



Designation: F 1660 – 95 (Reapproved 1999)

Standard Test Method for Elastic Static Bending of Metallic Bone Staples¹

This standard is issued under the fixed designation F 1660; 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 a procedure for determining the rigidity of bone staples.

1.2 The values stated in either inch-pound or SI units are to be regarded separately as the standard. The units given in parentheses are for information only.

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 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process³

F 382 Test Method for Static Bending Properties of Metallic Bone Plates⁴

F 564 Specification for Bone Staples⁴

3. Terminology

3.1 Definitions:

3.1.1 *staple, n*—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 bone pieces, or to fasten soft tissue or other material to bone.

3.1.2 *staple bridge, n*—the cross member of the staple connecting the legs; these may be smooth or possess spikes or projections on the underside for retention of soft tissue or other material.

3.1.3 *staple leg, n*—the parallel or nearly parallel extensions which are intended to penetrate the bone tissue; these may be round, square or polygonal in cross section, and may possess serrations or barbs to increase the fixation or purchase strength in the bone.

4. Summary of Test Method

4.1 This test method is based on a paper⁵ that examined the bending rigidity of bone staples. The authors identified the initial slope of the bending curve as a parameter which could distinguish the staple stiffness from one staple to another. This parameter may be determined by placing each staple leg in a beam-like holder (see Fig. 1) and then bending the system in a four-point bending load apparatus (see Fig. 2). The applied force and displacement in the direction of the applied load will produce a bending curve from which the initial slope may be determined.

5. Significance and Use

5.1 This test method is intended to help assess the structural stiffness or rigidity of metallic bone staples for use in fixating or immobilizing bone or in fastening soft tissue or other material to bone. Under some circumstances, the test method may be of use in maintaining the batch uniformity of a test lot.

6. Apparatus

6.1 *Testing Apparatus*—Fig. 1 and Fig. 2 show the test apparatus. Fig. 1 is a holder designed to hold one of the staple legs as the entire assembly is placed in a four-point bending load apparatus (see Fig. 2). The design in this figure is only a suggested type for a cylindrical wire type staple.

6.2 Staple Extension Blocks:

6.2.1 The staple extension blocks shown in Fig. 1 can be constructed of aluminum, steel, iron or any other metallic material. Each must be long enough to fit over the support roller bearings and be much stiffer than the staple. The dimensions shown in Fig. 1 are suitable, but not mandatory. Fig. 1 shows a system which can accommodate a 3/32 in. staple. When the staples are placed in the holders, each leg is held in place by two set screws on the side of the holder. When the staple is fully inserted into the holder, the underside of the staple bridge should contact the top surface of the staple extension block. For those staples that have stiffening webs, additional countersinking of the holding holes or the cutting of notches in the staple extension block may be necessary so that the bridge of the staple will fit in the extension blocks as shown in Fig. 2.

6.2.2 Other holding systems may be used. However, each

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.

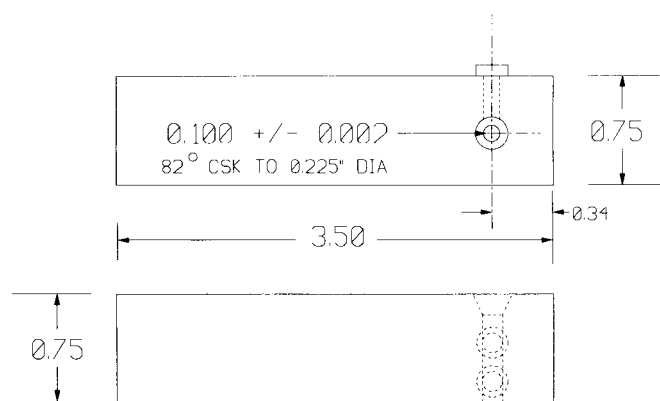
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² Annual Book of ASTM Standards, Vol 03.01.

³ Annual Book of ASTM Standards, Vol 14.02.

⁴ Annual Book of ASTM Standards, Vol 13.01.

⁵ Liberace, R., and Zvi L., "Mechanical Testing of Stainless Steel Bone Staples", *Journal of Testing and Evaluation*, Vol 20, No. 3, May 1992, pp. 217–224.



NOTE 1—All dimensions have a tolerance of ± 0.02 in. unless noted.

