INTERNATIONAL STANDARD

ISO 22926

First edition
2023-07

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

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Foreword

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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.

A.2   Term 'model'

A.2.1   General

The term 'model' appears in several different meanings and contexts in many international standards and academic articles. 'Implant for Surgery' and '3D bone model' in ISO 19233-1:2017, and 'cortical bone model' in ISO 19213:2017 have been defined. While there are several other terms exchangeable to model, such as 'dummy', 'phantom' and 'replica', this document uses the term 'model' to consistently refer to the digital anatomical bone model and the synthetic anatomical bone model defined in this document and other terms in past relevant standards.

Synthetic models can be classified as follow (see Figure A.1):

a)   Material models: These are intended to perform tests primarily for material characteristics. Shapes are geometrical and standardized for the convenience of analysis in material science. ISO 19213:2017 is about testing of material models for cortical bone. ASTM F1839-08 also provides a material specification for different ranges of foams as material models.

b)   Tissue block models: These are intermediate of material models and anatomical models to perform tests under more realistic conditions. These models can have complex shapes that are closer to anatomical shapes, yet the shapes remain standardized shapes. These can be composite materials. ASTM F1717-18[13] includes vertebrectomy model for testing of spinal implant assemblies.

c)   Anatomical models: These are intended to test under in situ loading and/or clinical conditions. These mimic the anatomical shape of the tissue or organ to represent. Anatomical models are often in composite materials.
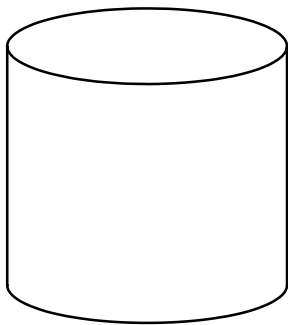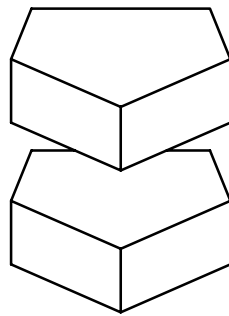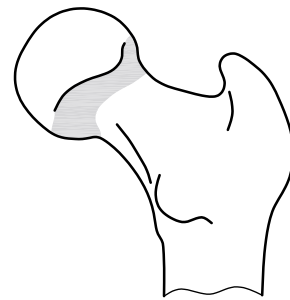
a) Material models   **b) Tissue block models**   **c) Anatomical models**

Figure A.1 — Synthetic models for testing of implants

A.2.2   Naming conventions

Model of tissues can have several different properties that the naming should systematically address. This document adopted the following naming conventions.

Model name: = [*type*] [*shape*] [*material*] [*texture*] {*part*} *model*

where

type	is the general type of model: *synthetic*, {*digital* | *numerical* | *virtual*}, *cadaver*, etc.;
shape	is the shape or geometrical properties: *anatomical*, *block*, *cylindrical*, etc.;
material	is the materials: *composite*, *UHMWPE (ultra-high molecular weight polyethylene),* etc.;
texture	is the texture or other properties: *trabecular*, *cortical*, *cancellous*, etc.;
part	is the part of organ or tissue: *femur*, *vertebral*, *bone*, *vessel*, etc.;
[]	is the omittable element;
{}	is the mandatory element;
A | *B*	is the alternation: A or B in this case.

In practice, some properties can be exchanged for better wording order. Some words can be omitted: e.g. *UHMWPE bone model.*

Annex B
(informative)

Example of model geometrical verification methods

B.1 General

Methods of model geometrical verification of a synthetic anatomical bone model can be chosen by considering how the geometrical characteristics identified in 4.2 a) and b) are specified. Geometrical characteristics are specified by the combination of

— anatomical landmarks, and

— digital anatomical bone model.

Anatomical landmarks and digital model are typical golden standards used to verify the synthetic model. This annex discusses verification of a synthetic model to these two types of specifications.

