Designation: F3014 – 14

Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures[1]

This standard is issued under the fixed designation F3014; 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.

INTRODUCTION

The purpose of this test method is to provide a common method for fixturing and measuring the penetration force of a surgical needle. Most surgical needles are coated to facilitate passage through tissue. This coating needs to be both lubricious and durable. The lubricity of the coating acts to lower the penetration force, while the durability of the coating maintains the needle's ability to pass through tissue multiple times with minimum increase in penetration force. It has been observed that, when a coating is found to be more lubricious, that coating is often less durable. Likewise, when a coating is found to be more durable, that coating is often less lubricious. Comparative measurements of lubricity and durability can provide an expectation of how the coated needle may perform during actual use. This standard does not presently address the testing medium. Test medium will be addressed in the next phase of this test method development. However, this test method does require certain medium characteristics to be identified.

1. Scope

1.1 This test method describes the procedure for penetration testing sharp and blunt needles used for the placement of surgical sutures. It only describes the test procedures (Phase 1) and does not define a test medium at this time. Test media will be address in the next phase (Phase 2) of this test method's evolution.

1.2 This test method applies to straight and curved surgical needles.

1.3 This test method does not intend to address the value of the test with respect to actual conditions of use.

1.4 In this test method, it is assumed the needles used for this test have passed all applicable quality standards and have no physical malformation that would inappropriately influence the test results.

1.5 This test method quantifies the force required for a needle to pass through a medium and its ability to do so multiple times.

1.6 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

1.7 *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:*[2]

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

F1840 Terminology for Surgical Suture Needles

3. Terminology

3.1 *Definitions*—Terms used in this test method are in accordance with Terminology F1840.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *compound curved surgical needle, n*—needle having more than one radius of curvature associated with the shape of the needle.

3.2.2 *needle test gripping location, n*—area in front of the attachment zone or tangent portion of the needle where the needle will be clamped/secured in the test fixture.

[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 F04.33 on Medical/Surgical Instruments.

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

3.2.2.1 *Discussion*—3.2.2 can be exempt for exceptionally small needles.

4. Summary of Test Method

4.1 Securely clamp the needle into the clamping fixture in a uniform area in front of the attachment zone or tangent portion of the needle, distal to the needle point. This is referred to as the needle test gripping location, such that the needle movement is restricted.

4.1.1 The needle shall be held so that the needle passes through the medium perpendicular to the test medium.

4.2 The clamping fixture is rotated forward to commence passing the needle through the media according to Table 1 or Table 2, as applicable.

4.3 As the needle penetrates and passes through the medium at 90°, data about the force needed to penetrate the medium is continuously collected.

5. Significance and Use

5.1 This test method provides a means of assessing the penetration force of a surgical needle through the chosen media.

5.2 The needle is passed through a chosen medium at a chosen speed and path which applies a force on the load cell that reflects the needle's resistance to penetration as a function of its shape and coating.

6. Apparatus

NOTE 1—Two methods of testing are possible for curved surgical needles—rotational, based on the rotational speed of the sample, and linear, based on the linear speed of the sample. Either method may be used. The method selected shall be indicated in any use of the data generated. The data generated by these methods cannot be compared to each other. Only like method comparisons shall be made.

6.1 *Clamping Fixture*—A device to clamp the surgical needle firmly.

6.2 *Data Collection System*—The data shall be collected as a function of force.

6.3 *Rotational Speed for a Curved Surgical Needle*—The needle-clamping fixture shall be rotated at a continuous and constant speed of 4° ± 2°/s.

6.4 *Linear Speed for a Straight Surgical Needle*—The needle-clamping fixture shall move at a continuous and constant speed. The minimum speed shall be 10.0 cm/min (4 in./min). The maximum speed shall be 30.5 cm/min (12 in./min) unless a greater test speed is required as a function of use.

TABLE 1 Curved Surgical Needle Testing Ranges

Needle Curvature	Equivalent Range (°)	Approximate Rotation (°)
1/4	70 to 115	45
3/8	116 to 155	45
1/2	156 to 200	60[A]
5/8	201 to 245	60[A]

[A] Less than 60° of rotation is acceptable provided that the entire point and a portion of the full body diameter have fully passed through the medium.

