone screws. The test method measures the torsional yield strength, maximum torque, and breaking angle of the bone screw under standard conditions.

A1.1.2 This test method is intended to provide a means of mechanically characterizing different bone screw designs. It is not the intention of this test method to define levels of performance for bone screws as insufficient knowledge is available to predict the consequences of the use of particular bone screw designs.

A1.1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A1.2 Apparatus

A1.2.1 *Test Speed*—The torsional force shall be applied at a constant rate between 1 to 5 r/min.

A1.3 Sampling

A1.3.1 Representative random samples may be taken from each lot or processing quantity in accordance with Practice E122.

A1.4 General Conditions

A1.4.1 Containers must be of sufficient size, so that the inspection item with the prescribed quantity of buffer solution has suitable sample separation.

A1.4.2 It must be ensured that the buffer solution cannot escape during the test from evaporation or any other type of loss.

A1.4.3 *Immersion Bath*—A suitable liquid heat-transfer medium in which the specimen shall be immersed. It shall be well-stirred during the test and shall be provided with a means of raising the temperature at a uniform rate.

A1.4.4 *Testing Times*—The choice of points of testing should be met accordingly. For a complete history of the dismantling behavior, there should be at least seven measuring points (for example, 0 h, 1 week, 4 weeks, 8 weeks, 12 weeks, 16 weeks, and 24 weeks). Whatever the intervals, they must be documented in the test report. The initial value (0 h) is tested unconditioned.

A1.4.5 The test samples must be completely enclosed by the solution.

A1.4.6 The samples shall be immersed in a bath or placed in a furnace with constant temperature of 37 ± 1°C.

A1.4.7 The test blocks shall be pre-soaked in the same solution as the samples. The blocks can be pre-drilled but should be tapped after removal from solution.

A1.5 Procedure

A1.5.1 *Torsional Yield Strength, Maximum Torque, and Breaking Angle*—Place the specimen in the holding device so that five threads, below the head of the screw, are exposed outside the holding device (that is, split collet). If the test specimen cannot accommodate this setup because the screw is too small or is partially threaded, alternate procedures may be used. For fully threaded screws that are too small, the gauge length of the specimen should represent 20 % of the threaded portion of the test specimen. For partially threaded screws, a large enough portion of the screw thread should be gripped to firmly secure the screw so that it does not rotate when under torsional load. There are no specific requirements on the gauge length or the grip length in this case; however, at least one full thread shall be exposed, if possible. Since the gauge length and grip length can vary for these screws, the only requirement is that both be reported.

A1.5.2 The gauge length or grip length should be kept the same length for test of similar design. If a split collet and collet holder are used, the following test method is appropriate: Place the split collet in the collet holder. Clamp the split collet and holder in the vise. The clamping force of the vise should be sufficient to prevent rotation of the screw or the split collet. Drive the specimen in the direction of insertion, using an appropriate size and configured screwdriver bit, by applying a torsional force. If an axial load is required to maintain the screwdriver bit in the screw head, its value should be noted. The torque device shall be driven at a rate between 1 to 5 r/min.

A1.5.3 The torsional yield strength will be determined by the offset method (Fig. A1.2), using the torque versus angle of rotation curve produced in A1.5.1.