NOTE 2—Extension block as shown is for a $\frac{3}{32}$ in. staple only; adjust dimensions accordingly.

FIG. 1 Staple Extension Block

system should firmly fasten the legs of the staple so that bending occurs only at the bends in the staple and not in the staple legs. The system shown uses two set screws for this purpose. For other shaped staples, triangular, square, etc., special holding blocks should be developed to custom fit the legs of the staples so that forces holding the staple legs are uniformly spread along the legs. For these staples an alternative holding procedure is to drill cylindrical holes large enough to accommodate the staple legs and then firmly cement the staple in place by using epoxy or some other agent. This procedure will eliminate the use of set screws that might produce uneven stresses upon the staple legs.

6.3 Four-Point Bending Fixture:

6.3.1 Fig. 2 shows the holders and a test staple placed in a four-point bending load apparatus. This apparatus is similar to that used in testing bone plates (see Test Method F 382):

L = the horizontal length between the two lower rollers' centers, and

A = the horizontal distance between upper and lower rollers' centers.

6.3.2 The lower supports consist of two rollers, $L = 120$ mm (4.7 in.) apart and the upper loading apparatus has rollers placed 40 mm (1.57 in.) apart, which are one-third the distance from the lower support, so that all loads shall be equally supported by the rollers. Thus, the horizontal distance, A , between the centers of the upper and lower rollers will also be 40 mm (1.57 in.). The direction of the applied load shall be restricted to that shown in Fig. 2. All rollers should be well lubricated and have diameters of 12.5 mm (0.50 in.). The applied force and crosshead or actuator displacement should be measured by instruments suitable for bending tests that conform to Practices E 4.

7. Sampling

7.1 Representative random samples may be taken from each processing quantity in accordance with Practice E 122.

8. Procedure

8.1 Measuring Testing Machine Compliance:

8.1.1 Before any staples are analyzed, the overall deflection produced by applying force to the test system must be examined. Deflection under load of the four-point bending

fixtures, staple extension, etc., should be determined experimentally. The deflections in the test fixtures can be neglected if the compliance of the staple extension blocks and other parts of the test system are less than 2 % of the measured compliance of the staples and fixtures.

8.1.2 A suggested means for estimating deflections in the test system alone is as follows: fabricate a single one-piece block of the same width and depth of the staple extension blocks and of a length sufficient to span beyond the two lower support rollers. The compliance of the test system alone can then be determined from the inverse of the initial slope of a plot of applied force versus crosshead or actuator displacement. A measurement of this quantity should then be obtained employing each distinct type of staple tested inserted in the extension blocks. If the ratios of compliances of the former test system to the latter test systems with staples are all less than 2 %, the compliance of the test fixtures can be neglected. Otherwise, compensation for measured fixture deflections should be made in the staple bending curves, or the staple extension blocks should be refabricated from a stiffer grade or type of metal.

8.2 Testing Procedures:

8.2.1 Place the staple in the extension blocks and in the four-point bending load apparatus as shown in Fig. 2.

8.2.2 Apply a load to the staple at a constant displacement rate of 1 in./min (25.4 mm/min) and measure the crosshead or actuator displacement.

8.2.3 Plot the applied load versus the crosshead or actuator displacement (as in Fig. 3).

8.2.4 The point at which the crosshead or actuator displacement should be stopped is determined by the operator's judgment. The only guides are:

8.2.4.1 A sufficient length of curve must be developed so that a suitable tangent to the initial portion of the curve can be drawn; and

8.2.4.2 No damage to the test fixture should occur.

8.2.5 Calculate staple stiffness by measuring the initial slope of the load-displacement curve and report the result in N/mm (lb/in.).

9. Report

9.1 All standard units for reporting results from this test method shall be in SI units.

9.2 Report the following information:

9.2.1 The staple description shall conform to those measurable quantities and descriptions stated in Specification F 564. For those staples which cannot be described by the procedure in Specification F 564, a drawing of the staples shall be furnished;

9.2.2 Material of composition;

9.2.3 Dimensions of the test apparatus and staple extension blocks, if different from that specified in 4.2 and 4.3;

9.2.4 The number of test specimens;

9.2.5 Mean and standard deviation of the slope of the bending curve; and

9.2.6 Manufacturer, part number, and lot number if available.