



Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials¹

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 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 orthopaedic bone cements based on acrylic resins, as specified in Specification F 451. 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. Furthermore, it is not the intention of this test method to directly simulate the clinical use of these materials.

1.4 A rationale is given in Appendix X1.

1.5 The values stated in SI units are to be regarded as the 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:

E 466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials²

E 467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System²

E 1823 Terminology Relating to Fatigue and Fracture Testing²

F 451 Standard Specification for Acrylic Bone Cement³

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 Torsion⁴

3. Terminology

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

3.2 *median fatigue strength at N 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.

3.3 *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.

3.4 *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.

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.

Current edition approved Sept. 10, 2003. Published October 2003. Originally approved in 2001. Last previous edition approved in 2001 as F2118 - 01a.

² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

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