Designation: F1536 – 95 (Reapproved 2015)ε1

Standard Test Method for Determining Strength and Setting Time of Synthetic Water-Activated Polyurethane Fiberglass Orthopaedic Casting Tape[1]

This standard is issued under the fixed designation F1536; 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.

ε1 NOTE—Editorial corrections were made in June 2016.

1. Scope

1.1 This test method covers the functional diametral compression strength of cylindrical test specimens formed from synthetic fiberglass polyurethane casting materials. The test specimens employed in this test method are similar in geometry and construction to casts used in orthopaedic applications. This test method is not intended to determine the strength of the base materials used for fabrication of the test specimen.

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

1.3 *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.* Specific warning statements are given in 6.7.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Verification of Testing Machines

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *diametral compression strength*—the load per unit width in lbs/in. (Newtons/mm), calculated by dividing either the peak failure load or the maximum deflection load by the nominal sample length (that is, manufacturer's stated tape width).

3.1.2 *maximum deflection load*—the test cylinder is compressed 0.4 in. (10 mm) from the initial load position without noticeable failure or a measurable decrease in load. The load at 0.4 in. (10 mm) deflection shall be called the maximum deflection load.

3.1.3 *peak failure load*—failure of the test cylinder with a concomitant decrease in load prior to 0.4 in. (10 mm) diametral compression. The highest load attained prior to the decrease shall be called the peak failure load.

4. Summary of Test Method

4.1 A test cylinder is prepared by immersing the casting tape in 75 ± 2°F (23.9 ± 1.1°C) water, squeezing per the manufacturer's instructions under the surface of the water, and then wrapping around either a 2.0 in. (50.8 mm) or 2.5 in. (63.5 mm) outside diameter cylindrical mandrel. The tape is wrapped layer upon layer producing a five layer cylinder. The test cylinder is removed from the mandrel after an initial setting period. After a specified time, the test specimen is positioned on its side between two flat platens in the testing machine and compressed to determine its strength. Ambient temperature and humidity are specified because of their pronounced effect on material properties during the curing period.

5. Significance and Use

5.1 Diametral compression strength is an important measure of the mechanical properties of casting materials. This test method simulates the loading pattern seen in lower extremity casting applications during ambulation. This test method cannot be used to determine cast life or measure bending or other modes of cast failure.

5.2 This test method measures but does not prescribe values.

6. Apparatus

6.1 *Testing Machines*—Machines used for compression testing shall conform to the requirements of Practices E4. For

[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, 2015. Published July 2015. Originally approved in 1995. Last previous edition approved in 2010 as F1536 – 95 (2010). DOI: 10.1520/F1536-95R15E01.

[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.

universal machines with a common test space, calibration shall be performed in compression.

6.1.1 The surfaces of the flat platens shall be perpendicular to the loading axis and parallel at all times within 0.005 in./in. (1.3 mm/mm). Platen surfaces should be clean and free of corrosion.

6.1.2 The testing machine shall be capable of producing a constant compression rate between 1 to 10 in./min (25.4 to 254 mm/min).

6.1.3 The testing machine shall be capable of measuring the compressive load within ±0.5 lbs (2.2 N).

6.2 *Test Specimen Preparation Mandrel*—A solid, cylindrical aluminum mandrel of sufficient length to accommodate three test specimens without end contact shall be mounted in a horizontal position (see Fig. 1). Either of two mandrel diameters may be used: Type I—2.00 in. (50.8 mm) diameter, or Type II—2.50 in. (63.5 mm) diameter.

6.2.1 *Option*—Three individual mandrels, either Type I or Type II, each capable of holding one test specimen, may be substituted for a single, solid mandrel.

6.3 *Constant Tension Method*—Each layer of tape shall be wrapped on the mandrel at a constant tension of 0.25 lbs/in. (4.5 g/mm) width of tape. Suggested methods for accomplishing this include the use of a dead weight clamped to the free end of the tape while the horizontally mounted mandrel is manually rotated (see Fig. 1), or the use of an automated constant torque winding mechanism (see Fig. 2).

6.4 *Water Container*—A container capable of holding at least 1 gal (3.78 L) of water and of sufficient depth to allow complete immersion of the casting tape.

6.5 *Release Liner*—A sheet form liner of nominal thickness, such as waxed paper, shall be used to cover the mandrel and prevent adhesion of the resin to the mandrel. The liner shall allow release of the cured specimen from the mandrel with minimal force, and shall be easily removable from the specimen inner diameter prior to compression testing.

6.6 *Timer*—A timing device accurate to ±1 s.

