INTERNATIONAL STANDARD

ISO 22926

First edition
2023-07

Implants for surgery — Specification and verification of synthetic anatomical bone models for testing

Reference number
ISO 22926:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Synthetic anatomical bone models can be useful to characterize mechanical performance of surgical implants and instruments, such as those used in musculoskeletal fixation or reconstruction surgery. A synthetic bone model is typically made by methods of casting, machining and/or recently by additive manufacturing, all of which can leverage medical image-based modelling. To use a synthetic anatomical bone model for mechanical testing of an implant, its similarity to natural bone in terms of shape and mechanical behaviour is of paramount importance to bone model users.

This document provides a way to specify, verify and report characteristics of synthetic bone models used for implant testing. The details of testing and the choice of a suitable bone model is outside the scope of this document. A more detailed rationale for this document is provided in Annex A.

There are two related standards for synthetic materials that are used as mechanical models of bone for implant testing. ASTM F1839[1] was first issued in 1997 and is a standard specification for rigid polyurethane foam. Polyurethane foam is a cellular solid that exhibits certain aspects of mechanical behaviour that are similar to bone such as the relationship between apparent density and its stress-strain response to mechanical loading. A second relevant standard is ISO 19213[2] which was first issued in 2017 and provides a list of test methods to describe synthetic material models of cortical bone. The methods referenced in ISO 19213 report material properties from long standing test methods for plastics, and include specialized tests to mimic certain orthopaedic surgical processes such as drilling, milling (burring) and cutting. This document goes beyond materials, and includes shape and structure of a synthetic bone model.

While the scope of this document is limited to bone models, it is intended to lay the framework for future models of other biologic tissues.

Implants for surgery — Specification and verification of synthetic anatomical bone models for testing

1 Scope

This document provides requirements and recommendations for specification and verification of synthetic anatomical bone models for use in testing of implants.

The anatomical source of the synthetic model can be digital data from computed tomography (CT) scanning or any other sources such as from cadaveric specimens or statistically determined shape data.

The specifications covered in this document are 3D shape and mechanical characteristics. Other characteristics, such as colour or cosmetic features, are not considered in this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
digital anatomical bone model
digital model
dataset to represent the shape and any other desired characteristics for target *synthetic model* (3.2)

Note 1 to entry: The procedure to produce digital model of the knee bone from computed tomography (CT) data can be found in ISO 19233-1.

EXAMPLE STL, CAD STEP, voxel-based model.

Note 2 to entry: Examples of other desired characteristics are: density, hardness, porosity, Young's modulus.

3.2
synthetic anatomical bone model
synthetic model
physical model resulting from the manufacturing process based on the *digital model* (3.1)

3.3
physical model characteristic
parameter or feature used to represent the physical anatomical bone in order to establish the design requirements for the *synthetic model* (3.2)

Note 1 to entry: The physical model characteristics include both geometrical shape, material and mechanical properties.

Note 2 to entry: Physical model characteristics can be specified by the *bone model producer* (3.4) and/or user.

3.4
bone model producer
model producer
organization or individual responsible for producing the *synthetic model* (3.2)

3.5
bone model user
model user
organization or individual that uses the *synthetic model* (3.2)

3.6
specification report
report which provides information of characteristics of the *synthetic model* (3.2) manufactured according to the design requirements established in this document

Note 1 to entry: See Annex C for an example.

4 Design and development of a synthetic model

4.1 General

The applicable requirements for characterizing physical and digital anatomical bone models, and verification after production are shown in 4.2 to 4.3.

The bone model producer shall establish appropriate system controls in order to ensure the traceability of each synthetic anatomical bone model throughout the design and development process.

4.2 Identification of physical model characteristics

The required physical model characteristics shall be specified by either the bone model producer or the bone model user. This specification shall include any of the following if required based on the intended application of the model:

a) the overall shape described geometrically in any manner, such as surface model (e.g. an STL file), solid vector model (e.g. CAD STEP file), or volumetric representation (e.g. voxel based model), as input for an overall digital bone model;

b) the description of the 3D shapes of any segments within the overall shape [of list item a)], such as cortical bone, cancellous bone and intramedullary canal;

c) the material and properties for the overall model or each segment, such as density, hardness, porosity, surface roughness and Young's modulus;

d) structural mechanical characteristics of the overall or part of the bone model, such as stiffness, ultimate strength and fatigue strength, under certain loading conditions;

e) any other characteristics such as chemical or thermal resistance, residual stress levels and dimensional stability due to manufacturing process, and fluid absorption in the intended working environment of the model.

The bone model user should determine which of the above characteristics are critical for their application and which verification model is needed.

NOTE Reference of material and mechanical characteristics for human bone segments can be collected from the published literature, for examples, see References [3] to [11].

4.3 Model verification

4.3.1 General

To verify that the synthetic anatomical bone model fulfils the requirements of desired digital model, this process shall be conducted by the bone model producer, and the results reported to the bone model user. This verification includes model geometrical and model mechanical performance if required, according to the following steps:

a) model geometrical verification (4.3.2),

b) model material verification (4.3.3), and

c) when necessary, model mechanical verification (4.3.4).

The bone model producer shall select and implement the processes for model geometrical, material and mechanical verifications of the synthetic anatomical bone model as required or agreed with the bone model users.

Results of verification shall be presented in specification report in accordance with Clause 5.

4.3.2 Model geometrical verification

Geometrical characteristics of the synthetic anatomical bone model shall be verified by examining the agreement to the geometrical specifications established in 4.2 a) and b). Geometrical characteristics are specified and referenced by the combination of

— anatomical landmarks, and

— digital anatomical bone model.

