INTERNATIONAL STANDARD

ISO 19213

First edition
2017-07

Implants for surgery — Test methods of material for use as a cortical bone model

Implants chirurgicaux — Méthodes d'essai des matériaux destinés à servir de modèle d'os cortical

Reference number
ISO 19213:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

Introduction

This document details requirements for a set of mechanical test methods to evaluate material used as a cortical bone model. Bone models have long been used in mechanical tests for devices or instruments such as those used in the orthopaedic surgery. The characteristics of the bone model, especially those of a cortical bone model, strongly influence the test results. Many devices and instruments are evaluated using bone models.

Newer bone models are needed because conventional bone model properties change the primary outcome of interest such as failure mode. This results in devices not being evaluated correctly. Animal bones such as those from pigs are still used. However, animal bones have many sanitary problems and can introduce large errors (standard deviation). Recently, several new bone models have been introduced and standardized methods for evaluating these materials are required.

This document introduces applicable standardized mechanical test methods for characterizing the material properties of cortical bone models. The mechanical properties of the cortical bone itself such as tensile strength and compressive strength have been measured for some time, and several models have been produced based on the results. However, these fundamental mechanical properties do not strictly conform to the tactile feedback experienced by physicians. Material models have differences in tensile, compressive and shear strengths properties since they do not reproduce the complex anisotropic bone structure. For example, a material can be an excellent bone model based on tensile strength, but have significant differences in compressive and shear strengths. Therefore, the model needs to be specific for the application to match the material properties as needed. This is because many kinds of fundamental properties are related in practical uses. Then, it is also necessary to perform practical tests of the bone model using devices and to show relationships of mechanical characteristics between from fundamental tests and from practical tests.

This document shows the relations and covers test methods for fundamental and practical tests. The final goal of this document is to facilitate the availability of good medical devices and instruments to patients. The mechanical properties under practical tests can also be useful to produce models of training and lectures of new devices, informed consent for patients and performances of pre-operation or surgical planning.

Implants for surgery — Test methods of material for use as a cortical bone model

1 Scope

This document specifies mechanical test methods for characterizing cortical bone model materials for use as a standard model for performing mechanical tests for devices or instruments used in orthopaedic surgery, plastic surgery, neurosurgery, and oral and maxillofacial surgery.

The document specifies static mechanical test and properties. Dynamic and viscoelastic/poroelastic tests and properties are not included in the scope of this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitute requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 179 (all parts), *Plastics — Determination of Charpy impact properties*

ISO 180, *Plastics — Determination of Izod impact strength*

ISO 291, *Plastics — Standard atmospheres for conditioning and testing*

ISO 527 (all parts), *Plastics — Determination of tensile properties*

ISO 604, *Plastics — Determination of compressive properties*

ISO 2039-2, *Plastics — Determination of hardness — Part 2: Rockwell hardness*

ISO 2602, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machine — Calibration and verification of the force-measuring system*

ISO 18397, *Dentistry — Powered scaler*

ASTM D256, *Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics*

ASTM D638, *Standard Test Method for Tensile Properties of Plastics*

ASTM D695, *Standard Test Method for Compressive Properties of Rigid Plastics*

ASTM F543-07, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

JIS T 5750, *Dentistry — Dental Handpieces — Ultrasonic Instruments And Tips For Multi-purpose Treatment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
cortical bone model
material with the mechanical characteristics of cortical bone for performing mechanical tests for devices or instruments used in orthopaedic surgery, plastic surgery, neurosurgery, and oral and maxillofacial surgery

4 Selection of test method

4.1 General

Mechanical test methods to evaluate cortical bone model materials are selected from tests for compressive strength, tensile strength, shear strength, hardness, Charpy and Izod impact, pull-out strength, strengths using ultrasonic or acoustic methods and drilling.

Annex A provides rationale on the relation of the test methods in this document to the properties that will affect the mechanical properties cortical bone model materials.

4.2 Fundamental tests

Shear strength, compressive strength, hardness tests, and Charpy and Izod impact can be performed using conventional ISO or ASTM methods, as described in Clauses 5 to 8. In the case of ductile materials, tensile strength measurements can be performed using ISO 527 (Clause 6). However, the Diametral Tensile Strength (DTS) test (Clause 10) is useful in the case of a cortical bone because cortical bone behaves more like a brittle material than a ductile material.

4.3 Practical tests

Pull-out strength and strengths using ultrasonic or acoustic methods and drilling shall be performed using test methods described in Clause 9 and Clause 12.

5 Compressive test

The compressive test is performed as specified in ISO 604 or ASTM D695.

6 Tensile test

The tensile test is performed as specified in ISO 527 or ASTM D638.

7 Hardness test

The hardness test is performed as specified in ISO 2039-2.

8 Charpy and Izod impact tests

The Charpy impact test is performed as specified in ISO 179, and the Izod impact test is performed as specified in ISO 180 or ASTM D256.

9 Torque and axial pull-out test

The test for bone screw torque and determination of axial pull-out strength of a bone screw is performed as specified in ASTM F543-07.

10 Diametral Tensile Strength (DTS) test

NOTE The Diametral tensile strength (DTS) is also called Brazilian test, Splitting Tensile Strength or Diametral compression of a disc, originally established for testing of concrete, according to the ISO 1920 series.

