Designation: ~~F382 – 14~~ F382 – 17

Standard Specification and Test Method for Metallic Bone Plates[1]

This standard is issued under the fixed designation F382; 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 specification and test method is intended to provide a comprehensive reference for bone plates used in the surgical internal fixation of the skeletal system. The standard establishes consistent methods to classify and define the geometric and performance characteristics of bone plates. The standard also presents a catalog of standard specifications that specify material; labeling and handling requirements; and standard test methods for measuring performance related mechanical characteristics determined to be important to the *in vivo* performance of bone plates.

1.2 It is not the intention of the standard to define levels of performance or case-specific clinical performance for bone plates, as insufficient knowledge is available to predict the consequences or their use in individual patients for specific activities of daily living. Futhermore, it is not the intention of the standard to describe or specify specific designs for bone plates used in the surgical internal fixation of the skeletal system.

1.3 This document may not be appropriate for all types of bone plates. The user is cautioned to consider the appropriateness of the standard in view of a particular bone plate and its potential application.

1.4 This document includes the following test methods used in determining the following bone plate mechanical performance characteristics:

1.4.1 Standard Test Method for Single Cycle Bend Testing of Metallic Bone Plates—Annex A1, and

1.4.2 Standard Test Method for Determining the Bending Fatigue Properties Of Metallic Bone Plates—Annex A2.

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

1.6 *Multiple test methods are included 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. In most instances, only a subset of the herein described test methods will be required.*

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

1.8 *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]

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

~~F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)~~

~~F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)~~

~~F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants~~

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

Current edition approved ~~Nov. 1, 2014~~Sept. 1, 2017. Published ~~January 2014~~October 2017. Originally approved in 1973. Last previous edition approved in ~~2008~~2014 as ~~F382 – 99 (2008)~~F382 – 14.~~ε1~~. DOI: ~~10.1520/F0382-14.~~10.1520/F0382-17.

[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.

