
**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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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Selection of test method	2
4.1 General	2
4.2 Fundamental tests	2
4.3 Practical tests	2
5 Compressive test	2
6 Tensile test	2
7 Hardness test	2
8 Charpy and Izod impact tests	2
9 Torque and axial pull-out test	2
10 Diametral Tensile Strength (DTS) test	2
10.1 Materials and apparatus	3
10.1.1 Compression testing machine	3
10.1.2 Compression tool	3
10.1.3 Measuring instrument	3
10.2 Test specimen	3
10.2.1 Shape and dimensions	3
10.2.2 Specimen inspection	3
10.3 Anisotropic materials	4
10.4 Number of test specimens	4
10.5 Test procedure	4
10.5.1 Test specimen	4
10.5.2 Test atmosphere	4
10.5.3 Setup	4
10.6 Preload	5
10.7 Recording of data	5
10.8 Calculation and expression of results	5
10.8.1 DTS	5
10.8.2 Strain (as measured by extensometry)	6
10.8.3 Maximum strain	6
10.8.4 Statistical parameters	6
10.8.5 Test report	6
11 Test method using ultrasonic bone cutting device (or ultrasonic surgical unit, instrument with an oscillating scalar tip) for cutting model	7
11.1 Test method references	7
11.2 Cutting under a constant feed rate or under a constant load	7
11.3 Key terms	7
11.3.1 Cutting depth	7
11.3.2 Cutting volume	7
11.4 Burning	7
11.5 Bounce-off	7
11.6 Tip angle	8
12 Test method using a bone drill	8
12.1 Drilling test	8
12.2 Position of drill to bone model surface	8

12.3	Test report.....	8
13	Final report	8
Annex A	(informative) Rationale	9
Bibliography		14

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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).

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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>