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Information technology — Medical image-based modelling for 3D printing —

Part 2: Segmentation

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Partie 2: Segmentation

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, Information technology.

A list of all parts in the ISO/IEC 3532 series can be found on the ISO and IEC websites.

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 and www.iec.ch/national-committees.

Introduction

This document was developed in response to the need for customization of 3D printing technology in the medical industry through the use of information and communication technology (ICT).

There are many points where the existing standards for additive manufacturing (AM) do not match the requirements of the medical industry. From medical images to 3D printing, medical device development is quite a complex journey with complicated management of multiple pieces of software.

With the emerging market for medical 3D printed parts, there are many points requiring standardization.

There is currently no standardized process for the creation of protocols and validation procedures to ensure that medical imaging data can be consistently and accurately transformed into a 3D printed object.

For medical 3D printing, segmentation techniques should be optimized and combined according to the characteristics of the medical images and corresponding body parts to get an optimal 3D model.

In particular, during medical image segmentation, identification of the pixels of organs or lesions from raw data such as computed tomography (CT) or magnetic resonance (MR) images, is one of the most challenging analysis tasks.

For example, segmentation of the orbital bone is necessary for orbital wall reconstruction in cranio-maxillofacial surgery to support the eye globe position and restore the volume and shape of the orbit. However, orbital bone segmentation is challenging as the orbital bone is composed of cortical bone with a high intensity value, and trabecular and thin bone with low intensity values, similar to soft tissue.

The human bone is delineated and extracted by segmentation techniques, and a 3D skeletal model is built from this segmentation. The minimization of errors during segmentation of relevant body parts of interest is critical. As there are several known critical issues for this segmentation, a verification process is made before proceeding.

Not only single segmentation techniques but also combinations of those techniques should be adopted for accurate extraction of a target body part. However, this process depends heavily on the operator. For minimization of errors during this job, operators should know which segmentation technique is most used in their imaging software and possess the necessary skills for that technique.

Thresholding techniques which are provided by a default Hounsfield unit (HU) range do not completely recover true bony structure.[1] An operator should typically adjust the extent of the segmentation manually. The problem is usually under-segmentation. However, over-segmentation will also be problematic for further designing processes, especially for surgical implants. Various techniques have been suggested to reduce human error and improve performance and consistency for segmentation issues.[2]

This document proposes a standardized process for the optimization of segmentation.

Information technology — Medical image-based modelling for 3D printing —

Part 2: Segmentation

1 Scope

This document provides an overview of the segmentation process for medical image-based modelling of human bone. This document specifies a standardized process to improve the performance of human bone segmentation.

This document is also applicable to medical 3D printing systems that include medical 3D modelling capabilities.

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 15708-1, *Non-destructive testing — Radiation methods for computed tomography — Part 1: Terminology*

ISO/IEC 2382, *Information technology — Vocabulary*

ISO/ASTM 52950, *Additive manufacturing — General principles — Overview of data processing*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/ASTM 52950, ISO 15708-1, ISO/IEC 2382 and the following 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
image acquisition
scanning of the structure of interest using computed tomography (CT), magnetic resonance (MR) imaging or other three-dimensional imaging technology

3.2
image annotation
process of attaching labels to an image

3.3
label
classifying phrase or name applied to a target

3.4
learning
<machine learning> process by which a biological or an automatic system gains knowledge or skills that it may use to improve its performance

[SOURCE: ISO/IEC 2382:2015, 2122966, modified — Notes to entry have been removed.]

3.5
segmentation
process of separating the objects of interest from their surroundings

Note 1 to entry: Segmentation can be applicable to 2D, 3D, raster or vector data.

3.6
ground-truth label
correct answer of the training set for segmentation based on supervised learning

3.7
region of interest
ROI
specified boundary as defined in the image

3.8
machine learning
ML
process of optimizing model parameters through computational techniques, such that the model's behaviour reflects the data or experience

[SOURCE: ISO/IEC 22989:2022, 3.3.5]

3.9
labelled data
group of data that have been tagged with one or more labels

3.10
hyperparameter
characteristic of a machine learning algorithm that affects its learning process

Note 1 to entry: Hyperparameters are selected prior to training and can be used in processes to help estimate model parameters.

Note 2 to entry: Examples of hyperparameters include number of network layers, width of each layer, type of activation function, optimization method, learning rate for neural networks; the choice of kernel function in a support vector machine; number of leaves or depth of a tree; the K for K-means clustering; the maximum number of iterations of the expectation maximization algorithm; the number of Gaussians in a Gaussian mixture.

[SOURCE: ISO/IEC 22989:2022, 3.3.4]

3.11
medical image
type of images generated by medical imaging devices

4 Abbreviated terms

AI	artificial intelligence
AIM	annotation and image markup
CAD	computer-aided diagnosis
CCL	connected component labelling
CNN	convolutional neural network
CRF	conditional random field
CT	computed tomography
DICOM	digital imaging and communications in medicine
DL	deep learning
DSC	dice similarity coefficient
FCN	fully convolutional network
FOV	field of view
FN	false negative
FP	false positive
HU	Hounsfield unit
IoU	intersection over union
MIoU	mean intersection over union
ML	machine learning
MR	magnetic resonance
MRI	magnetic resonance imaging
NIfTI	neuroimaging informatics technology initiative
PET	positron emission tomography
SPECT	single-photon emission computerized tomography
TN	true negative
TP	true positive
US	ultrasonography

5 Objective of segmentation

5.1 Background

The purpose of segmentation is to extract a specific region or organ from a patient's CT/MR medical image and use it to create a 3D model.

