Designation: F3437 – 23

Standard Test Methods for Metallic Bone Plates Used in Small Bone Fracture Fixation[1]

This standard is issued under the fixed designation F3437; 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 standard is intended to provide guidance for the static testing of small bone metallic plates used for fracture fixation. Small bone plates referred to in this standard would be used in minimally load-bearing anatomical areas of the far extremities, such as the fingers and toes, and in the cranium and upper face. Lower face/mandible, wrist, and ankle fixation plates would generally be larger and carry a substantial amount of load and should not be evaluated under this standard.

1.2 ASTM Specification F382 and ISO 9585 are currently available for the testing of metallic bone plates as well, so the user can choose to use any of the tests in these standards for small bone plates. However, due to plate size, Specification F382 and ISO 9585 test setup and execution difficulty can be increased for small bone plates. Thus, this standard offers alternative test methods that are more appropriate for metallic bone plates used in small bone fracture fixation.

1.3 This standard is not intended to address the mechanical performance of the plating construct or accessory components (for example, screws and wires).

1.4 This standard is intended to provide a basis for the mechanical comparison of small bone plates. Due to the complex and varying biomechanics found in the areas of the body where these plates are used, this standard should only be used to compare the *in vitro* mechanical performance of small bone plates and not used to infer *in vivo* performance characteristics.

1.5 This standard describes static tests by specifying load types and specific methods of applying these loads. Tests for evaluating and characterizing these loads include the following: static torsion, static cantilever beam bending, static lateral bending, and static three-point bending.

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

1.7 Multiple tests are cited in this standard. However, it must be noted that the user is not obligated to test using all of the described methods. Instead, the user should only select test methods that are appropriate for a particular device design.

1.8 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Calibration and Verification of Testing Machines

E2309/E2309M Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines

E2624 Practice for Torque Calibration of Testing Machines

F382 Specification and Test Method for Metallic Bone Plates

F983 Practice for Permanent Marking of Orthopaedic Implant Components

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *ISO Standards:*[3]

ISO 9585 Implants for surgery—Determination of bending strength and stiffness of bone plates

ISO 14602 Non-active surgical implants—Implants for osteosynthesis—Particular requirements

3. Terminology

3.1 *Definitions – Geometric:*

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

Current edition approved April 1, 2023. Published April 2023. DOI: 10.1520/F3437-23.

[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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.1 *bone plate*—a metallic device with two or more holes or slot(s), or both, and a cross section that consists of at least two dimensions (width and thickness). The device is intended to provide alignment and fixation of two or more bone sections, primarily by spanning the fracture or defect. The device is typically fixed to the bone using bone screws.

3.1.2 *bone plate length, L (mm)*—the linear dimension of the bone plate measured along the longitudinal axis, as illustrated in Fig. 2.

3.1.3 *bone plate thickness, b (mm)*—the linear dimension of the bone plate measured parallel to the screw hole axis, as shown in Fig. 2. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section (see Fig. 3).

3.1.4 *bone plate width, w (mm)*—the linear dimension of the bone plate measured perpendicular to both the length and thickness axes, as shown in Fig. 2.

3.1.5 *contouring*—the manipulation and bending of a bone plate, either preoperatively or intraoperatively, to match the anatomic geometry of the intended fixation location.

3.1.6 *crescent section*—a bone plate cross section shape (perpendicular to the long axis of the bone plate) where the thickness is not constant along the section. Typically, the section is thickest along the bone plate's center line and tapers to a smaller thickness at the bone plate's edges (see Fig. 3).

3.1.7 *uniform width*—referring to a bone plate where the width is constant along the bone plate's length.

3.2 *Definitions – Mechanical/Structural:*

3.2.1 *active length*—the straight-line distance representing the portion of the plate being tested; for example, for torsion testing, the distance between the test fixtures (see Fig. 4); for three-point bending, the active length would be "H" in Fig. 7 (see 8.7).

3.2.2 *bending or torsional stiffness, K (N/mm or Nmm/degree)*—the maximum slope of the linear elastic portion of the load (or torque) displacement curve for a bone plate (see line at Point B in Fig. 1).

3.2.3 *bending ultimate load or ultimate torque (N or Nmm)*—the maximum compressive load or the maximum torque applied to the implant (see Point E in Fig. 1). The ultimate load or torque should be a function of the device and not of the load cell or testing machine.

