Designation: EASSI Standard Test Method for Penetration Testing of Needles Used With Surgical Sutures

INTRODUCTION

The purpose of this test method is to provide a common method for measuring the penetration force of a surgical suture needle.

1. Scope

1.1 This test method describes the procedure for penetration testing surgical needles. It also describes the test procedures.

1.2 This test method applies to surgical suture 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.

2. Summary of Test Method

2.1 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 unintended needle movement is restricted.

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

2.3 The clamping fixture is rotated to pass the needle through the medium.

2.4 As the needle penetrates the medium, data about the force needed to penetrate the medium is continuously collected.

3. Significance and Use

3.1 This test method provides a means of assessing the penetration force of a surgical needle through a chosen medium (e.g. material such as Porvair, Permair, EPDM, synthetic rubber, etc. of recommended thickness 0.4mm - 1.5mm).

3.2 The needle is passed through a chosen medium at specified speed and path. This applies a force on the load cell that corresponds to the needle's resistance to penetration as a function of needle shape and coating (if any).

4. Apparatus

NOTE 1: Two methods of testing are possible for surgical needles: rotational (based on the rotational speed of the curved needle sample) and linear (based on the linear speed of the straight needle sample). The method selected shall be indicated in any use of the data generated. The data generated by these two methods cannot be compared to each other; only like-method comparisons shall be made.

4.1 *Clamping Fixture:* A device to clamp the surgical needle firmly.

4.2 *Data Collection System:* A system to collect the data as a function of force.

4.3 *Linear speed:* 305 mm/minute is recommended. Other machine speeds (such as 50 to 100 mm/minute depending on needle length) are acceptable provided they have been appropriately validated.

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

5. Procedure

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

Curved or Straight Surgical Needle:

5.1 The needle shall be clamped in a uniform area in front of the attachment zone, distal to the needle point.

5.2 Always check the needle before and after each penetration to ensure the needle has not moved in the fixture and is properly positioned, perpendicular to the test medium.

5.3 The portion of the needle that extends beyond the fixture, or beyond the needle test gripping location, may be removed to avoid the end of the needle hitting the test medium. This may be necessary for 5/8 circle needles or needles with a large radius.

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

5.5 The needle shall penetrate and pass through the medium perpendicular to the medium.

5.6 The force values obtained must include testing of the needle to its full body diameter (i.e., beyond the tip geometry). The maximum peak force from the test is recorded.

5.7 The needle shall pass through the test medium such that the needle's major axis of curvature is followed throughout the test.

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

NOTE 3: Each penetration pass shall be performed in an unadulterated portion of the test medium. If a needle passes through a hole made by a previous penetration or is interfered with by a previous test ole, that needle shall be discarded along with the test findings and recorded accordingly.

Test Medium Support - The medium shall be held firmly and supported sufficiently at its perimeter to minimize unintended deflection (tenting) as a function of inadequate support.

Test Fixture - The aperture underneath the area of

penetration may range between 3 and 19 mm in diameter or dimension. The aperture opening beneath the medium shall be designed to minimize unintended deflection (tenting) of the medium during testing.

A smaller needle-clamping fixture may be needed to test smaller needles. The fixture for large needles may be too large or may distort the smaller needle's curvature, thus requiring a smaller needle holder, which would require a smaller medium holder.

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

Environment: (recommended)

- Room temperature 22°C ±2°C.
- Relative humidity ≤70 %

6. Calculation

Data shall be reported as force in Newtons. Grams-force may be used as an alternative unit of measure.

7. Sampling

Acceptable Quality Level (AQL): sampling plans should be developed based upon the product performance needs, process capability, and risk management. For statistical purposes, a minimum of 30 needles is recommended.

8. Report

All data should be reported, including the following information:

8.1 Sample identification, test conditions, and apparatus;

8.2 Test medium and lot number, if applicable;

8.3 Medium thickness.

8.4 Maximum force per complete penetration;

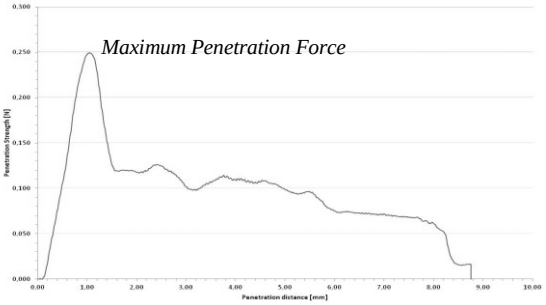
8.5 Average force for each penetration or pass, if testing multiple needles;

8.6 Maximum and minimum force (that is, the range of force) for each penetration repetition (e.g. 10 times), if testing multiple penetration passes;

8.7 Test date and test technician;

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

8.9 Test equipment identification, and calibration date and expiry date**.**



9. Precision and Bias

9.1 *Precision* - The precision of the results of this test method is dependent on the test equipment and the medium.

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

10. Keywords

Surgical needle penetration force; load cell; needle; penetration; test speed

FIG. 1 Penetration for straight and curved needle