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Standard Specification and Test Methods for Metallic Bone Staples¹

This standard is issued under the fixed designation F564; 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.

~~^{ε1}Note—Units information was editorially corrected in September 2009.~~

1. Scope

1.1 This specification covers characterization of the design and mechanical function of metallic staples used in the internal fixation of the muscular skeletal system. It is not the intention of this specification to describe or specify specific designs for metallic bone staples.

1.2 This specification includes the following four test methods for measuring mechanical properties of metallic bone staples:

1.2.1 Test Method for Constant Amplitude Bending Fatigue Tests of Metallic Bone Staples—Annex A1.

1.2.2 Test Method for Pull-Out Fixation Strength of Metallic Bone Staples—Annex A2.

1.2.3 Test Method for Soft Tissue Fixation Strength of Metallic Bone Staples—Annex A3.

1.2.4 Test Method for Elastic Static Bending of Metallic Bone Staples—Annex A4.

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

1.4 *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

E4 Practices for Force Verification of Testing Machines

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

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F382 Specification and Test Method for Metallic Bone Plates

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F629 Practice for Radiography of Cast Metallic Surgical Implants

3. Finish

3.1 Staples conforming to this specification shall be finished and identified in accordance with Practice F86, as appropriate.

4. Inspection Practices

4.1 Staples made in accordance with Specification F75 should be inspected in accordance with Practice F601 or X-rayed in accordance with Practice F629.

5. Care and Handling

5.1 Staples should be cared for and handled in accordance with Practice F565, as appropriate.

¹ This specification 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.

6. Keywords

6.1 bending test; bone fixation; fatigue test; fixation devices; metallic bone staples; orthopaedic medical devices; pullout test; soft tissue fixation; surgical implants

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR CONSTANT AMPLITUDE BENDING FATIGUE TESTS OF METALLIC BONE STAPLES

A1.1 Scope

A1.1.1 This test method covers procedures for the performance of constant amplitude fatigue testing of metallic staples used in internal fixation of the musculoskeletal system. This test method may be used when testing in air at ambient temperature or in an aqueous or physiological solution.

A1.1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A1.1.3 *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.*

A1.2 Summary of Test Method

A1.2.1 Metallic bone staples are tested under bending loads until the specimen fails or a predetermined number of cycles has been applied to it. Bending tests may be performed in one of two modes: either pure, in-plane bending; or tension (or compression) combined with in-plane bending. Tests using either of these methods may be conducted at ambient conditions or in aqueous or physiological solutions (at either room temperature or 37°C).

A1.3 Significance and Use

A1.3.1 This test method is used to determine the fatigue resistance of metallic bone staples when subjected to repetitive loading for large numbers of cycles. This information may also be useful for comparing the effect of variations in staple material, geometry, surface condition, or placement under certain circumstances.

A1.3.2 It is essential that uniform fatigue practices be established in order that such basic fatigue data be comparable and reproducible and can be correlated among laboratories.

A1.3.3 The results of fatigue tests are suitable for direct application to design only when the service conditions parallel the test conditions exactly. This test method may not be appropriate for all types of bone staple applications. The user is cautioned to consider the appropriateness of the test method in view of the materials being tested and their potential application.

A1.4 Apparatus

A1.4.1 *Testing Machines*, conforming to the requirements of Practices E4 and E467. The loads used for determining strengths shall be within the loading range of the testing machine as defined in Practices E4 and E467.

A1.4.2 Gripping Devices:

A1.4.2.1 *Staple Extensions*—Pairs of specially designed metal blocks that permit the holding of individual staples for the application of bending fixture loads. The legs of each staple are fitted into fixation holes in each block with minimal clearance to restrict bending of the staple within the hole. The staple is fixed securely in the block using a moldable filling or grouting agent. The extension design should minimize the weight to reduce the influence on the staple while maintaining sufficient stiffness to transfer the load to the staple without undesirable deflection. Holes for pin and clevis fixation are optional (see Figs. A1.1-A1.3).

NOTE A1.1—Variations in fixation hole configuration may be required for staple legs with noncircular cross sections. Also, it is necessary to provide a gap between the underside of the staple bridge and edge of the staple extender in most cases. This is necessary to eliminate contact between the staple bridge (or other bridge features such as tissue spikes) and the staple extender. However, this gap should be standardized within any test group as required.

A1.4.2.2 *4-Point Bend Fixture*—A standard or modified bending fixture that produces pure bending in the staple without appreciable shear or torsion when used to apply load to the staple through the staple extensions.

