Designation: F 384 – 9900

Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices[1]

This standard is issued under the fixed designation F 384; 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 a comprehensive reference for angled devices used in the surgical internal fixation of the skeletal system. This standard establishes consistent methods to classify and define the geometric and performance characteristics of angled devices. This standard also presents a catalog of standard specifications that specify material and labeling and handling requirements, and standard test methods for measuring performance related mechanical characteristics determined to be important to the *in vivo*performance of angled devices.

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

1.3 This standard may not be appropriate for all types of angled devices. The user is cautioned to consider the appropriateness of this standard in view of a particular angled device and its potential application.

1.4 This standard includes the following test methods used in determining the following angled device mechanical performance characteristics:

1.4.1 Standard test method for single cycle compression bend testing of metallic angled orthopedic fracture fixation devices (see Annex A1).

1.4.2 Standard test method for determining the bending fatigue properties of metallic angled orthopedic fracture fixation devices (see Annex A2).

1.5 Unless otherwise indicated, the values stated in SI units shall be regarded as the standard.

NOTE 1—There is currently no ISO standard that is either similar to equivalent to this standard.

2. Referenced Documents

2.1 *ASTM Standards:*

[1] These specifications and test methods are under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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E 4 Practices for ~~Load~~ Force Verification of Testing Machines[2]
E 8 Test Methods for Tension Testing of Metallic Materials[2]
E 122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process[3]
F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[4]
F 75 Specification for C~~ast C~~obalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical ~~Implant Applications~~ Implants (UNS R30075)[4]
F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[4]
F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications[4]
F 138 Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar~~s~~ and Wire for Surgical Implants ~~(Special Quality)[4]~~ (UNS S31673)
F 139 Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip ~~and~~ for Surgical Implants ~~(Special Quality)~~ (UNS S31673)[4]
F 382 Specification and Test Methods for Metallic Bone Plates[4]
F 543 Specification for ~~Cortical~~ Metallic Medical Bone Screws[4]
F 565 Practice for Care and Handling of Orthopedic Implants and Instruments[4]
F 620 Specification for Titanium-6 Aluminum-4 Vanadium ELl Alloy Forgings for Surgical Implants (UNS R56401)[4]
F 621 Specification for Stainless Steel Forgings for Surgical Implants[4]
F 983 Practice for Permanent Marking of Orthopedic Implant Components[4]
F 1295 Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700)[4]
F 1314 Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese -2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants[4]
F 1472 Specification for Wrought Titanium ~~Ti~~-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[4]
F 1713 Specification for Wrought Titanium -13 Niobium-13 Zirconium Alloy for Surgical Implant Applications[4]

2.2 *ISO Standards:*[5]
ISO 5835 Implants for Surgery - Metal Bone Screws with Hexagonal Drive Connection - Spherical Under Surface of Head, Asymmetrical Thread
ISO 5836 Implants for Surgery - Metal Bone Plates - Holes Corresponding to Screws with Asymmetrical Thread and Spherical Under Surface
ISO 9268 Implants for Surgery - Metal Bone Screws with Conical Under-Surface of Head - Dimensions
ISO 9269 Implants for Surgery - Metal Bone Plates - Holes and Slots Corresponding to Screws with Conical Under-Surface
ISO14602 Non-active Surgical Implants– Implants for Osteosynthesis – Particular Requirements

3. Terminology

3.1 *Definitions:* Geometric

3.1.1 *angle, n*—defined at either the barrel/sideplate or blade/sideplate junction (see Fig. 1 and Fig. 2).

3.1.2 *angled device, n*—a class of orthopedic devices for the fixation of fractures in the methaphyseal areas of long bones that has a component aligned at an angle to the bone's long axis.

3.1.3 *barrel, n*—the portion of an angled device which captures the lag screw (see Fig. 1).

3.1.4 *barrel length, L_{BR}, n*— the distance from the free end of the barrel to the interior vertex of the barrel/sideplate junction (see Fig. 1).

3.1.5 *blade, n*—the portion of an angled device which transmits the off axis loading of the anatomical loading condition to the sideplate portion of the angled device (see Fig. 2).

3.1.6 *blade length, L_{BD}, n*—the distance from the free end of the blade to the interior vertex of the blade/sideplate junction (see Fig. 2).

3.1.7 *lag screw, n*—that component of a compression hip screw angled device which is threaded into the metaphyses and transmits the off axis load to the sideplate through the barrel (see Fig. 1).

3.1.8 *lag screw length, n*—the straight line distance measured between the proximal and distal ends of the lag screw (see Fig. 1).

3.1.9 *sideplate, n*—that portion of the angle device generally aligned with the bone's long axis which attaches to the bone via bone screws (see Fig. 1 and Fig. 2).

[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] Available form American National Standards Institute, 11 W. 42nd St., New York, NY 10036.

