Designation: F2502 – 11

Standard Specification and Test Methods for Absorbable 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 cover the mechanical characterization of plates and screws for orthopedic internal fixation. Covered devices are fabricated from one or more hydrolytically degradable polymer (from this point on referred to as "absorbable") resins or resin composites.

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

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

1.4 This specification may not be appropriate for all absorbable devices, especially those that possess limited hydrolytic susceptibility and degrade *in vivo* primarily through enzymatic action. The user is cautioned to consider the appropriateness of the standard in view of the particular absorbable device and its potential application.

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

1.6 *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

F1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation

F1185 Specification for Composition of Hydroxylapatite for Surgical Implants

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

[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, http://www.ansi.org.

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 *absorbable, adj*—in the body, referring to an initially distinct foreign material or substance that either directly or through intended degradation can pass through or be assimilated by cells and/or tissue.

NOTE 1—See Appendix X1.5 for a discussion regarding the usage of "absorbable" and other related terms.

3.2.2 *absorbable composite*—an absorbable polymer resin or construct incorporating a particulate and/or fibrous bioactive and/or absorbable filler material.

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

3.2.4 *bone plate*—a device, when affixed with screws or cerclage wire, intended to provide alignment of two or more bone sections, primarily by spanning the fracture or defect. A bone plate has two or more holes. Its width and thickness usually are not the same in magnitude.

3.2.5 *deterioration*—the reduction or worsening of mechanical or other functional performance properties of a device.

3.2.6 *hydrolytically degradable polymer*—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).

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

3.3 *Definitions of Terms Specific to This Standard:*

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

4. Significance and Use

4.1 Absorbable devices are intended to degrade and absorb over time once they are implanted into the body. This makes a removal operation unnecessary, which is especially advantageous for pediatric patients.

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 mechanically effective fracture fixation systems based on absorbable devices is to provide an adequate level of fixation strength and stiffness for a time frame that exceeds that expected for fracture healing. Once the fracture is healed, the device can be completely absorbed by the body. The biological performance of the device, particularly for application at a bony site, may be enhanced by incorporation of bioactive fillers in the polymer.

4.3 Absorbable devices will be tested using test methods that are similar to those used to evaluate conventional metallic devices. The pre-test conditioning requirements, handling requirements, and time-dependent mechanical property evaluations for absorbable devices shall be considered.

5. Materials and Manufacture

5.1 Absorbable 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 Specifications F1925, F1088, and F1185.)

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

5.3 All absorbable 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.

6. General Requirements and Performance Considerations

6.1 *Absorbable Bone Screws*—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.

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

6.1.2 *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.

6.1.3 *Driving 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

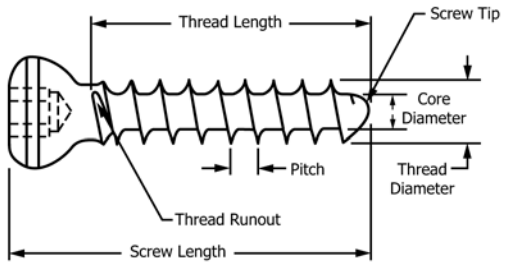

FIG. 1 Screw Parameters

insertion torque may be determined using the test methods described in Annex A2.

6.1.4 *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.

6.2 *Absorbable Bone Plates:*

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

6.2.2 *Bending Properties*—The bending properties are critical characteristics of bone plates for orthopedic applications since the bone plate provides the primary means of stabilizing the bone fragments. In addition, the bending stiffness of the bone plate may affect the rate and quality of healing.

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

7. General Sampling, Conditioning, and Testing Considerations

7.1 *Apparatus, Equipment, and Materials:*

7.1.1 *Sample Container*—A self-enclosed glass or plastic container capable of holding the test sample and the conditioning solution shall be used. The container shall be sealable to prevent solution loss due to evaporation. 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.

7.1.2 *Conditioning/Soaking Solution*—A phosphate buffered saline (PBS) or other adequately pH-controlled aqueous 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 necessary, the solution shall be changed periodically in order to maintain the pH within the acceptable limits. These materials may be hazardous and all persons using them should review the material safety data sheet (MSDS) before handling and use all recommended safety precautions.

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

7.1.3 *Constant Temperature Bath or Oven*—An aqueous bath or heated air oven capable of maintaining the samples and containers at a physiologic temperature (37 ± 2°C) for the specified testing periods shall be used. It shall be well stirred during the test and shall be provided with a means of raising the temperature at a uniform rate.