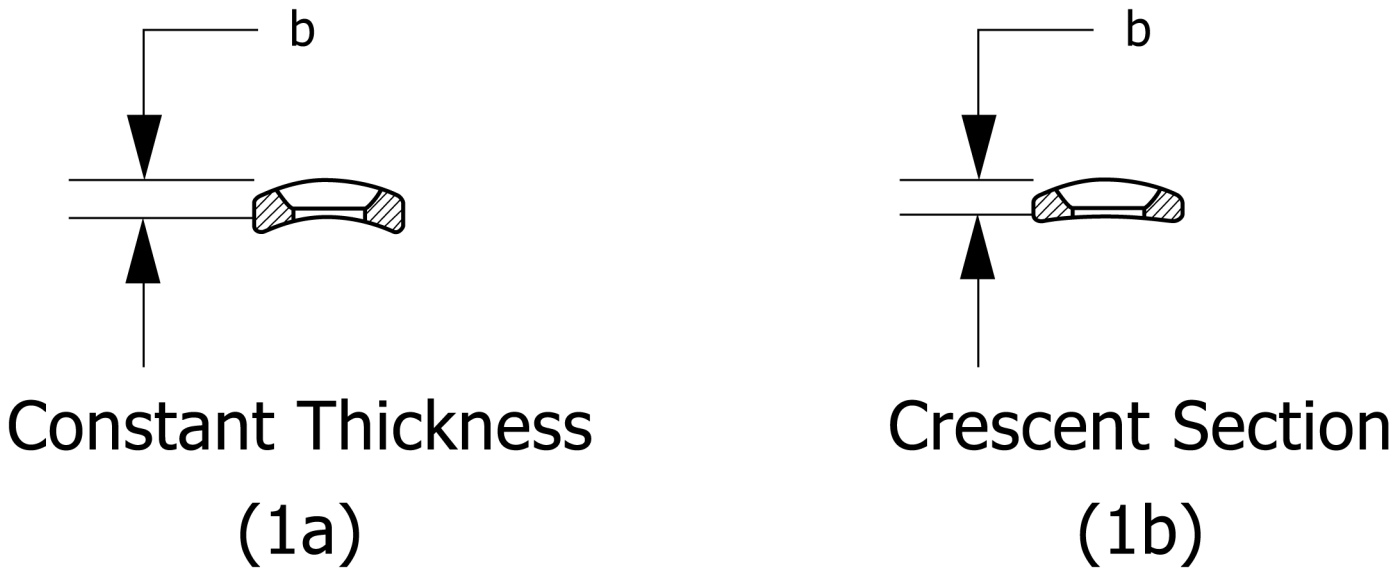

FIG. 1 Bone Plate Cross-sections

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)
F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
F139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)
F543 Specification and Test Methods for Metallic Medical Bone Screws
F565 Practice for Care and Handling of Orthopedic Implants and Instruments
F620 Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition
F621 Specification for Stainless Steel Forgings for Surgical Implants
F983 Practice for Permanent Marking of Orthopaedic Implant Components
F1295F2503 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium–13 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
F1713 Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)

2.2 *ISO Standard:*[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:*

3.1.1 *auto compression*—a type of bone plate that by its design can generate a compressive force between adjacent unconnected bone fragments through the use of one or more ramped holes or another type of slot geometry. This ramp or slot geometry contacts the underside of the screw head, and induces compressive force as the screw is inserted and tightened to the bone plate.

3.1.2 *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) which generally are not the same in magnitude. 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 through the use of bone screws or cerclage wire. A partial list of general types of bone plates is given in Section 4.1.