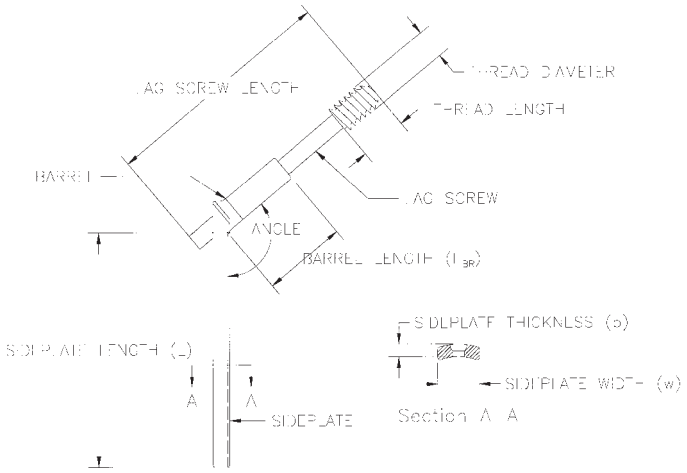

FIG. 1 Diagram Illustrating Compression Hip Screw Angled Devices

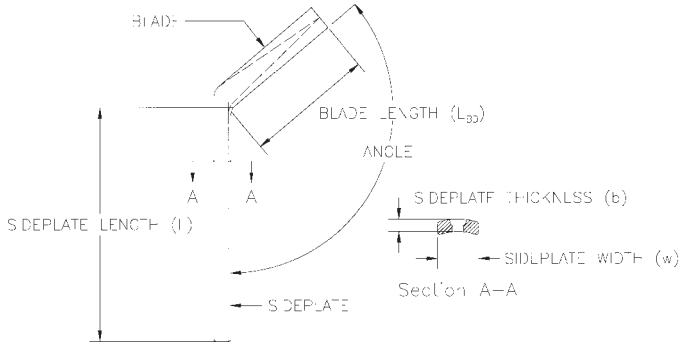

FIG. 2 Diagram Illustrating Blade Plate Angled Devices

3.1.10 *sideplate length, L, n*—the distance from the free end of the sideplate to the interior vertex of the barrel/sideplate junction, shown in Fig. 1 and Fig. 2.

3.1.11 *sideplate thickness, b, n*—the thickness of the sideplate as shown in Fig. 1 and Fig. 2.

3.1.12 *sideplate width, w, n*—the width of the sideplate as shown in Fig. 1 and Fig. 2.

3.1.13 *thread diameter, n*—the maximum outside diameter of the lag screw (see Fig. 1).

3.1.14 *thread length, n*—the straight line distance measured between the tip and thread runout positions of the screw (see Fig. 1).

3.2 *Definitions:* Mechanical/Structure:

3.2.1 *bending strength, n— of the sideplate*, the bending moment necessary to produce a 0.2 % offset displacement in the sideplate when tested as described in Annex A1 of Specification and Test Methods F 382.

3.2.2 *bending structural stiffness, EI_e, n—of the sideplate*, the sideplate'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 of Specification and Test Methods F 382.

3.2.3 *compression bending stiffness, (K), n—of a device*, the maximum slope of the linear elastic portion of the load versus displacement curve, when tested as described in Annex A1.

3.2.4 *compression bending strength, n—of a device*, the bending moment necessary to produce a 0.2 % offset displacement in the device when tested as described in Annex A1.

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

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

4. Classification

4.1 Angled devices used in general orthopedic surgery represent a subset of bone plates. Angled devices are mainly used in the treatment of fractures in the metaphyseal areas of long bones. Angled devices can be categorized into general types according to the following classifications:

4.1.1 *Blade Plate*— an angled device where the component of the device that is oriented at an angle from the long axis of the

bone is fixed relative to the sideplate; this component often is shaped like a blade to achieve fixation into the metaphyses (see Fig. 2), and

4.1.2 *Compression Hip Screw*—an angled device where the component of the device which is oriented at a angle from the long axis of the bone is free to translate relative to the sideplate through a barrel; this component often achieves fixation into the metaphyses through the use of deep threads (see Fig. 1).

5. Marking, Packaging, Labeling and Handling

5.1 Dimensions of angled devices should be designated by the standard definitions given in 3.1.

5.2 Angled devices shall be marked using a method specified in accordance with either Practice F 983 or ISO 14602.

5.3 Markings on angled devices shall identify the manufacture or distributor and shall be made away from the most highly stressed areas, where possible.

5.4 Packaging shall be adequate to protect the angled device during shipment.

5.5 Package labeling for angled devices 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 Device angle,

5.5.6 Barrel (blade) length,

5.5.7 Number of screw holes,

5.5.8 Sideplate width,

5.5.9 Sideplate length,

5.5.10 Sideplate thickness,

5.5.11 Screw hole size, and

5.5.12 ASTM specification designation number.

5.6 Bone plates should be cared for and handled in accordance with Practice F 565, as appropriate.

6. Materials

6.1 All angled devices made of materials which can be purchased to an ASTM specification shall meet those requirements given in the ASTM specification. Such specification include: F 67, F 75, F 90, F 139, F 543, F 1295, F 1314, F 1472, and F 1713.

6.2 Angled devices of forged Specification F 136 shall meet the requirements of Specification F 620.

6.3 Angled devices of forged Specification F 138 shall meet the requirements of Specification F 621.

7. General Requirements and Performance Considerations

7.1 *Geometric Considerations*—For angled devices that are intended to be used with bone screws that conform to ISO 5835 or ISO 9268, the screw holes shall correspond to the dimensions and tolerances of ISO 5836 or ISO 9269, respectively.

7.2 *Bending Properties*—Bending properties are a critical characteristic of angled devices for orthopedic applications since the plate provides the primary means of stabilizing the bone fragments. Additionally, the bending stiffness of the angled device may directly affect the rate and ability of healing.

7.2.1 The relevant compression bending properties (compression bending stiffness and compression bending strength) of the device shall be determined using Annex A1.

7.2.2 The relevant bending properties (bending stiffness, bending structural stiffness and bending strength) of the sideplate shall be determined using the Annex A1 of Specification and Test Methods F 382.