B.2 Verification to anatomical landmarks

Measurement of anatomical landmarks are often associated to measurement protocol. Adopting established protocol helps bone model users to understand the meaning of verification. If no such protocol has been found, the bone model producer may establish the appropriate one. The bone model producer may also adopt their own measurement protocol.

B.3 Verification to digital model

When geometrical characteristics is specified as a digital model, model geometrical verification can be performed using spatial registration followed by generating a quality map of the dissimilar (and similar) spatial regions. This method delivers a review of the overall 3D shape which is particularly informative for developing synthetic anatomical bone models because they do not have simple geometry. This method requires digitizing the synthetic bone model using 3D scanning technology such as laser, segmented and reconstructed optical or industrial X-ray CT to generate a digital model. This digital model of the synthetic model can be used for spatial registration with the reference digital model to review quantifiable regional variations in geometry.

Spatial registration is a computational alignment process that places the digitized synthetic model into the same coordinate system as the required digital model without changing its shape (rigid registration). This alignment process can be manual, semi-automatic or fully automatic. The example presented in Annex C performed semi-automatic alignment using an open source 3D mesh processing program. The alignment process uses mutual fiducial points selected by the operator then automatically processes a refinement to converge on a best fit alignment between the two digital model data sets with an output of average error. Following spatial registration, the Hausdorff distance between two digital models is computed which provides the minimum, the maximum, the mean and the root mean square (RMS) values and a colorized map may be generated to visualize regional variation in geometry, see Reference [14]. The choice of where the fiducial points were selected is important. More concentration or exclusive selection of one region of the bone will usually give more weighting for alignment to the region. This is sometimes done deliberately if one region of the bone is of more interest than others, this is why detailed documentation is important.

A simple 3D geometrical measures such as volume may also be used to compare the reference digital model and a synthetic model, however it does not give a regional indication where differences and similarities exist between the models.

B.4 Verification as a user — Producer communication

Verification of a synthetic model can be considered as a part of necessary communication between bone model producer and user. Therefore, it is important that the verification methods including the protocol, measurement methods and devices, and software are easily understood by bone model users. This is different and should be in addition to the product's quality management and control documentation.

Annex C
(informative)

Example of a specification report

C.1 General

This annex is an example of a specification report, a detailed account of design and development work for a synthetic anatomical composite human tibia.

Although there are published articles on related works, the scenario was modified for the purpose of this document. The content of this annex is not intended to demonstrate a real, complete process. Verification and specification report can vary depending on the intended purpose, the source, the manufacturing process and the method of verification.

## C.2 Scenario

C.2.1 Intended use

The intended use for this synthetic model is for mechanical testing of orthopaedic implants such as those used for osteosynthesis and joint arthroplasty surgery. Anatomy and mechanical characteristics of the model are intended to simulate healthy adult bone.

C.2.2 Reference bone

The reference bone was a left tibia from a 152 cm tall, 84 kg adult male cadaver. The digital model of this human tibia consists of cortical, cancellous and intramedullary regions depicted in Figure C.1.

