



Designation: F 1610 – 95 (Reapproved 1999)

Standard Test Method for Soft Tissue Fixation Strength of Metallic Bone Staples¹

This standard is issued under the fixed designation F 1610; 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 test method covers testing the soft tissue fixation strength of metallic staples used in internal fixation of the musculoskeletal system. This test method may be used with physiologic soft tissue and bone or synthetic substitutes for either, or both. This test method may also be used when testing in an aqueous or physiological solution.

1.2 The values stated in SI units are to be regarded as the standard.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines²

F 564 Specification for Bone Staples³

3. Summary of Test Method

3.1 Soft tissue, or a synthetic substitute, is fixed to bone (or a substitute) using single or multiple bone staples. Tension is applied to the soft tissue (or substitute) at a right angle to the plane of the staple legs until rupture or tearing of the soft tissue (or substitute) occurs or the staple purchase in the bone (or substitute) is disrupted. Tests using this test method may be conducted at ambient conditions or in aqueous or physiological solutions (either at room temperature or 37°C).

4. Significance and Use

4.1 This test method is intended to help assess the tissue holding characteristics of various metallic bone staples, such as those described in Specification F 564, used to fix soft tissue (tendons, ligaments, other grafts, etc.) to bone. This information may be useful for comparisons of staple materials, design, or placement under certain circumstances.

4.2 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.

4.3 *Measurement System*—Dimensions, loads, etc. shall be stated in SI units.

5. Apparatus

5.1 *Testing Machines*, conforming to the requirements of Practices E 4. The loads used in determining strengths shall be within the loading range of the testing machine as defined in Practices E 4.

5.2 *Gripping Devices:*

5.2.1 *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 soft tissue (or substitute). These grips must allow for variation in bone geometry and permit proper orientation and alignment of the bone (or substitute) during the test.

5.2.2 *Soft Tissue Grips*—Grips designed specifically for secure grasping of soft tissue or a synthetic substitute in the proper orientation with minimal damage during the application of tension.

5.3 *Constant Temperature Bath*—An aqueous bath capable of maintaining the samples and containers at physiologic temperatures, 37 ± 2°C, for the specified testing periods.

6. Test Specimens

6.1 *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.

6.2 *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.

6.3 *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.

6.4 *Bone*—Fresh, fresh frozen, or preserved bone with

¹ This test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

material properties representative of the staple placement site; either cadaveric or animal bone may be suitable.

6.5 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.

6.6 Soft Tissue— Fresh, fresh frozen, or preserved soft tissue (ligament, tendon, etc.) representative of tissue affixed with staples; either cadaveric or animal tissue may be suitable.

6.7 Soft Tissue Substitute—A material with known, consistent properties, similar in strength, stiffness, or behavior to fresh, fresh frozen, or preserved soft tissue. Suitable substitutes may be flat or round in cross section, consisting of either woven, twisted, or braided natural or synthetic fibers.

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

7. Procedure

7.1 Prepare the staple fixation site(s) on the bone (or substitute); predrilling in accordance with the manufacturer's recommendation may be required to accommodate the staple legs without damage or fracture to the bone.

7.2 Insert and seat the staples in the bone (or substitute) in a standardized, repeatable manner using all appropriate surgical instrumentation specified by the manufacturer. The staples should be centered over the soft tissue or substitute, interposing them between the staple bridge and bone surface. Record the insertion method (manual or mechanical), distance between the staples (if applicable), staple orientation, and position from known landmarks (if applicable).

NOTE 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 or fix staple angulation, control insertion depth, or standardize insertion forces, provided that they do not alter the normal insertion mechanics substantially. Any use of nonstandard surgical instrumentation for staple insertion must be described and reported fully.

7.3 Fix the bone (or substitute) in the machine grips and align so that tension can be applied to the soft tissue (or substitute) parallel to its long axis. Grip the bone or soft tissue a sufficient distance from the staple fixation site(s) so they are not damaged or disturbed (see Fig. 1).

NOTE 2—Failure of the bone or soft tissue (or their substitutes) at the interface with the grips shall not be considered a fixation failure.