7.2.3 Determine the relevant angled device bending fatigue properties according to the methods described in Annex A2.

7.2.4 Determine the relevant side plate bending fatigue properties according to the methods described in Annex A2 of Specification and Test Methods F 382.

8. Keywords

8.1 angled devices; bend testing; blade plate; compression hip screw; fatigue test; orthopedic medical devices; surgical devices; surgical implants

ANNEXES

(Mandatory Information)

A1. STANDARD TEST METHOD FOR SINGLE CYCLE COMPRESSION BEND TESTING OF METALLIC ANGLED ORTHOPEDIC FRACTURE FIXATION DEVICES

A1.1 Scope

A1.1.1 This test method describes methods for single cycle bend testing for determining intrinsic, structural properties of metallic angled orthopedic fracture fixation devices. The test method measures the angled device's compression bending stiffness and compression bending strength.

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

A1.1.3 This test method is designed to provide flexibility in the testing configuration so that a range of clinical failure modes for the angled fixation devices (for example, sideplate, lag screw, and barrel fractures) can be evaluated.

A1.1.4 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 and health practices and determine the applicability of regulatory limitations prior to use.*

A1.2 Referenced Documents

A1.2.1 *ASTM Standards*:

E 4 Practices for Load Verification of Testing Machines[2]

E 122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process[3]

A1.3 Terminology

A1.3.1 *Definitions:*

A1.3.1.1 *0.2 % offset displacement, q, n*—permanent deformation (mm) equal to 0.2 % of the lever arm length (see point B in Fig. A1.1).

A1.3.1.2 *compression bending stiffness, K, n—of an angled device*, the maximum slope (N/m) of the linear elastic portion of the load versus displacement curve, when tested as described in A1.8. (See the slope of line 0m in Fig. A1.1).

A1.3.1.3 *compression bending strength, n—of an angled device*, the bending moment (N - m) necessary to produce a 0.2 % offset displacement in the angled device when tested as described in A1.8 (the bending moment corresponding to point P in Fig. A1.1). If the angled device fractures before the proof load is attained, the compression bending strength shall be defined as the bending moment at fracture.

A1.3.1.4 *fracture load, F_{max}, n*— the applied load (N) at the time when the angled device fractures.

A1.3.1.5 *lever arm, L, n*—the instantaneous distance (mm) from the line of load application to the surface of the sideplate that is intended to be in contact with the bone at the most proximal location where the sideplate contacts the test fixture support (shown in Fig. A1.2); the initial unloaded angled device lever arm length shall be held constant for comparative tests.

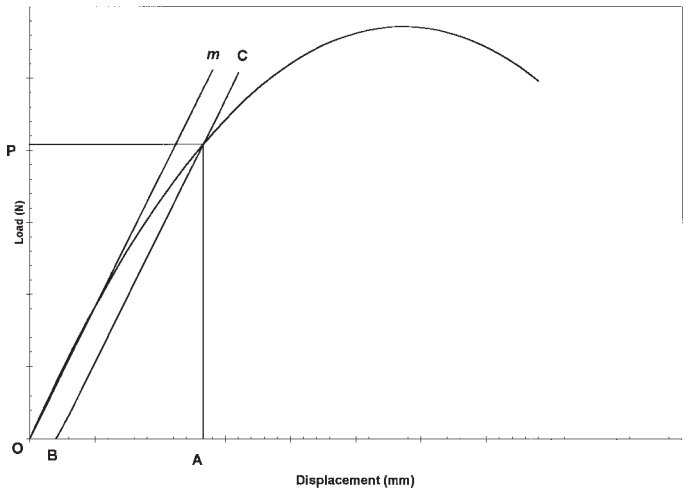

FIG. A1.1 Diagram Illustrating Methods for Determining Bending Properties of Angled Devices