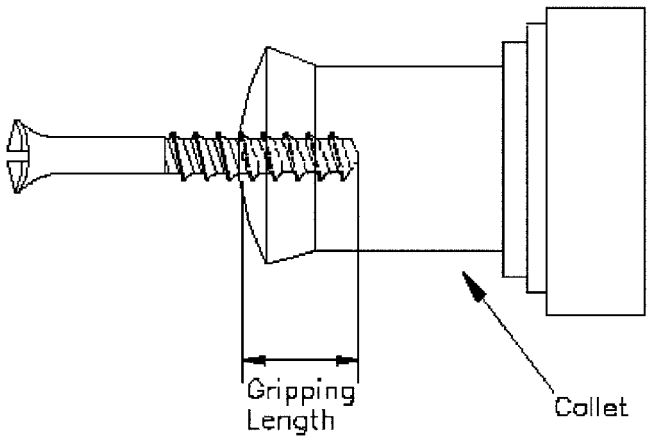

FIG. A1.1 Example of a Test Setup

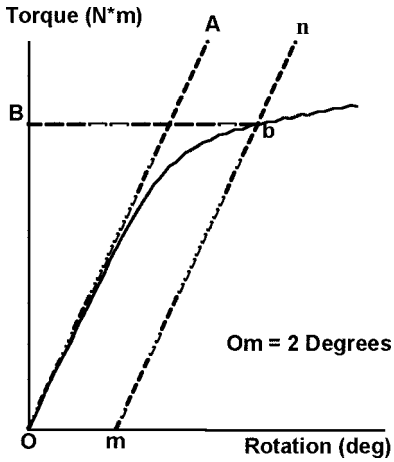

FIG. A1.2 Typical Torque versus Angle of Rotation Curve

A1.5.4 On the torque versus angle of rotation curve, locate point *m* equal to a rotation of 2°. Draw *mn* parallel to *OA*, and locate *b*, the intersection of *mn* with the torque versus angle of rotation curve. Torque *B* is defined as the torsional yield strength.

A1.5.5 The maximum torque is determined by the largest value of torque on the torque versus angle of rotation curve.

A1.5.6 Bioabsorbable bone screws typically do not exhibit a distinctive failure point due to the plastic tearing that occurs once the maximum torque has been reached. Therefore, the breaking angle shall be defined as the angle of rotation at the point where the maximum torque is reported.

A1.6 Report

A1.6.1 Report the following information for each specimen tested:

A1.6.1.1 Screw identification. Reference any applicable ASTM or ISO specification that may apply to the specimen.

A1.6.1.2 Screw composition.

A1.6.1.3 Gauge length.

A1.6.1.4 Test speed.

A1.6.1.5 Number of specimens tested.

A1.6.1.6 Conditioning.

A1.6.1.7 Solution.

A1.6.1.8 Loaded or unloaded (if loaded, list the load).

A1.6.1.9 Torsional yield strength.

A1.6.1.10 Maximum torque.

A1.6.1.11 Mean and standard deviations of the yield strength for the set of screws tested.

A1.6.1.12 Mean and standard deviations of the maximum torque for the set of screws tested.

A1.6.1.13 Torque versus angle of rotation plot.

A1.6.1.14 Grip length. Does not have to be reported for a fully threaded screw of ASTM or ISO specification whose overall length is given.

A1.6.1.15 Fracture location. The location can be specified by listing the number of threads below the head at which the screw fails or by measuring the distance below the head to the approximate fracture point.

A1.6.1.16 Additional damage. Indicate if any damage to the test specimen occurred during the test (for example, stripping of the head, deformation of the test specimen, and so forth).

A1.7 Precision and Bias

A1.7.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A1.7.2 *Bias*—No statement of bias can be made, since no acceptable reference values are available, nor can they be obtained since this test is a destructive test.

A2. TEST METHOD FOR DRIVING TORQUE OF BIOABSORBABLE BONE SCREWS

A2.1 Scope

A2.1.1 This test method is used to measure the torque required to drive a bone screw into a standard material. The results obtained in this test method bear no direct correlation to the insertion torque required to insert the subject bone screw in human or animal bone. This test method is used only for purposes of maintaining the uniformity of the product tested.

A2.2 Apparatus

A2.2.1 *Test Speed*—The torsional force shall be applied at a constant rate between 1 to 5 r/min.

A2.3 Sampling

A2.3.1 Representative random samples may be taken from each lot or processing quantity in accordance with Practice E122.

A2.4 Procedure

A2.4.1 *Insertion*—Insert the screw according to the following requirements.

A2.4.1.1 *Insertion*—Place the specimen in the test fixture as illustrated in Fig. A2.1. Drive the specimen into the test block,

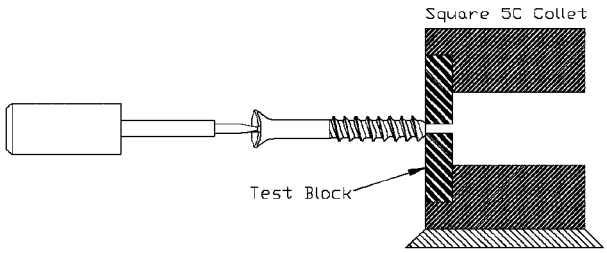

FIG. A2.1 Screw insertion Test Setup

using the appropriate size and configured screwdriver bit, by applying a torsional force at a rate of 1 to 5 r/min, to the head of the specimen with a motor driven torque device. The insertion torque shall be the maximum reading recorded during the initial four revolutions of the specimen. Values should be reported in Newton-metres. A 1.14 kgf or less axial load should be used to maintain the screwdriver bit in the screw head during the insertion procedure. If a larger axial load is applied, this load shall be recorded on the report form. This load may be measured by any appropriate method.