3.2.4 *bending yield load or yield torque (N or Nmm)*—the bending load or torque necessary to produce permanent deformation equal to 0.002 times the active length or moment arm (for load) or 2° (for torque) exposed to testing (see Point D in Fig. 1).

3.2.5 *bending yield moment (Nmm)*—bending moment, defined as the moment arm times load, at the yield load.

3.2.6 *coordinate system/axes*—three orthogonal axes are defined by the following. The center of the coordinate system is located at the geometric center of the bone plate. The length and width of the bone plate would lie in the X-Y plane (see Fig. 2). The positive Z-axis is directed superiorly. The compressive axial force is defined as the component in the negative Z-direction. Torsional load is defined as the component of torque about the X-axis. Lateral load is defined in the negative Y-direction.

3.2.7 *displacement at offset yield (mm or degrees)*—the displacement of a plate at the yield load (or torque) (see Point A in Fig. 1).

3.2.8 *offset displacement (mm or degrees)*—offset equal to 2° (for torsion) or 0.002 times the active length or moment arm (see Point F in Fig. 1).

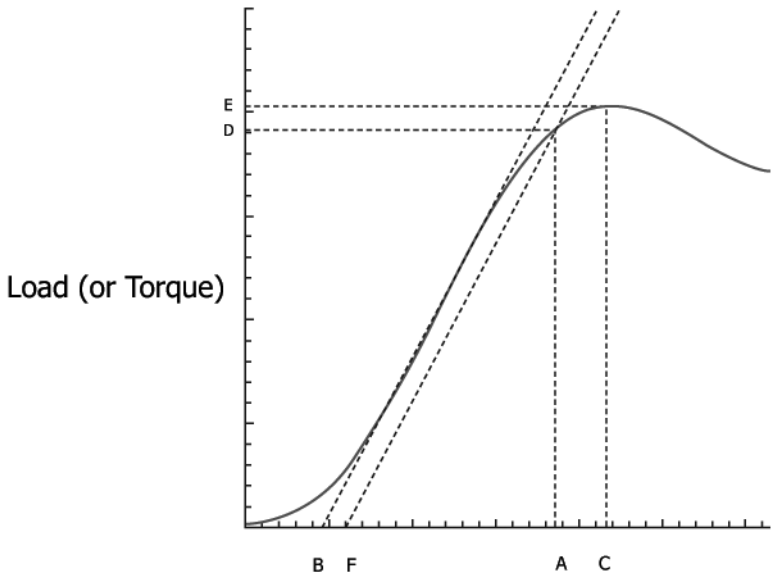


FIG. 1 Typical Load (or Torque) Displacement Curve

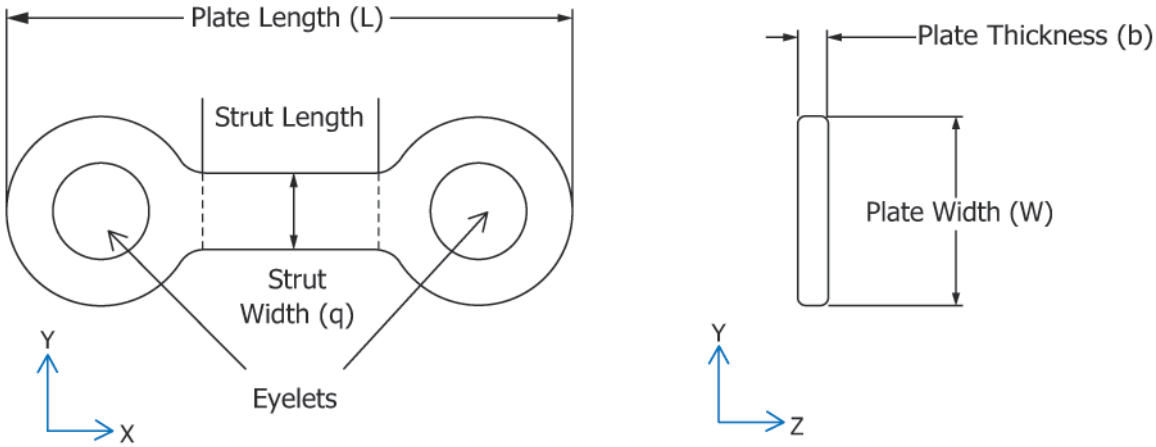


FIG. 2 Basic Two-Hole Small Bone Plate and Dimensions

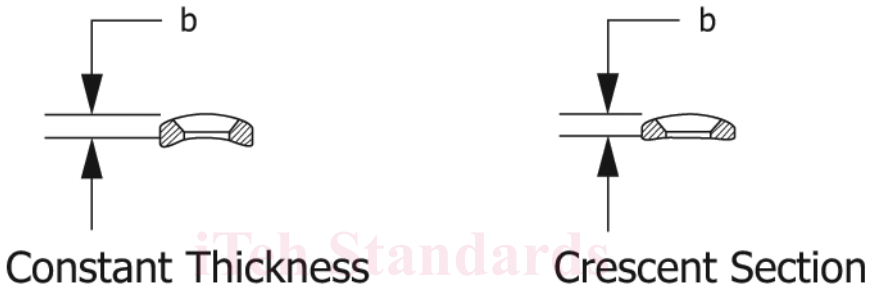


FIG. 3 Bone Plate Cross Sections

3.2.9 *ultimate displacement or ultimate angular displacement (mm or degrees)*—the displacement or angular displacement associated with the ultimate load or torque (see Point C in Fig. 1).

4. Significance and Use

4.1 Due to the variety of small bone fractures, plates used for the fixation of these fractures come in a variety of shapes and configurations. Table 1 categorizes the plate types for each anatomical area. Flat plates are the simplest; see Fig. 2 for an example of a basic flat plate. Many other plates have features to accommodate specific anatomies, such as condylar, complex (such as cuneiform), pre-contoured (such as metatarsophalangeal joint (MPJ)), step, orbital, orthognathic step, and wedge plates. Other plates, such as mesh-based and burr hole plates, are generally flat but are designed to be used in specific anatomical regions, so their designs are not the same as conventional straight plates. If test data is used from one type of plate for justification of the mechanical properties of another type of plate, this justification shall be described in the final report.

4.2 Most of the testing described herein is focused on a "functional unit," which can be described as a single-line fracture being spanned by a plate with one screw hole on each side of the fracture. This configuration allows for the simplest determination of worst-case size if the strut geometry is the determining factor for the worst case. If a worst-case size cannot be isolated to a functional unit/strut geometry, perhaps due to irregular screw hole patterns or the shape of the plate, it is understandable that some tests would need to be modified, or possibly removed from test consideration, to accommodate the shape of the plate or the screw hole. Any test modifications or omissions shall be described in the final report with a rationale related to the plate's anatomical use, indications, and functional requirements.

5. Marking, Packaging, Labeling, and Handling

5.1 Dimensions of bone plates should be designated by the standard definitions given in 3.1.

5.2 Bone plates shall be marked using a method specified in accordance with either Practice F983 or ISO 14602.

5.3 If plates are large enough, markings on the plates shall identify the manufacturer or distributor and shall be located away from the most highly stressed areas, if possible.

5.4 Packaging shall be adequate to maintain original plate specifications.

5.5 Package labeling for bone plates shall include, when possible, the following information:

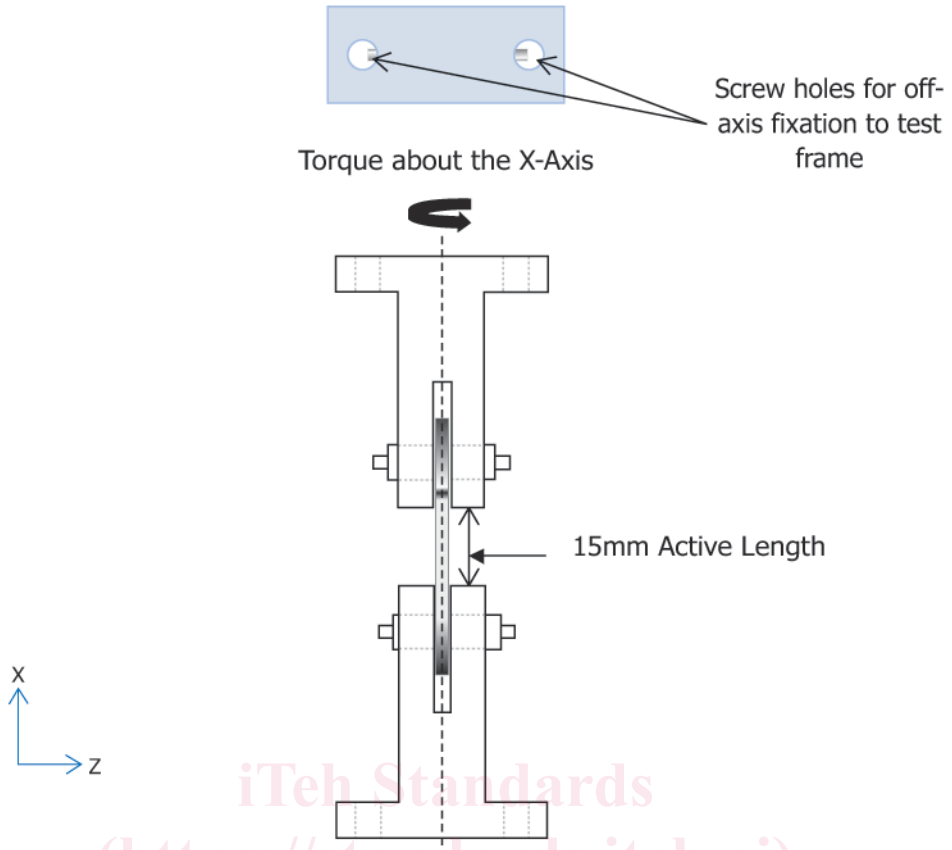
5.5.1 Manufacturer and product name;