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

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

7.1.6 *Driving Instruments*—Specification F116 provides related dimensional information for several types of medical screwdrivers

7.2 *Sample Acquisition and Evaluation Frequency:*

7.2.1 *Sampling*—If appropriate, representative random samples shall be taken from each lot or processing quantity in accordance with Practice E122. The test specimen shall be a completely fabricated and finished absorbable bone screw sterilized as intended by the manufacturer.

7.2.2 *Conditioning Intervals*—For a complete history of the behavior of a sample during absorption, there should be at least seven measuring points spanning the duration of mechanical longevity. For example, 0 h, 1 day, 1 week, 4 weeks, 8 weeks, 12 weeks, 16 weeks, and 24 weeks may be appropriate for L-PLA based devices. An initial (0 h) sample is to be tested without conditioning, while data acquired at 1 day post-immersion provides representation of an initial equilibration of the sample within the conditioning solution. The testing intervals shall be documented in the test report.

7.3 *Sample Conditioning:*

7.3.1 Test specimens shall be conditioned by immersion in a pH-controlled aqueous solution at physiologic temperatures (37 ± 2°C) for time intervals appropriate for the device(s) being evaluated.

7.3.1.1 *Conditioning without Loading*—This approach, which omits mechanical loading, is the most common and exposes the sample only to hydrolysis. Such conditioning necessitates a subsequent test to quantify the impact of hydrolysis on the sample's mechanical properties.

7.3.1.2 *Conditioning under Applied Load*—If the device is intended for use in a loaded physiological condition, it is important to consider characterization of the influence that static and/or fatigue loading have on the deterioration of the test specimen. Conditioning load types and magnitudes that are representative of anticipated physiological conditions should be used.

7.3.2 *Conclusion of Conditioning*—Once the appropriate thermal conditioning period is complete, the immersed sample is then removed from the elevated temperature bath. The thermally conditioned sample is to remain immersed in the conditioning fluid until mechanical testing is commenced. Testing shall commence within 1 h of sample retrieval from the elevated temperature bath.

7.4 *Sample Testing:*

7.4.1 *Care and Handling*—Care, handling, and positioning of the absorbable device sample should be conducted in accordance with Practice F565, as appropriate.

7.4.2 *Timing*—Testing shall commence within 1 h after the sample container is retrieved from elevated temperature bath.

7.4.3 *Retrieval*—Testing is to occur immediately after removal of the thermally conditioned sample from the conditioning solution. Once retrieved, excess fluid shall be removed and the sample shall be then promptly positioned in accordance with the specific test method.

7.4.4 *Room Temperature Testing*—Testing is to be performed at room temperature (23 ± 2°C). Unless otherwise deemed relevant, samples should be tested in a non-dried or wet condition per Practice F1635. Testing of dried or drying samples shall be avoided due to potential to affect the values and/or variability of the mechanical property under measurement.

7.4.5 *Immersion Testing (Optional)*—The best approximation of *in vivo* loading is to test specimens while fully immersed in water at 37°C. Depending on the sample and test method, such testing can often be impractical to implement, which leads to the herein optional designation. However, if conducted, such immersion testing can replace room temperature testing.

7.4.6 *Reporting Requirements*—The selected sample testing condition shall be included in the report (See X1.4).

8. Keywords

8.1 absorbable; bend testing; bone plates; bone screw; conditioning; dimensions; insertion; pullout; shear; torsion

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR DETERMINING THE TORSIONAL PROPERTIES OF ABSORBABLE 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 absorbable bone screws. It 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 Factors considered important, but for which values and test methods have not been established, are the shear strength of the head of a screw, shear strength of the threaded region of a screw, and clinically relevant *in vitro* conditioning of enzymatically degradable polymer resins.

A1.1.4 *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 *Data acquisition device*—The data recorder shall be suitable for continuously recording torque versus angle of rotation, and linear displacement, calibrated in units of Newton-meters for torque and degrees for angle of rotation. The value of torque shall have a resolution of at least 5 % of torsional yield strength. The angular displacement scale shall have sufficient sensitivity so as to enable an accurate offset measurement capability for a 2° angular displacement (see A1.4.6).

A1.2.2 *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.

A1.2.3 *Test block*—The test block shall be fabricated from a uniform material that conforms to Specification F1839. See Specification F543, Annex 2.

A1.2.4 *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.

A1.2.5 *Test specimen*—The test specimen shall be a completely fabricated and finished absorbable bone screw sterilized as intended by the manufacturer.

A1.2.6 *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 clockwise and counterclockwise rotation, to be encountered in the test method, shall be provided.