TABLE 2 Straight Surgical Needle Testing Ranges

Overall Needle Length	Approximate Percent Length of Testing (before Cutting, if Applicable)
5 to 152 mm	30
153 mm and longer	30

6.5 *Linear Speed for a Curved Surgical Needle*—The needle-clamping fixture shall move at a continuous and constant speed. The minimum speed shall be 10.0 cm/min (4 in./min). The maximum speed shall be 30.5 cm/min (12 in./min).

6.5.1 Speed can be set to address a special use of the needle.

7. Sampling

7.1 There should be a minimum of ten penetrations per needle. However, the actual number of penetrations may be more to reflect intended use.

7.2 For statistical purposes, a minimum of 30 needles is recommended.

8. Procedure

NOTE 2—Accurate fixturing is important. The greater the number of degrees the needle is tested through, the greater the chance for a fixturing error to be introduced to the test.

8.1 *Curved Surgical Needle:*

8.1.1 The needle shall be clamped in a uniform area in front of the attachment zone or tangent portion of the needle, distal to the needle point.

8.1.2 Always check the needle before and after each penetration to ensure the needle has not moved in the fixture and is properly positioned.

8.1.3 The portion of the needle that is behind the fixture, or the point at which the needle is held may be cut to avoid the needle hitting the test medium. This would be necessary for 5/8 circle needles or a needle with a very large radius (see Fig. 1).

8.1.4 The needle shall pass through a test medium at a uniform speed such that the needle passes through the medium according to Table 1.

8.1.4.1 Refer to Table 1 for testing ranges.

8.1.5 The needle shall penetrate the medium, at minimum, to the values listed in Table 1 as long as the value contains the full body diameter of the needle. Refer to Fig. 2.

8.1.6 The needle shall pass through the test media such that the needle's major axis is followed throughout the test.

8.1.7 Upon completion of the penetration pass, move the needle or the medium to an unpenetrated surface before initiating the next penetration test. This distance should be at minimum twice the wire diameter of the test sample.

NOTE 3—Each penetration performed shall be in an unadulterated portion of the test medium. If a needle does pass through a hole made by a previous penetration, that needle shall be discarded along with the test findings and noted accordingly.

