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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

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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

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Foreword

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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

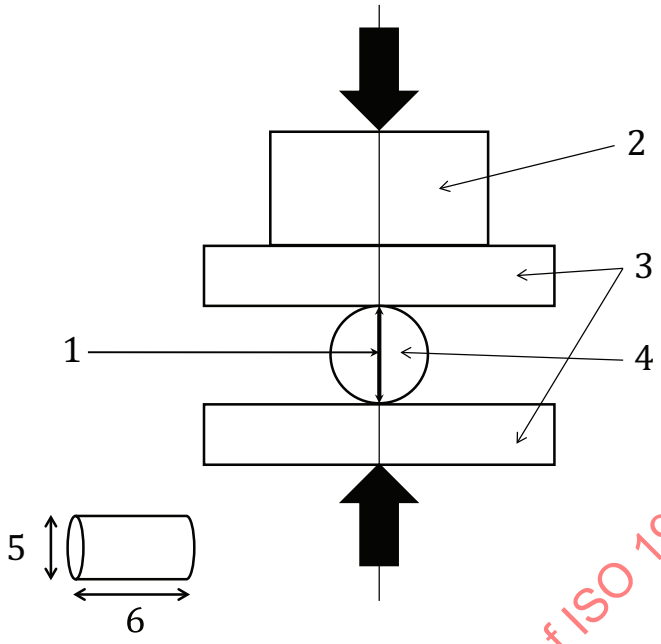
Test specimen shall be conditioned in standard atmospheres specified in ISO 291 before testing.

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):

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

where

DTS is the diametral tensile strength of the specimen, expressed in pascals (Pa);

P is the maximum applied force, expressed in Newton (N);

D is the diameter of the test specimen, expressed in meters (m);

L is the axial length of the test specimen, expressed in meters (m).

Report the calculated DTS.

10.8.2 Strain (as measured by extensometry)

Calculate the strain parameters using Formula (2):

$$\varepsilon = \frac{\Delta D}{D} \tag{2}$$

where

ε is the strain parameter, expressed as a dimensionless ratio or as a percentage;

ΔD is the decrease in the test specimen diameter between the gauge marks, expressed in millimetres;

D is the vertical diameter of the test specimen, expressed in millimetres.

10.8.3 Maximum strain

The maximum strain is the strain of the maximum force. Report the maximum strain and observe the failure position.

10.8.4 Statistical parameters

Calculate the arithmetic mean of each set of ten test results and, if required, the standard deviation and 95 % confidence interval of the mean value by the procedure given in ISO 2602.

10.8.5 Test report

The test report shall include the following information:

a) all details necessary for complete identification of the material tested, including type, source, manufacturer's code number and history, where these are known;

b) a description of the nature and form of the material under test, i.e. whether it is a product, semi-finished product, test plate or specimen, and including principal dimensions, shape, method of manufacture, order of layers, preliminary treatment, etc;

c) the test specimen diameter and axial length, giving the mean, minimum and maximum values, if applicable;

d) details of the method used to prepare the test specimens;

e) if the material is in the form of a finished or semi-finished product, the orientation of the test specimen in relation to the finished or semi-finished product from which it was cut;

f) the number of specimens tested;

g) the atmosphere used for conditioning and for testing, plus any special conditioning treatment carried out if required by the International Standard for the material or product;

h) the accuracy grading of the test machine (see ISO 5893);

i) the type of extensometer used;

j) the type of compression tool used;

k) the individual test results determined for the properties (DTS and maximum strain) and observation of failure point;

l) the mean value of each of the properties measured, quoted as the indicative value(s) for the material tested;

m) the standard deviation and/or coefficient of variation and/or confidence limits of the mean;

n) whether any test specimens were rejected and replaced and, if so, the reasons;

o) the date of the test.

11 Test method using ultrasonic bone cutting device (or ultrasonic surgical unit, instrument with an oscillating scalar tip) for cutting model

11.1 Test method references

The test method is specified with references to ISO 18397 or JIS T 5750.

11.2 Cutting under a constant feed rate or under a constant load

In case of cutting under a constant feed rate or under a constant load, either the depth of cutting in a unit of time or the cutting volume is specified as measurement value using ultrasonic cutting device.

11.3 Key terms

11.3.1 Cutting depth

The cutting depth is defined as the distance between the surface of the bone model and the edge in the bone model.

The measurement is performed using a scalar or displacement gauge.

11.3.2 Cutting volume

The cutting volume is a weight difference before and after cutting. The measurement of weight is performed using a weight scale (electric balance).

11.4 Burning

In case of cutting under a constant feed rate or under a constant load, the burning of the model or the tip surface should be avoided.

11.5 Bounce-off

In case of cutting under a constant load, bounce-off should be avoided.

11.6 Tip angle

The tip angle to the surface of model is set at the angle with maximum cutting volume.

12 Test method using a bone drill

12.1 Drilling test

The drilling test provides data on torque, thrust forces, or feed rate using a drill into a bone model with measurement of feed rate.

The drilling test is performed with either a constant feed rate or under a constant load.

12.2 Position of drill to bone model surface

The drill stands normal to the surface of model.

