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Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials[1]

This standard is issued under the fixed designation F2118; 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 describes test procedures for evaluating the constant amplitude, uniaxial, tension-compression uniform fatigue performance of acrylic bone cement materials.

1.2 This test method is relevant to orthopedic bone cements based on acrylic resins, as specified in Specification F451 and ISO 16402. The procedures in this test method may or may not apply to other surgical cement materials.

1.3 It is not the intention of this test method to define levels of performance of these materials. It is not the intention of this test method to directly simulate the clinical use of these materials, but rather to allow for comparison between acrylic bone cements to evaluate fatigue behavior under specified conditions.

1.4 A rationale is given in Appendix X2.

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 *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.*

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2. Referenced Documents

2.1 *ASTM Standards:*[2]

E466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

E1823 Terminology Relating to Fatigue and Fracture Testing

F451 Specification for Acrylic Bone Cement

ASTM F2118-14

2.2 *ISO Standard:*

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ISO 16402 Flexural Fatigue Testing of Acrylic Resin Cements Used in Orthopedics[3]

3. Terminology

3.1 Unless otherwise given, the definitions for fatigue terminology given in Terminology E1823 will be used.

3.2 *Definitions:*

3.2.1 *mean fatigue life at N cycles*—the average number of cycles to failure at the specified load level. For the purposes of this test method, the fatigue life will be determined at 5 million load cycles. A rationale for this is provided in X2.4.

3.2.2 *median fatigue life at a given stress level*—the number of cycles to failure at which 50 % of the tested samples failed at the specified stress level.

3.2.3 *runout*—a predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed. For the purposes of this test method, the runout will be 5 million load cycles.

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[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[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.

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3.2.4 *specimen failure*—the condition at which the specimen completely breaks or is damaged to such an extent that the load frame is no longer able to apply the intended stress within the required limits.

3.2.5 *stress level*—the value of stress at which a series of duplicate tests are performed. For the purposes of this test method, the stress level is reported as the maximum stress applied to the specimen.

4. Summary of Test Method

4.1 Uniform cylindrical reduced gage section test specimens are manufactured from acrylic bone cement and mounted in a uniaxial fatigue frame. The specimen is subjected to fully reversed tensile and compressive loading in a sinusoidal cyclic manner at a specified frequency in phosphate buffered saline (PBS). The fatigue loading is continued until the specimen fails or a predetermined number of cycles (run-out limit) is reached.

5. Significance and Use

5.1 This test method describes a uniaxial, constant amplitude, fully reversed fatigue test to characterize the fatigue performance of a uniform cylindrical waisted specimen manufactured from acrylic bone cement.

5.2 This test method considers two approaches to evaluating the fatigue performance of bone cement:

5.2.1 Testing is conducted at three stress levels to characterize the general fatigue behavior of a cement over a range of stresses. The stress level and resultant cycles to failure of the specimens can plotted on an *S-N* diagram.

5.2.2 Another approach is to determine the fatigue life of a particular cement. The fatigue life for orthopaedic bone cement is to be determined up to 5 million (5×10^6) cycles.

5.3 This test method does not define or suggest required levels of performance of bone cement. This fatigue test method is not intended to represent the clinical use of orthopaedic bone cement, but rather to characterize the material using standard and well-established methods. The user is cautioned to consider the appropriateness of this test method in view of the material being tested and its potential application.

5.4 It is widely reported that multiple clinical factors affect the fatigue performance of orthopaedic bone cement; however, the actual mechanisms involves multiple factors. Clinical factors which may affect the performance of bone cement include: temperature and humidity, mixing method, time of application, surgical technique, bone preparation, implant design, anatomical site, and patient factors, among others. This test method does not specifically address all of these clinical factors. The test method can be used to compare different acrylic bone cement formulations and products and different mixing methods and environments (that is, mixing temperature, vacuum, centrifugation, and so forth).

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6. Apparatus

6.1 *Uniaxial Load Frame*—A testing machine capable of applying cyclic sinusoidal tensile and compressive loads.

6.1.1 The crossheads of the load frame shall be aligned such that the alignment meets the requirements of section 8.2 of Practice E466. The alignment should be checked at both the maximum tensile and minimum compressive load to be applied during the course of a test program.

6.2 *Cycle Counter*—A device capable of counting the number of loading cycles applied to a specimen during the course of a fatigue test.

6.3 *Load Cell*—A load cell capable of measuring dynamic tensile and compressive loads in accordance with Practice E467.

6.4 *Limit*—A device capable of detecting when a test parameter (for example, load magnitude, actuator displacement, DC error, and so forth) reaches a limiting value, at which time the test is stopped and the current cycle count recorded.

6.5 *Environmental Chamber*—A chamber designed to immerse the fatigue specimen completely in a solution. The chamber should have provisions for maintaining a constant temperature to an accuracy of ±2°C.