A1.2.7 *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 with an accuracy of ±1 % of reading, both in clockwise and counterclockwise rotation, shall be used.

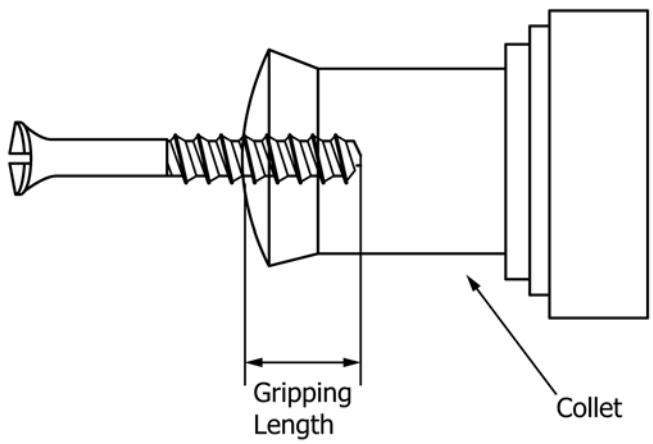

FIG. A1.1 Example of a Test Setup

A1.3 Testing

A1.3.1 The test samples shall be completely immersed in the solution.

A1.3.2 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 the solution.

A1.4 Procedure

A1.4.1 Place the specimen in the holding device so that five threads below the head of the screw are exposed outside the holding device (for example, a 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 but shall be described in the test report. 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 the torsional load. There are no specific requirements for 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.

A1.4.2 The gauge length or grip length should be kept the same length for a 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.

A1.4.3 *Test Speed*—The torsional force shall be applied at a constant rate between 1 to 5 revolutions/min.

A1.4.4 The torsional yield strength shall be determined by the offset method (see Fig. A1.2), using the torque versus angle of rotation curve.

A1.4.5 On the torque versus angle of rotation curve, locate point *m* equal to a rotation of 2°. Draw line *mn* parallel to *OA*, and locate *b*, the intersection of line *mn* with the torque versus angle of rotation curve. Torque *B* is defined as the torsional yield strength.

A1.4.6 The maximum torque is determined by the largest value of torque on the torque versus angle of rotation curve.

A1.4.7 Absorbable 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.

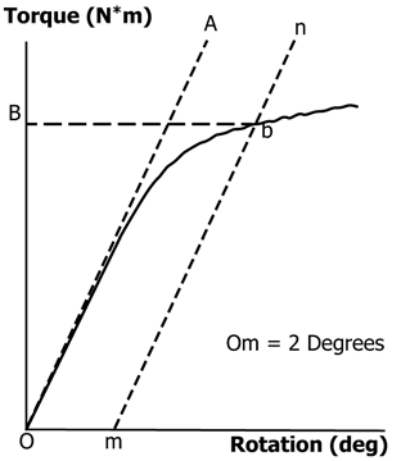

FIG. A1.2 Typical Torque versus Angle of Rotation Curve

A1.5 Report

A1.5.1 Report the following information for each specimen tested:

A1.5.1.1 Screw identification. Reference any applicable ASTM or ISO specification that may apply to the specimen.

A1.5.1.2 Screw composition.

A1.5.1.3 Gauge length.

A1.5.1.4 Test speed.

A1.5.1.5 Number of specimens tested.

A1.5.1.6 Conditioning details.

A1.5.1.7 Solution.

A1.5.1.8 Loaded or unloaded (if loaded, list the load).

A1.5.1.9 Torsional yield strength.

A1.5.1.10 Maximum torque.

A1.5.1.11 Mean and standard deviations of the yield strength for the set of screws tested.

A1.5.1.12 Mean and standard deviations of the maximum torque for the set of screws tested.

A1.5.1.13 Torque versus angle of rotation plot.

A1.5.1.14 Grip length. This does not have to be reported for a fully threaded screw of ASTM or ISO specification whose overall length is given.

A1.5.1.15 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.

A1.5.1.16 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).

A1.6 Precision and Bias

A1.6.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A1.6.2 *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.

A2. TEST METHOD FOR DRIVING TORQUE OF ABSORBABLE 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 Testing

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

A2.3 Procedure

A2.3.1 *Insertion*—Insert the screw as follows:

A2.3.1.1 *Insertion*—Place the specimen in the test fixture as illustrated in Fig. A2.1. Drive the specimen into the test block, 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.

A2.3.1.2 *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.