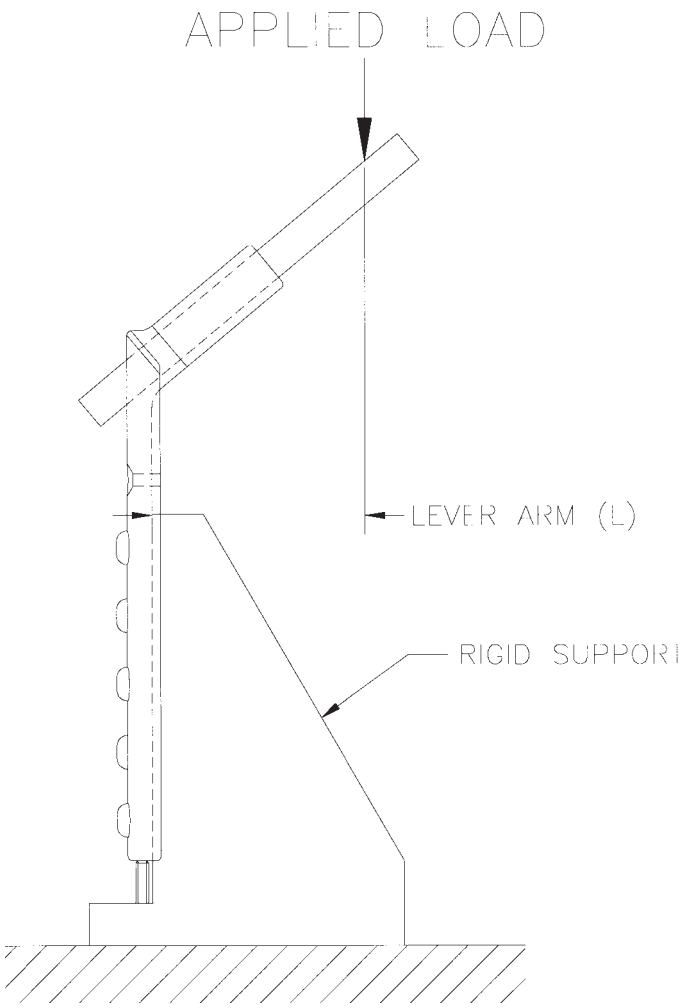

FIG. A1.2 Test Configuration

A1.3.1.6 *permanent deformation , n*—the relative change (mm) in the load application point's position (in the direction of the applied load) remaining after the applied load has been removed.

A1.3.1.7 *potential critical stress concentrator, CSC, n*—any change in section modulus, material property, discontinuity, or other feature of an angled device design expected to cause a concentration of stress, that is located in a region of the angled device expected to be highly stressed under the normal anticipated loading conditions.

A1.3.1.8 *proof load, P, n*—the applied load (N) at the intersection point of line *BC* with the load versus total displacement curve, (see Fig. A1.1).

A1.3.1.9 *proof point displacement, n*—the total displacement associated with the angled device's compression bending strength, (see point A in Fig. A1.1).

A1.3.1.10 *total displacement, n*—the relative change (mm) in the load application point's position (in the direction of the applied load) when a specified load is applied.

A1.4 Summary of Test Method

A1.4.1 Angled devices are subjected to a single-cycle load introduced at the device's angled portion. This results in the simultaneous application of compressive and cantilever bending stresses to the device. The device's compression bending stiffness and compression bending strength are then derived from the test record generate during the test using relevant test configuration parameters.

A1.5 Significance and Use

A1.5.1 This compression bend test is used to determine values for the mechanical response of angled devices to a specific type of bending load. The information resulting from this test can give the surgeon some insight into the mechanical response of a given angled device.

A1.5.2 Since the loading on the angled device *in situ* will, in general, differ from the loading configuration used in this test method, the results obtained from this test method cannot be used directly to predict *in vivo* performance of the angled device being tested. Such mechanical property data can be used to conduct relative comparisons of different angled device designs.

A1.5.3 Since the test method provides flexibility to evaluate a variety of clinical failure modes, the user must first determine which failure mode will be evaluated. Futhermore, the user should determine the relevance of the failure mode for the angled device being evaluated.

A1.5.4 The angled device's compression bending stiffness, as defined in A1.3.1.2, is an indicator of the angled device's stiffness when subjected to a compression-bending load. This mechanical property is a comparative indicator of the stability that the user can achieve in the treatment of methaphyseal fractures with the angled device.

A1.5.5 The angled device's compression bending strength, as defined in A1.3.1.3, identifies the bending moment that must be applied to the angled device in order to produce a specific amount of permanent deformation.

A1.5.6 This test method assumes that linear-elastic material behavior will be observed and, therefore, the test method is not applicable for the testing of materials that exhibit non-linear elastic behavior.

A1.6 Apparatus

A1.6.1 A typical test configuration is illustrated in Fig. A1.2.

A1.6.2 The plate of the angled device being tested is rigidly attached to an anchor block that is fully constrained. Alternative test setups are allowed (for example, the device support is unconstrained with rollers as allowed by the previous version of this standard) as long as the following conditions are met.

A1.6.2.1 The angled device shall be loaded in such a manner to satisfy the goals or requirements of A1.4.1, A1.5.1, and X2.1.

A1.6.2.2 If the angled device's support is allowed to translate normal to the test machine's loading axis in reaction to the applied load during the test, then the lever arm distance shall be monitored during the test. This information shall then be used to correct the load versus displacement curve and the compression bending stiffness and strength values calculated in A1.8.2.1.

A1.6.2.3 If the loading adapter's contact point is allowed to translate normal to the test machine's loading axis in reaction to the applied load during the test, then the lever arm distance shall be monitored during the test. This information shall then be used to correct the load versus displacement curve and the compression bending stiffness and strength values calculated in A1.8.2.1

~~A1.6.3 Care should be exercised when designing mechanisms to apply the load to the angled device. The~~

A1.6.3 The applied load should act only parallel to the sideplate's long axis. ~~This requires~~ Apply the ~~development of~~ load at a ~~more complex loading adapter than either~~ point that will produce a ~~loading roller~~ lever arm length that is equivalent to 80 % of either the blade length or ~~a simple angled loading applicator.~~ the longest screw. Equivalent lever arm lengths must be used for comparative tests. Deviations to this requirement shall be noted and justified in the final report. Additionally, the application of off axis loads to the load cell must be avoided since, depending on their magnitude, they can confound the determination of the device's actual loading ~~condition. A test fixture suitable for these loading requirements is illustrated in Fig. A1.3~~ condition.

A1.6.4 The test fixture should, in general, support the angled device in such a way to generate the failure ~~mode~~ being evaluated (sideplate, lag screw, or barrel fracture). A typical configuration ~~and fixture arrangement~~ that can be used to evaluate the angled device's sideplate failure characteristics ~~are~~ is illustrated in Fig. ~~A1.2 and Fig. A1.3.~~ A1.2.

A1.6.5 The device being tested should be suitably anchored to the support fixture. The intent of the test method is to evaluate the angled device and not the sideplate anchors.

