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~~Test Method for~~ Designation: F 2118 – 03 (Reapproved 2009)

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 F 2118; 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~~ test method describes test procedures for evaluating the constant amplitude, uniaxial, tension-compression uniform fatigue performance of acrylic bone cement materials.

1.2 This ~~standard~~ test method is relevant to orthopaedic bone cements based on acrylic resins, as specified in Specification F 451. The procedures in this ~~guide~~ test method may or may not apply to other surgical cement materials.

1.3 It is not the intention of this ~~standard~~ test method to define levels of performance of these materials. Furthermore, it is not the intention of this ~~standard~~test method to directly simulate the clinical use of these materials.

1.4 A rationale is given in Appendix X1.

~~1.5The values stated in SI units are to be regarded as the standard.~~

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 associated with its use. It is the responsibility of the user of this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E 466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials

E 467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

E 1823 Terminology Relating to Fatigue and Fracture Testing

F 451 ~~Standard~~ Specification for Acrylic Bone Cement

2.2 *ISO Standard:*

ISO 7206-8 Implants for Surgery, Partial and Total Hip Joint Prostheses, Part 8—Endurance Performance of Stemmed Femoral Components with Application of Torsion[3]

3. Terminology ~~Unless~~

3.1 Unless otherwise given, the definitions for fatigue terminology given in Terminology E 1823 will be used.

~~3.1~~3.2 ~~*Median Fatigue Strength*~~*median fatigue strength at N* ~~*Cycles*~~*cycles*—The maximum stress at which 50 % of the specimens of a given sample would be expected to survive *N* loading cycles. For the purposes of this test method, the fatigue strength will be determined at 5 million load cycles. A rationale for this is provided in the Appendix X1.4.

~~3.2*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.~~

3.3 ~~*Stress Level*—The value of stress at which a series of duplicate tests are performed. For the purposes of this method, the stress level is reported as the maximum stress applied to the specimen.~~ runout—A predetermined number of cycles at which the

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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* ~~, Vol 03.01.~~volume information, refer to the standard's Document Summary page on the ASTM website.

~~[3] Annual Book of ASTM Standards, Vol 13.01.~~

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

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.

3.4 ~~*Specimen Failure*~~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.

3.5 *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.

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 (runout 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 are plotted on an *S-N* diagram.

5.2.2 Another approach is to determine the fatigue strength of a particular cement. The fatigue strength for orthopaedic bone cement is to be determined at 5 million (5×10^6) cycles. The "two-point method" is the specified procedure for conducting fatigue testing to determine fatigue strength ~~[~~(1~~]~~).[4]

5.3 This ~~standard~~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 involved are not well understood. 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, and patient factors, among others. This test method does not specifically address 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).

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 8.2 of Practice E 466. 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 E 467.

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. Sterilization methods have been shown to have an effect on fatigue performance. Any deviations of the test cement from the clinically used product must be reported.

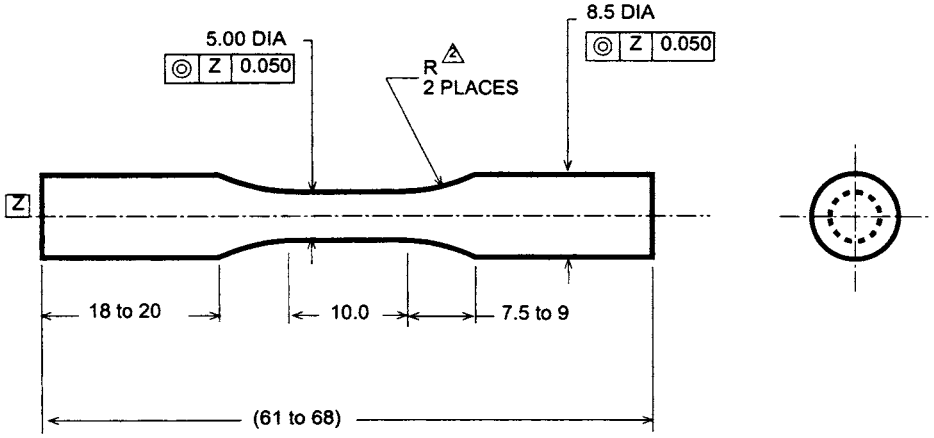
7.2 Cylindrical reduced gage section test specimens with a straight 5-mm diameter by 10-mm-long gage section shall be used. The diameter of the specimen ends shall be substantially greater than the gage diameter to ensure that fracture occurs in the gage section. A smooth radius or taper between the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

8. Specimen Preparation

8.1 *Cement Mixing*

~~[4] Available from American National Standards Institute, 25 W. 43rd St, 4th Floor, New York, NY 10036.~~

[4] The boldface numbers in parentheses refer to a list of references at the end of this standard.



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

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

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 from this point using a stopwatch. 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 X1.13 for further information.

8.2 *Specimen Fabrication*—The cylindrical reduced gage section test specimens are fabricated using one of two methods:

8.2.1 *Direct Molding*:

8.2.1.1 Insert the mixed cement into a specimen mold (manufactured from silicone, aluminum, ~~Teflon,~~TFE-fluorocarbon, or other suitable material) with an internal cavity which has the same dimensions as the final cement test specimen. Close the mold. Record the method of cement insertion into the mold (that is, pour or inject) and method used to close the mold.

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 the specimens have polymerized for at least 1 h, the specimens may be removed from the mold. Appendix X2 describes a suggested procedure for molding cement specimens.

8.2.2 *Machining*:

8.2.2.1 Insert the mixed cement into cylindrical mold (manufactured from aluminum, glass, or ~~Teflon~~TFE-fluorocarbon tube). The inside diameter of the molding tube should be a few millimetres greater than the final specimen grip diameter.