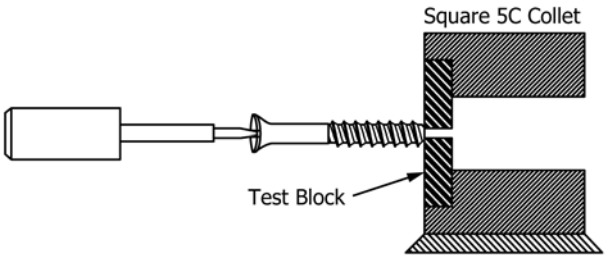

FIG. A2.1 Screw insertion Test Setup

A2.3.1.3 *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.

A2.4 Report

A2.4.1 Report the following information for each specimen tested:

A2.4.1.1 Screw identification. Reference any applicable ASTM or ISO standard specification that may apply to the specimen.

A2.4.1.2 Screw composition.

A2.4.1.3 Test speed.

A2.4.1.4 Number of specimens tested.

A2.4.1.5 Conditioning details.

A2.4.1.6 Conditioning solution.

A2.4.1.7 Loaded or unloaded (if loaded, list the load).

A2.4.1.8 Insertion torque.

A2.4.1.9 Axial load applied.

A2.4.1.10 Insertion depth (may be calculated or measured).

A2.4.1.11 Whether the pilot holes were pre-tapped. If tapped, report the tap size, tap diameter, and tap length.

A2.4.1.12 Insertion test speed.

A2.4.1.13 Mean and standard deviations of the insertion torque for the set of screws tested.

A2.4.1.14 Test block material description.

A2.4.1.15 Test Blocks. Indicate whether the blocks were pre-soaked or not soaked.

A2.4.1.16 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).

A2.5 Precision and Bias

A2.5.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A2.5.2 *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 ABSORBABLE BONE SCREWS

A3.1 Scope

A3.1.1 This test method is used to measure the axial tensile force required to remove, or fracture, an absorbable 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

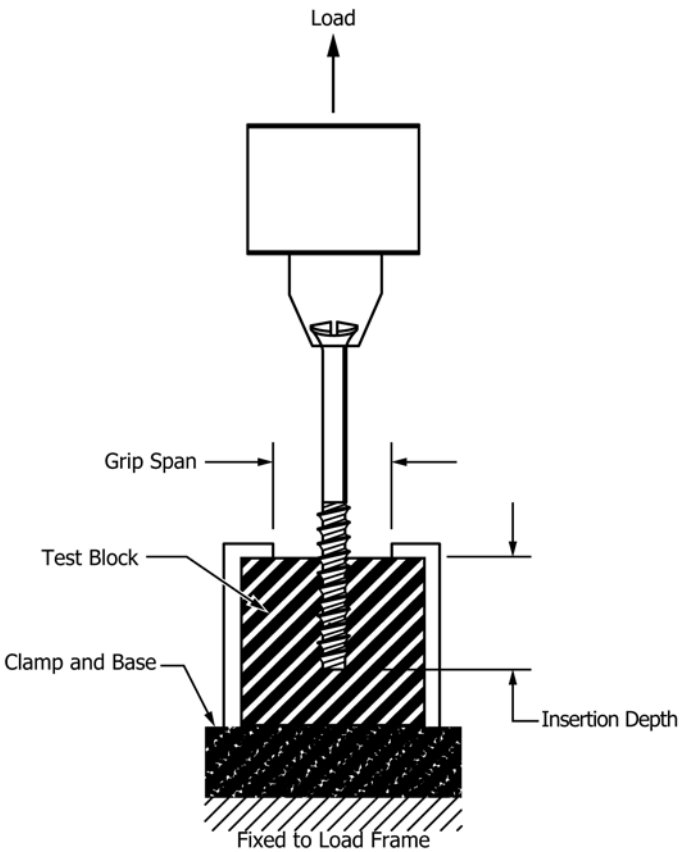

FIG. A3.1 Pullout Test Fixture

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 Procedure

A3.3.1 *Insertion of the Test Specimen*—The bone screws shall be inserted into the standard material in accordance with the insertion torque test method (see 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.

A3.3.2 *Axial Pullout Strength of the Test Specimen*—The test block and test block clamp depicted in Annex A2 shall be fixed to the base of the load frame so that the longitudinal axis of the screw is aligned with the direction of the applied load. The screw's head shall be placed in the slot of the load fixture and seated in the spherical recess. The load fixture shall then be attached to the load frame. A tensile load shall be applied to the test specimen at a rate 5 mm/min until the screw fails or releases from the test block. Load (Newtons) versus load fixture displacement (millimetres) shall be recorded by a data acquisition device, noting the maximum load applied and the mode of failure (screw shaft, screw threads, or material failure).