A1.6.6 Displacement shall be measured as the displacement of the load application point parallel to the sideplate's long axis.

A1.6.7 Alternative loading configurations are allowed[6] but must be noted and fully described in the final report.

A1.6.8 Machines used for the bending test shall conform to the requirements of Practice E 4.

A1.6.9 The test machine and fixtures (test system) should be sufficiently stiff that their deformation under the load is negligible relative to that of the angled device being tested. The test system's machine compliance (combined test machine and fixture compliance) should be measured and reported. Typically, the test system's machine compliance should be less than 1 % of the tested angled device's compliance.

A1.7 Sampling

A1.7.1 Determine sample size using the methods outlined in Practice E 122.

A1.7.2 In those circumstances when there is insufficient information to utilize the guidance of Practice E 122, the sample size shall be no less than three.

A1.7.3 Angled devices of different lengths but nominally identical cross-sections, and made of the same material, may be used to constitute a sample.

A1.7.4 Only unused and untested angled devices are allowed for the comparative tests.

A1.8 Procedure

A1.8.1 Apply loads of increasing magnitude to the angled device at a recommended test control rate of 10 mm/min, and generate a load versus displacement diagram either auto-graphically or from numeric data acquired during the test. Displacement-controlled testing is strongly preferred over load-controlled testing. The measured deformation behavior past the yield point can be different for load-controlled testing due to non-linear displacement rates.

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[6] Peterson, R. R., Lynch, G. E., Brasher, T. W., "Cyclic Cantilever Fatigue Testing of Compression Hip Screw Plates," *ASTM STP 1217, Clinical and Laboratory Performance of Bone Plates*, pp. 72-81, 1994, American Society of Testing and Materials, West Conshohocken, PA 19428.

A1.8.2 Determine the compression bending stiffness and compression bending strength for each tested angled device according to the following:

A1.8.2.1 Produce a load versus displacement curve (see Fig. A1.1) either autographically or from numerical data acquired during the test.

A1.8.2.2 On the load versus displacement diagram generated during the test, draw a best-fit straight line (*Om*) through the initial (linear) portion of the load versus displacement curve.

A1.8.2.3 Determine the angled device's compression bending stiffness by calculating the slope of the line, *Om*, drawn in A1.8.2.2.

A1.8.2.4 Calculate the 0.2 % offset displacement (*q*) from the equation:

$$q = 0.002 \cdot L \tag{A1.1}$$

where:

L = the lever arm.

A1.8.2.5 On the load versus displacement diagram, lay off *OB* equal to *q*. Then draw line *BC* parallel to *Om*.

A1.8.2.6 Locate the proof load at the intersection point of line *BC* with the load versus displacement curve.

A1.8.2.7 Calculate the compression bending strength of the angled device from the equation:

$$\textit{compression bending strength} = P \cdot L \tag{A1.2}$$

where:

P = the proof load, and

L = the lever arm.

A1.8.2.8 If the angled device fractures prior to the intersection of the load versus displacement curve and the offset line *BC*, calculate the compression bending strength from the equation:

$$\textit{compression bending strength} = F_{max} \cdot L \tag{A1.3}$$

where:

F_{max} = the fracture load, and

L = the lever arm.

A1.9 Report

A1.9.1 Report the following information:

A1.9.1.1 Adequate description of the test article, including the number of angled devices tested,

A1.9.1.2 Adequate description of the test configuration,

A1.9.1.3 The unloaded lever arm length (*L*),

A1.9.1.4 The 0.2 % offset displacement used to determine the compression bending strength,

A1.9.1.5 Mean and standard deviations of the compression bending stiffness values for the set of angled devices tested,

A1.9.1.6 Mean and standard deviation of the compression bending strength values for the set of angled devices tested,

A1.9.1.7 Number of angled devices fractured during the test,

A1.9.1.8 The method (either displacement or load) and rate utilized for controlling the test.

A1.10 Precision and Bias

A1.10.1 *Precision*—Data establishing the precision of this test method have not yet been obtained.

A1.10.2 *Bias*—No statement of bias can be made, since no acceptable reference values are available, nor can they be obtained in that this test is a destructive test.

A2. STANDARD TEST METHOD FOR DETERMINING THE BENDING FATIGUE PROPERTIES OF METALLIC ANGLED ORTHOPEDIC FRACTURE FIXATION DEVICES

A2.1 Scope

A2.1.1 This test method describes methods for bending fatigue testing in order to determine intrinsic structural properties of metallic angled devices. The test method may be used to determine the fatigue life at a specific or over a range of maximum bending moment levels or to estimate the fatigue strength for a specified number of fatigue cycles of an angled device.

A2.1.2 This standard is intended to provide a means to mechanically characterize different angled device designs. It is not the intention of this standard to define angled device performance levels since insufficient knowledge is available to predict the consequences of the use of a particular angled device design.

A2.1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

A2.1.4 *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 to determine the applicability of regulatory limitations prior to use.

NOTE A2.1—Currently, there is no ISO standard that is similar, or equivalent, to this test method.

A2.2 Referenced Documents

A2.2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines[2]

E 467 Practice for Verification of Constant Amplitude Dynamic Force in an Axial Fatigue Testing System[2]

E 1823 Terminology Relating to Fatigue and Fracture Testing[2]

E 1942 Guide for Evaluating Data Acquisition Systems Used in Cyclic Fatigue and Fracture Mechanics Testing[2]

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments[4]

A2.3. Terminology

A2.3.1 *Definitions*— Unless otherwise defined in this test method, the terminology related to fatigue testing that is used in this test method will be in accordance to the definitions of Terminology E 1823.