Dimension in millimetres
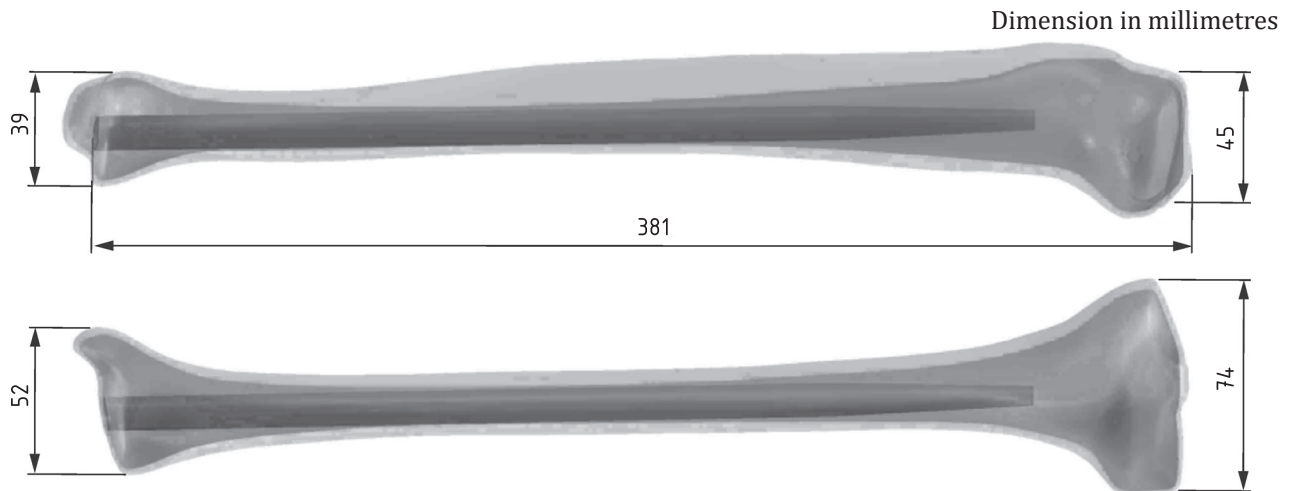
a) Two semi-transparent shaded views depicting three spatial regions
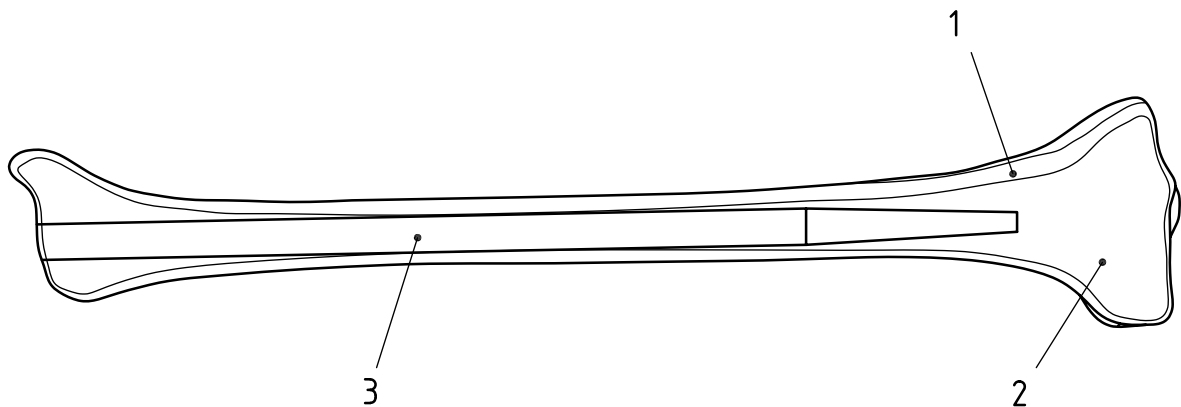
b) Wireframe cross-section view

Key
1   cortical spatial region
2   cancellous spatial region
3   intramedullary spatial region

Figure C.1 — Digital tibia model

C.2.3   Material specifications

Required material selection and characteristics for each spatial region defined within the digital model are listed in Table C.1. In addition, structural characteristics are listed in Table C.2 whereby the synthetic model must fall within range of those parameters obtained from cadaveric in vitro testing as reported in Reference [15].

Table C.1 — Material specification for specified spatial regions

	Properties	Nominal	Test method
Cortical region: Short fibreglass filled epoxy	Density	1,64 g/cm^3	ASTM D792[16]
	Tensile modulus, longitudinal	16 GPa	ASTM D638, Type I[17]
	Tensile modulus, transverse	10 GPa	ASTM D638, Type I[17]
	Tensile strength, longitudinal	106 MPa	ASTM D638, Type I[17]
	Tensile strength, transverse	93 MPa	ASTM D638, Type I[17]
	Compressive modulus	17 GPa	ASTM D695[18]
	Compressive strength	157 MPa	ASTM D695[18]
Cancellous region: Rigid polyurethane foam	Density	0,27 g/cm^3	ASTM D1622[19]
	Compressive modulus	155 MPa	ASTM D1621[20]
	Compressive strength	6,2 MPa	ASTM D1621[20]
NOTE Specification for intramedullary region is not listed as it is hollow.			