8.2.2.2 Maintain the temperature of the mold at at 37 ± 2°C. After the specimens have polymerized for at least 1 h, the specimens may be removed from the mold.

8.2.2.3 Machining should not be performed until at least 24 h after initial mixing to ensure that the cement is completely polymerized.

8.3 *Specimen Examination*:

8.3.1 Radiographically examine the fabricated specimens for internal defects. Visually examine specimens for surface defects. 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 μm in major diameter. In addition, the specimens shall be examined radiographically in two orthogonal planes. Specimens with internal defects greater than 1 mm in major diameter in the gage section 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 X1.11.

NOTE 1—The development of fabrication defects may be related to the tendency of a material to develop porosity during polymerization. The amount of porosity or fabrication defects in the test specimens may be a characteristic of the cement being evaluated. The rejection rate may give a general indication of a material's tendency toward porosity formation.

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.

8.5 *Specimen Measurement*—Measure the diameter of the specimens at a minimum of three places along the gage length of each specimen. The average of these measurements shall be used as the specimen's gage diameter for calculation of the required load.

8.6 *Specimen Conditioning*:

8.6.1 Place the test specimens in PBS which is maintained at a temperature of 37 ± 2°C.

8.6.2 Maintain the specimens in the PBS solution for a minimum of 7 days. The cement specimens shall be maintained in the PBS solution for 7 to 60 days. The specimens shall be continually immersed in the test solution so that they do not dry out. Distilled water shall be added to the soaking chamber during the soaking period to make up for evaporation loss. Each specimen should be soaked up to the time immediately before its being mounted on the load frame. See X1.5 for further information.

9. Fatigue Test Procedures

9.1 Mount the specimens in a test frame test such that a uniaxial load is applied. Collets, Jacob's chucks, or pressurized grips should be used to firmly grip the specimen at each end. Ensure the longitudinal centerline of the test specimens are aligned with test machine loading axis such that no bending moment may be applied to the specimens.

9.2 Mount an environmental chamber on the load frame and fill with fresh test solution immediately after the specimen is mounted to keep the specimen from drying out. The chamber should be filled to a level such that the entire specimen is immersed. Distilled water shall be added to the test chamber during the course of a test to make up for evaporation loss. The temperature controller should be programmed and activated to heat the test solution to 37°C, and then maintain that temperature within ±2°C. Fatigue testing should not begin until at least ½ h after the solution temperature has reached 37°C to ensure equilibration.

9.3 Program the test frame controller to apply a fully reversed sinusoidal cyclic waveform at a constant frequency. When testing at frequencies above 2 Hz, the user should verify that, for the formulation being tested, the chosen frequency has a negligible effect on the test results. See X1.6 for further information.

9.4 Program the test frame controller to apply the desired maximum stress level and a stress ratio of $R = -1$, indicating fully reversed loading. A rationale for using fully reversed loading is provided in Appendix X1.10. The load shall be calculated by multiplying the desired stress by the specimen's cross-section area, based on each specimen's gage diameter determined in 8.5.

9.4.1 Report the stress level to the nearest 0.5 MPa.

9.4.2 When developing an *S-N* curve, it is recommended that testing be conducted at the following maximum stress levels: 15, 12.5, and 10 MPa. Other stress levels may also be appropriate. See X1.7 for a rationale regarding the selection of the recommended stress levels.

9.4.3 When determining a fatigue strength, the stress levels shall be chosen in accordance with the "two-point method" ~~[~~(1~~]~~.

9.5 *Number of Specimens*—When developing an *S-N* curve, a minimum of ~~eight~~fifteen specimens shall be tested at each stress level. The desired statistical power of the comparison and the variability to be expected from the cement formulation(s) being investigated should be considered when determining the appropriate sample size. See X1.12 for further information.

9.5.1 When determining a fatigue strength, the number of specimens shall be chosen in accordance with the "two-point method" ~~[~~(1~~]~~.

9.6 After the solution has reached the temperature requirements in 9.2, activate the test frame controller to begin the test.

9.7 Set the cycle counter and limit settings of the test frame controller to record the cumulative number of cycles applied to the test specimen and the appropriate test limits values to indicate specimen failure or deviations from the intended load system performance.

9.8 Testing shall continue until specimen failure or the runout limit is reached.

10. Calculation and Interpretation of Results

10.1 The maximum stress and the cycles to failure for each specimen should be recorded and plotted on an *S-N* diagram ~~[~~(2~~]~~. The techniques used to estimate mean fatigue lives, determine probability of survival curves, compare statistical differences between sample groups, and calculate fatigue strength are described in 10.2-10.7.

10.2 *Mean Fatigue Life*—For each stress level, the mean fatigue life and standard deviation about the mean shall be determined assuming a log-normal distribution ~~[~~(3~~]~~. The mean log fatigue life is first determined according to the following equation:

$$X_{log} = \frac{[\sum \log_{10} (N_i)]}{n} \quad (1)$$

where:

X_{log} = mean log fatigue life,
N_i = number of cycles to failure of i^{th} specimen, and
n = total number of specimens in the sample group.

Using a similar approach, the standard deviation of the mean log fatigue life (S_{log}) is determined.

These are expressed in more familiar terms, as cycles to failure, by calculating the following:

$$\text{mean fatigue life} = 10\hat{} (X_{log}) \quad (2)$$

$$\text{mean} + 1 \text{ standard deviation} = 10\hat{} (X_{log} + S_{log}) \quad (3)$$

$$\text{mean} - 1 \text{ standard deviation} = 10\hat{} (X_{log} - S_{log}) \quad (4)$$

10.3 *Probability of Survival Curves* —For each stress level, a probability of survival curve, assuming a logarithmic failure