



Designation: F 1539 – 95 (Reapproved 1999)

Standard Test Method for Constant Amplitude Bending Fatigue Tests of Metallic Bone Staples¹

This standard is issued under the fixed designation F 1539; 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 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.

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

E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing Machine²

F 564 Specification for Bone Staples³

3. Summary of Test Method

3.1 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).

4. Significance and Use

4.1 This test method is used to determine the fatigue resistance of metallic bone staples, such as those described in Specification F 564, 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.

4.2 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.

4.3 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.

5. Apparatus

5.1 *Testing Machines*, conforming to the requirements of Practices E 4 and E 467. The loads used for determining strengths shall be within the loading range of the testing machine as defined in Practices E 4 and E 467.

5.2 Gripping Devices:

5.2.1 *Staple Extensions*—Pairs of specially designed metal blocks that permit the holding of individual staples for the application of bending fatigue 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 Fig. 1, Fig. 2, and Fig. 3).

NOTE 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.

5.2.2 *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.

5.2.3 *Pin and Clevis Fixture*—A standard or modified fixture used to apply a distractive or compressive load to the

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.

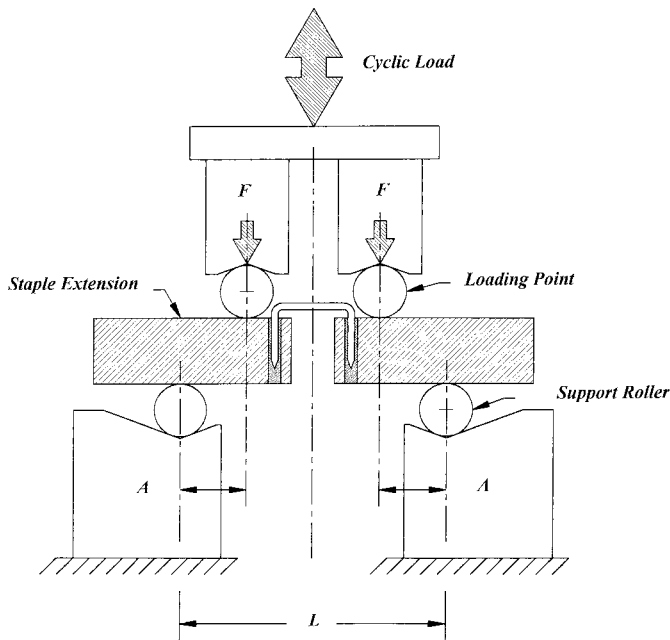


FIG. 1 4-Point Bending of Staples in Extension

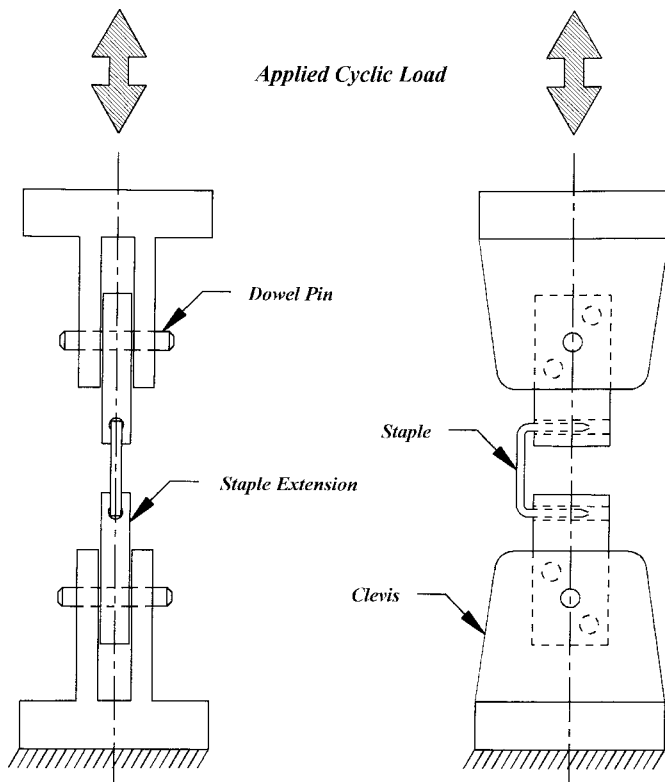


FIG. 2 Combined Tension (or Compression) and Bending of Staples

staple through the staple extensions to produce bending in the staple similar to that seen in vivo.

5.3 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.

5.4 Aqueous Solution—Tap water, distilled water, physi-

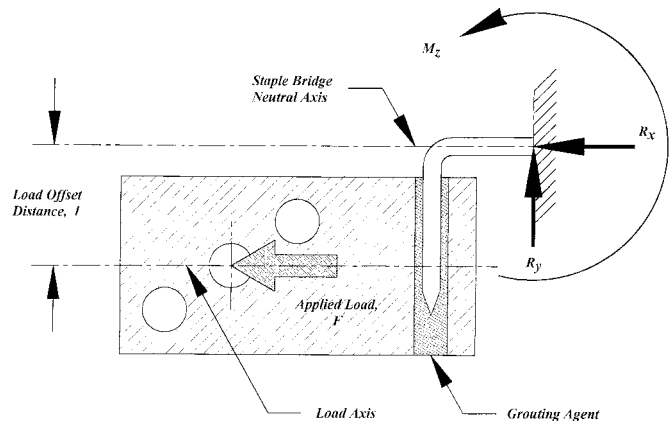


FIG. 3 Diagram of Extender-Staple Forces Under Combined Bending and Tension

ological saline, or similar aqueous solutions, used to immerse the test specimens fully during the test.

5.5 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.

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.

7. Procedure

7.1 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 2—This distance is at the discretion of the operator, but it determines the portion of the staple subjected to the bending loads.

7.2 4-Point Bend Testing:

7.2.1 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 on the centerline between the support rollers (see Fig. 1).