A detailed example of a model geometrical verification is provided in Annex B.

The results of the model geometrical verification shall be reported in accordance with Clause 5.

The interpretation of the agreement between the synthetic model and its reference shall also consider effects and errors from the measurement protocol, the measurement device and the software used in the protocol, including

— the choice of fiducial points including their location, and

— the variability of the results from registration and computation of the deviation between the synthetic and the intended digital model.

When the protocol or instruments used for measurement of the digital anatomical and synthetic anatomical bone models differ, such differences shall be reported.

4.3.3 Model material verification

Materials and other characteristics for each spatial segment or region of the synthetic anatomical bone model shall be verified by comparison to the specifications established in 4.2 c). The results of the model material verification shall be reported in accordance with Clause 5.

NOTE Testing methods of material characteristics can be found in various ISO and ASTM standards. For cortical segment, the mechanical characteristics of the bone materials can be tested according to ISO 19213.

4.3.4 Model mechanical verification

Structural mechanical characteristics of the synthetic anatomical bone model shall be verified by comparison to the specifications established in 4.2 c) or d). The results of the model mechanical verification shall be reported in accordance with Clause 5.

5 Specification report

The specification report shall include at least the following information.

Provide reporting recommendations for model definition, creation, verification and use.

a) Intended use: The intended use of the synthetic anatomical bone model typically has, but is not limited to the following:

   — anatomical part that the model represents,

   — population that the model assumes to reflect,

   — if any anomaly that the model represents,

   — expected implants that is used with the model,

   — tests that are performed with the model, and

   — if any contraindication or warning regarding reasonably foreseeable misuse of the model.

   EXAMPLE Femur model for primary stiffness evaluation of fracture fixation constructs. Such a model is typically used for stiffness testing of various fracture fixation constructs simulating orthopaedic trauma treatments. The model here simulates a fractured or intact femur repair with one or more trauma plates and screws, and the stiffness of the construct is tested in anterior-posterior bending, medial-lateral bending, axial compression and/or torsion, or any combination of those.

b) Geometrical characteristics identified in 4.2 a) and b) and measurement methods to verify them. Typical examples are:

   — name or any identification information to specify the digital anatomical bone model,

   — dimensions of anatomical landmarks, e.g. total length,

   — for measurements to create the digital anatomical bone model, the measurement methods (e.g. CT scan) and details of the protocol used,

   — effects and errors from measurement protocol, measurement device and software used,

   — error allowance of those specifications,

   — result of measurements, either in absolute dimensions or relative bias or deviation from the digital anatomical bone model. This may be written in the maximum, mean value, etc.,

   — for characterization of the synthetic anatomical bone model, the measurement methods and devices used, number of specimens (assume three when omitted), and how the resulting measurements for different specimens are combined in data processing and interpreted, and

   — any other measurement conditions that can affect the results of geometrical verification, e.g. ambient temperature.

c) Material and other characteristics in 4.2 c), and testing methods.

d) If there are applicable mechanical characteristics, methods to verify them.

e) If any, other characteristics that can affect the results of testing using the model.

   EXAMPLE Estimated lifetime, manufacturing process, storage conditions.

NOTE 1 See Annex C for an example.

NOTE 2 The contents of this specification report are only related to model geometrical, material and mechanical verification. Other characteristics can be also included to inform to the bone model users.

Annex A
(informative)

Background, detailed scope and rationale

A.1 General

This document is intended to provide a way to specify, verify and report characteristics of synthetic bone models used for implant testing. This document is useful for the model producer and model users, because it defines the terms that are necessary to describe the synthetic models and provides a suggested set of characteristics that can be useful in specifying the model. A specification report based on this document will help both the producer and the user of a bone model to have structure and clarity in what a bone model is, how it was tested, the results of the verification tests and how the models from different producers can be more easily compared.

This document has been proposed as a response to the demands and progress of technology, including:

— increasing demands on in situ bench testing of implants for even greater patient safety;

— emerging technology of the digital transformation in production of both implants and bone models, including digital data workflow, 3D images or digitizer, 3D CAD, numerical control machining and additive manufacturing;

— potential of the patient specific implants.

Therefore, this document assumes that the workflow is centred around the digital model. However, this document does not specifically assume bone models for patient specific implants or models produced by the additive manufacturing. It is also applicable and useful for bone models not manufactured from digital data such as casting, which is indeed the majority production method to date.

These new technologies made production of bone models easier, with variety of shapes, in different sizes, of genders, ages and so on. However, verification and documentation of such models have not been standardized. This document provides a guidance how to establish the verification for synthetic anatomical models by classifying geometrical and mechanical verification of the model. On the other hand, this document clarified that the validation of the anatomical model is primarily the model user's task. To help the user to perform mechanical tests with the synthetic model and validate the test results, this document also provides guidance on the specification report that the model producer issues.

This document does not cover the following matters:

— Determination of model geometry, for example, selection of representative population. It is totally dependent to the intended purpose, intended patients of the implant therefore there is no golden rule to determine.

— Specific design method and manufacturing process. This document is not intended to mandate specific ways to design and manufacture synthetic models.

— Synthetic anatomical bone models including physiological behaviour, such as bone remodelling.

— Verification of synthetic anatomical bone models by numerical simulation such as finite element analysis (FEA). Although FEA has certain potential to supplement the model mechanical verification when experimental verification is not reasonably achievable, for instance, when the number of experimental conditions are too many to conduct experiments or when experiments can be expensive to perform for every custom-made bone model.