10.1 Materials and apparatus

10.1.1 Compression testing machine

The compression testing machine, calibrated according to ISO 7500-1, shall be capable of applying and recording an axial compressive force to the head/neck assembly, with an accuracy of ±1 %.

The test machine shall be capable of maintaining a test speed of (0,5 ± 0,1) mm/min.

The test machine load indicator shall incorporate a mechanism capable of showing the total compressive force sustained by the test specimen.

10.1.2 Compression tool

Hardened-steel compression plates for applying the deformation load to the test specimen constructed so that the load sustained by the test specimen is axial to within 1:1 000 and is transmitted through polished surfaces which are flat to within 0,025 mm parallel to each other and perpendicular to the loading axis.

10.1.3 Measuring instrument

The dimensions and shape of the anvils shall be suitable for the specimens being tested and shall not exert a force on the test specimen such as to detectably alter the dimension being measured.

A micrometer, or other appropriate instrument, capable of reading to 0,01 mm or better shall be used to measure the axial length and the diameter.

The dimensions and shape of the anvils shall be suitable for the specimens being tested and shall not exert a force on the test specimen such as to detectably alter the dimension being measured.

10.2 Test specimen

10.2.1 Shape and dimensions

The test specimen shall be in the shape of a cylinder.

The preferred dimensions for test specimens are 12 mm in axial length and 6 mm in diameter.

NOTE These dimensions were selected as the preferred dimensions because of the typical geometry of cortical bones.

The axial length of the test specimen shall be at least twice the diameter of the test specimen to meet the assumptions of the DTS test method.

10.2.2 Specimen inspection

The test specimens shall be checked for conformity with these requirements by visual observation against straight edges, circles and flat plates and by measuring with micrometer callipers.

Test specimens showing measurable or observable departure from one or more of these requirements in 10.2.1 shall be rejected or machined to proper size and shape before testing.

10.3 Anisotropic materials

In the case of anisotropic materials, the test specimens shall be chosen so that the compressive stress will be applied in the test procedure in the same or a similar direction to that experienced by the products during service in the intended application, if known.

The relationship between the dimensions of the test specimen and the size of the product will determine the possibility of using preferred test specimens.

10.4 Number of test specimens

Test at least 10 specimens for each sample in the case of isotropic materials.

Test at least 10 specimens, 10 normal to and 10 parallel to the principal axis of anisotropy, for each sample in the case of anisotropic materials.

Test specimens that break at some obvious flaw shall be discarded and replacement specimens shall be tested.

10.5 Test procedure

10.5.1 Test specimen

10.5.1.1 Dimension measurement

Measure the axial length and diameter of each test specimen at three points and calculate and register the mean value of the cross-sectional area.

Measure the axial length and the diameter of each test specimen to 1 % accuracy.

10.5.1.2 Conditioning

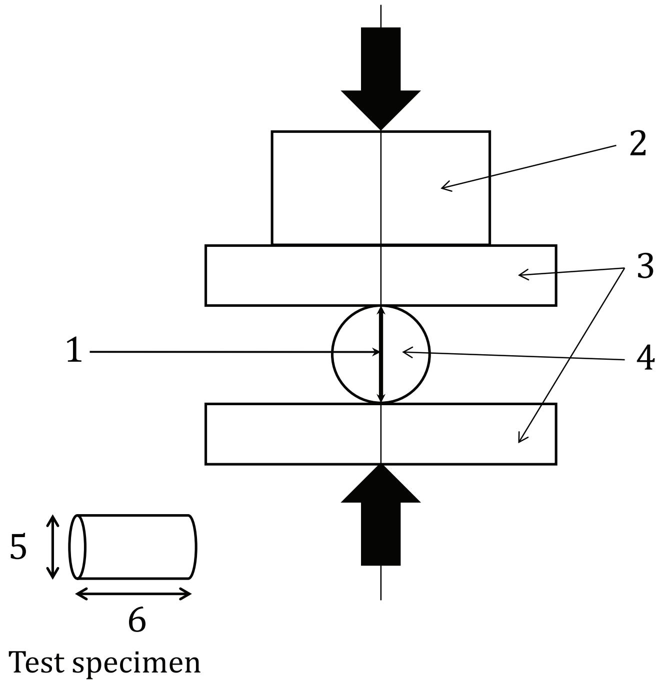
Test specimen shall be conditioned in standard atmospheres specified in ISO 291 before testing.

10.5.2 Test atmosphere

Perform the test in one of the standard atmospheres specified in ISO 291, preferably the same atmosphere as used for conditioning.

10.5.3 Setup

Place the test specimen between the surfaces of the compression plates in Figure 1 and align the centrelines of the compression plate surfaces.



Key

1 diameter
2 load cell
3 compression plate
4 specimen
5 diameter (D) [6 mm]
6 axial length (L) [12 mm]

Figure 1 — Test specimen setup

10.6 Preload

The test specimen shall not be loaded substantially prior to the test. Such loads might be necessary, however, to avoid a curved region at the start of the stress/strain diagram.

10.7 Recording of data

Determine the force (stress) and the corresponding compression (strain) of the test specimen during the test. It is preferable to use an automatic recording system which yields a complete stress/strain curve for this operation.

10.8 Calculation and expression of results

10.8.1 DTS

The DTS of the specimen shall be calculated using Formula (1):

$$\text{DTS} = \frac{2P}{\pi DL} \tag{1}$$