A2.4.1.2 *Specific Screw Performance Tests*—Fully insert the longest screw of the given screw design into the test block whose thickness is greater than the length of the screw being tested.

A2.4.1.3 *Comparative Screw Performance Tests*—Insert each screw into a test block, whose thickness is greater than the length of the screw being tested, until the greatest equivalent insertion depth possible for all of the screw designs being compared is reached.

A2.5 Report

A2.5.1 Report the following information for each specimen tested:

A2.5.1.1 Screw identification. Reference any applicable ASTM or ISO standard specification that may apply to the specimen.

A2.5.1.2 Screw composition.

A2.5.1.3 Test speed.

A2.5.1.4 Number of specimens tested.

A2.5.1.5 Conditioning.

A2.5.1.6 Solution.

A2.5.1.7 Loaded or unloaded (if loaded, list the load).

A2.5.1.8 Insertion torque.

A2.5.1.9 Axial load applied.

A2.5.1.10 Insertion depth (may be calculated or measured).

A2.5.1.11 Specification of whether the pilot holes were or were not pre-tapped, if so, specifications of the tap size, tap diameter, and tap length.

A2.5.1.12 Insertion test speed.

A2.5.1.13 Mean and standard deviations of the insertion torque for the set of screws tested.

A2.5.1.14 Test block material description.

A2.5.1.15 Test Blocks. Indicate whether the blocks were pre-soaked or not soaked.

A2.5.1.16 Additional damage. Indicate if any damage to the test specimen occurred during the test (for example, stripping of the head, deformation of the test specimen, and so forth).

A2.6 Precision and Bias

A2.6.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A2.6.2 *Bias*—No statement of bias can be made, since no acceptable reference values are available, nor can they be obtained since this test is a destructive test.

A3. TEST METHOD FOR AXIAL PULLOUT OF BIOABSORBABLE BONE SCREWS

A3.1 Scope

A3.1.1 This test method is used to measure the axial tensile force required to remove or fail a bioabsorbable bone screw from a defined material. The results obtained in this test method are not intended to predict the force required to remove the subject bone screw from human or animal bone. This test method is intended only to measure the uniformity of the products tested or to compare the strength of different products.

A3.1.2 This test method may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested and their potential application.

A3.2 Apparatus

A3.2.1 *Test Fixture*—Machines used for testing the axial pull out strength of screws shall conform to the requirements of Practices E4. A suitable test fixture as shown in Fig. A3.1 may be used for testing. This fixture shall incorporate the test block material which conforms to Specification F1839 and a test block clamp. In addition to these requirements, the test block clamp should be sufficiently rigid such that deflection under the required loading conditions is negligible. The test block clamp should have a minimum grip span of five times the major diameter of the bone screw with the screw centered between the grips. The grip span should be consistent throughout testing.

A3.2.2 *Test Block*—The test block shall be fabricated from a uniform material that conforms to Specification F1839. The top and bottom surfaces shall be flat, smooth, and parallel (within ±0.4 mm) as required to ensure that the test block will be supported in the fixture with the top surface at an angle of 90° to the centerline of the test specimen. The edges of the test block shall be of such contour or squareness as required to ensure that the test block clamp shall hold the test block free of relative motion without deformation of the test block during clamping or testing.

A3.2.3 *Data Acquisition Device*—The data recorder shall be suitable to continuously record load versus displacement.

A3.2.4 *Load Frame*—Machines used for testing shall conform to the requirements of Practices E4. The loads used for the test method shall be within the loading range of the test machine as defined in Practices E4.

A3.2.5 *Load Fixture*—A suitable fixture shall be used to place a tensile load on the bone screw. The load shall be transferred through the head of the screw and should be aligned with the screw's longitudinal axis. The fixture shall have a slot to capture the head of the screw without contact being made with the screw's shaft. To ensure proper alignment, the slot shall have a spherical recess into which the screw head can be seated directly under the applied load.

A3.3 Sampling

A3.3.1 Representative random samples may be taken from each lot or processing quantity in accordance with Practice E122.

A3.4 Procedure

A3.4.1 *Insertion of the Test Specimen*—The bone screws shall be inserted into the standard material in accordance with the insertion torque test method, Annex A2. The screws shall be inserted at a rate of 1 to 5 r/min to a depth of 60 % of the overall length of a fully threaded screw and partially threaded screws should have all the threads inserted into the testing medium.