



Designation: F 1540 – 95 (Reapproved 1999)

Standard Test Method for Pull-Out Fixation Strength of Metallic Bone Staples¹

This standard is issued under the fixed designation F 1540; 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 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.

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 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.

4. Significance and Use

4.1 This test method is intended to help assess the axial holding strength of various metallic bone staples, such as those described in Specification F 564, 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.

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.

5. Apparatus

5.1 *Testing Machines*, conforming to the requirements of Practices E 4. The loads used for 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 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.

5.2.2 *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.

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 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.

6.3 *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.

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 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.

6.7 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.

7. Procedure

7.1 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).

7.2 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 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.

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

7.4 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. 1).

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

NOTE 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.

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

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

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

8. Test Termination

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

8.1.1 A significant drop in tensile load after peak,

8.1.2 Visible tearing or rupture of the strap (or substitute),

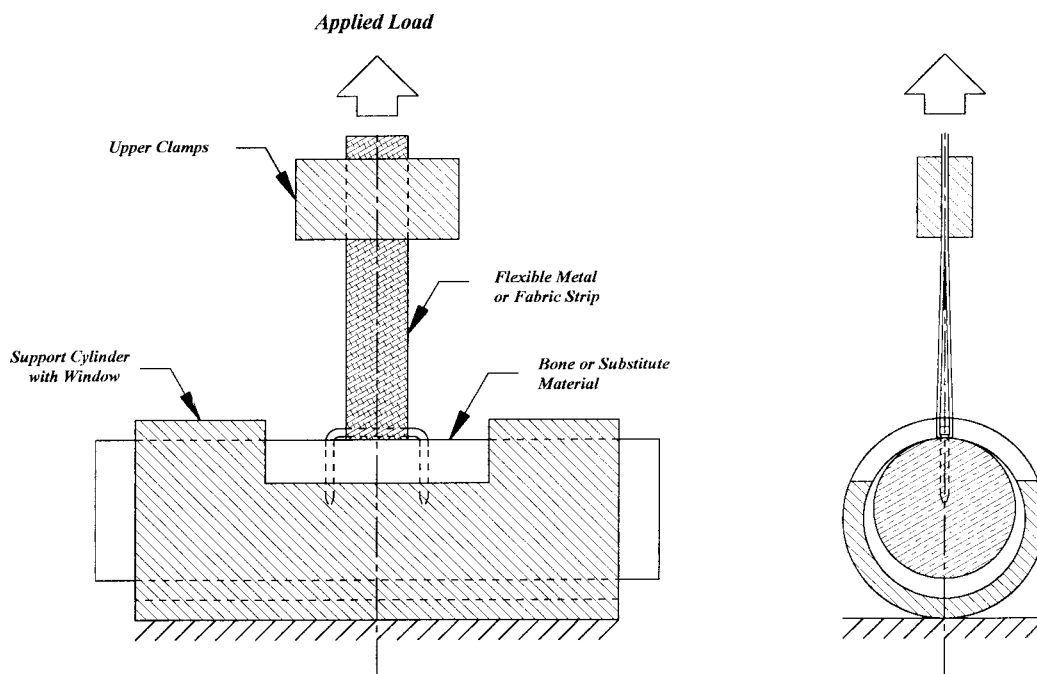


FIG. 1 Schematic of Staple Pull-Out Testing