Designation: ~~F2502 – 11~~ F2502 – 17

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~~ safety, health and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *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]

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

[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.

Current edition approved ~~June 1, 2011~~Sept. 1, 2017. Published ~~July 2011~~October 2017. Originally approved in 2005. Last previous edition approved in ~~2009~~2011 as ~~F2502 – 05 (2009)~~F2502 – 11.~~ε1~~. DOI: ~~10.1520/F2502-11.~~10.1520/F2502-17.

[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.

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
F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide
F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants
F2902 Guide for Assessment of Absorbable Polymeric Implants
F3160 Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical 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 *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.

4.4 This specification and accompanying test methods are intended to complement the more general considerations for the assessment of absorbable polymeric implants that are described within Guide F2902.

5. Materials and Manufacture

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

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

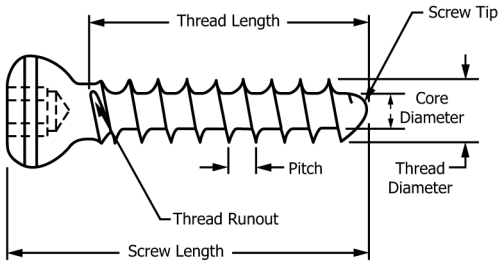

FIG. 1 Screw Parameters

5.1.1 L-lactide, D-lactide, DL-lactide, glycolide, or other known hydrolytically degradable polymer resins or copolymers. ~~(See ISO 13781, ISO 15814, Test Method~~ (for additional information, see complementary test methods found in ISO 13781, ISO 15814, and F1635, and in related Specifications F1925, ~~F1088~~F2313, and ~~F1185~~F2579.)

5.1.2 Other absorbable polymeric, ceramic, or metallic based constructs that degrade through non-hydrolytic means, such as those described in Specifications F1088 and F1185, and Guide F3160 may be considered, but precautions should be undertaken to assure a materials-appropriate degradation environment is maintained.

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 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 anti-microbial 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.

7.4.1.1 Consider Practice F2503 to identify potential hazards produced by interactions between the device and the MR environment and for terms that may be used to label the device for safety in the MR environment.

7.4.2 *Timing*—Testing shall commence within 1 h after the sample container is retrieved from the 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~~capable of 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~~capable of 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.

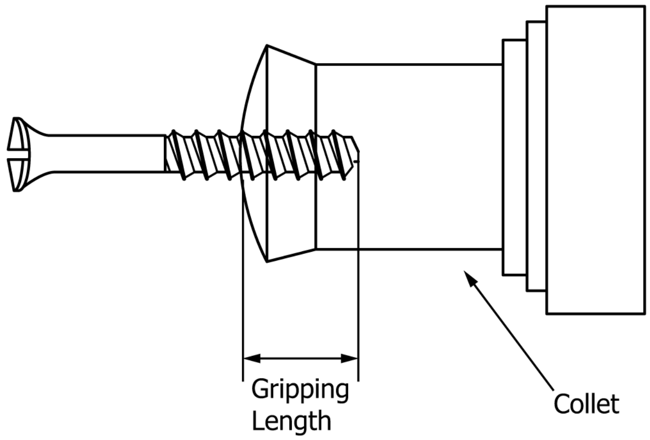

FIG. A1.1 Example of a Test Setup

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.