A3.4 Calculation or Interpretation of Results

A3.4.1 *Axial Pullout Strength*—Determine the axial pullout strength (Newtons) of the test specimen from the load-displacement curve at the maximum load reached during the test.

A3.5 Report

A3.5.1 Report the following information:

A3.5.1.1 Screw identification. Reference any applicable ASTM or ISO specification that may apply to the specimen.

A3.5.1.2 Screw composition.

A3.5.1.3 Test speed.

A3.5.1.4 Number of specimens tested.

A3.5.1.5 Conditioning details.

A3.5.1.6 Conditioning solution.

A3.5.1.7 Loaded or unloaded (if loaded, list the load).

A3.5.1.8 Axial pullout strength.

A3.5.1.9 Mean and standard deviations of the axial pullout strength for the set of screws tested.

A3.5.1.10 Insertion depth.

A3.5.1.11 Test block thickness.

A3.5.1.12 Test block material description.

A3.5.1.13 Mode of failure.

A3.5.1.14 Test blocks. Indicate whether the blocks were pre-soaked or not soaked.

A3.5.1.15 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.)

A3.6 Precision and Bias

A3.6.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A3.6.2 *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.

A4. TEST METHOD FOR SINGLE CYCLE BEND TESTING OF ABSORBABLE BONE PLATES

A4.1 Scope

A4.1.1 This test method describes methods for single cycle bend testing in order to determine intrinsic structural properties of absorbable bone plates. The test method measures the bending stiffness, bending structural stiffness, and bending strength of bone plates.

A4.1.2 This test method is intended to provide a means of mechanically characterizing different bone plate designs. It is not the intention of this test method to define levels of performance for bone plates as insufficient knowledge is available to predict the consequences of the use of particular bone plate designs.

A4.2 Terminology

A4.2.1 *0.2 % offset displacement, q (mm)*—permanent deformation equal to 0.2 % of the center loading span distance (point *B* in Fig. A1.2).

A4.2.2 *bending stiffness, K (N/mm)*—of a bone plate, the maximum slope of the linear elastic portion of the load versus load-point curve when tested as described in A4.5 (see the slope of line *OA* in Fig. A4.1).

A4.2.3 *bending strength (N-m)*—of a bone plate, the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as described in A4.5 (the bending moment corresponding to point *B* in Fig. A4.1). If the bone plate fractures before the proof point is attained the bending strength shall be defined as the bending moment at fracture.

A4.2.4 *bending structural stiffness, EI_e (N-m^2)*—of a bone plate, the bone plate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration. For this test method, the bending structural stiffness is determined from the single cycle bending response of the bone plate and the testing configuration.

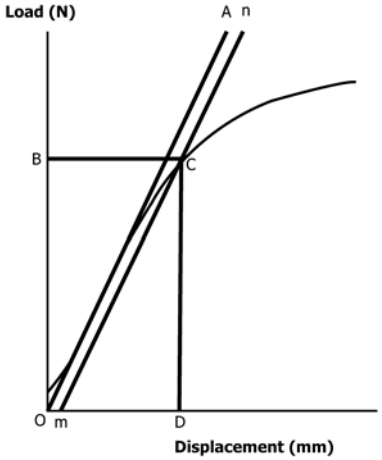

FIG. A4.1 Load—Displacement Diagram

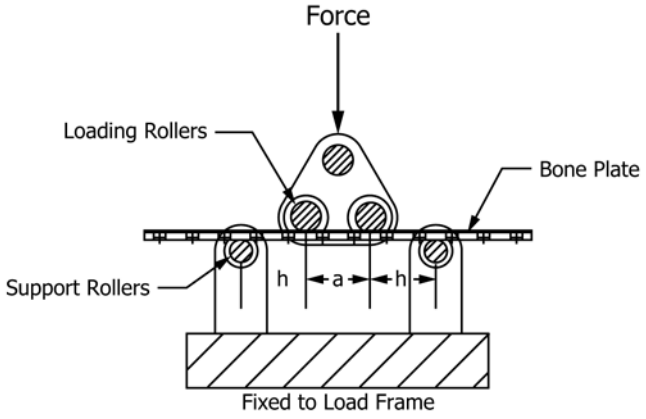

FIG. A4.3 Bend Test Fixturing

A4.2.5 *bone plate length, L (mm)*—the linear dimension of the bone plate measured along the longitudinal axis as illustrated in Fig. A4.2.