12.3 Test report

The test report shall include the following information:

a) test method, especially “under a constant feed rate” or “under a constant load”,

b) model size and the drill size;

c) the geometry of drill, especially thread, edge, any other related to the characterization of drill;

d) the spindle speed;

e) the feed rate if it is performed under a constant feed rate or the load if it is performed under a constant load;

f) the name of the cooling medium, the volume per time, and how the cooling medium was introduced to the drill and bone model if a cooling system using a medium such as liquid or air was employed during the drilling test;

g) the estimated effect of the cooling system on the drilling test;

h) if punching is performed, the process of punching;

i) characterization of the shape of pieces (chips) produced by drilling (e.g. flow type, crack type, etc.).

13 Final report

The final report shall include the following information:

a) the procedure for selection of the methods;

b) the report for each method selected.

Annex A
(informative)

Rationale

A.1 Purpose

With the establishment of this document, comparisons of bone models with many kinds and new materials can be performed. It is important to share the characteristics of bone models to the users and the sharing will promote the development of the devices or the instruments.

Mechanical properties of a cortical bone model is also necessary to be specified for training and lecture for use of medical devices or instruments, informed consent for patient, performing pre-operation of surgery and surgical planning.

Previous references have taken compressive test, shear test and pull-out tests. Then in this document, two types of mechanical test are categorized. One is a fundamental test such as the uniaxial tensile test. The fundamental test is performed with a test machine based on ISO 5893. This test is usually used for determining modulus such as Young's modulus or compression modulus. The other is a practical test using devices or instruments. This test is used for measurement of forces under similar situations to those experienced by medical operators as measurement of tactile feedback, i.e. sensory feedback to the operator. This document covers both test methods.

Table A.1 shows the relation of the test method to the mechanical properties. Table A.2 shows a list of mechanical properties that will affect the properties of a bone model in case of evaluation of medical devices.

A.2 Comparison of mechanical properties of a bone model

A.2.1 Sample designation

In order to check the comparison of mechanical properties of a bone model, three tests using several cortical bone models including porcine bone were performed. Samples designated 1 is porcine bone and 2, 3 and 4 are commercially available cortical bone models. Three samples were used for each test.

A.2.2 Drilling test (Clause 12)

The experimental setup included a milling machine (VHR-SD, Shizuoka Machine Co., Ltd) and a system for measurement and recording of the thrust force with a dynamometer (Kistler, 9257B, KISTLER Co., Ltd), a charge amplifier, and a computer. An implant drill (Twist drill, Novel Biocare Japan Co., Ltd) with 2,0 mm diameter was used for this drilling test. The drilling was conducted under a spindle speed of 560 r/min and a feed rate of 0,035 mm/rev. The specimens were cut to a 20,0 × 20,0 × 20,0 mm cubic shape from the samples. A thrust force against the depth was recorded.

Figure A.1 shows the relationship between insertion depth and thrust force during drilling at 0,035 mm/rev. The average and the standard deviation of the samples were calculated.

A.2.3 Compressive test

The compression force was measured using a universal machine (AG-X, SHIMADZU CORPORATION Co., Ltd) at a crosshead speed of 0,5 mm/min (see Clause 4). The specimens were manufactured with 6,0 mm diameter and 12,0 mm height from the samples. The compressive stress against the compression strain was recorded. Figure A.2 shows the compressive strengths of the samples.

Table A.1 — Relation of the test method to the mechanical properties

Test method	The mechanical properties related to mechanical tests										Normative references of ISO/ASTM/JIS		
	Tensile strength	Compressive strength	Shear strength	Elastic modulus	Compressive modules	Shear modulus	Bending strength	Bending modulus	Toughness, fracture	Hardness		Reference 1	Reference 2
Tensile test	*			*							ISO 527, ASTM D638	[3]	[4]
Compressive test		*			*						ISO 604, ASTM D695	[5]	[6]
Shear test			*			*					ASTM F1839/C273	[7]	[8]
Bending (flexural) test	*			*	*		*	*			ISO 178/5833	[9]	[10]
Charpy or Izod impact test									*		ISO 179/180,ASTM D256	[11]	[4]
Rockwell hardness										*	ISO 2039	[9]	[10]
DTS	*		*									[12]	[13]
Pull-out			*								ASTM F183991/F543	[14]	[15]
Push-on			*								ASTM F1839/F543	[14]	[15]
Ultrasound test			*						*		JIS T 5750	[16]	
Drill test			*						*	*	Appendix		

Table A.2 — Relation of the mechanical properties needed for the evaluation of medical devices

Device	Mechanical properties to be needed for bone model in case of evaluation of medical devices									
	Tensile strength	Compressive strength	Shear strength	Bending strength	Elastic modulus	Compressive modules	Shear modulus	Bending modulus	Toughness, fracture	Hardness
Bone plate	*			*	*	*		*	*	
Bone screw		*	*	*		*	*	*	*	
Bone pin		*		*		*	*	*		*
Bone drill			*				*		*	*
Bone saw			*						*	*
Cable (wire)		*				*				*
Intramedullary nail	*	*	*	*					*	*