A2.3.1.1 *M-N diagram, n*—a plot of maximum moment versus the number of cycles to a specified failure point.

A2.3.1.2 *maximum moment, n*—the applied bending moment having the highest algebraic value during the loading cycle. A moment that generates a tensile stress on the surface of the angled device specimen that does not come in contact with the bone when implanted is considered positive. Correspondingly, a moment that generates a compressive stress on this surface is considered negative.

A2.3.1.3 *median fatigue strength at N cycles, n*—an estimate of the maximum moment at which 50 % of the specimens of a given sample population would be expected to survive N loading cycles at a given *R*-ratio.

A2.3.1.4 *minimum moment, n*—the applied bending moment having the lowest algebraic value during the loading cycle. A moment that generates a tensile stress on the surface of the angled device specimen that does not come in contact with the bone when implanted is considered positive. Correspondingly, a moment that generates a compressive stress on this surface is considered negative.

A2.3.1.5 *R-ratio, n*—the algebraic ratio relating the minimum and maximum values of the loading parameters of a fatigue cycle. For the purposes of this test method the *R*-ratio is defined as:

$$R = \frac{Minimum\ Moment}{Maximum\ Moment} \tag{A2.1}$$

A2.3.1.6 *runout, n*—a predetermined number of cycles at which the testing on a particular specimen stopped, and no further testing on that specimen will be performed. When the intent of the fatigue test program is to determine the fatigue strength at *N* cycles, the runout usually is specified as *N* cycles.

A2.4 Summary of Test Method

A2.4.1 The sideplate of an angled device is anchored rigidly and is loaded in cantilever bending with a load applied parallel to the long axis of the sideplate. The angled device is subjected to a constant frequency sinusoidal cyclic bending moment waveform with the cantilever bending loading configuration. The fatigue loading is continued until the specimen fails, a limit is reached which is indicative of failure, or the runout cycle count is reached.

A2.4.2 The data generated from a series of test samples is compiled and presented in a manner that is consistent with the goals of the study. The results can either be presented in a semi-log *M-N* diagram that will characterize the general fatigue behavior of the angled device over a range of applied bending moments or simply the fatigue strength determined for a specified *N* number of cycles.

A2.5 Significance and Use

A2.5.1 The test method establishes a uniform cantilever bending fatigue test to characterize and compare the fatigue performance of different angled device designs. This test method may be used to determine an angled device's fatigue life at either a specific or over a range of maximum bending moment conditions. Additionally, this test method may be alternatively used to estimate an angled device's fatigue strength for a specified number of fatigue cycles.

A2.5.2 The test method utilizes a simplified angled device cantilever bending load model that may not be exactly representative of the in-situ loading configuration. The user should note that the test results generated by this test method can not be used to directly predict the in-vivo performance of the angled device being tested. The data generated from this test method can be used to conduct relative comparisons of different angled device designs.

A2.5.3 This test method may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the devices being tested and their potential application.

A2.5.4 This test method assumes that the angled device is manufactured from a material that exhibits linear-elastic material behavior; therefore, this test method is not applicable for testing angled devices made from materials that exhibit nonlinear elastic behavior.

A2.5.5 This test method is restricted to the testing of angled devices within the material's linear-elastic range; therefore, this test method is not applicable for testing angled devices under conditions that would approach or exceed the bending strength of the angled device being tested.

A2.6 Apparatus

A2.6.1 Test machines used for the bending fatigue test shall conform to the requirements of Practice E 4 and E 467.

A2.6.2 The suitability of any data acquisition systems used in monitoring the progress of these tests should be evaluated in accordance to the guidelines of Guide E 1942.

A2.6.3 The typical cantilever bend test loading conditions employed for this test is illustrated in Fig. A2.1. Suitable test fixtures for the test will meet the requirements of A1.6.

A2.6.4 A cycle counter is required that is capable of counting the cumulative number of loading cycles that are applied to the specimen during the course of the fatigue test.

A2.6.5 When required, a limit detector that is capable of sensing when a test parameter, for example, load, actuator displacement, DC error, etc., reaches a limiting value and produces a signal or action that terminates the test.

A2.7 Test Specimens and Sampling

A2.7.1 All test components shall be representative of implant quality products with regard to material, cross-section, surface finish, markings, and manufacturing processes. Any deviation from this requirement must be noted in the final report.

A2.7.2 In accordance with Practice F 565, angled devices that have been either implanted or contoured (reshaped) for implantation are not suitable for this test method and shall be excluded from the sample.

A2.7.3 Angled devices of different lengths but nominally identical cross-sections, and made of the same material, may be used to constitute a sample.