C.2.4   Mechanical specifications

Table C.2 — Structural characteristics required for synthetic model

Structural parameter	Reported range	Reference
Bending rigidity, anterior tension	136 Nm^2 to 304 Nm^2	Cadaver, n = 6[15]
Bending rigidity, lateral tension	124 Nm^2 to 253 Nm^2	Cadaver, n = 6[15]
Axial stiffness	6,24 kN/mm to 7,25 kN/mm	Cadaver, n = 6[10]
Torsion rigidity	1,24 Nm^2/deg to 3,51 Nm^2/deg	Cadaver, n = 6[15]

C.2.5   Established digital model

A cadaver tibia was prepared for laser scanning to create outer geometry of the reference digital model. The cancellous region was prepared from cross-sectional measurements of the cadaver bone and converted into a digital model. The intramedullary canal was approximated with a cylindrical hollow region defined in the digital model.

C.2.6   Manufacturing process

Casting process was used to manufacture both cortical and cancellous regions. Special considerations resulting from the manufacturing method include:

a)   the direction of flow path for short fibre filled epoxy is parallel to the long axis of tibia,

b)   a hollow 3 mm hole extends across the tibia plateau as shown in Figure C.2,

c)   a hollow 9 mm in diameter and 325 mm in length canal representing the intramedullary cavity extends through distal cortex, shown in Figure C.3.

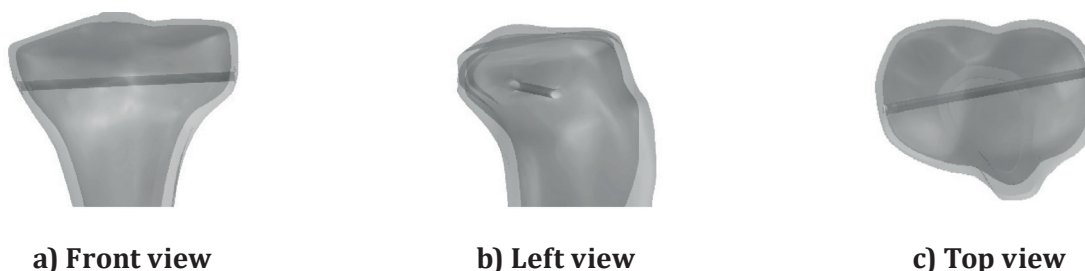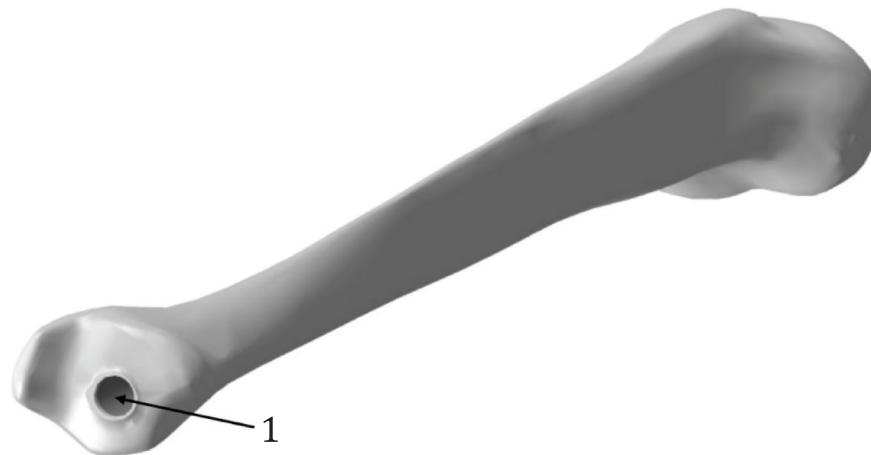| a) Front view	b) Left view	c) Top view