Segmentation is the process of partitioning an image into different meaningful segments. For medical images, segmentation techniques should be optimized and combined according to the characteristics of image acquisition modalities and body parts to get an ideal 3D visualization. The human bone is delineated and extracted by segmentation techniques, and a 3D skeletal model is built from this segmentation. The minimization of errors during segmentation of relevant anatomy is critical.

Modelling for medical 3D printing requires optimized segmentation to provide better overlaying and matching processes for human tissues and organs. However, most of the commercially available image software cannot segment human bone effectively.

For improved medical image based 3D modelling, formalization and standardization of these procedures is required.

5.2 Types of segmentation methods

Several methods have been investigated that segment human bone from CT images.[18][19][22][23]

Semi-automatic segmentation: Thresholding is the simplest method of image segmentation, and thresholding can be used to create binary images. This method replaces each pixel in an image with an object pixel if the pixel intensity is greater than a specific human bone threshold value, or replaces it with a background pixel if the pixel intensity is less than a specific human bone threshold value.

Deformable model-based segmenation: Deformable models are curves or surfaces for segmentation in the image domain, which deform under the influence of internal and external forces to delineate the object boundaries. The internal forces are defined such that they preserve the shape smoothness of the model, while the external forces are defined by the image features to drive the model toward the desired region boundary. By constraining extracted boundaries to be smooth and incorporating other prior information about the shape, deformable models offer robustness to both image noise and boundary gaps.[35][36] However, there is a limit due to the difficulty of segmentation at the weak object boundary of a thin bone with a low intensity value similar to soft tissue.

CNN-based segmentation: The FCN is a network that does not contain any dense layers. Instead, it contains 1x1 convolutions that perform the task of fully connected layers. The U-Net network, which is commonly used for medical image segmentation, is based on a fully convolutional network and consists of a contracting path and an expansive path, which gives it the U-shaped architecture.

6 Overall segmentation process

6.1 General

The overall segmentation process consists of seven steps in total, as described in 6.2 to 6.8. Figure 1 shows the overall process flow of segmentation, where the numbers in parenthesis refer to clauses of this document.

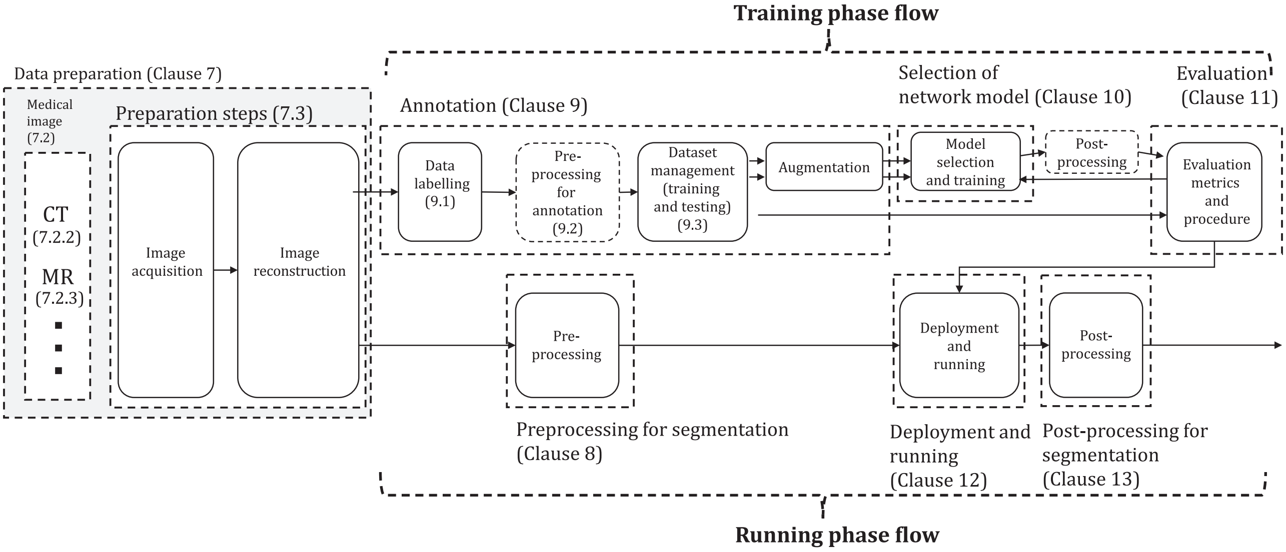

Figure 1 — Overall process flow of segmentation

The software developer should implement the optimized segmentation process for medical image-based modelling.

The considerations of the optimized segmentation process for medical image-based modelling should be referenced from this document.

6.2 Step 1: data preparation

The objective of the data preparation stage is to transform the raw data so that the segmentation algorithm can be applied. Detailed information is provided in Clause 7.

6.3 Step 2: preprocessing for segmentation

The objective of the preprocessing for segmentation stage is to normalize the data quality and induce consistent segmentation results. This stage is an important step that affects the ability of the network model to learn. Detailed information is provided in Clause 8.

6.4 Step 3: annotation

The objective of the annotation stage is to make the labelled training data fit for the learning of ML/DL-based segmentation network models. Detailed information is provided in Clause 9.

6.5 Step 4: selection of segmentation network model

The objective of the segmentation network model selection stage is to select the optimal segmentation network model. Detailed information is provided in Clause 10.

6.6 Step 5: performance evaluation

The objective of the performance evaluation stage is to calculate the agreement between the result of applying the segmentation technique and the ground-truth label. Detailed information is provided in Clause 11.