5.5.2 Catalog number;

5.5.3 Lot or serial number;

5.5.4 Unique identifier numbers, such as Global Trade Item Number (GTIN), if applicable to market;

5.5.5 Material and, where applicable, its associated ASTM or ISO specification designation number;



NOTE 1—To prevent looseness of the plate at the pins, washers shall be used to rigidly secure the plate.

FIG. 4 Suggested Torsion Apparatus—Wire Frame Side View and Top View

TABLE 1 Plate Types for Each Anatomical Area

Anatomical Location	Geometric Type
Maxillofacial (non-mandible)	Flat Orbital Floor Orthognathic Step
Hand	Flat Condylar
Foot	Flat Step Wedge Pre-Contoured Complex
Neurosurgical and Cranial	Flat Mesh-Based Burr Hole Orbital Roof

5.5.6 Number of screw holes;
5.5.7 Bone plate width;
5.5.8 Bone plate length; and
5.5.9 Bone plate thickness.

5.6 Consider Practice F2503 to identify potential hazards produced by interactions between the device and the magnetic resonance (MR) environment and for terms that may be used to label the device for safety in the MR environment.

6. Materials

6.1 Bone plates shall be fabricated from a metallic material intended for surgical implant applications. In addition, the materials shall be biocompatible for the intended application. Materials should be chosen based on the design requirements of the particular device. ASTM Subcommittee F04.12 maintains a number of standard specifications for metallic materials suitable for implant applications.

7. General Requirements and Performance Considerations

7.1 *Geometric Considerations*—Bone plates that are intended to be used with bone screws shall have design features (for example, screw holes, slots, or locking threads) that conform to or appropriately fit the indicated bone screw.

7.2 *Bending Properties*—This is a critical characteristic of bone plates for orthopedic applications since the bone plate provides the primary means of stabilizing the bone fragments. Additionally, the bending stiffness of the bone plate may directly affect the rate and completeness of healing.

8. Apparatus

8.1 Test machines shall conform to the requirements of Practices E4, E2309/E2309M, and E2624.

8.2 *Fixture Blocks*—Fixture blocks shall be generally made from stainless steel, except for inserts, which shall be made