Figure C.2 — Three views of a hole of 3 mm in diameter in the proximal tibia

Key

1   cylindrical canal

Figure C.3 — Cylindrical canal of 9 mm in diameter that extends past the distal tibia leaving a hole

C.3   Synthetic bone model verification

C.3.1   Model geometrical verification

C.3.1.1   General

Model geometrical verification was performed in the steps listed in C.3.1.2 to C.3.1.6. This example shows the model geometrical verification of the surface. The same method may apply for model geometrical verification of cancellous bone inside the bone.

C.3.1.2   Step 1: Generate surface models for analysis

3D scanning of the reference bone and synthetic model was performed using the same laser scanner (HD Laser scanner, NextEngine Inc.[1]). The generated surface models are in Figure C.4.

a) STL generated reference digital model

b) STL generated synthetic model

Figure C.4 — Surface mesh files (STL)

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[1]   HD Laser scanner of NextEngine Inc. is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

C.3.1.3 Step 2: Compare geometrical measures

The volume computed for each surface model is 288,8 cm^3 and 318,8 cm^3 for the reference digital model and synthetic model, respectively. The results indicate the synthetic model produced is 10 % larger than the referenced digital model.

C.3.1.4 Step 3: Align surface models gobally

Surface mesh files are aligned into the same coordinate system using a semi-automatic process in Meshlab version 2016.12 (https://www.meshlab.net/[2]). The program initially aligns two digital models using fiducial points in Figure C.5 then automatically refines the alignment and result is shown in Figure C.6. The average alignment error result equalled to 0,828 mm.

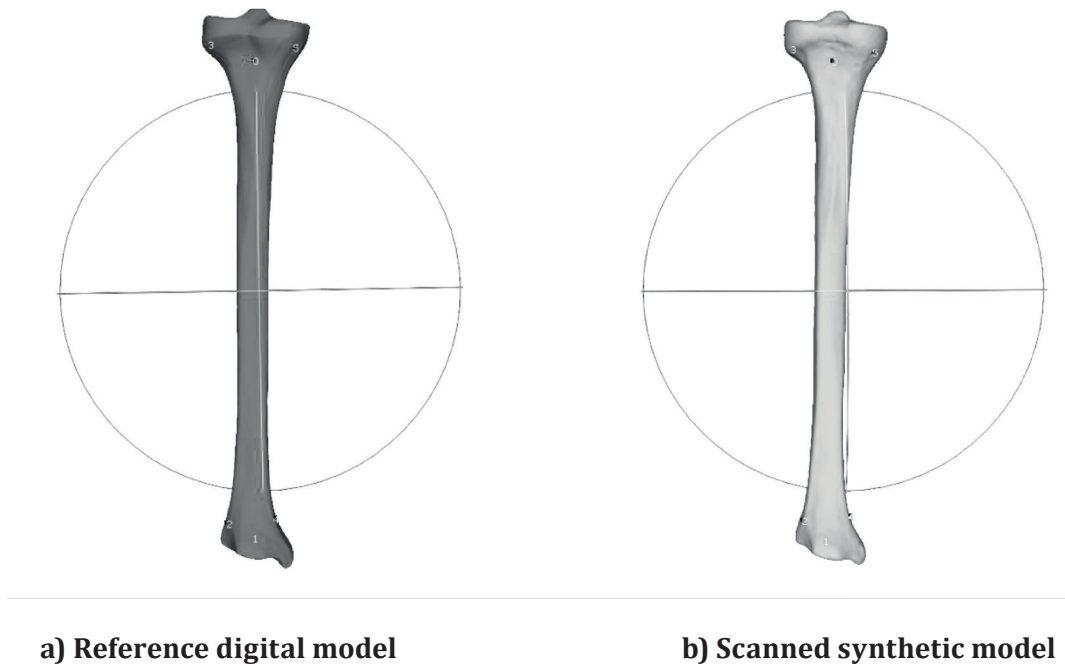a) Reference digital model   b) Scanned synthetic model