6.7 *Gloves*—Gloves capable of protecting the hands from contact with the resin, for example, latex surgical gloves. (**Warning—**Contact with uncured or curing resins should be avoided. These resins may adhere to the skin and be difficult to remove. In addition, most polyurethane resins contain isocyanate to which some individuals are or may become sensitized. Gloves should be worn at all times when handling uncured or curing casting tape.)

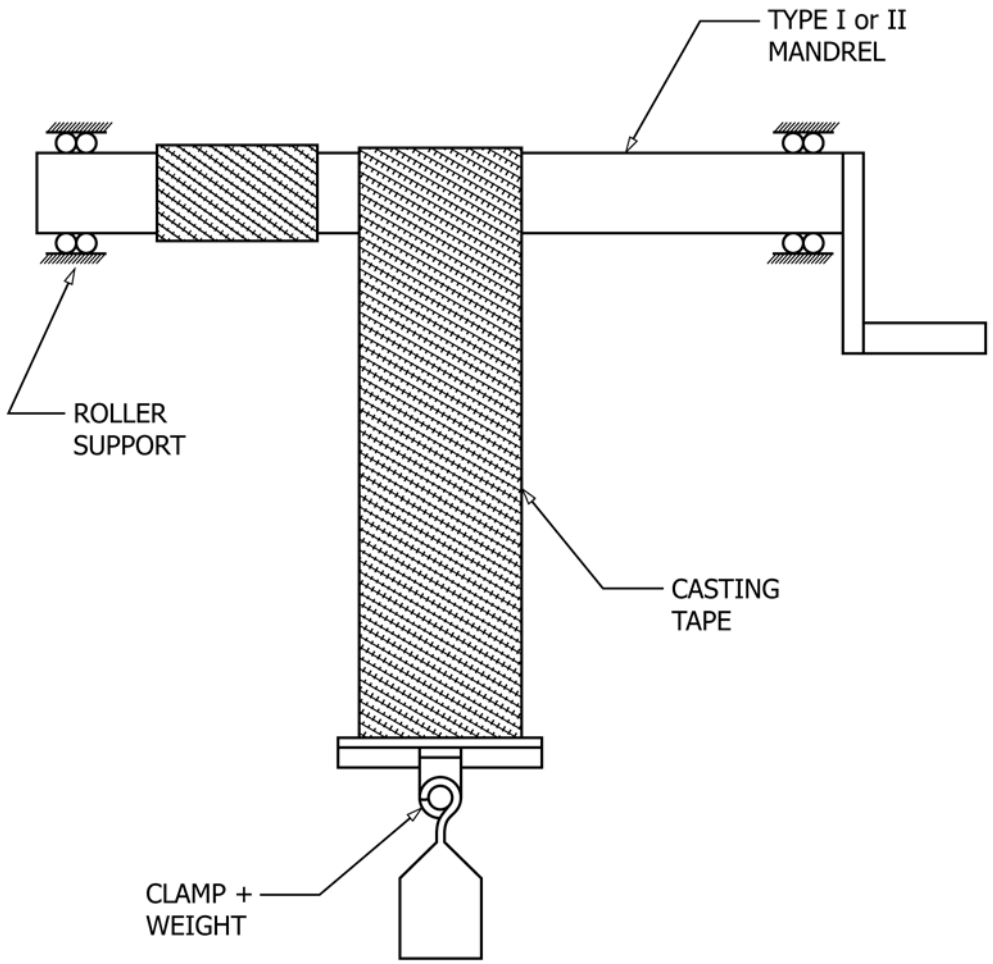

FIG. 1 Manual Preparation Method

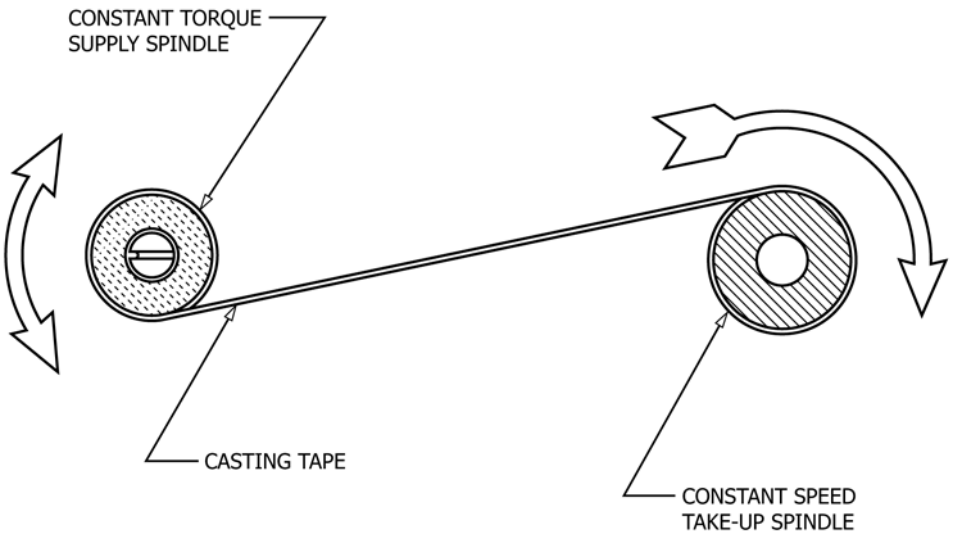

FIG. 2 Automated Constant Torque Preparation Method

6.8 *Thermometer*— A device capable of measuring temperatures within ±1°F (0.5°C) in the 70 to 80°F (21.1 to 26.7°C) range.

7. Reagents and Materials

7.1 At least three rolls of the casting tape shall be tested; one roll for each of the three specified time periods. Three test cylinders shall be prepared from each roll without the use of manual molding techniques.

NOTE 1—If testing of cylinders with the use of manual molding is desired, a secondary group of samples should be prepared using the desired molding technique.

7.2 Water for initiation of the curing process shall be maintained at 75 ± 2°F (23.9 ± 1.1°C).

7.2.1 The water shall be changed after three rolls have been prepared.

8. Sample Conditioning

8.1 Store each package flat, with each roll on its side, at 70 ± 5°F (21.1 ± 2.8°C) for at least 24 h before use.

8.2 Open each package immediately prior to use.

9. Specimen Preparation

9.1 Before opening each package, record the manufacturer's name, product description, size (width and length), and lot number.

9.2 Wrap the release liner around the test specimen preparation mandrel and secure with tape.

9.3 Open the package and loosely grasp roll with core perpendicular to fingers in palm of hand.

9.4 Start the timer, fully immerse roll in water and squeeze following manufacturer's instructions. Record immersion time and number of squeezes.

9.5 Remove the roll from the water and allow excess water to drain for not more than five seconds. DO NOT SQUEEZE to remove excess water.

9.6 Wrap a five-ply cylinder on the mandrel as rapidly as possible using constant tension (see Fig. 1 or Fig. 2). Each succeeding layer shall be aligned directly over the preceding layer with complete overlap. Cut the tape at the end of the fifth ply within ±¼ in. (6.4 mm) relative to the starting end of the first ply.

9.7 Immediately wrap a second five-ply cylinder as rapidly as possible by repeating 9.6.

