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

1. Scope
This test method describes the procedure for bend testing standard needles used for the placement of surgical sutures. Micro-needles are not in scope of this test method.

2. Summary of Test Method
Surgical needles are grasped approximately two-thirds of the distance from the point of the needle. The force deflection data obtained from the test is used to calculate the yield bend moment and the maximum bend moment. Further, (reshape) ductility may be assessed.

3. Significance and Use
3.1 This test method provides a means of assessing the yield moment, bend strength, and reshape ductility of a surgical suture needle.
3.2 The first characteristic measured is the torque applied to the needle to bend the needle to 90°. This quantifies how easily the needle bends or breaks.
3.3 The second characteristic measured is the needle's ability to withstand repeated bending movements before breaking (i.e. reshape ductility)
3.4 The needle is bent at the approximate locations where a pair of needle holders would grip it. This simulates the actual bending of a needle while in surgical use.

4. Apparatus
4.1 The torque measurement machine: to bend a straight or curved needle from 0 to 90 degrees. In addition of measuring the torque, this machine may record the number of cycles (backward and forward movement) before the needle breaks. The clamp must be fitted with a radius placed close to the rotating axis. For curved needles, the angle of the needle must be opened up to 90°.
The closed clamp (without needle) must be placed on the rotating axis of the clamp.
The edges of the clamp are rounded off.
4.2 Bending machine parameters

- Torque measurement accuracy: 0,1 N-cm
- Bending angle: 90° ± 1°
- Rotating speed (recommended): 5°/s ± 1°/s (in 1st cycle of 90°) and 25°/s ± 1°/s (in successive cycles of 90° until the breakage of the needle)*

(*) As a guideline:
If these values are not used, parameters have to be repeatable as documented by the testing facility.

OR:
4.3 Clamping Fixture: a device to firmly clamp and rotate the needle.
4.4 Bending Platform: the surface on which the curved needle will exert force during the test. The bending platform will have its top surface located along the horizontal axis of the center of rotation of the clamping fixture.
4.5 Knife Edge: The knife edge will be placed parallel to the centerline of rotation to provide a single point of contact for reading the torque generated by the needle.
4.6 Data Collection System: A system to collect the data as a function of the rotational speed.
4.7 Rotational Speed: The clamping fixture must be rotated at a continuous and constant speed. This speed is recommended to be less than 30°/s.

OR:
4.8 Manual reshape ductility measurement is conducted with surgical needle drivers to simulate the type of abuse encountered in surgery.

5. Procedure (see Fig. 1)
5.1 Place the needle into the clamp. The needle must be held by the end of the needle, but just before the attachment area.
5.2 Put the clamp in a position where the needle is placed between the two fingers without applying a force on them.
5.3 For curved needles, orient the needle such that the needle is bent less than its own curve.
5.4 Apply the load to start the test. Continue applying load until the needle is bent 90 degrees. Then reverse load until the test machine returns to its original (0 degree) position. Repeat the cyclic loading until the needle breaks.
5.5 The test ends when the needle is broken. Needle breakage is detected by the machine. The needle is considered broken even if the two parts are not completely separated.
5.6 Record this maximum value of torque and the accumulated degrees to break the needle (ductility) (Fig. 2). Ductility may also be assessed as the number of reshapes.

OR:
5.7 Securely clamp the needle into the clamping fixture at a position approximately two-thirds of the distance back from the tip of the needle.
5.8 Rotate the clamping fixture forward until the needle touches the bending platform or knife edge. Continue rotating the clamping fixture through a sufficient angle to generate the required data. While the needle is bending, collect the bending force data as a function of the bend angle.
5.9 Needle should exhibit enough ductility to resist fracture during the course of this test.

OR:

Alternate method to manually assess reshape ductility:

5.10 Secure the needle into the tip of the forceps at the point of bend (Fig. 3). The needle should be positioned as close to the tip of the forceps as possible such that the jaws do not flex when bending the needle. Bend the needle to at least 90 degrees.

5.11 Using a soft piece of leather or other protective medium, put pressure on the back of the needle and push forward with the index finger to reshape to original outline, being careful to reach but not exceed the original curvature. Stop test and visually confirm that full reshape has been achieved. While the needle is still in the forceps, place thumb (protected by leather) inside the radius and re-bend to the same angle imparted during the bend test (Fig. 4).