8.2 *Straight Surgical Needle:*

8.2.1 The needle shall be clamped in a uniform area in front of the attachment zone.

8.2.2 The needle shall pass through a test medium at a uniform speed.

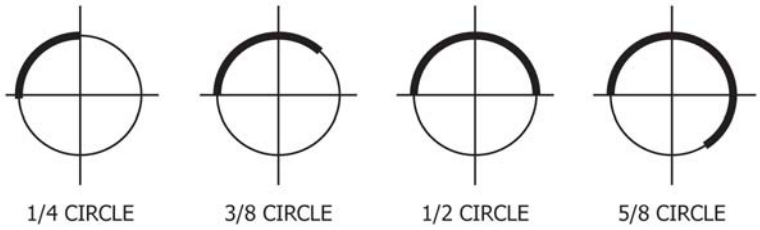

FIG. 1 Representation of Degrees of Curvature

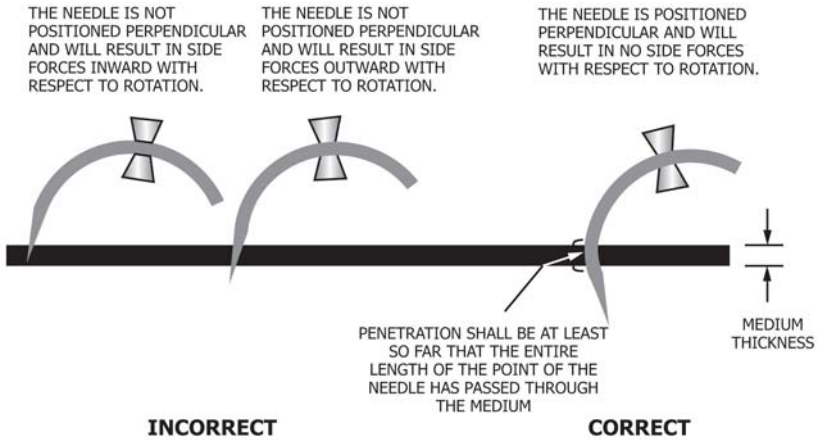

FIG. 2 Correct Penetration

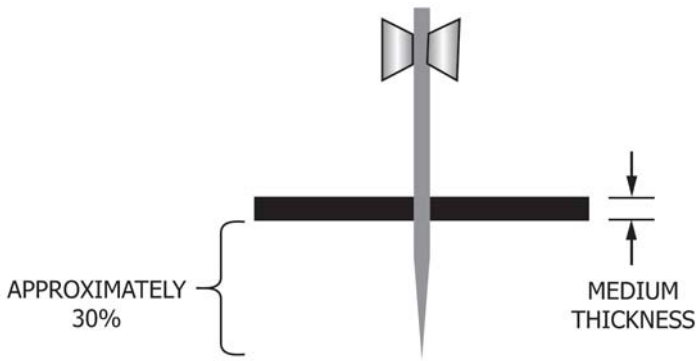

FIG. 3 Straight Needle Penetration

8.2.3 The needle should penetrate the medium, at minimum, to the values listed in Table 2 as long as the value is, as a minimum, equal to the body diameter of the needle. Refer to Fig. 3.

8.2.4 The needle shall be perpendicular to the surface of the medium throughout the test.

NOTE 4—The needle may be reduced in length to accommodate the test equipment as long as the reduction allows for full body testing of the needle.

8.2.5 Upon completion of the penetration pass, move the needle or medium to an unpenetrated portion of the medium before initiating the next penetration.

NOTE 5—Each penetration performed shall be in an unadulterated portion of the test medium. If a needle does pass through a hole made by a previous penetration, that needle shall be discarded along with the test findings and noted accordingly.

8.3 *Compound Curved Surgical Needle*—It is acceptable to test only the primary curve on multiple curved needles. This is typically the curve associated with the point.

8.4 *Test Medium*—The medium shall be held firmly and supported sufficiently to minimize deflection (tenting).

8.5 *Test Fixture:*

8.5.1 The aperture underneath the area of penetration may range between 3 and 19 mm (0.120 and 0.750 in.) in diameter or dimension. The aperture opening beneath the medium shall be designed to minimize or control tenting of the medium during testing.

8.5.2 A smaller needle-clamping fixture may be necessary to allow for smaller needles to be tested. This may be necessary as the fixture for large needles may be too large or distort the

needle's curvature, thus requiring a smaller needle holder, which would require a smaller medium holder.

8.6 *Data Acquisition*—Data acquisition should be a minimum of 150 Hz for data collection.

8.7 *Environment:*

8.7.1 *Room temperature,* 22 ± 2°C.

8.7.2 *Relative humidity,* ≤70 %.

9. Calculation

9.1 Data shall be reported as force in Newtons. Grams-force may be used as an alternative measure if it is deemed appropriate for the needle being tested.

10. Report

10.1 Include the following information:

10.1.1 Sample identification, test conditions, and apparatus;

10.1.2 Test medium and lot number, if applicable;

10.1.3 Maximum force per complete penetration;

10.1.4 Average force for each penetration or pass, if testing multiple needles;

10.1.5 Maximum and minimum force (that is, the range of force) for each penetration repetition, if testing multiple needles;

10.1.6 Test date and test technician;

10.1.7 Test speed and test approach (linear or rotational); and

10.1.8 Medium thickness.

11. Precision and Bias

11.1 *Precision*—The precision of the results of this test method is dependent on the equipment selected.

11.2 *Bias*—No standard material has been selected for reference; therefore, bias for this test method cannot be determined.

12. Keywords

12.1 curved surgical needle force; load cell; needle; penetration; speed; straight surgical needle; suture