A1.4.2.3 *Pin and Clevis Fixture*—A standard or modified fixture used to apply a distractive or compressive load to the staple through the staple extensions to produce bending in the staple similar to that seen in vivo.

A1.4.3 *Filling or Grouting Agent*—A stiff, moldable filler, such as epoxy, acrylic cement, or a low-melting point alloy (for example, Wood's metal) used to secure the staple leg within the staple extension.

A1.4.4 *Aqueous Solution*—Tap water, distilled water, physiological saline, or similar aqueous solutions, used to immerse the test specimens fully during the test.

A1.4.5 *Constant Temperature Bath*—An aqueous bath capable of maintaining the samples and containers at physiologic temperatures, $37 \pm 2^\circ\text{C}$, for the specified testing periods.

A1.5 Test Specimen

A1.5.1 *Staple*—A generally U-shaped metal loop, with at least two legs, that is driven into the surface of bone to either fix or

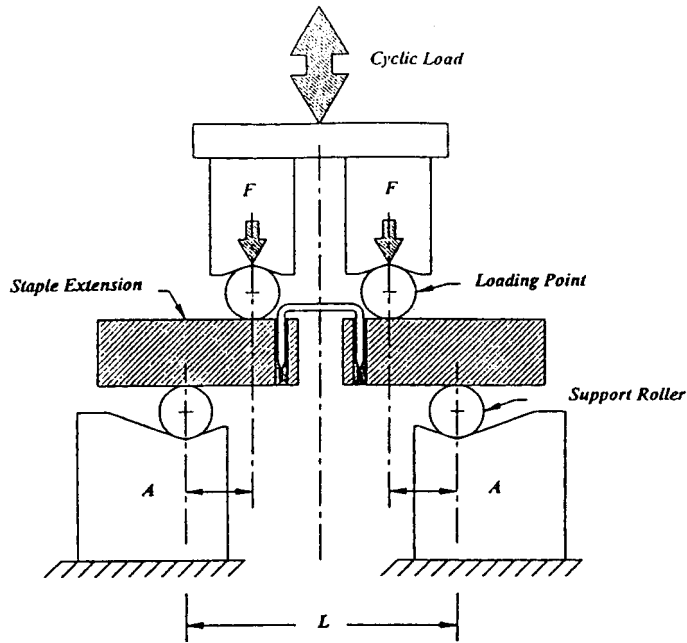


FIG. A1.1 4-Point Bending of Staples in Extension

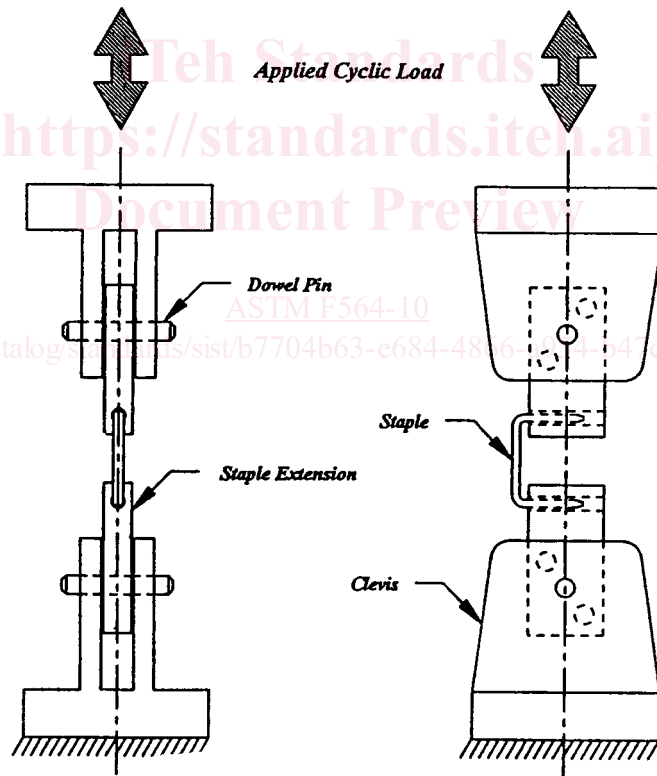


FIG. A1.2 Combined Tension (or Compression) and Bending of Staples

immobilize adjacent pieces of bone or to fasten soft tissue or other material to bone. All test samples shall be representative of the material under evaluation. Samples for comparative tests shall be produced from the same material lot or batch and under the same fabricating conditions, unless noted specifically.