A4.2.6 *bone plate thickness, b (mm)*—the thickness of the bone plate as shown in Fig. A4.2.

A4.2.7 *bone plate width, w (mm)*—the width of the bone plate as shown in Fig. A4.2.

A4.2.8 *center span, a (mm)*—the distance between the two loading rollers as shown in Fig. A4.3.

A4.2.9 *flexural strength*—maximum flexural stress sustained by the test specimen during a bending test. Some materials that do not break at strains of up to 5 % may give a load deflection curve that shows a point at which the load does not increase with an increase in strain, that is, a yield point, *Y*. (Test Methods D790, Section 12.4.)

A4.2.10 *fracture load, F_{max} (N)*—the applied load at the time when the bone plate fractures.

A4.2.11 *loading span, h (mm)*—the distance between the loading roller and the nearest support as shown in Fig. A4.3.

A4.2.12 *plastic deformation (mm)*—the permanent change in shape or size of a body without fracture, produced by a sustained stress beyond the elastic limit of the material.

A4.2.13 *proof load, P (N)*—the applied load at the intersection point of line *mC* with the load versus load-point displacement curve (see Fig. A4.1).

A4.3 Apparatus

A4.3.1 The typical test configuration is illustrated in Fig. A4.3.

A4.3.1.1 All loads shall be applied through rollers of equal diameters (the roller diameter is dependant on the plate size). The selected roller diameter should not be greater than the distance between two adjacent screw holes in the bone plate to be tested.

A4.3.1.2 Cylindrical rollers shall be used to test flat bone plates and bone plates of curved cross-section, in which the

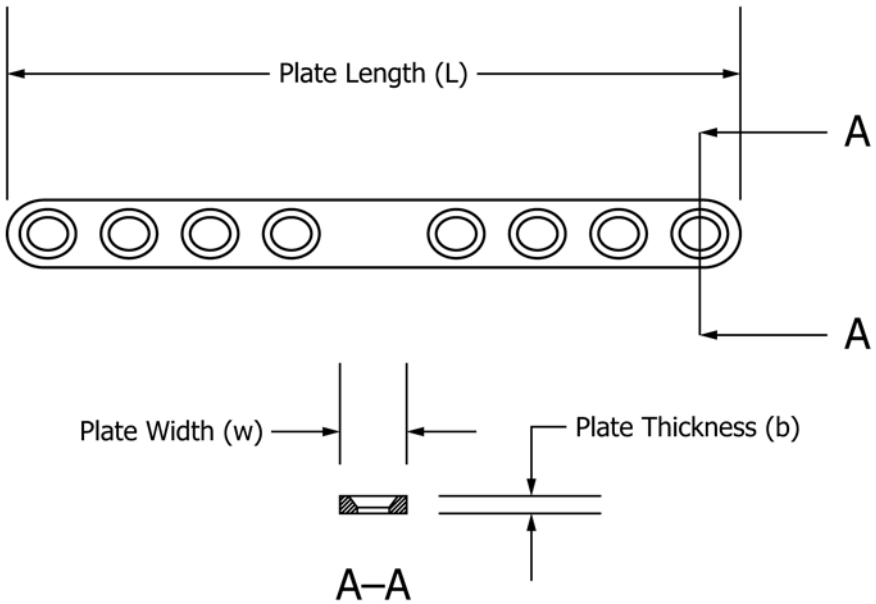

FIG. A4.2 Bone Plate Dimensions

deviation from flatness at the center of the bone plate does not exceed w/6. Test other bone plates using rollers of profiled form corresponding to the cross-section of the bone plate to be tested (see Fig. A4.3).

A4.3.1.3 The loading and support rollers shall be positioned as follows:

(1) The loading rollers shall be positioned so that two screw holes will be located between the loading rollers. Record the center span distance.

(2) The support rollers shall be positioned equal distances away from the adjacent loading roller so that two screw holes will be located between the adjacent loading and support rollers. Record the distance between the loading roller and the nearest support roller.

(3) The recommended testing configuration locates the loading rollers at approximately the one-third points between the supporting rollers.

(4) The applied load shall be shared equally by both loading rollers.

A4.3.1.4 Alternative test configurations utilized in determining the single cycle bending properties of bone plates shall be described in the test report.

A4.4 Sampling

A4.4.1 Bone plates of different lengths but nominally identical cross sections, and made of the same material, may be used to constitute a sample.

