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Implants for surgery — Orthopaedic joint prosthesis —

Part 1:
Procedure for producing parametric 3D bone models from CT data of the knee

Implants chirurgicaux — Prothèses articulaires orthopédiques —

Partie 1: Mode opératoire de production de modèles paramétriques d'os en 3D à partir de données de CT du genou

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Foreword

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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 4, *Bone and joint replacements*.

A list of all parts in the ISO 19233 series can be found on the ISO website.

Introduction

In accordance with its widespread use of medical X-ray computed tomography apparatus, three-dimensional (3D) bone models reconstructed from digital tomographic images have been widely used for various applications such as preoperative planning, surgical navigation, robotic surgeries, patient matched instruments and personalized total knee joint prosthesis. However, the conditions of taking tomographic images are different among hospitals and not internationally unified. To measure bones accurately, precise 3D bone models reconstructed from tomographic images should be used. On the other hand, since conditions of this reconstruction process are left up to operators' and/or medical institutions' discretion, this document provides a standard way of reconstructing 3D bone models.

Implants for surgery — Orthopaedic joint prosthesis —

Part 1:
Procedure for producing parametric 3D bone models from CT data of the knee

1 Scope

This document provides requirements for capturing necessary bone geometries, when using a medical X-ray computed tomography apparatus, to provide the information for applications such as preoperative planning, surgical navigation, robotic surgeries, patient matched instruments and personalized total knee joint prosthesis. The conditions to scan images of bones and the conditions to reconstruct three-dimensional bone models are provided.

NOTE   Requirements for the competence of testing laboratories appropriate to help to ensure the reliability and accuracy of the computational measurements can be found in ISO/IEC 17025.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes 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 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 21536, *Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants*

IEC 61223-2-6, *Evaluation and routine testing in medical imaging departments — Part 26: Constancy tests — Imaging performance of computed tomography X-ray equipment*

IEC/TR 60788, *Medical electrical equipment — Glossary of defined terms*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788, IEC 61223-2-6, ISO 21536, ISO 7207-1 and the following 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

3.1.1
3D bone model
bone model that is reconstructed based on CT images and made from 3D shape data in the computer

3.1.2
personalized artificial knee joint
knee joint prosthesis specifically designed for each patient

3.1.3
field of view
scanning field of view which includes the intended side of the lower limb

3.1.4
CT apparatus
X-ray computed tomography
technology that uses computer-processed x-rays to produce tomographic images (virtual "slices") of specific areas of the scanned object, allowing the user to see what is inside it without cutting it open

Note 1 to entry: Digital geometry processing is used to generate a three-dimensional (3D) image of an object from two-dimensional (2D) radiographic images taken by the CT apparatus in a spiral path around a single axis of rotation.

3.2 Abbreviated terms

2D   two-dimensional

3D   three-dimensional

CT   computed tomography

4 Principles

In order to perform applications which require information on the bone shape of the patient, it may be necessary to accurately obtain the 3D bone geometry in detail. A medical CT apparatus, which has high spatial resolution and does not require surgical invasion, can be used to reconstruct and measure the 3D bones geometries.

One example may be the design of a personalized total knee joint prosthesis. In this example, at the time of implantation, leg alignments need to be considered. Therefore, it is necessary to measure the dimensions of bones after establishing proper leg alignments.

5 Requirements

5.1 Imaging conditions

5.1.1 Medical imaging apparatus

A CT apparatus shall be used for measuring bone geometry from medical images with accurate information. A multi-slice CT apparatus should be used for scanning in short times and to obtain clear images.

Consideration should be given to scan time and the amount of time a patient is required to not move during scanning to ensure that one obtains a quality image without distortion due to patient movement.

5.1.2 Region of interest

The selected region of interest shall include the knee articulation and is intended to take geometric measuring from the physiological bone structure. The selected region of interest can comprise:

a)   the full length of the leg;

b)   the femoral head, the knee joint, and the talocrural joint;

c) the knee joint.

Selected regions of interest are illustrated in Figure 1.

In case of c) only joint scanning in Figure 1, plain X-ray images of a leg in a standing position shall be taken to identify leg alignment (see 5.1.10).