5.12 Repeat cyclic bending and unbending until the needle fails. The number of bend and unbend cycles assess the reshape ductility. Needles should exhibit a Reshape Ductility Value of at least 0,5 (bending) and preferably 1,0 (a full cycle of one bend and one unbend) or greater.

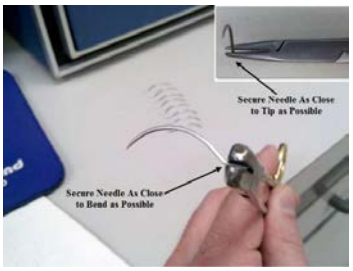


FIG 3. Holding the needle for Manual Reshape Ductility Test

NOTE: Each time the needle is bend 90 degrees, the Reshape Value is increased by 0,5 Reshapes.

FIG 4. Grasping the needle for manual reshape.

Definition of Reshape Ductility Value:

- Needle breaks before being bent 90 degrees from original shape: 0 or “break”
- Needle bent 90 degrees from original shape: 0,5
- Needle bent back to original shape: l,0
- Needle bent to 90 degrees again: l,5
- Needle bent to original shape again: 2,0

If the needle breaks during the initial bending, it is considered a "break" for the ductility evaluation and a value of zero is recorded as Reshape Value for that needle. If the needle breaks during the its first return from 90 degrees, it is called "0,5" Reshape Value. Record Reshape Value for each needle tested.

6. Calculation (see Fig. 2)

6.1 Data will be reported as a moment versus degrees of rotation and additional parameters if needed (number of re-shapes, maximum bend moment, etc.). Units will be reported.

6.2 *Yield Bend Moment:* Using the graph obtained during the needle bend test, calculate the initial slope of the graph. Draw a line with the same slope through the 2° offset on the degree axis. Read the bending moment at the point where the 2° offset slope crosses the data line. This is the yield bend moment.

6.3 *Yield Bend Angle:* Read the angle at the point where the 2° offset slope line crosses the data line.

6.4 *Maximum Bend Moment:* The maximum bend moment is the maximum bending moment achieved by the needle during the bend test.

6.5 *Reshape Ductility Value:* see Section 6.12.

7. Sampling

Acceptable Quality Level (AQL): sampling plans should be developed based upon the product performance needs, process risk, and risk management. A sample size of no less than five needles shall be used.

8. Report

8.1 All data should be reported, including the following information:

8.1.1 Sample identification, test conditions, apparatus.

8.1.2 Test date and test technician.

8.2 Additional data may be reported as required:

8.2.1 Yield bend moment,

8.2.2 Maximum bend moment (angle at which it was achieved should be reported),

8.2.3 Yield bend angle,

8.2.4 Ductility,

8.2.5 Reshape Ductility Value.

9. Precision and Bias

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

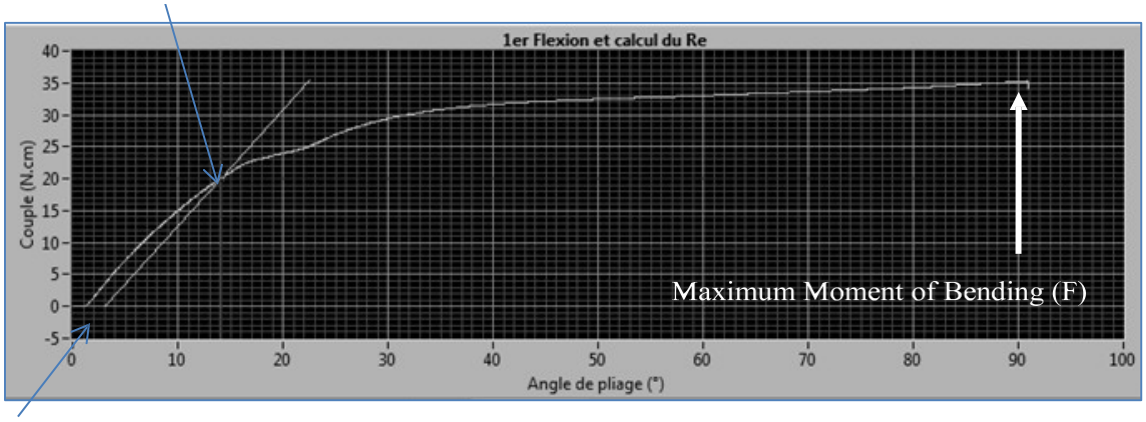
9.3 *Bias*—No standard material has been selected for reference; therefore, bias for this test method cannot be determined.