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

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

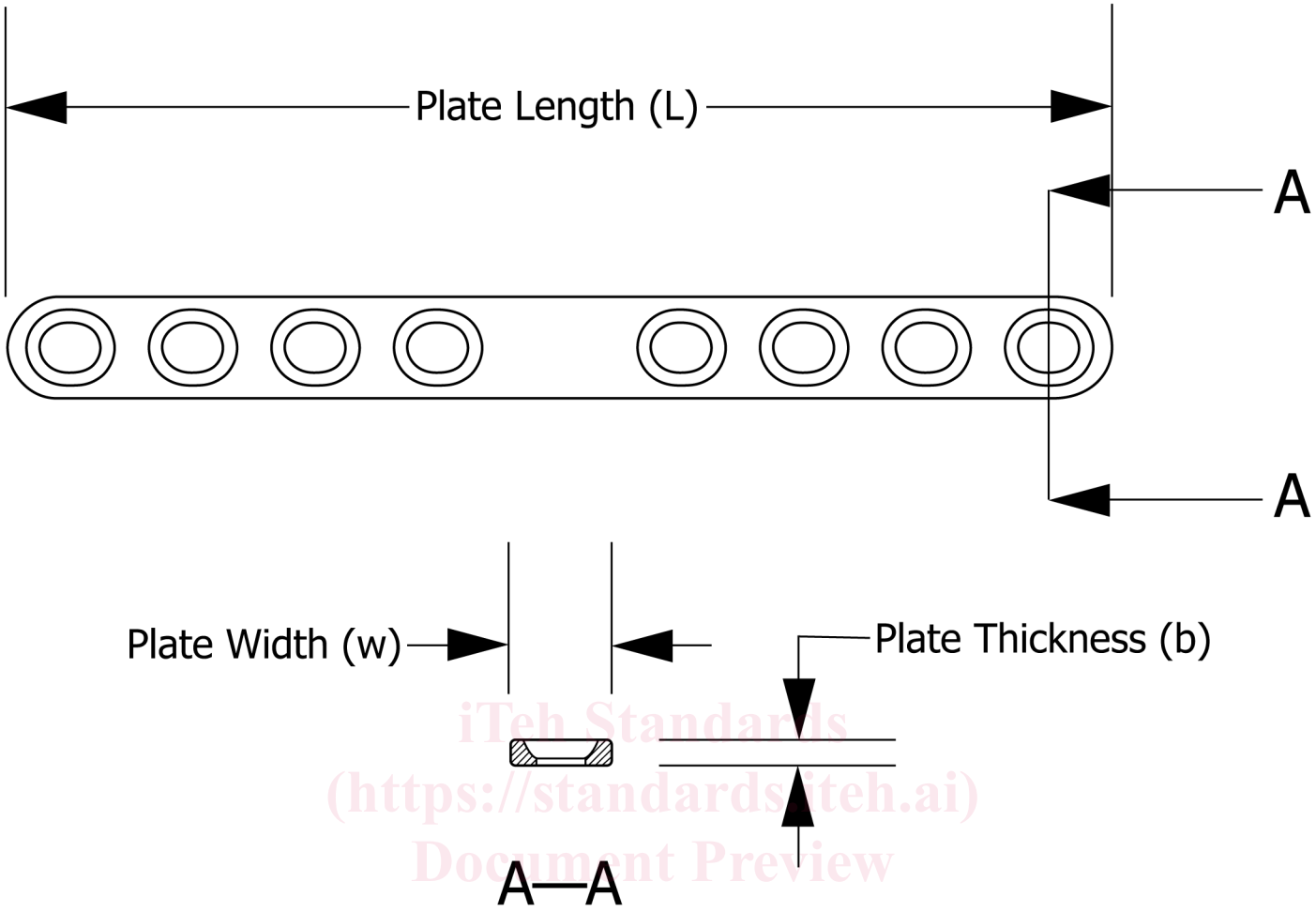

FIG. 2 Bone Plate Dimensions

3.1.4 *bone plate thickness, b (mm)*—the linear dimension of the bone plate measured parallel to the screw hole axis as shown Figs. 1a, 1b, and 2. For a bone plate with a crescent section, the thickness is measured at the thickest point along the section.

3.1.5 *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.

3.1.6 *contouring*—the manipulation and bending of a bone plate, either pre-operatively or intra-operatively, to match the anatomic geometry of the intended fixation location.

3.1.7 *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 centerline and tapers to a smaller thickness at the bone plate's edges (see Fig. 1b).

3.1.8 *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 *bending stiffness, K (N/mm)— of a bone plate*, the maximum slope of the linear elastic portion of the load versus load-point displacement curve for a bone plate when tested according to the test method of Annex A1.

3.2.2 *bending strength (N-m)— of a bone plate*, the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as described in Annex A1.

3.2.3 *bending structural stiffness, El (N-m^2)—of a bone plate*, the bone plate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested according to the method described in Annex A1.

3.2.4 *fatigue life, n*—the number of loading cycles of a specified character that a given specimen sustains before failure of a specified nature occurs.

3.2.5 *fatigue strength at N cycles*—An estimate of the cyclic forcing parameter (for example, load, moment, torque, stress, and so on) at a given load ratio, for which 50 % of the specimens within a given sample population would be expected to survive *N* loading cycles.

4. Classification

4.1 Bone plates used in general orthopaedic surgery can be categorized into general types according to the following classifications:

4.1.1 *Cloverleaf Plate*—A bone plate that has one three-lobed end which contains screw holes.

4.1.2 *Cobra Head Plate*—A bone plate that has one flared triangular or trapezoidal end which contains multiple screw holes or slots, or both. This type of bone plate is often used for hip arthrodesis.

4.1.3 *Reconstruction Plate*—A bone plate that does not have a uniform width, but usually has a smaller cross-section between the screw holes or slots. The reduced cross-section between screw holes/slots facilitates contouring the bone plate in several planes. Reconstruction plates are often used in fractures of the pelvis and acetabulum.

4.1.4 *Straight Plate*—A bone plate with uniform width and a straight longitudinal axis. Straight plates are often used for fractures of the diaphyses of long bones.

4.1.5 *Tubular Plate*—A bone plate whose cross-section resembles a portion of a tube, and which has a constant thickness or a crescent section. Tubular plates are often used for fractures of the smaller long bones (that is, radius, ulna, fibula).

5. Marking, Packaging, Labeling, and Handling

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

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

5.3 Markings on bone plates shall identify the manufacturer or distributor and shall be located away from the most highly stressed areas, where possible.

5.4 Packaging shall be adequate to protect the bone plates during shipment.

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

5.5.5 Number of screw holes;

5.5.6 Bone plate width;

5.5.7 Bone plate length;

5.5.8 Bone plate thickness; and

5.5.9 ASTM specification designation number.

5.6 Bone plates should be cared for and handled in accordance with Practice F565, as appropriate.

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

6. Materials

~~6.1 All bone plates made of materials which have an ASTM committee F04 standard designation shall meet those requirements given in the ASTM standards. A majority of materials having ASTM specifications can be found in the list of referenced ASTM standards of Section 2.1.~~

6.1 Bone plates ~~of forged Specification~~shall be fabricated ~~F136 shall meet the requirements of Specification~~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 ~~F620.~~particular device. ASTM committee F04.12 maintains a number of metallic material specifications suitable for surgical implant applications.