9.8 Immediately wrap a third five-ply cylinder as rapidly as possible by repeating 9.6. Cut off excess tape.

9.9 *Molding*—Primary test samples should be prepared without the use of manual molding. If testing of samples with the use of manual molding is desired, a secondary group of samples should be prepared using the desired molding technique. Record the molding time and degree of manipulation used.

9.10 *Setting Time*—This is determined by a manual indentation test, that is, the time elapsed from the initial immersion until the test cylinder cannot be indented by moderate fingernail pressure. Begin indentation testing for material setting after all three samples from a single roll are wrapped. Repeat the test every 15 s until all samples are set. Record the three times and report the average as the *setting time*.

9.11 After the test cylinders have set, remove them from the mandrel taking care to avoid deforming them. Remove the release liner from the inside of the test cylinders.

9.12 Stand test specimens on end with enough space between samples to allow air to freely circulate between the cylinders.

10. Procedure

10.1 *Testing Speed*—The recommended constant crosshead (or actuator) speed shall be between 1 to 10 in./min (25.4 to 254 mm/min). Report the exact speed.

NOTE 2—Testing speeds outside the recommended range may be used provided that there are no demonstrable rate-dependent effects on the

material and that complete data capture is assured at higher rates.

10.2 *Load Range Selection*—Set the load range of the testing machine so that the maximum expected load is at least 20 % of the range selected.

10.3 *Thirty Minute Diametral Compression Strength*—This test is performed 30 ± 5 min after the time of initial immersion of the sample roll.

10.3.1 Place each specimen, one at a time, between the platens of the testing machine. Center the test cylinder on the lower platen, the platen being sufficiently large to support the specimen over its entire length. Orient the test cylinder so that the transition or overlap area, that is, where the first ply begins and the fifth ply ends, is in contact with either the upper or lower platen.

NOTE 3—The presence or absence of an overlap between the first and fifth ply affects the strength of the transition area, by either increasing or decreasing it from that of the surrounding area with a uniform number of plies. Since sample failure generally occurs in regions of high tensile stress on the free outer wall of the test cylinder, it is important that the overlap, or transition area, not be in the high tensile stress region.