A1.5.2 *Staple Leg*—The parallel or nearly parallel extensions that are intended to penetrate the bone tissue; these may be round, square, or polygonal in cross section, and they may possess serrations or barbs to increase the fixation or purchase strength in the bone.

A1.5.3 *Staple Bridge*—The cross member of the staple connecting the legs; the bridge may be smooth or possess spikes or

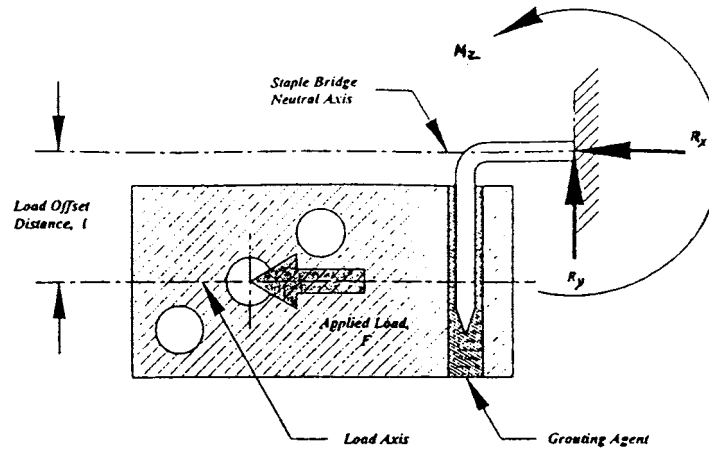


FIG. A1.3 Diagram of Extender-Staple Forces Under Combined Bending and Tension

projections on the underside for the retention of soft tissue or other material.

A1.6 Procedure

A1.6.1 *Mounting the Specimen*—Fix the staple leg in an extension block using the filling agent. A fixture should be used to ensure proper in-plane alignment of the two extensions and the staple during this process. Also, each staple should be fixed such that the bridge is the same distance from the top of each extension.

NOTE A1.2—This distance is at the discretion of the operator, but it determines the portion of the staple subjected to the bending loads.

A1.6.2 4-Point Bend Testing:

A1.6.2.1 Place the staple and attached staple extensions in the 4-point bending fixture such that the loading point and support rollers contact the staple extensions on either side of the staple; direct contact of the rollers with the staple shall not be permitted during the test. Alignment of the loading point rollers shall be symmetric to the centerline between the support rollers (see Fig. A1.1).

A1.6.2.2 Apply cyclic loads (sinusoidal, sawtooth, and so forth), generating bending moments in the staple without permanent deformation. Appropriate starting loads should be 50 to 75 % of the static bending strength, unless indicated otherwise.

NOTE A1.3—It may be necessary to provide a low-friction means of maintaining the position of the staple and attached extensions. Also, the fixtures should be designed so that loads are applied equally at the loading points during each deflection throughout the test.

A1.6.2.3 Compute the bending moment, M , by the following formula, where F = force applied at each loading point and A = distance between the loading point and support roller, $M_{\text{bending}} = FA$.

A1.6.2.4 Continue the test until failure of the staple or staple, the fixation, or a predetermined number of load cycles has been applied.

A1.6.3 Combined Tension or (Compression) and Bending:

A1.6.3.1 Place the staple and attached staple extensions in the axial bending fixture. The pins and clevises should permit free rotation of the staple extensions, with minimal friction, while maintaining alignment of the staple legs (and extensions) in the same plane (see Fig. A1.2).

A1.6.3.2 Apply cyclic loads (sinusoidal, sawtooth, and so forth), generating bending moments in the staple without permanent deformation. Appropriate starting loads should be 50 to 75 % of the static yield strength, unless indicated otherwise.

NOTE A1.4—It may be necessary to maintain a minimum tensile or compressive load on the specimen throughout the test, since operating at or near zero load may result in either loss of machine control due to discontinuity in the load feedback loop or undesirable transient loading of the staple.

A1.6.3.3 Compute the bending moment in the staple bridge, M , by the following formula, where F = force applied at each center of each pin and L = distance between the load application axis, that is, the pin center, and the neutral axis of the staple bridge, $M_{\text{bending}} = FL$ (see Fig. A1.3).

NOTE A1.5—The application of this test method produces bending, tensile (or compressive), and shear stresses in the staple. The direction and magnitudes of these stresses should be analyzed using superposition theory or other suitable methods.