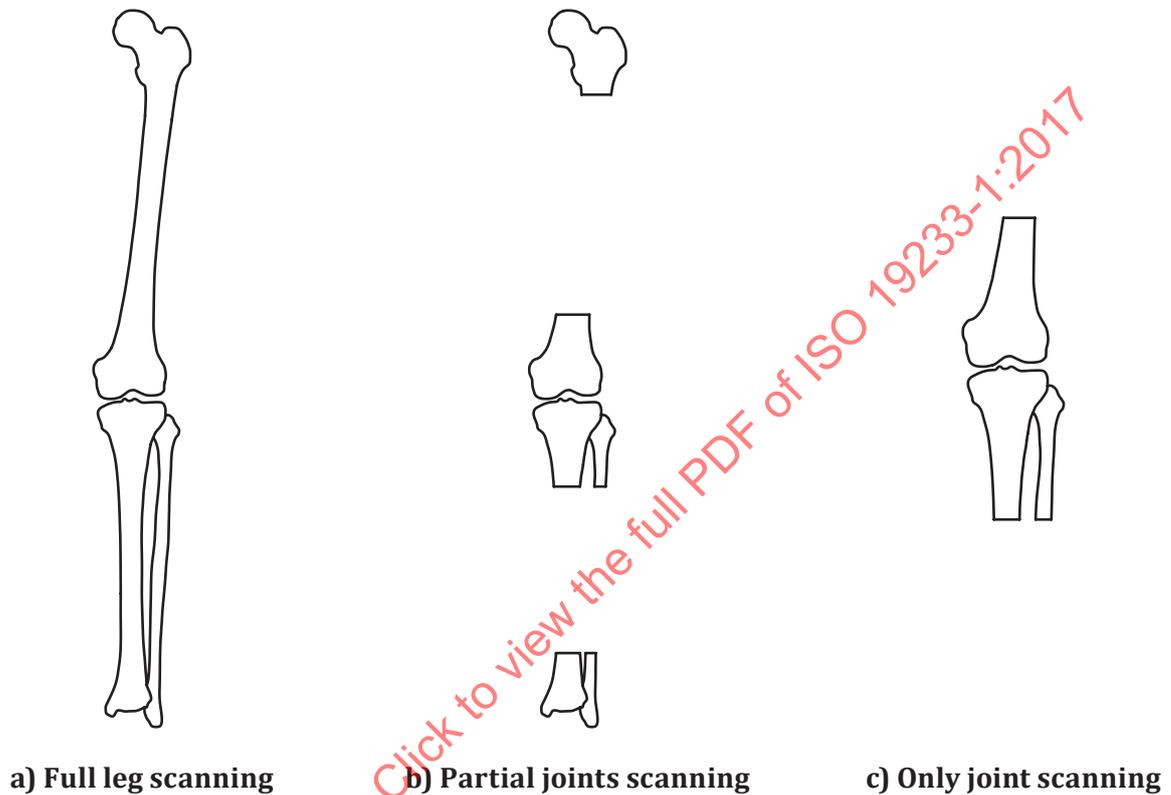For other cases, appropriate measures should be taken to identify leg alignment (see 5.1.10).

a) Full leg scanning   **b) Partial joints scanning**   **c) Only joint scanning**

Figure 1 — Illustrations of region of interest

5.1.3 Body position

Body position for scanning shall be the supine position with knee in extension.

5.1.4 Field of view (FOV)

Field of view shall exceed the dimension of the target anatomy, but also be limited to ensure the resolution of the reconstructed image.

Generally, the field of view is appropriate between 200 mm to 250 mm. For bilateral CT scanning cases, it shall be extended to 320 mm.

5.1.5 Slice thickness and slice spacing

Since the reproducibility can be affected by reconstruction conditions, optimum conditions should be set for each software. Slice thickness and slice spacing should be determined appropriately for each subject and the value of these should be minimized.

As slice thickness and slice spacing increase, the information between the slice images becomes imprecise, and the accuracy of the reconstructed 3D bone models decreases.

In case of the slice thickness and slice spacing exceeding more than 2,0 mm and 1,5 mm respectively, it is strongly recommended to perform validation in a proper manner. Annex A presents a procedure for software validation.

5.1.6 Reconstruction kernel

Choose the most appropriate reconstruction kernel of the CT apparatus used to reconstruct 3D bone models.

5.1.7 X-ray tube current

X-ray tube current should be set so as not to cause signal noise which may significantly decrease the precision of 3D bone models. Also, use of the Automatic Exposure Control (AEC) system for the CT apparatus is recommended to reduce exposure dose.

5.1.8 X-ray tube voltage

Set the appropriate X-ray tube voltage within the range of 80 kV to 140 kV according to the conditions of the CT apparatus used and the subject.

5.1.9 Precautions

Attention shall be taken to:

1) presence of metals around the scanning region of interest which can produce artefacts in the CT scan image

    It especially includes metallic implants in the subject or opposite legs. And in case of implanted metallic components in the opposite leg, a proper positioning of the body can prevent or reduce metal artefacts.

2) body moving while scanning

    The subject cannot move while scanning. If the subject moves while scanning, another scan is required.