~~6.3 Bone plates of forged Specification F138 shall meet the requirements of Specification F621.~~

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 (screw holes or slots) that conform or appropriately fit the corresponding bone screw.

7.2 *Pending 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.

7.2.1 The relevant bending properties (bending stiffness, bending structural stiffness, and bending strength) shall be determined using the standard test method of Annex A1.

7.2.2 The relevant bending fatigue properties shall be determined in accordance with the methods described in Annex A2.

8. Keywords

8.1 bend testing—surgical implants; fatigue test; bone plate; orthopedic medical devices—bone plates; surgical devices; test methods—surgical implants

ANNEXES

A1. STANDARD TEST METHOD FOR SINGLE CYCLE BEND TESTING OF METALLIC BONE PLATES[1]

A1.1 *Scope*:

A1.1.1 This test method describes methods for single cycle bend testing in order to determine the intrinsic, structural properties of metallic bone plates. The test method measures the bending stiffness, bending structural stiffness, and bending strength of bone plates.

A1.1.2 This test method is intended to provide a means to characterize mechanically different bone plate designs. It is not the intention of this standard to define levels of performance for bone plates as insufficient knowledge is available to predict the consequences of the use of particular bone plate designs.

A1.1.3 This test method is intended to evaluate the bending strength, bending structural stiffness, or the bending stiffness of the bone plate, and may not be appropriate for all situations. When the structurally critical region of the bone plate is shown to be located through a non-uniform region of the bone plate (i.e., a peri-prosthetic, contoured plate), it may be necessary to evaluate the bending strength, bending structural stiffness, or bending stiffness of this region of the bone plate using a different test method. This is because it may not be physically possible to fit the non-uniform region between the loading rollers of a four-point bend test. Structurally critical regions may be identified through such methods as hand calculations, Finite Element Analysis, etc. Screw holes or other interlocking features or contoured regions may be located at the proximal or distal extremities of a bone plate, and may result in structurally critical regions at these locations.

A1.1.4 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A1.1.5 *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~~ safety, health and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to ~~use.~~use..*

NOTE A1.1—There is currently an ISO standard (ISO 9585—Implants for Surgery—Determination of Bending Strength and Stiffness of Bone Plates) that is similar, but not equivalent to this test method.

A1.2 *Referenced Documents:*

A1.2.1 *ASTM Standards:*[2]

E4 Practices for Load Verification of Testing Machines

E122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process

A1.3 *Terminology*:

A1.3.1 Definitions:

A1.3.1.1 *0.2 % offset displacement, q (mm)*—permanent deformation equal to 0.2 % of the center loading span distance. (point B in Fig. A1.1).

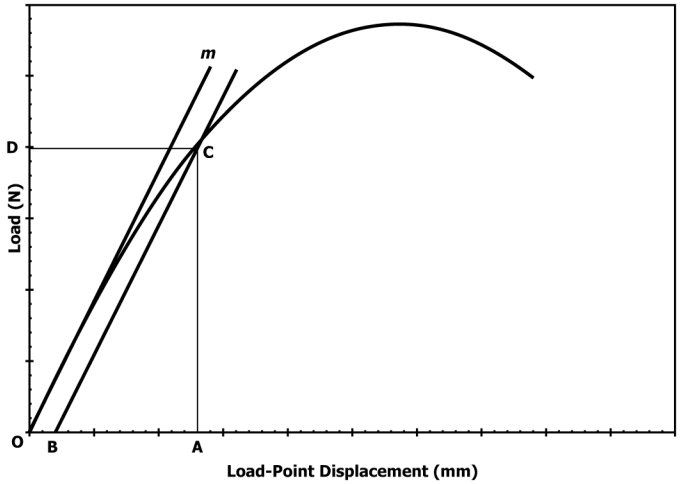

FIG. A1.1 Diagram Illustrating Methods for Determining the Bending Properties of Bone Plates

A1.3.1.2 *bending strength (N-m)—of a bone plate*, the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as described in Section A1.8 (the bending moment corresponding to point D in Fig. A1.1.). If the bone plate fractures before the proof point is attained the bending strength shall be defined as the bending moment at fracture.