A2.7.4 *M-N Diagram Testing*—The minimum sample size necessary for reporting the fatigue life of a given angled device at a given maximum bending moment condition is three. A rudimentary *M-N* diagram with a corresponding fatigue curve would

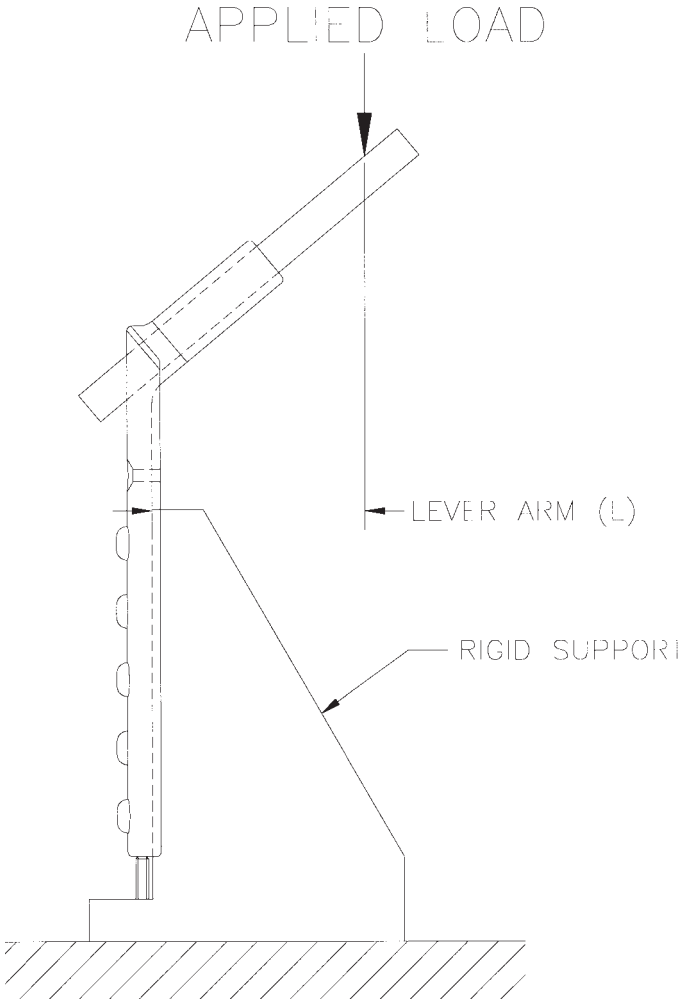

FIG. A2.1 Representative Test Configuration

require three replicate tests at three load levels. Under ideal conditions, conduct five replicate tests at each of five maximum bending moment levels in order to enhance the statistical significance of the resulting information.

A2.7.5 *Fatigue Strength Testing*—No minimum sample size can be identified for this testing method since the total number of data points needed to make such a determination is dependent upon the methodology used and many other related factors. The user should be aware that such a study may require approximately twenty test specimens in order to generate statistically meaningful results.

A2.8 Procedure

A2.8.1 Prior to testing, the bending moment level(s) for testing must be determined. To evaluate the fatigue performance of an angled device, the user has several methodologies at their disposal whose selection is based upon the output goals of the study. Two recommended methods are as follows:

A2.8.1.1 *M-N Diagram*— The user may test a given angled device design over a range of maximum bending moment levels to characterize the general fatigue behavior trend of the device. The user's experience is the best guide that can be used for determining the initial loading conditions. In the absence of such experience, the best recommendation would be to use initial fatigue loads corresponding to 75, 50, and 25 % of the bending strength determined in accordance with Annex A1. The applied moment and the cycle to test termination data are then plotted on a semi-log *M-N* diagram. A curve fit may be applied appropriately to the data to develop an *M-N* curve.

A2.8.1.2 *Fatigue Strength Determination* —The user may also test a given angled device design in order to determine the fatigue strength at a given number of fatigue cycles. This test method recommends that the fatigue strength estimation be determined at one million loading cycles (see rationale in Appendix X3). The maximum difference between the load levels used for the fatigue strength determination shall be no greater than 10 % of the bending strength determined in accordance to this standard's Annex A1 test method. Acceptable methods, which can be employed to determine the angled device's fatigue strength, include the up and down method and a modified up and down method.[7,8]

A2.8.2 Anchor the angled device in the testing fixture and position it so that the angled device will be loaded consistent with the clinical failure mode being investigated.

A2.8.3 Ensure that the load is applied to the tested device in a manner consistent with the requirements of A1.6.3.

A2.8.4 Load the test specimen with the test system in load control using an appropriate waveform so that the resultant time dependent bending moment generated in the test specimen is cyclic and sinusoidal in nature. Select a cyclic frequency for the tests that will not produce strain sensitive effects in the angled device's material. Typically, a cyclic frequency of 5 Hz is more than adequate for completing the test in a timely manner and will still not affect the angled device's material.

A2.8.5 The recommended *R*-ratio is 0.1. Any deviations from this should be reported and justified in the final report.

A2.8.6 The cycle counter shall record the cumulative number of cycles applied to the test specimen, and the appropriate limits should be set to indicate specimen failure, or deviations, or both, from the intended load parameters.

A2.8.7 Testing shall continue until the specimen breaks, a limit is reached that terminates the test, or the total cycle count reaches the runout limit.

A2.9 Calculation or Interpretation of Results

A2.9.1 Record the results of each test including the maximum moment, cycle count at test termination, and the failure location and failure mode, if applicable.

A2.9.2 If the goal of the study is to generate an *M-N* diagram, then the maximum moment and cycles to test termination data is plotted on a semi-log graph. Various techniques may be used to estimate the mean or median fatigue lives, statistical differences between groups, curve fits to the fatigue data, probability of survival curves, etc.[9,10]

A2.9.3 If the goal of the study is to determine the fatigue strength at *N* cycles, it is recommended that the fatigue strength be determined as the median fatigue limit (50 % probability of survival), using an applicable industry accepted techniques.[7,8]

A2.10 Report

A2.10.1 The test report will include the following information:

A2.10.1.1 Manufacturer of the angled device specimen.