A1.6.3.4 Continue the test until failure of the staple or the fixation or a predetermined number of load cycles has been applied.

A1.6.4 *Stress Verification*—It is recommended that strain gages (or extensometry) be used to measure the bending strains induced in the specimen. This is accomplished most easily on the staple bridge, but it may be possible to perform on a portion of the staple leg or at the leg-bridge junction under certain circumstances and with certain staple designs. The recommended technique is to strain gage the actual fatigue test specimens, if possible, provided that the installation of strain gage will not influence the test results.

A1.7 Test Termination

A1.7.1 Continue the tests until the specimen fails or a predetermined number of cycles has been applied to the specimen. Failure should be defined as complete separation, a crack visible at a specified magnification, a crack of certain dimensions, or by some other criterion. State the criterion selected for defining failure when reporting the results.

A1.7.2 A test shall be considered invalid if a loosening of the staple occurs in the embedding ~~medium~~ or medium, if noticeable yielding occurs, or permanent deformation occurs in the specimen.

A1.8 Report

A1.8.1 Report the following information:

A1.8.1.1 *Staple Description*—Type, size, special features (barbs, spikes, and so forth), manufacturer, material, batch or lot number, and dimensions (including leg length, bridge width, and length), as appropriate.

A1.8.1.2 *Test Type*—4-point or combined tension (or compression) and bending.

A1.8.1.3 *Fixation Geometry*—Load point separation distances (4-point bending), load offset distance (combined tension and bending), staple bridge-extension distance, and so forth.

A1.8.1.4 Minimum and maximum cycle loads, test frequency (for example, cycles/s), and forcing function type (sine, ramp, saw tooth, and so forth).

A1.8.1.5 Bending moment, M (N-m).

A1.8.1.6 Load ratio, R , where R = minimum load/maximum load.

A1.8.1.7 *Test Environment*—Ambient air or physiological solution.

A1.8.1.8 Number of cycles at failure or test termination (runout).

A1.8.1.9 Location of fatigue fracture (if applicable).

A1.8.1.10 Reason for test termination, that is, staple failure, fixation failure, runout to specified cycle limit, and so forth.

A1.9 Precision

A1.9.1 Intralaboratory and interlaboratory reproducibility have not been determined systematically.

A1.10 Rationale (Nonmandatory Information)

A1.10.1 This test method is intended to aid in characterizing the fatigue behavior of metallic bone staples used for the fixation of bone to bone or soft tissue to bone. The data obtained using this test method may be used to compare staple materials, designs, or placements under certain circumstances.

A1.10.2 This test method is intended to simulate potential in vivo staple loading conditions. However, in vitro testing of these devices may not duplicate their in vivo behavior adequately.

A2. TEST METHOD FOR PULL-OUT FIXATION STRENGTH OF METALLIC BONE STAPLES

A2.1 Scope

A2.1.1 This test method covers testing of the hard tissue pull-out fixation strength of metallic staples used in the internal fixation of the musculoskeletal system. This test method may be used with physiologic bone or a synthetic substitute. It may also be used when testing in an aqueous or physiological solution.

A2.1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A2.1.3 *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.*

A2.2 Summary of Test Method

A2.2.1 A thin, flat, flexible metal or fabric strap is fixed to bone (or a substitute) using a single staple. Tension is applied equally to both ends of the strap in a direction parallel to the staple legs until loss of staple fixation occurs. Tests using this test method may be conducted at ambient conditions or in aqueous or physiological solutions at either room temperature or 37°C.

A2.3 Significance and Use

A2.3.1 This test method is intended to help assess the axial holding strength of various metallic bone staples used to fix either soft or hard tissue to bone. This information may be useful for comparisons of staple materials, designs, or placement under certain circumstances.

A2.3.2 This test method may not be appropriate for all types of bone staple applications. The user is cautioned to consider the appropriateness of the test method in view of the materials being tested and their potential application.

A2.4 Apparatus

A2.4.1 *Testing Machines*, conforming to the requirements of Practices E4. The loads used for determining strengths shall be within the loading range of the testing machine as defined in Practices E4.

A2.4.2 *Gripping Devices:*

A2.4.2.1 *Hard Tissue Grips*—Grips designed specifically for secure grasping of bones, bone segments, or bone substitutes with minimal material effects at the staple fixation site during the application of tension to the metal or fabric strap. These grips must allow for variation in bone geometry and permit proper orientation and alignment of the bone (or substitute) during the test.