A4.5 Procedure

A4.5.1 Place the bone plate in the testing fixture and position it in accordance with the following:

A4.5.1.1 Place the bone plate so that the loading rollers are in contact with the surface of the bone plate intended to be in contact with the bone.

A4.5.1.2 If the bone plate is symmetrical, place it symmetrically with the two innermost screw holes between the loading rollers.

A4.5.1.3 If the bone plate has a central screw hole, place it with the central screw hole and one other screw hole symmetrically between the loading rollers.

A4.5.1.4 If the bone plate is asymmetrical, place it with two screw holes between the loading rollers so that the position of the fracture for which it is intended to be used shall be between the loading rollers.

A4.5.1.5 Ensure that the loading rollers are not in contact with parts of the bone plate where there is a screw hole. Wherever possible, the support rollers should not be in contact with parts of the bone plate which include a screw hole.

A4.5.1.6 Align the long axis of the bone plate so that it is perpendicular to the axes of the rollers.

A4.5.2 Apply loads of increasing magnitude or by using displacement control and generate a load versus load-point displacement or load versus displacement diagram either autographically or from numeric data acquired during the test.

A4.5.3 Determine the bending stiffness, bending structural stiffness, and bending strength for each tested bone plate according to the method that follows:

A4.5.3.1 A load versus load-point displacement curve (see Fig. A4.1) is produced either autographically or from numerical data acquired during the test.

(1) On the load versus load-point displacement diagram generated for the test, draw a best fit straight line (*Om*) through the initial (linear) portion of the load versus load-point displacement curve.

(2) Determine the bone plate's bending stiffness by calculating the slope of the line, *Om*.

(3) Determine the bone plate's bending structural stiffness with the following expression:

$$EI_e = \frac{(2h+3a)\,Kh^2}{12} \qquad \text{(A4.1)}$$

where:

EI_e = the bending structural stiffness (N-m^2),
K = the bending stiffness (N/mm),
a = the center span distance (mm), and
h = the loading span distance (mm).

Note—Since the test method requires the inclusion of screw holes in the center span region, then the bone plate's bending structural stiffness really represents an average of the EI_e over the center span region.

(4) Calculate the 0.2 % offset displacement from the expression:

$$q = 0.002 \cdot a \qquad \text{(A4.2)}$$

where:

q = the offset displacement, and
a = the center span distance (mm).

(5) On the load versus load-point displacement diagram lay off *Om* equal to *q*. Then draw line *mn* parallel to *OA*.

(6) Locate the proof load at the intersection point of line *mC* with the load versus load-point displacement curve.

(7) Calculate the bending strength of the bone plate from the expression:

$$\text{bending strength} = \frac{(Ph)}{2} \qquad \text{(A4.3)}$$

where:

P = proof load (N), and
h = loading span (mm).

(8) If the bone plate fractures prior to the load versus load-point displacement curve intersecting the offset line *BC*, calculate the bending strength form the expression:

$$\text{bending strength} = \frac{F_{max} \cdot h}{2} \qquad \text{(A4.4)}$$

where:

F_{max} = fracture load (N), and
h = loading span (mm).

A4.6 Report

A4.6.1 Report the following information:

A4.6.1.1 Bone plate identification. Reference any applicable ASTM or ISO standard specification that may apply to the specimen.

A4.6.1.2 Description or photograph, or both, of the test configuration.

A4.6.1.3 The center span and loading span dimensions (*h* and *a*).

A4.6.1.4 Number of specimens tested.

A4.6.1.5 Conditioning details.

A4.6.1.6 Conditioning solution.

A4.6.1.7 Loaded or unloaded (if loaded, list the load).

A4.6.1.8 The 0.2 % offset displacement, *q*, used to determine the bending strength.

A4.6.1.9 Plastic Deformation. The permanent change in shape or size of a body without fracture, produced by a sustained stress beyond the elastic limit of the material.

A4.6.1.10 Mean and standard deviations of the bending stiffness values for the set of bone plates tested.

A4.6.1.11 Mean and standard deviations of the bending structural stiffness values for the set of bone plates tested.

A4.6.1.12 Mean and standard deviations of the bending strength values for the set of bone plates tested.

A4.6.1.13 Number of bone plates fractured during the test.

A4.6.1.14 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).

A4.6.1.15 The method (either displacement or load) and rate utilized for controlling the test.