10. Keywords

Suture needle bend test; needle yield moment; needle bend strength; needle reshape ductility; needle; strength

FIG 1. Bend Test Sample

Yield Bend Moment



2°
Offset

FIG. 2 Bend Test Data Curve
Bending Force as a function of bending angle.

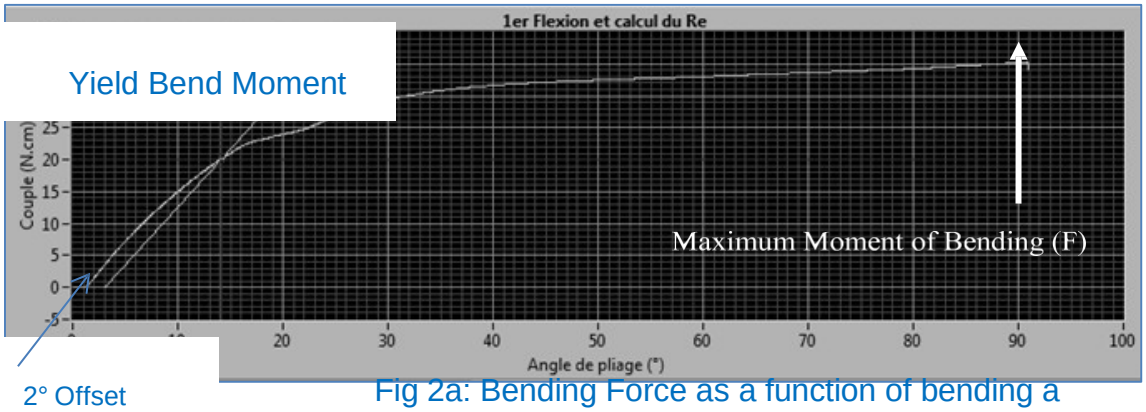


Fig 2a: Bending Force as a function of bending angle.

Needle breakage

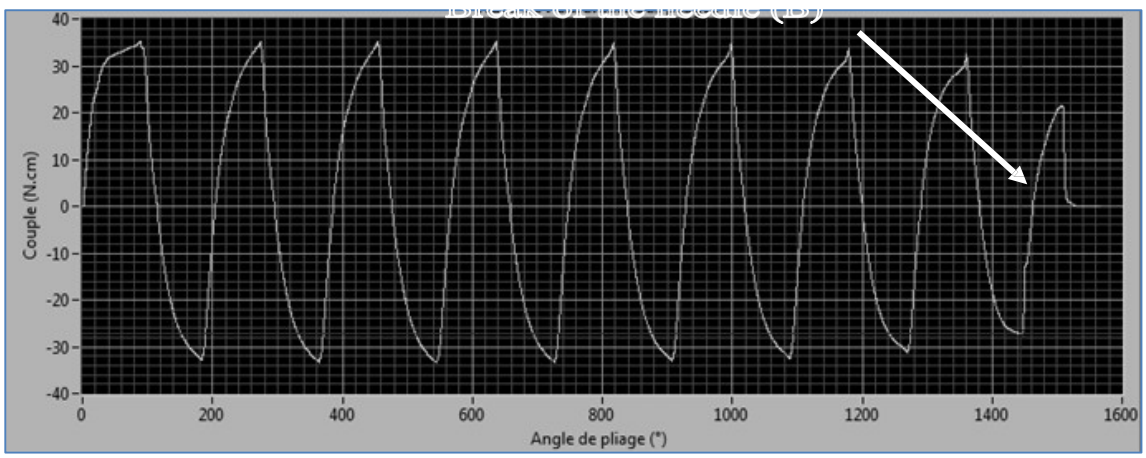


Fig 2b: Number of bending cycles till the needle breaks.