Designation: F2183 – 02 (Reapproved 2008)

Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants[1]

This standard is issued under the fixed designation F2183; 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 covers the determination of mechanical behavior of ultra-high molecular weight polyethylene (UHMWPE) by small punch testing of miniature disk specimens (0.5 mm in thickness and 6.4 mm in diameter). The test method has been established for characterizing UHMWPE surgical materials after ram extrusion or compression molding (**1**,**2**)[2]; for evaluating as-manufactured implants after radiation crosslinking and sterilization (**3**,**4**); as well as for testing of implants that have been retrieved (explanted) from the human body (**5**,**6**).

1.2 The parameters of the small punch test, namely the peak load, ultimate displacement, ultimate load, and work to failure, provide metrics of the yielding, ultimate strength, ductility, and toughness of UHMWPE under multiaxial loading conditions. Because the mechanical behavior of UHMWPE is different when loaded under uniaxial and multiaxial loading conditions (**3**), the small punch test provides a complementary mechanical testing technique to the uniaxial tensile testing specified for medical grade UHMWPE by Specification F648.

1.3 In addition to its use as a research tool in implant retrieval analysis, the small punch test can be used as a laboratory screening test to evaluate new UHMWPE materials, such as those created by gamma or electron beam irradiation (**1**). The test method is also well suited for characterization of UHMWPE before and after accelerated aging (for example, Guide F2003), and in that regard it can provide ranking of the mechanical degradation of different UHMWPE samples after oxidative degradation (**4**,**7**).

1.4 The small punch test has been applied to other polymers, including polymethyl methacrylate (PMMA) bone cement, polyacetal, and high density polyethylene (HDPE) (**8**,**9**). However, the small punch testing of polymers other than UHMWPE is beyond the scope of this standard.

1.5 The values stated in SI units are to be regarded as standard. The units in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered 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.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

D695 Test Method for Compressive Properties of Rigid Plastics

D883 Terminology Relating to Plastics

E4 Practices for Force Verification of Testing Machines

E83 Practice for Verification and Classification of Extensometer Systems

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

F1715 Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices (Withdrawn 2006)[4]

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air

F2102 Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants

3. Terminology

3.1 *Definitions*—The features of a typical small punch test load versus displacement curve for UHMWPE are illustrated in Fig. 1.

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

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

[3] 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.

[4] The last approved version of this historical standard is referenced on www.astm.org.

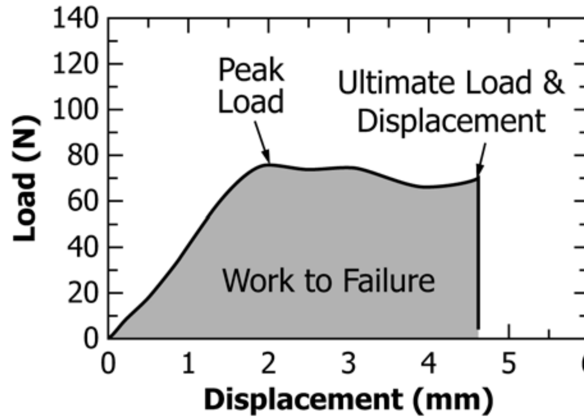

FIG. 1 Features of the Small Punch Test Load Versus Displacement Curve for Unirradiated UHMWPE, Including the Peak Load, Ultimate Load and Displacement, and Work to Failure

3.1.1 *peak load*—an initial local maximum in the load versus displacement curve (Fig. 1). In certain radiation crosslinked UHMWPE materials, the load versus displacement curve increases monotonically and a shoulder, rather than an initial peak load, may be observed.

3.1.2 *small punch test*—a test wherein the specimen is of miniature size relative to conventional mechanical test specimens, is disk-shaped, and is loaded axisymmetrically in bending by a hemispherical-head punch.

3.1.3 *ultimate displacement*—the displacement at rupture (failure) of the specimen (Fig. 1).

3.1.4 *ultimate load*—the load at rupture (failure) of the specimen (Fig. 1).

3.1.5 *work to failure*—the area under the load versus displacement curve (Fig. 1).

4. Significance and Use

4.1 Miniature specimen testing techniques are used to characterize the mechanical behavior of UHMWPE stock materials and surgical implants after manufacture, sterilization, shelf aging, radiation crosslinking, thermal treatment, and implantation (**1**). Furthermore, experimental UHMWPE materials can be evaluated after accelerated aging and hip or knee wear simulation. Consequently, the small punch test makes it possible to examine relationships between wear performance and mechanical behavior of UHMWPE. This test method can also be used to rank the mechanical behavior of UHMWPE relative to a reference control material (such as the NIST Ultra-High Molecular Weight Polyethylene Reference Material #8456).

4.2 Small punch testing results may vary with specimen preparation and with the speed and environment of testing. Consequently, where precise comparative results are desired, these factors must be carefully controlled.

5. Apparatus

5.1 *Small Punch Test Apparatus*[5]—A system consisting of a hemispherical head punch, a die, and a guide for the punch, as shown in Fig. 2. The parts shall be fabricated from a hardened steel.

5.1.1 *Guide*—The function of the guide is to align the punch relative to the specimen, which rests in a disk-shaped recess. The inner diameter of the guide bore shall be 0.1010 +0.0002/-0.0000 in. (2.565 +0.005/-0.000 mm), and the specimen recess shall be 0.0200 +0.0004/-0.0000 in. (0.508 +0.010/-0.000 mm) in depth and 0.2520 ± 0.0005 in. (6.401 ± 0.013 mm) in diameter.

5.1.2 *Die*—The function of the die is to constrain the sample during testing. The inner diameter of the die bore shall be 0.1500 ± 0.0005 in. (3.810 ± 0.013 mm).

5.1.3 *Punch*—The hemispherical head punch shall have a diameter of 0.1000 in. (2.540 mm), with a tolerance of +0.0000/-0.0002 in. (+0.000/-0.005 mm).

5.2 *Testing Machine*—Any suitable testing machine as described in Method D695, consisting of a drive mechanism and a load indicator. The load indicator shall have a full range of 250 N (56.2 lbs). The accuracy of the machine shall be verified at least once per year, as specified by Method D695 and Practice E4.

5.3 *Compressometer*—This instrument, described in Section 5.2 from Method D695, can be used to determine the distance between the die and the punch during the test. If the actuator displacement of the testing machine can be shown to determine punch displacement within 1 % of the value measured by a suitably calibrated compressometer (as defined in Practice E83), actuator displacement shall be used as reference.

[5] Small punch testers suitable for use and meeting the requirements of this test method are available from Exponent, Inc., 2300 Chestnut St., Suite 150, Philadelphia, PA, 19103.