INTERNATIONAL STANDARD

ISO 9585

First edition
1990-12-15

Implants for surgery — Determination of bending strength and stiffness of bone plates

Implants chirurgicaux — Détermination de la résistance au pliage et de la rigidité des plaques pour os

Reference number
ISO 9585:1990(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9585 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

INTERNATIONAL STANDARD ISO 9585:1990(E)

Implants for surgery — Determination of bending strength and stiffness of bone plates

1 Scope

This International Standard describes a test method for determining the bending strength and stiffness of straight bone plates. It may also be used to test plates having a small initial curvature intended to produce pre-loading of the bone when fitted and to test the straight portion of angled plates. This test method is not recommended for plates of length less than 50 mm nor for plates designed to be used with, or forming parts of, intramedullary devices.

NOTE 1 A test method for plates of length less than 50 mm is in preparation.

2 Definitions

For the purposes of this International Standard, the following definitions apply.

2.1 moment: Turning effect of a force about an axis, expressed numerically by the product of the force F and the distance h measured perpendicularly from the axis to the line of action of the force.

Unit: N·m

2.2 bending moment, M_b: Moment acting about an axis perpendicular to the long axis of a body and generally producing lateral deflection.

Unit: N·m

2.3 deflection: Linear displacement due to bending measured perpendicular to the original axis of the plate.

Unit: m

2.4 bending strength: Value of the bending moment at fracture, or at a specified proof point, whichever is the lower.

Unit: N·m

2.5 equivalent bending stiffness: Stiffness of the plate calculated from the dimensions of the test configuration and the slope S of the linear part of the load/deflection diagram defined by the mechanical test.

Unit: N·m²

NOTE 2 This equivalent bending stiffness takes account of the holes or slots in the plate.

3 Apparatus

3.1 Test rig, to produce a loading system in accordance with figure 1, the four rollers (indicated by hatched circles) being so constrained that their axes remain parallel.

3.2 Rollers, of cylindrical form and of equal diameters within the range of 8 mm to 13 mm, or of profiled form corresponding to the cross-section of the plate to be tested, and having a mean diameter within the range 8 mm to 13 mm. It is desirable that one of the rollers be secured to the specimen to restrain longitudinal movement and that all rollers are secured to maintain their relative position.

3.3 Means of applying forces, e.g. a mechanical testing machine.

3.4 Device(s), for measurement of relative displacement(s).

4 Procedure

4.1 General

Conduct bending tests using the apparatus specified in clause 3. Use the cylindrical rollers to test flat plates and plates of curved cross-section, in which the deviation from flatness at the centre of the plate does not exceed $b/6$, where b is the width of the plate. Test other plates using rollers of suitable profile.

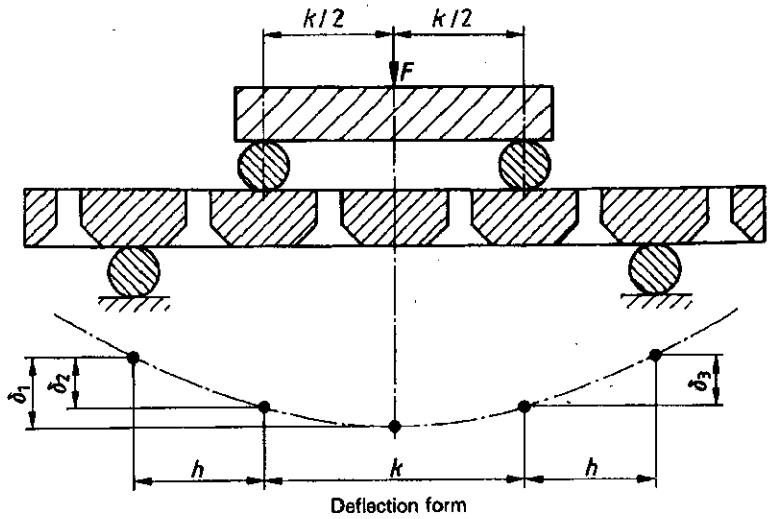

Figure 1 — General arrangement of four-point bend test

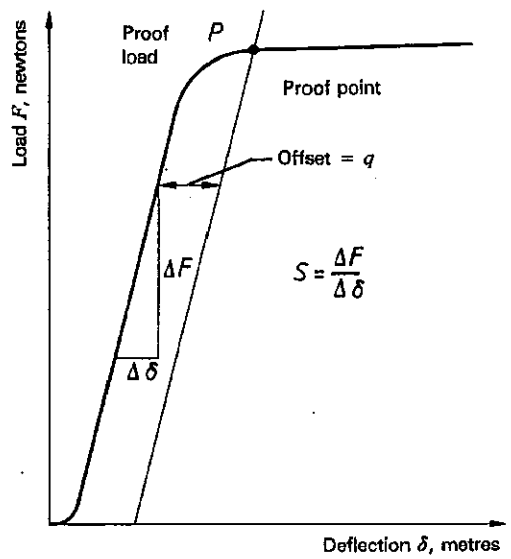

Figure 2 — Load deflection diagram

Calculate q from the expression:

$$q = 0{,}02(2h + k)$$

Calculate the bending strength, in newton metres, from the expression:

$$\text{Bending strength} = 0{,}5Ph$$

where

P is the proof load in newtons;

h is the distance between inner and outer rollers, in metres.

If fracture of the plate occurs before the load/deflection curve intersects the offset line, calculate the bending strength, in newton metres, from the expression:

$$\text{Bending strength} = 0{,}4F_{max} \times h$$

where

F_{max} is the maximum load, in newtons;

h is the distance between inner and outer rollers, in metres.

NOTE 3 This expression uses an equivalent proof load, equal to 0,8 times the maximum load.

6 Test report

The test report shall include the following information:

a) the bending strength, in newton metres;

b) the offset q, in metres, used to determine the proof point;

c) the equivalent bending stiffness, in newton metres squared, calculated from equation 1 or 2 as appropriate;

d) if the plate fractures before the proof deflection is attained, this shall be recorded;

e) the identity of the plate, e.g. type, length in millimetres, manufacturer's catalogue number and batch number, as supplied by the party requesting the test.