10.3.2 Bring the platens together until they just touch the test cylinder, but no load has been applied.

10.3.3 Initiate the test at the prescribed rate. Continue the test at a uniform rate until the one of the following conditions occurs: either cylinder failure occurs or the maximum deflection is reached.

10.3.4 If the test cylinder has not set in 30 min, do not test for the 30 min diametral compression strength.

10.3.5 Record for each cylinder the maximum reading in pounds (Newtons), that is, the *peak failure load* or the *maximum deflection load*, whichever occurs first. The 30 min diametral compression strength is the average of the three values calculated from the readings.

10.4 *Sixty Minute Diametral Compression Strength*—This test is identical to the 30 min diametral compression test and is performed 60 ± 5 min after the time of initial immersion of the sample roll.

10.5 *Twenty-Four Hour Diametral Compression Strength*—This test is identical to the 30 and 60 min diametral compression tests and is performed 24 h ± 30 min after the time of initial immersion of the sample roll.

10.5.1 Maintain specimens for the 24 h diametral compression test at 75 ± 5°F (23.9 ± 2.8°C) and 50 ± 10 % relative humidity for the 24 h curing period.

11. Report

11.1 Report the following information:

11.1.1 *Product Identity*—Manufacturer, product description, product size (width and length) and manufacturing lot code;

11.1.2 *Initiation Data*—Total immersion time and number of squeezes used for initiation of polymerization;

11.1.3 *Set Time*—Average of the three measurements (in seconds);

11.1.4 *Constant Tension Method*—Manual or automated;

11.1.5 *Mandrel Type*—Type I or Type II;

11.1.6 *Testing Speed*—Report crosshead or (actuator) displacement rate as inch/min (mm/min);

11.1.7 *Diametral Compression Strengths*—Average of the three (3) calculated values for each roll tested at each time interval. Report the load type (*peak failure* or *maximum deflection*); and

11.1.8 *Molding*—Degree and duration of molding used on a secondary set of samples.

12. Precision and Bias

12.1 Precision and bias of this test method will be determined after interlaboratory tests are carried out and the results tabulated. The interlaboratory tests will be carried out following Practices E691.

13. Keywords

13.1 orthopaedic casting tape—diametral compression strength; orthopaedic casting tape—mechanical testing; orthopaedic casting tape—setting time; polyurethane—biomedical applications; polyurethane/fiberglass orthopaedic casting tape

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary purpose of this test method is to provide a standard method for determining the strength and setting time of synthetic water-activated polyurethane fiberglass orthopaedic casting tape. This includes sample preparation, testing procedure, and data reporting.

X1.2 Specimen preparation in this test method is not intended to duplicate all actual casting tape use. It is intended to produce uniform samples upon which mechanical testing may be performed with minimal variability.

X1.3 Wrapping by hand may produce samples in which there are variations in adhesion between layers, or along the sample width because of variations in wrapping tension. Sample-to-sample variation may also be increased when using manual methods. Therefore, samples should be prepared using a method that employs constant tension during wrapping of the plies (see Fig. 1 and Fig. 2).

X1.4 Manual molding of the casting tape, while an integral part of the normal cast application process, is extremely subjective, making standardization of this process difficult. Variations in molding pressure and molding time can greatly influence test results. Therefore, this test method provides for testing to be performed on a primary set of specimens prepared

without molding. Should it be desirable to quantify the effects of molding, a secondary set of samples should be prepared *with* a molding technique.

X1.5 The mandrel diameters (Type I and Type II) were selected based on the need to limit the number of possible diameters and still remain in a reasonable anatomic size range. Mandrel material has been limited to aluminum in order to maintain reasonable fixture mass, and to provide a material that was relatively corrosion-resistant. Because ferrous metals, non-ferrous metals, and polymers have intrinsically different masses and heat conduction coefficients, changes in materials or design (that is, solid versus hollow) could alter heat conduction between the mandrel and the curing tape. If the peak exothermic temperature or the curing temperature profile was affected in this manner, unpredictable changes in setting time and measured compression strengths could result.

X1.6 The testing procedure in this test method is not intended to replicate actual casting tape use, nor duplicate all failure modes. It is meant to provide a standard, repeatable test method for comparison of the relative strengths for various synthetic water-activated polyurethane fiberglass orthopaedic casting tapes. The prescription of tests at 30 min, 60 min and 24 h is intended to provide useful information regarding the curing profile for materials tested, and provide some objective measure of relative strengths for partially cured and fully cured casting tape samples.

X1.7 This test method is not intended to restrict the curing temperature regimes should alternate curing chemistries be developed.