A2.4.2.2 *Metal or Fabric Strap Grips*—Grips designed for secure grasping of the metal or fabric strap with minimal damage during the application of tension. Typical grips may be actuated mechanically, pneumatically, or hydraulically to compress the strap between two flat grip faces parallel to the line of load application. The grip faces may be smooth or serrated.

A2.4.2.3 *Constant Temperature Bath*—An aqueous bath capable of maintaining the samples and containers at physiologic temperatures, $37 \pm 2^\circ\text{C}$, for the specified testing periods.

A2.5 Test Specimen

A2.5.1 *Staple*—A generally U-shaped metal loop, with at least two legs, that is driven into the surface of bone to either fix or immobilize adjacent pieces of bone or to fasten soft tissue or other material to bone. All test samples shall be representative of the material under evaluation. Samples for comparative tests shall be produced from the same material lot or batch and under the same fabricating conditions, unless noted specifically.

A2.5.2 *Staple Leg*—The parallel or nearly parallel extensions that are intended to penetrate the bone tissue; these may be round, square, or polygonal in cross section, and they may possess serrations or barbs to increase the fixation or purchase strength in the bone.

A2.5.3 *Staple Bridge*—The cross member of the staple connecting the legs; the bridge may be smooth or possess spikes or projections on the underside for the retention of soft tissue or other material.

A2.5.4 *Bone*—Fresh, fresh frozen, or preserved bone with material properties representative of the staple placement site; either cadaveric or animal bone may be suitable.

A2.5.5 *Bone Substitute*—A material with known, consistent properties, similar in strength, density, or rigidity to fresh, fresh frozen, or preserved bone. Substitutes such as natural wood, solid plastics, composites, or rigid foams may be suitable, depending on type, material properties, and configuration.

A2.5.6 *Metal or Fabric Tension Strap*—A thin, flat, flexible, highly conformable metal strip or fabric (woven or braided) that is used to apply a balanced lifting or pull-out force under the staple bridge. The strap should have a width sufficient to support 90 % of the staple bridge and have sufficient tensile properties so that it does not deform plastically or rupture under the applied loads.

A2.5.7 *Aqueous Solution*—Tap water, distilled water, physiological saline, or similar aqueous solutions, used to either maintain hydration of the soft tissue and bone used in the test or bathe or immerse the test specimens fully during the test.

A2.6 Procedure

A2.6.1 Prepare the staple fixation site(s) on the bone (or substitute); this may require predrilling to accommodate the staple legs without damage or fracture of the bone (or substitute).

A2.6.2 Insert and seat the staple in the bone (or substitute) in a standardized, repeatable manner using all appropriate surgical instrumentation specified by the manufacturer. The staple should be positioned over the tension strap, interposing the metal or fabric between the staple bridge and bone surface, leaving equal lengths of the strap on either side of the staple bridge. The strap should also be centered under the staple bridge, and the strap bulk should permit the staple to be seated against the bone fully. The staple bridge should be perpendicular to the long axis of the strap.

NOTE A2.1—In order to either reduce the inherent variability of manual staple insertion techniques or investigate the effects of deliberate variation of insertion parameters, it is permissible to devise special instrumentation in addition to that provided by the manufacturer. These additional instruments may be used to limit staple angulation, control insertion depth, or standardize insertion forces. However, any use of nonstandard surgical instrumentation for staple insertion must be described and reported fully.

A2.6.3 Record the insertion method (manual or mechanical), staple orientation, and position from known landmarks (if applicable).

A2.6.4 Fix the bone (or substitute) in the machine grips and align so that tension can be applied to the strap ends parallel to the staple legs. The bone should be gripped at a sufficient distance from the staple fixation site so that the fixation site is left undamaged and undisturbed (see the schematic of staple pull-out testing in Fig. A2.1).

A2.6.5 Grasp the ends of the strap, place them together, and secure them between the flat grip faces under equal tension (see Fig. A2.1).

NOTE A2.2—It is recommended that self-alignment devices such as universal joints, pin pivots, and so forth be placed in the load train in order to minimize the eccentric loading of either the tension strap or the staple.

A2.6.6 Apply load to the strap at a constant displacement, load, or strain rate.

A2.6.7 Monitor the load-displacement continuously until one of the test termination criteria is reached.

NOTE A2.3—Elastic deformation in the strap may require a separate method of monitoring staple movement during the test.

A2.7 Test Termination

A2.7.1 Testing of the samples shall be terminated when one or more of the following has occurred: