



Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants¹

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 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 May 1, 2008. Published June 2008. Originally approved in 2002. Last previous edition approved in 2002 as F2083 – 02. DOI: 10.1520/F2183-02R08.

² The boldface numbers in parentheses refer to the list of references at the end 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.

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.

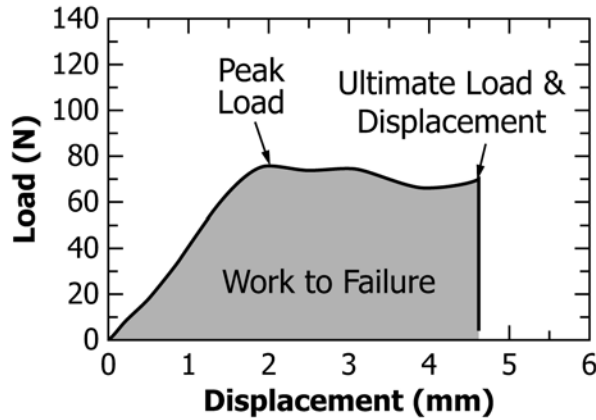


FIG. 1 Features of the Small Punch Test Load Versus Displacement Curve for Unirradiated UHMWPE, Including the Peak Load, Ultimate Load and Displacement, and Work to Failure

3.1.1 *peak load*—an initial local maximum in the load versus displacement curve (Fig. 1). In certain radiation cross-linked 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.

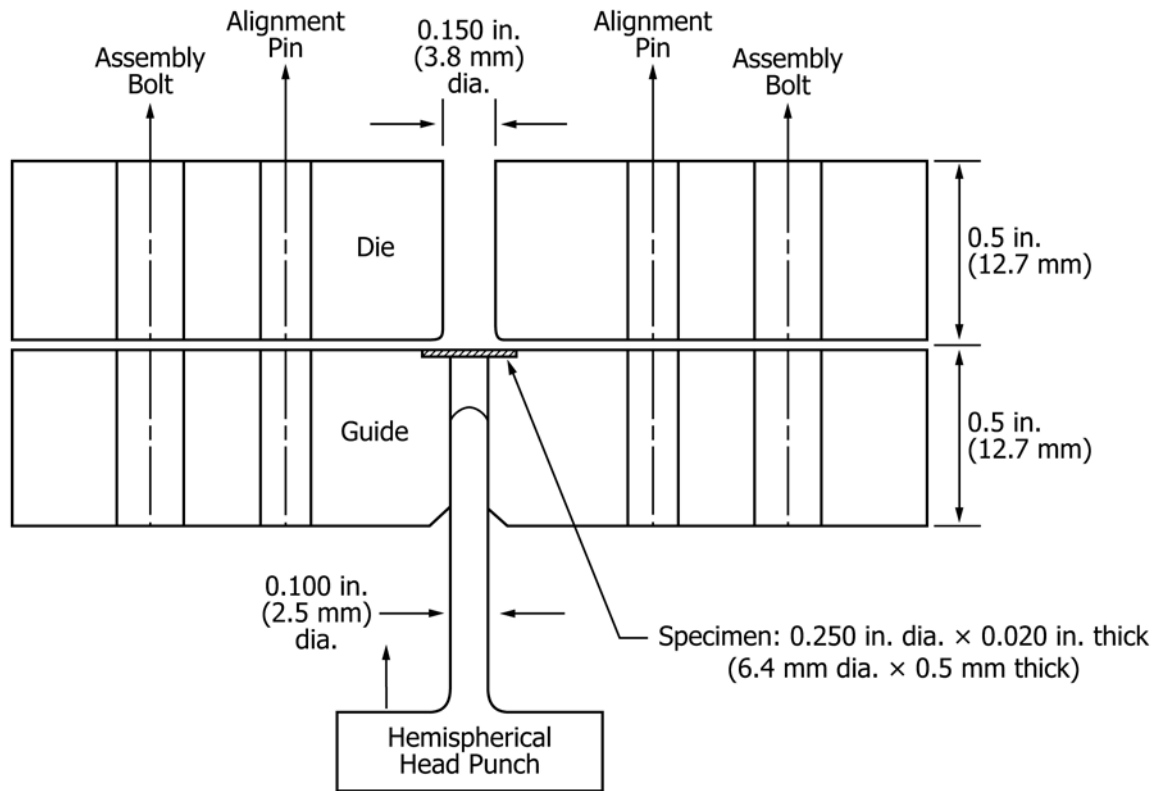


FIG. 2 Schematic of the Small Punch Test Apparatus, Including the Die, Guide, Hemispherical Head Punch, and Miniature Disk Shaped Specimen

5.4 *Compression Platen*—The punch shall rest on a compression platen or tool for applying the load to the punch.

5.5 *Micrometers*—Suitable micrometers, reading to 0.0001 in. (0.0025 mm), shall be used to record the diameter and thickness of the specimens.

5.6 *Thermometer*—A suitable thermometer or thermocouple, reading to 0.1°C, shall be used to record the test temperature within the range 20 to 24°C.

6. Test Specimens

6.1 As the test results are known to be sensitive to preparation technique, the specimens described in 6.2 and 6.3 shall be used. The specimens may be prepared by machining operations from materials in sheet, rod, plate, or implant form. All machining operations shall be done carefully so that smooth surfaces result. Great care shall be taken in machining the faces so that smooth, parallel surfaces result.

NOTE 1—Although specimen fabrication methods other than machining (for example, microtoming) may be used, the use of alternate specimen preparation methods have not yet been shown to provide equivalent test results to machined specimens.

6.2 If specimens are prepared from stock UHMWPE materials, the orientation of the test specimen with respect to the manufacturing direction (for example, perpendicular to the extrusion or compression molding axis) shall be recorded, along with the distance from the surface of the stock material. If the specimens are machined directly from actual implants, the orientation and depth from the articulating surface shall be recorded.

6.3 The standard test specimen shall have a thickness of $0.0200 +0.0002/-0.0003$ in. ($0.508 +0.005/-0.008$ mm) and a diameter of $0.250 +0.000/-0.005$ in. ($6.350 +0.000/-0.127$ mm).

6.4 Specimens falling outside the dimensional tolerances specified in 6.2 shall be discarded.

7. Number of Test Specimens

7.1 A minimum of five specimens per material condition is recommended, especially for thermally treated and highly crosslinked UHMWPE materials. However, due to the repeatability of the test as reported in the literature, four specimens per material condition may be sufficient to establish significant differences between unirradiated UHMWPE material groups.

8. Speed of Testing

8.1 The test results are sensitive to testing speed. Therefore, the speed of the testing machine shall be calibrated to within 1 % accuracy at least once per year, as specified in Method D695.

8.2 The reference speed for small punch testing shall be 0.5 mm min^{-1} , unless otherwise indicated by the customer or specification.

9. Conditioning

9.1 Condition the test specimens at $23 \pm 2^\circ\text{C}$ for at least 1 h prior to testing, unless otherwise specified by the customer or specification.

9.2 The small punch test results are sensitive to test temperature. Therefore, conduct tests in the standard laboratory conditions of $23 \pm 2^\circ\text{C}$, unless otherwise indicated by the customer or specification. In cases of disagreement, the tolerances shall be 1°C (1.8°F).

9.3 UHMWPE is a nonpolar, hydrophobic polymer. Consequently, relative humidity is not expected to play a major role in the results of the small punch testing of UHMWPE.

10. Procedure

10.1 Specimens are placed within the aforementioned specimen recess in the punch guide. The specimen guide, die, and punch are mounted within a testing frame.

10.2 Mechanical testing is performed in bending by indentation of the disk-shaped UHMWPE specimens with the hemispherical head steel punch. The specimen is loaded by the hemispherical head punch moving into the specimen at a constant displacement rate until failure of the specimen occurs.

10.3 The load applied to the punch, as well as the displacement of the punch, are recorded continuously during the test.

10.4 Failure of the specimen and termination of the test will be indicated by a load drop in the load versus displacement curve, or when the ultimate load drops to 5 N.

11. Calculations

11.1 Calculate the initial peak load (if applicable), the ultimate load, ultimate displacement, and work to failure as shown in Fig. 1. The units for the initial peak load and ultimate load shall be in newtons. Ultimate displacement shall be reported in millimetres, and the work to failure shall be reported in millijoules.

11.2 For each of the small punch test metrics, calculate to three significant figures the arithmetic mean of all values obtained and report as the “average value” for the particular metric in question.