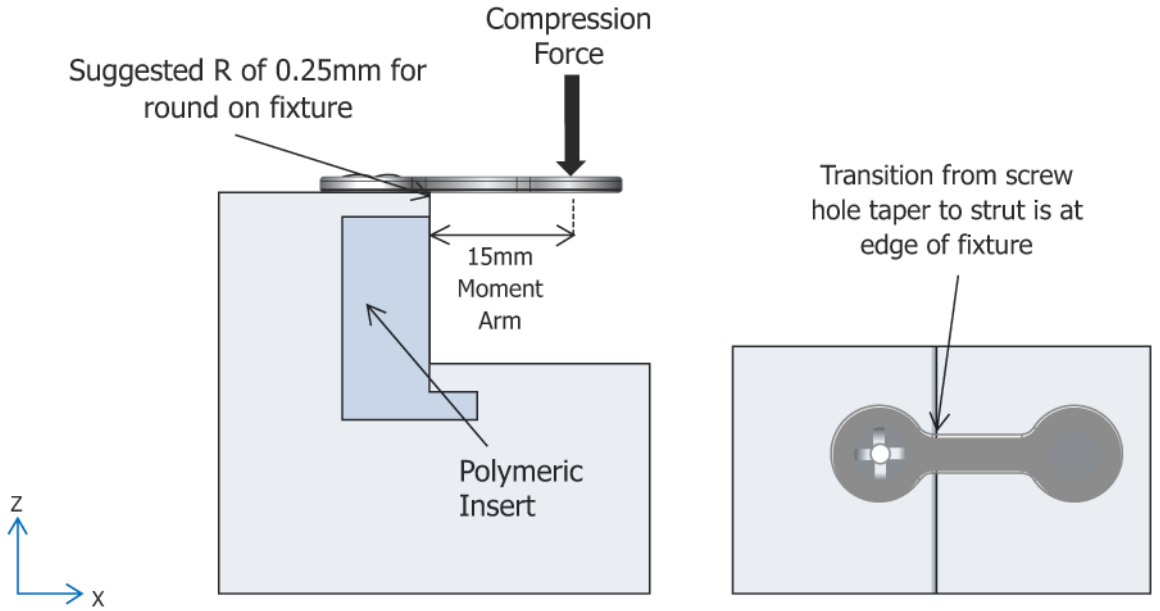
preferably from ultra-high molecular weight polyethylene (UHMWPE), but other polymers can be used if justified. Any polymer used shall be rigid enough as to not allow any axial pullout of the screw from the block.

8.3 Due to the complexity and abundance of small bone plate designs, all apparatuses shown in this standard are recommendations. All test fixtures shall be described and justified in the test report.

8.4 *Torsion Apparatus*—Fixation of the plate can be achieved using an apparatus with pinned slots to hold the plate both superiorly and inferiorly. One end of the plate shall be placed in a slot in the test fixture to a depth where just the eyelet portion of the plate is in the slot. The strut (see Fig. 2) shall be the only feature unconstrained. The apparatus can then be fixated to the test frame using two off-axis screws. See Fig. 4. Another fixation possibility is using grips. Any plates used for mechanical comparison must use the same active length (if possible). A 15 mm active length is recommended if worst-case strut geometry can be included in this span. If the span is reduced for shorter plates or increased to include the entire worst-case geometry, a justification should be provided.

8.5 *Cantilever Beam Apparatus*—For bending testing along the long axis of the plate, the plate shall lay flat, eyelets upward, with one of the eyelets resting on the block. The strut and adjacent eyelet shall be unsupported. A bone screw is then placed into the hole of the supported eyelet, then through a drilled hole in the metal fixture, and lastly securely screwed into the polymeric insert. The screw shall not experience any loosening during testing. Visual inspection of the screw post-testing is recommended to confirm that the screw remained fixated. The moment arm is defined as the distance from the compression force to the edge of the fixture (see Fig. 5). Unsupported plate length beyond the moment arm distance should be minimized. The fixed screw position on the test block shall be placed where the strut is fully unsupported. Thus, the screw hole and the taper from the screw hole to the strut shall be supported on the test block so the effective distance from the fixed plate hole to the edge of the fixture will be determined by the design of the plate. Another fixation possibility is using toe clamps to secure the plate. A 15 mm moment arm is recommended if worst-case strut geometry can be included in this span. If the span must be reduced for shorter plates or increased to include the entire worst-case geometry, any plates used for mechanical comparison must use the same moment arm (if possible). Any deviations in moment arm shall be described and justified in the test report.

8.6 *Lateral Bending Apparatus*—Fixation of the plate shown in Fig. 6 involves a clamshell fixture block with a slot in the side that is tall and wide enough to insert the plate sideways. To prevent the plate from rotating during testing, it is recommended to insert more than one plate eyelet in the fixture. To prevent the plate geometry from interfering with the force application point during testing, a bushing or similar accessory slid over the plate might be required. Furthermore, a sliding X-Y table can help prevent off-axis loading. An alternate test setup is attaching the plate via bone screws to the side of the test fixture; this setup, however, would require more than one attachment point to prevent plate rotation during testing. The moment arm is defined as the distance from the compression force to the point of contact/fixation with the fixture (see Fig. 6). If strut geometry varies, the worst case (that is, weakest strut or hole geometry, or both) shall be evaluated, and worst-case orientation should be considered. A 15 mm moment arm is recommended if worst-case strut geometry can be included in this span. If the span must be reduced for shorter plates or increased to include the entire worst-case geometry,



NOTE 1—The polymeric insert shall fit tightly in the fixture.

FIG. 5 Suggested Cantilever Beam Test Apparatus