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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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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.

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

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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.

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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

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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

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