A4.7 Precision and Bias

A4.7.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A4.7.2 *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.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 *General Discussion*:

X1.1.1 The use of absorbable polymers for internal fixation implants has a number of potential and theoretical advantages compared to metals. They eliminate the need for surgical removal. They reduce the potential for stress shielding. As they are absorbed they transfer load back to the healing bone. They do not interfere with X-ray or MRI imaging techniques. However they do have a number of limitations. As they degrade they release the acidic monomer which can lead to autocatalytic degradation and acidosis, particularly for thicker section pieces. They are not 'bioactive' and as such will not bond to bone and have little potential to be replaced by bone when fully absorbed. They are invisible to X-rays.

X1.1.2 In order to overcome some of the deficiencies of the polymers alone, a number of synthetic absorbable composites have been developed. These consist of a polymer matrix combined with a bioactive ceramic filler such as tricalcium phosphate (TCP) or hydroxyapatite (HA). The filler confers a number of advantages to the polymer. It provides a source of osteoconductive calcium-based particles to aid integration with the adjacent bone. It increases the modulus of the polymer so modulus-matching to bone becomes possible. It enhances the X-ray absorption, helping visualization and provides a buffering effect to help minimize the potential for autocatalytic degradation and acidosis. In addition it provides the potential to be replaced by bone as the implant is absorbed.

X1.1.3 With the development of absorbable polymers and polymer/ceramic composites for use in implantable devices, there is a need to define standard testing methods that aid in characterizing material and mechanical properties with time in a simulated physiological environment. This specification is intended to provide useful and consistent information related to the terminology, performance, and application of test methods for absorbable devices.

X1.2 The use of test coupons or specimens in forms other than final implant configurations may be helpful in assessing relevant polymer properties. For example, rectangular or round rods may be necessary to measure flexural properties, while a screw geometry may be required to evaluate the performance of a specific implantable device.

X1.3 The specified soaking solution is taken directly from Test Method F1635, Section X1.6. The addition of sodium azide at a concentration of 0.1 % is common. Other antimicrobials that are commonly used include penicillin (100 U/mL), streptomycin (100 µg/mL), and amphotericin (0.25 to 2.5 µg/mL). Regardless of the antibiotic or antimicrobial agent(s) that is used, it is incumbent upon the investigator to determine that their use does not affect the degradation rate of the hydrolytically degradable polymer under investigation. As noted previously, these materials may be hazardous and all persons using them should review the material safety data sheet (MSDS) before handling and use all recommended safety precautions.

X1.4 The Committee recommends that, where practical, testing be performed on specimens that are immersed in water at 37°C. Alternatively, testing can be performed under unimmersed conditions at room temperature (23°C). However, the user is cautioned that moisture evaporation (even under normal room temperature conditions) can impart significant changes in physical properties since water plasticizes these polymers, especially when they have become partially degraded. Thus, in order to avoid erratic and/or erroneous results, keeping the sample moist through testing is essential. Whichever test

condition is chosen shall be reported.

X1.5 *Nomenclature* :

X1.5.1 Synthetic implants fabricated from hydrolysable alpha-hydroxy polyesters have been described as "absorbable" since the first polyglycolide-based sutures were commercialized in the United States in the 1970s. At that time, both poly(glycolide) (DEXON—Davis and Geck) and poly(glycolide-co-lactide) copolymer (VICRYL—Ethicon) based sutures were classified as "Absorbable Surgical Suture" by the United States Pharmacopeia (USP) and the United States Food and Drug Administration (US-FDA), a designation that remains to this day. In contrast with "Nonabsorbable Surgical Suture," synthetic glycolide-lactide and collagen-based sutures undergo hydrolytic and/or enzymatic driven chain scission, generating byproducts that are then absorbed by the body. Since designation, other terms such as "degradable" and "resorbable" have been used interchangeably to describe absorbable implants, with the prefix "bio-" often applied to all these terms.

X1.5.2 Based on historical usage and regulatory precedent, this document preferentially utilizes the term absorb/absorbable/absorption to describe implantable synthetic hydrolysable polymers and devices. The prefix "bio" is avoided since it is redundant in the context of implant applications. "Resorb" and its derivatives are avoided since they are accepted medical terms routinely utilized to describe natural resorption processes present in dynamic tissue, such as osteoclastic driven bone remodeling. "Degrade" and its various derivatives are avoided when referring to either an implantable device or a raw material since common utilization is routinely applied broadly to include composting and other natural processes (including ultra-violet radiation) that cause materials to either intentionally or unintentionally break down into chemical and/or particulate matter. However, use of the term "degrade" and its derivatives is considered acceptable when referring to chain scission within the implantable device or polymer (for example, "The absorbable implant degrades through hydrolysis." or "During extrusion, absorbable polyglycolide is prone to thermal degradation.").

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