NOTE   Scan images with a thin, cylindrical rod attached and parallel to the patient's leg are useful for detecting patient movement. If the scan image of the rod is not straight, it means that the patient has moved while scanning.

5.1.10 Leg alignment

Since it is impossible to determine alignments correctly only from CT images of the knee joint, plain X-ray images of a leg in a standing position should be used together.

When taking plain X-ray images, attention should be paid to the rotation and to the use of the exact coronal and sagittal images, including the range from femoral head to ankle joint.

As distortions of plain X-ray images are caused by the distance between the focal point, object and film at the time of taking plain X-ray images, image correction could be necessary.

Using appropriate landmarks for obtaining the images, construct the mechanical axis and the bone axes. Then, measure the angles between each axis, and apply them to 3D bone models reconstructed from CT images.

See Figure 2.
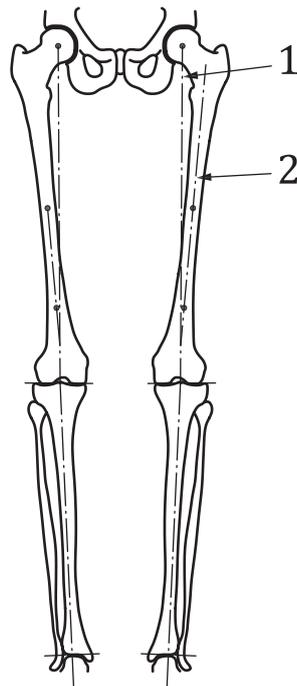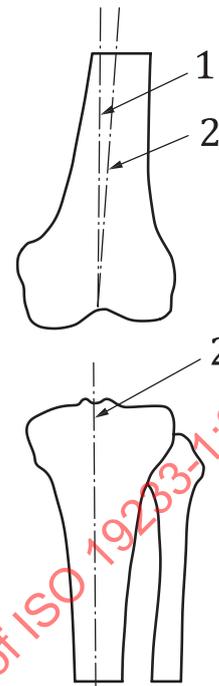
a) Example of plain X-ray image   **b) Example of 3D models**

Key

1   mechanical axis

2   anatomical axis

Figure 2 — Example of plain X-ray image and 3D models

5.2   Software regulatory requirements

For the generation of bone models, a software intended to be used as a segmentation system for the transfer of imaging information from a CT medical scanner to an output file shall be used.

As this software is also used to diagnose and investigate the lower leg anatomy, the software should comply with the regulations on Medical Device Software. Functional verification testing should be conducted to verify that design outputs meet the requirements. Review efforts throughout the software design cycle shall be traceable and documented in the design history file. Risk analysis shall be performed in accordance with ISO 14971.

Validation of the software should be done in order to prevent accuracy deterioration of reconstructed 3D bone model due to the lack of data while transferring of images from CT medical scanners. In addition, the image segmentation and 3D bone model generation algorithms should be properly validated.

5.3   Generation of bone models

5.3.1   Segmentation methods for bone and cartilage region

Segmentation methods allow the classification of anatomical tissues and parts in non-overlapping constituent regions. Pixel-based techniques classify regions based on homogenous image characteristics such as texture and brightness level. Shape-based techniques incorporate prior knowledge obtained from a population to classify regions.

The level of operator intervention is categorized as manual, semi-automatic or automatic. The latter two aim to reduce operator intervention and inter- and intra-operator variability.

Validation of automatic methods can be realized by comparison with manual segmented cases. The success rate of the automated segmentation algorithm can only be accurately determined if tested on a large batch of data.

5.3.2 3D reconstruction

The bone region extracted from each image should be reconstructed as 3D voxel data, based on positional information of each image. Then 3D bone models should be reconstructed by marching cubes or other 3D shape extracting algorithms. Verification of the 3D model can be achieved by inspecting the contours of the 3D bone model on the 2D images.

Calibrated and automated medical device software is intended to be used in this process. The software should be developed in compliance with the state-of-the-art methods in medical device software development and properly validated for its intended use.

Alternatively, linear dimensions can be measured by multiplanar reconstruction (MPR) images. In this case, reconstruction of bone surface is not necessary.

5.3.3 Data format

The data of 3D bone models are recommended to be formatted to stereolithography (STL) file format, which represents 3D bone geometry properly.

In the case of a reconstructed bone surface, which has software derived defects such as a planar hole, overlapping or intersecting triangle, where edge discontinuities are found on a 3D bone model, further evaluation is warranted. Local manual correction may be possible to correct some observed defects. Consideration should be given to whether the defect is indicative of an underlying defect in the reconstruction software.