7. Test Specimen

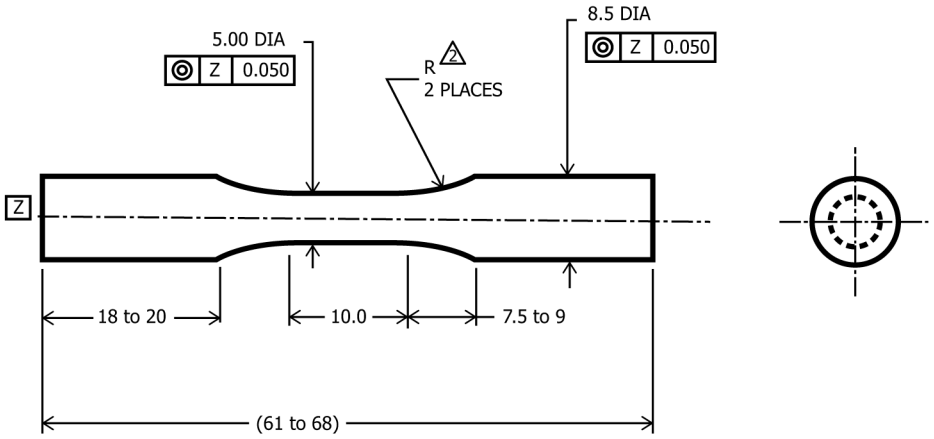
7.1 Test specimens shall be fabricated from cement that is representative of the final product with regard to materials, manufacturing processes, sterilization, and packaging. Certain sterilization methods have been shown to have an effect on fatigue performance (for example, gamma sterilization of the powder). Any deviations of the test cement from the clinically used product must be reported.

7.2 Cylindrical reduced gage section test specimens with a straight 5-mm diameter by 10-mm-long gage section shall be used. The diameter of the specimen ends shall be substantially greater than the gage diameter to ensure that fracture occurs in the gage section. A smooth surface of the test specimen in the radius or taper between the specimen ends and gage section is essential to reduce variation in reported fatigue life. Suggested specimen dimensions are provided in Fig. 1.

8. Specimen Preparation

8.1 *Cement Mixing:*

8.1.1 Store the liquid and powder portions of the cement according to the manufacturer's instructions before mixing.



1. All dimensions in mm
2. Radius to blend smoothly with gage section
3. Tolerances: X. = ± 1.0
   X.X = ± 0.5
   X.XX = ± 0.1

FIG. 1 Specimen Dimensions

8.1.2 Allow the mixing equipment to equilibrate to room temperature before mixing. Record the room temperature at the onset of mixing.

8.1.3 Mix the powder and liquid components according to the manufacturer's instructions and begin recording the time using a stopwatch when the liquid and powder are initially mixed. Report any deviations from the manufacturer's storage and mixing recommendations.

8.1.4 Report the mixing method and any equipment used. The method used for mixing the cement may affect its fatigue behavior. See X2.13 for further information.

8.2 *Specimen Fabrication*—The cylindrical reduced gage section test specimens are fabricated using the following method:

8.2.1 *Direct Molding:*

8.2.1.1 Inject the mixed cement into a specimen mold during the dough phase as determined by Specification F451 (manufactured from silicone material, see Appendix X3 (suggested specimen molding method)) with an internal cavity which has the same dimensions as the final cement test specimen. Record the method of cement insertion into the mold (that is, syringe injected). A 150 mL syringe with an inner diameter of 38 mm and a nozzle tip diameter of 10 mm should be considered for use. The mold should be placed on a flat surface. The cement injection should be performed from top to bottom in direction allowing the cement to flow down axially to the bottom . The bottom of the mold is placed on a flat surface as the bone cement is being injected into the mold unixaially from the top down. If air is entrapped and leads to resistance to injection, the mold should be rocked back and forth to release trapped air from the bottom of the mold. This will allow for air to escape from the bottom of the mold. (See X3.6 for standard operating procedure for making bone cement specimens.)

8.2.1.2 Place the mold in a container of phosphate buffered saline (PBS). The PBS solution should be maintained at 37 ± 2°C. After at least 1 h in the PBS bath, the specimens may be removed from the mold. Appendix X3 describes a suggested procedure for molding cement specimens.

8.3 *Specimen Examination:*

8.3.1 Visually examine specimens for surface defects. Surface defects in the gage or transition sections (radii) shall be rejected from testing and discarded. A surface defect is defined as a surface discontinuity greater than 250 mm in major diameter. All specimens should be photographed to document surface finish prior to testing. In addition, the specimens' straightness should be compared to the metal positive blank to ensure that the specimen is will not product bending moments during the ~~unaxial~~uniaxial fatigue testing. Straightness can be assessed by rolling the specimens and determining if there is a visible wobble as compared to the straight metallic blank used to make the mold. Specimens with surface defects or deemed not to be straight shall be rejected from testing and discarded. The total number of specimens rejected divided by the total number of specimens manufactured (rejection rate) shall be reported. A rationale for these rejection criteria is provided in X2.11.

8.4 *Specimen Finishing*—If necessary, lightly polish the gage length of the specimens with 600-grit abrasive paper in the longitudinal direction until the surface is free of machining and/or mold marks. It should be noted that molds can wear over time as they are used, and a visual inspection of the surface roughness of each specimen should be done to ensure smoothness. New molds should be made when the smoothness can no longer be achieved with light polish.

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