11.3 Calculate the standard deviation (estimated) and report to two significant figures.

12. Report

12.1 Report the following information:

12.1.1 Complete identification of the material tested, including type, source, manufacturer’s lot number, form, irradiation level, sterilization method, shelf age, and so forth,

12.1.2 Method of preparing test specimens,

12.1.3 Specimen dimensions,

12.1.4 Conditioning procedure used,

12.1.5 Temperature in test room,

12.1.6 Number of specimens tested,

12.1.7 Orientation and location of specimens with respect to original stock material or implant,

12.1.8 Speed of testing,

12.1.9 Average value and standard deviation for initial peak load (if present on the load displacement curve),

12.1.10 Average value and standard deviation for ultimate load,

12.1.11 Average value and standard deviation for ultimate displacement,

12.1.12 Average value and standard deviation for work to failure,

12.1.13 Date of test, and

12.1.14 Date of test method.

13. Precision and Bias

13.1 *Precision*—The repeatability of the small punch test metrics is reported in the literature to be less than 10 % for virgin, unirradiated UHMWPE materials (1). An interlaboratory study is currently planned to provide quantification of reproducibility.

13.2 *Bias*—There are no recognized standards on which to base an estimate of bias for this test standard.

14. Keywords

14.1 mechanical behavior; miniature specimens; small punch test; UHMWPE; ultra-high molecular weight polyethylene

REFERENCES

- (1) Edidin, A. A. and Kurtz, S. M., “Development and Validation of the Small Punch Test for UHMWPE Used in Total Joint Replacements,” In *Functional Biomaterials*, Eds. N. Katsube, W. Soboyejo and M. Sacks. Winterthur, Switzerland: Trans Tech Publications Ltd., 2001.
- (2) Kurtz, S. M., Foulds, J. R., Jewett, C. W., Srivastav, S., and Edidin, A. A., “Validation of a Small Punch Testing Technique to Characterize the Mechanical Behavior of Ultra-High Molecular Weight Polyethylene,” *Biomaterials*, Vol 18, 1997, pp. 1659–1663.
- (3) Kurtz, S. M., Pruitt, L. A., Jewett, C. W., Foulds, J. R., and Edidin, A. A., “Radiation and Peroxide Crosslinking Promote Strain Hardening Behavior and Molecular Alignment in UHMWPE During Multiaxial Loading Conditions,” *Biomaterials*, Vol 20, 1999, pp. 1449–1462.
- (4) Kurtz, S. M., Jewett, C. W., Foulds, J. R., and Edidin, A. A., “A Miniature-Specimen Mechanical Testing Technique Scaled to the Articulating Surface of Polyethylene Components for Total Joint Arthroplasty,” *J Biomed Mater Res (Appl Biomater)*, Vol 48, 1999, pp. 75–81.
- (5) Edidin, A. A., Rimnac, C. M., Goldberg, V., and Kurtz, S. M., “Mechanical Behavior, Wear Surface Morphology, and Clinical Performance of UHMWPE Acetabular Components after 10 Years of Implantation,” *Wear*, Vol 250, 2001, pp. 152–158.
- (6) Kurtz, S. M., Rimnac, C. M., Pruitt, L., Jewett, C. W., Goldberg, V., and Edidin, A. A., “The Relationship Between the Clinical Performance and Large Deformation Mechanical Behavior of Retrieved UHMWPE Tibial Inserts,” *Biomaterials*, Vol 21, 2000, pp. 283–91.
- (7) Edidin, A. A., Jewett, C. W., Kwarteng, K., Kalinowski, A., and Kurtz, S. M., “Degradation of Mechanical Behavior in UHMWPE after Natural and Accelerated Aging,” *Biomaterials*, Vol 21, 2000, pp. 1451–1460.
- (8) Edidin, A. A. and Kurtz, S. M., “The Influence of Mechanical Behavior on the Wear of Four Clinically Relevant Polymeric Biomaterials in a Hip Simulator,” *J. Arthroplasty*, Vol 15, 2000, pp. 321–331.
- (9) Giddings, V. L., Kurtz, S. M., Jewett, C. W., Foulds, J. R., and Edidin, A. A., “A Small Punch Test Technique for Characterizing the Elastic Modulus and Fracture Behavior of PMMA Bone Cement Used in Total Joint Replacement,” *Biomaterials*, Vol 22, 2001, pp. 1875–1881.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org). Permission rights to photocopy the standard may also be secured from the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, Tel: (978) 646-2600; <http://www.copyright.com/>