A2.10.1.2 The angled device's description and catalog number (if applicable).

A2.10.1.3 The angled device's material including applicable ASTM or ISO specifications.

A2.10.1.4 Deviations from normal implant product.

A2.10.1.5 The unloaded lever arm length (*L*).

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[7] Little, R. E., and Jebe, E. H., *Manual on Statistical Planning and Analysis for Fatigue Experiments*, STP 588, American Society of Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, 1975.

[8] Little, R. E., "Optimal Stress Amplitude Selection in Estimating Median Fatigue Limits Using Small Samples," *Journal of Testing and Evaluation*, ASTM, 1990, pp. 115–122.

[9] Conway, J. B., and Sjodahl, L. H., *Analysis and Representation of Fatigue Data*, ASM International, Materials Park, OH, 1991.

[10] Collins, J. A., *Failure of Materials in Mechanical Design*, John Wiley and Sons, New York, NY, 1981.

A2.10.1.6 *R*-ratio.
A2.10.1.7 Test frequency.
A2.10.1.8 Description of the test environment.
A2.10.1.9 Deviations from recommended test method.
A2.10.1.10 Tabular listing that summarizes the maximum moment and the resulting cycles to test termination data.
A2.10.1.11 A description of the failure mode and failure location for each specimen that failed.
A2.10.1.12 If appropriate, a semi-log plot of the *M-N* diagram is generated. Include descriptions of any analytical or statistical techniques used when interpreting the fatigue data.
A2.10.1.13 If appropriate, an estimate of the fatigue strength should be reported. Include descriptions of any analytical or statistical techniques used for determining the fatigue strength.

A2.11 Precision and Bias

A2.11.1 *Precision*— Data establishing the precision of the test method have not yet been obtained.
A2.11.2 *Bias*—No statement of bias can be made, since no acceptable reference values are available, nor can they be obtained since this test method is a destructive test.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR MAIN TEXT

X1.1 This standard is intended to provide useful and consistent information related to the terminology, performance, application of test methods, and the application of angled devices used for maintenance of alignment and fixation during the bone healing process. Angled device geometrical definitions, classification and terminology, material specifications, and performance definitions are provided.

X1.2 The orthopedic surgeon should be able to select the device he/she feels is appropriate for the indication being treated. In order to do this, the surgeon must have confidence that the designation of size has a specific, known meaning that is quantifiable and reliable regardless of the manufacturer or design. The mechanical behavior and material properties must also be described in a reliable, known manner irrespective of the manufacturer or design. In order to accomplish this uniformity of designations, the terminology, mechanical properties, material properties must be standardized.

X1.3 The subcommittee's goal is to produce a single standard identifying all pertinent information, requirements, and test methods for orthopedic angled devices. The first step in achieving this goal was to combine the current versions of F 384 and F 787. This revision of F 384 completes this first step.

X2. RATIONALE FOR ANNEX A1

X2.1 This test method in Annex A1 is designed to measure the mechanical properties of angled devices subjected to a compression-bending load, which is the most common type of loading encountered *in vivo*. This test method addresses itself to properties of the device rather than the material from which the plate is made.

X2.2 The test method's intent is to specify the requirements of the loading configuration and not the design of the test fixtures needed to meet those requirements. The elimination of absence of any standardized test fixture design in the test method allows for the creative problem solving by the individual conducting the test in order to addresses the requirements of any given set of test conditions. One of the problems with the previous version of the standard was that the test configuration did not lend itself easily to the testing of angled devices in an environment.

X2.3 The offset displacement criteria used to determine the angled device's bending strength has been set at 0.2 % for two reasons; to establish a bending strength criteria that was minimally influenced by non-elastic bending of the angled device, and to make the test method consistent with the previous version. In the previous version of the test method, the lever arm length was set at 3.0 in. with an offset displacement criteria of 0.005 in. (approximately 0.2 % of the lever arm length). Additionally, the typical offset chosen is small enough that the elastic limit has just been reached, but large enough that any slippage or singular behavior at the elastic limit is avoided (0.1 % and 0.2 % for E 8).

X3. RATIONALE FOR ANNEX A2

X3.1 Angled device fatigue properties are an important factor when considering the surgical treatment of skeletal fractures. The angled device may be subjected to a significant number of repetitive stress cycles during the healing process. In some situations, the angled device may be expected to experience these conditions for several weeks until the bone healing process progresses adequately so that the bone can provide mechanical support that will reduce the stresses in the angled device. It is important, therefore, for the surgeon to have some means to judge the fatigue performance of a given angled device.

X3.2 Since the time frame, number of loading cycles and loading conditions are uncontrollable and unpredictable, there is no acceptable limit that can be set for the bending moment or number of cycles of load which the angled device should withstand in any given case.

X3.3 One of the objectives of this test method is to provide a consistent methodology for determining an estimate of the angled device fatigue strength at 10^6 cycles for comparative purposes. Angled devices are classified as temporary skeletal fixation devices since fractures and skeletal deformity corrections generally are resolved within two to three months (approximately 150 000 to 250 000 cycles). Even though the test method's recommendation of one million cycles for estimating the fatigue strength has been arbitrarily chosen, it still can be considered conservative since no angled device in clinical service would normally be expected to withstand 10^6 high stress loading cycles.

X3.4 The reporting of cyclic bending fatigue strength or fatigue life, or both, using this standard testing technique only are suitable for comparative evaluations between devices of different sizes, designs and materials.