7.4 Apply load to the soft tissue (or substitute) at a constant displacement, load, or strain rate.

NOTE 3—It is recommended that self-alignment devices such as universal joints, pin pivots, etc. be placed in the load train in order to minimize eccentric loading of either the soft tissue or the staple.

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

8. Test Termination

8.1 Testing of samples shall be terminated when one or more of the following has occurred:

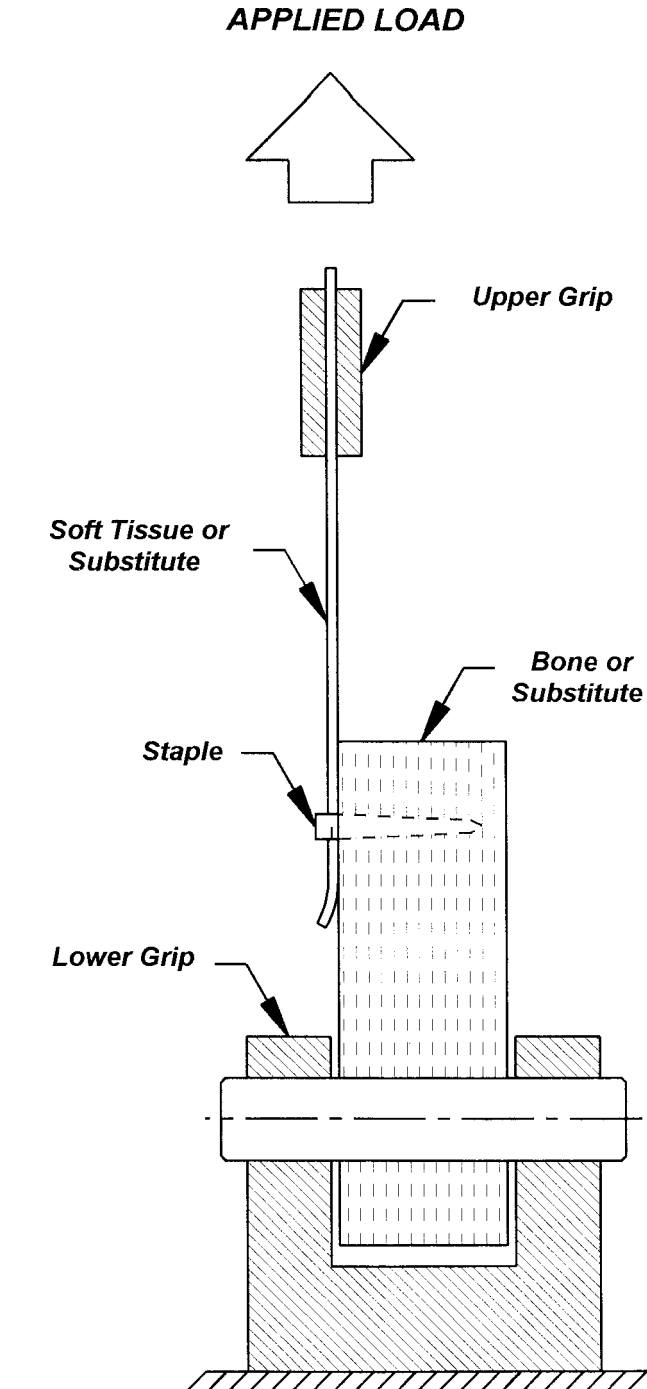


FIG. 1 Schematic of Tissue Fixation Strength Test

- 8.1.1 A significant drop in tensile load after peak,
- 8.1.2 Visible tearing or rupture of the soft tissue (or substitute),
- 8.1.3 Slippage of the soft tissue from under the staple(s),
- 8.1.4 Fracture of the bone (or bone substitute), and
- 8.1.5 Loosening of the staple(s) or disruption of the staple-bone interface.

9. Report

9.1 Report the following information:

- 9.1.1 Staple type, size, special features (barbs, spikes, and so forth.), manufacturer, material, batch or lot number, and