A1.3.1.3 *bending structural stiffness, (EI_e) (N-m^2)*—of a bone plate, the bone plate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration. For this test method, the bending structural stiffness is determined from the single cycle bending response of the bone plate and the testing configuration.

A1.3.1.4 *bending stiffness, K (N/mm)—of a bone plate*, the maximum slope of the linear elastic portion of the load versus load-point curve when tested as described in section A1.8. (See the slope of line Om in Fig. A1.1).

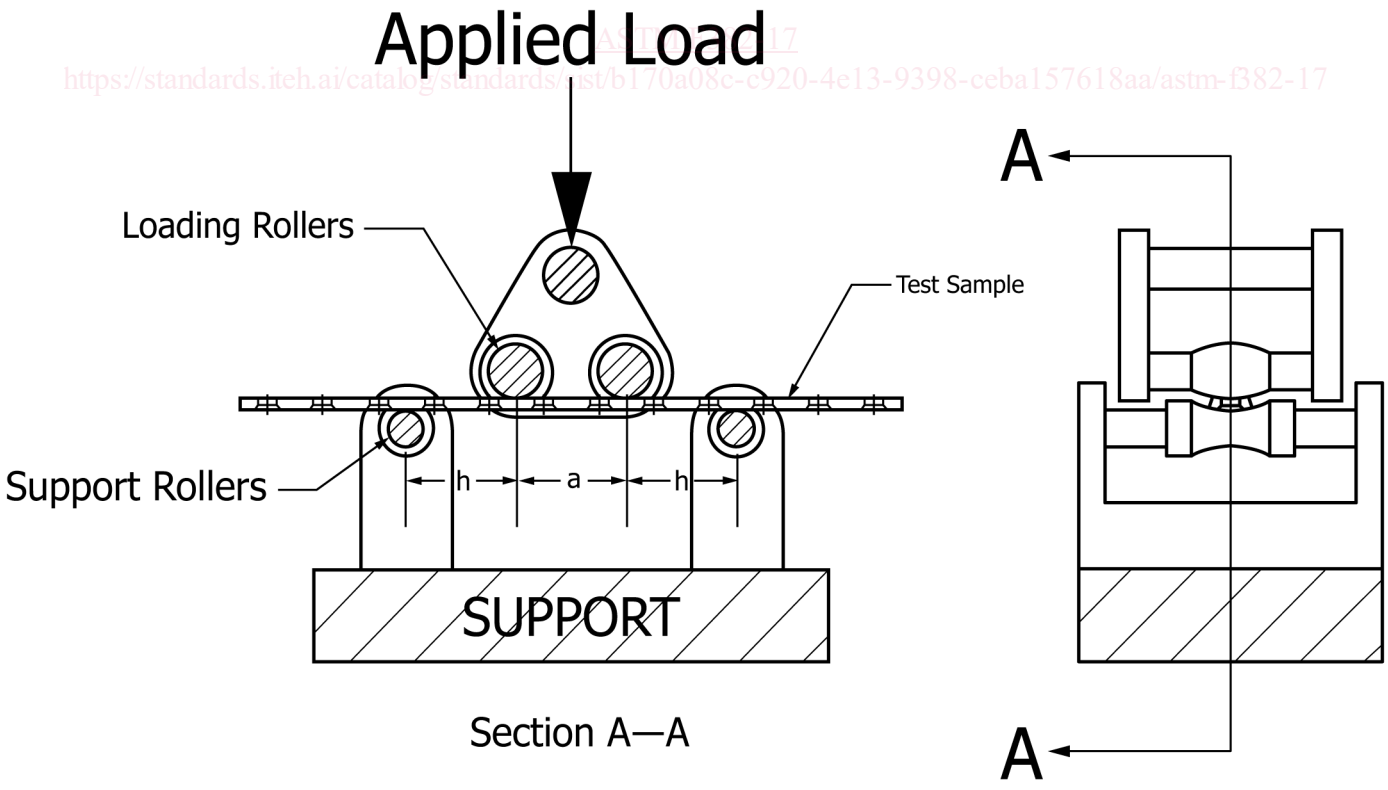

FIG. A1.2 Test Configuration