Figure C.5 — Reference digital model and scanned synthetic model with fiducial points for initial alignment indicated as numbers on the surface
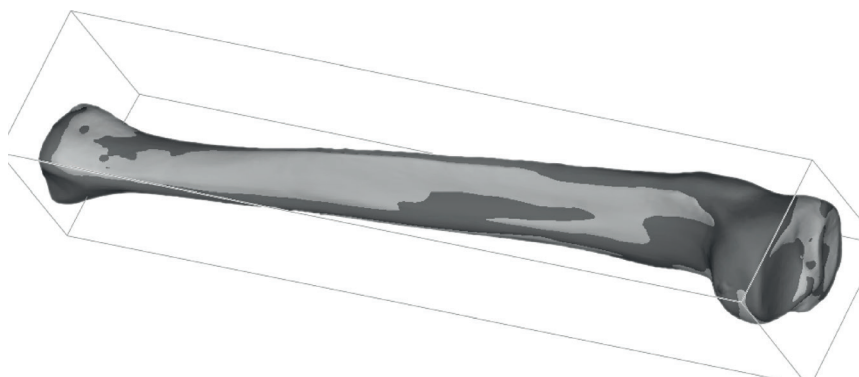

Figure C.6 — Screen capture of alignment with both surface models visible and output of alignment result

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2)   Meshlab version 2016.12 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

C.3.1.5   Step 4: Run Hausdorff distance algorithm to determine regional variation in geometry

The Hausdorff process sampled 225 064 vertices to measure distance between the two surface models and results are listed in Table C.3.

Table C.3 — Results of Hausdorff distance

	Maximum	Mean	RMS
Hausdorff distance (mm)	5,27	1,21	1,65
Percentage of bounding box diagonal (402,8 mm)	1,30	0,30	0,41

C.3.1.6   Step 5: Generate colour map of Hausdorff distance

A colour map of Hausdorff distance is applied to the synthetic model where blue represents locations of zero Hausdorff distance and red represents locations of the maximum Hausdorff distance shown in Figure C.7.
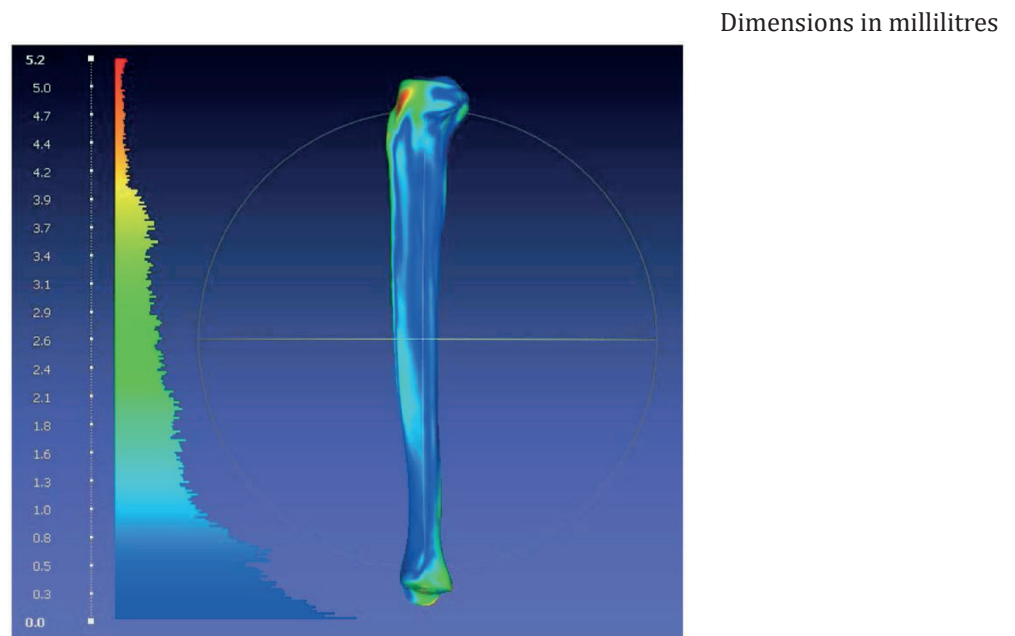
Dimensions in millilitres

Figure C.7 — Histogram of the Hausdorff distance distribution between surface models

C.3.2   Model material verification

Material testing was conducted according to required ASTM methods, those results are shown in Table C.4.

Table C.4 — Mean and coefficient of variation (C_{ov}) reported from test reports

	Properties	Nominal	Mean	C_{ov}	Test method
	Density	1,64 g/cm^3	1,63 g/cm^3	0,2 %	ASTM D792[16]
	Tensile modulus, longitudinal	16 GPa	15,7 GPa	3 %	ASTM D638, Type I[17]
	Tensile modulus, transverse	10 GPa	10,1 GPa	7 %	ASTM D638, Type I[17]
Cortical region: Short fibreglass filled epoxy	Tensile strength, longitudinal	106 MPa	107 MPa	5 %	ASTM D638, Type I[17]
	Tensile strength, transverse	93 MPa	93,4 MPa	7 %	ASTM D638, Type I[17]
	Compressive modulus	17 GPa	16,2 GPa	7 %	ASTM D695[18]
	Compressive strength	157 MPa	156 MPa	10 %	ASTM D695[18]
Cancellous region: Rigid polyurethane foam	Density	0,27 g/cm^3	17,6 g/cm^3	1 %	ASTM D1622[19]
	Compressive modulus	155 MPa	156 MPa	4 %	ASTM D1621[20]
	Compressive strength	6,2 MPa	6,8 MPa	4 %	ASTM D1621[20]
NOTE Measurement result for intramedullary region is not listed as it is hollow.					

C.3.3   Model mechanical verification

Structural characteristic testing was conducted with six synthetic models. A summary of those results in comparison to the required structural characteristics are shown in Figure C.8. These results are rendered graphically based on the numerical values published in Reference [15] where more details on the scientific methods, results and discussion can be found.
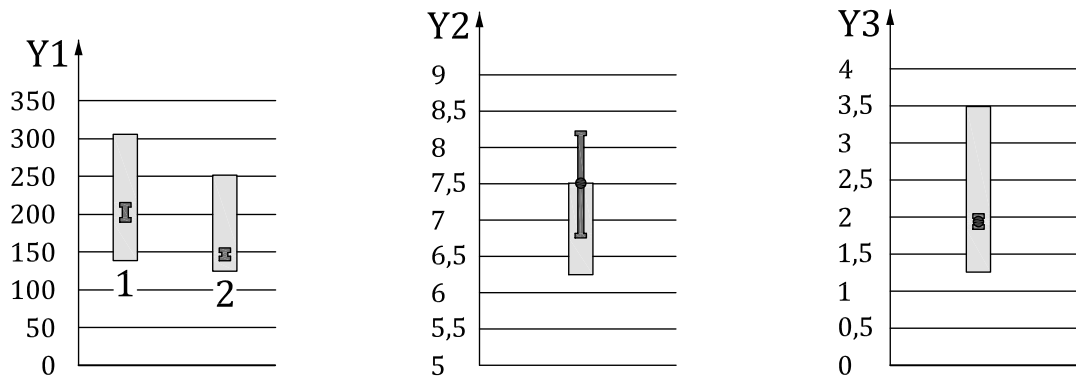
Key

1   anterior surface in tension bending

2   posterior surface in tension bending

Y1   bending rigidity (Nm^2)

Y2   axial stiffness (kN/mm)

Y3   torsional rigidity (Nm^2/deg)

Figure C.8 — Graphical results of structural characteristics where the grey box indicates minimum and maximum values of cadaver data with an overlay of the mean with coefficient of variation error bars for the synthetic model tested

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