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

Part 1: General requirements

Technologies de l'information — Modélisation médicale à base d'images pour l'impression 3D —

Partie 1: Exigences générales

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Foreword

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

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Introduction

This document was developed in response to the need for customization of 3D scanning and 3D printing technology within the medical industry, which can be achieved by taking full advantage of information and communication technology (ICT).

This document addresses the overview of medical image processing and requirements for image-based modelling. 3D printing technology has caused a revolution in health care delivery. New classes of medical devices embody the true meaning of personalized medicine. Medical device designers and practitioners are able to practically and efficiently create devices that were very difficult or impossible to create before. In addition to using 3D printing technology to create standard medical devices with features like intricate lattice structures, clinicians and engineers work in conjunction to produce what are known as patient-specific devices or patient-matched devices. These are medical devices designed to fit a specific patient's anatomy, typically using medical imaging from that patient. Anatomically matched devices have very complex geometrical contours and shapes. Several challenges exist in the design process between the input data and the final device design. Most of these steps definitely depend on software-based management of medical images.

Overall, the world revenue from 3D printing technology in the healthcare industry is expected to grow exponentially, yet very few guides exist for 3D printing for medical practice. Medical images from the human body are different from solid objects due to the non-geometric nature of the human body. To perform 3D printing for medical practice, an accurate and consistent approach for image processing and data creation from medical images is needed. Standardization for 3D printing processes in medicine is urgently required for education, diagnosis, neurosurgical treatment, developing simulation models, medical equipment (including surgical guides) and surgical implantable devices in the clinical fields. Regulatory bodies from several countries (US, Republic of Korea, etc.) have already published their own guidelines for approval. However, those guidelines are not specifically designed for 3D printing technology.

Applications of 3D printing in medicine are thriving, and include surgical simulation models, surgical guides, educational models, surgical implants, etc. Those which are manufactured by 3D printing technology require patient- and/or procedure-specific data (e.g. planned surgical technique and others) and medical image data acquisition processing. Most of the processing of medical images for 3D printing medical devices is software-based. In order to accurately and consistently visualize human body anatomy, appropriate software-based modelling for 3D printing is needed. This document provides requirements for software-based medical image processing for the purpose of producing 3D models for 3D printing. Valuable information related to optimized medical image data for additive manufacturing can be found in ISO/ASTM TR 52916.

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

Part 1:
General requirements

1 Scope

This document specifies the requirements for medical image-based modelling for 3D printing for medical applications. It concerns accurate 3D data modelling in the medical field using medical image data generated from computed tomography (CT) devices. It also specifies the principal considerations for the general procedures of medical image-based modelling. It excludes soft tissue modelling from magnetic resonance image (MRI).

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/IEC 2382, *Information technology — Vocabulary*

ISO/ASTM 52900, *Additive manufacturing — General principles — Fundamentals and Vocabulary*

3 Terms, definitions and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO/IEC 2382, ISO/ASTM 52900 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 Terms and definitions

3.1.1
image acquisition
scanning of the structure of interest using computed tomography (CT), magnetic resonance imaging or other three-dimensional imaging technology

3.1.2
slice distance
slice spacing
distance between the centre of the slices, which is calculated by the difference in the slice locations of two adjacent slices

3.1.3
hard tissue
tissue which is mineralized and has a firm intercellular matrix (such as bone, tooth enamel, dentin and cementum)

3.1.4
soft tissue
tissue that connects, supports or surrounds other structures and organs of the body, excluding *hard tissue* (3.1.3)

3.1.5
solid organ
organ which has firm tissue consistency such as the heart, kidney, liver, lungs, pancreas, etc., excluding hollow organs (such as the organs of the gastrointestinal tract) and tissue with liquid consistency (such as blood)

3.1.6
pixel
picture element
smallest two-dimensional element of a display image that can be independently assigned attributes such as color and intensity

[SOURCE: ISO/IEC 2382:2015, 2125999, modified — Notes to entry have been removed.]

3.1.7
voxel
volume element
smallest three-dimensional element in volume or volumetric (solid) modelling that can be independently assigned attributes such as colour and intensity

[SOURCE: ISO/IEC 2382:2015, 2126000, modified — Notes to entry have been removed; "solid" has been replaced by "volume or volumetric (solid)".]

3.1.8
vector data
vector image
vector model
digital description of 2D image or 3D model stored as a series of points and mathematical functions to describe the geometric figure

[SOURCE: ISO 12651-1:2012, 4.139, modified — "image" has been replaced by "2D image or 3D model".]

3.1.9
raster data
raster image
raster model
bitmap data
bitmap image
bitmap model
2D image or 3D model data formed by a set of *picture elements* (3.1.6) or *volume elements* (3.1.7) arranged in a grid pattern

3.1.10
volume model
solid model
three-dimensional geometric model which deals with the solid characteristics of an object in order to represent its internal structure as well as its external shapes

Note 1 to entry: See ISO/IEC 2382 for definitions of volume modelling and solid modelling.

Note 2 to entry: Volume model can be represented with *raster model* (3.1.9) or *vector model* (3.1.8).

3.1.11
surface model
boundary model
data set of a model which represents the surfaces of objects

Note 1 to entry: See ISO/IEC 2382 for definitions of surfacing and surface modelling.

3.1.12
facet model
faceted model
surface model (3.1.11) of which surfaces consist of group of polygons

Note 1 to entry: A triangle is widely used as a polygon.

3.1.13
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* (3.1.8).

3.1.14
3D visualization
presentation intended for human viewing of a scene on a flat display surface, using graphics techniques to convey depth information and knowledge of the arrangement and shapes of the visualized scene in a three-dimensional space

Note 1 to entry: The graphics techniques can include use of perspective, occlusion, stereoscopy, lighting and environmental effects, and ability to navigate the viewpoint to alternate positions and orientations.

3.1.15
3D modelling
activity intended to create a digital representation of the form and arrangement of one or more 3D objects in a three-dimensional space

Note 1 to entry: 3D models can contain geometric information such as mesh vertices, appearance, lighting, and animation information. The created representation is a prerequisite to creating a *3D visualization* (3.1.14) of the modelled objects.

3.1.16
maximum intensity projection
MIP
scientific visualization method for 3D data that projects, in the visualization plane and with maximum intensity, the voxels that fall in the way of parallel rays traced from the viewpoint to the plane of projection

3.1.17
minimum intensity projection
MinIP
data visualization method that enables detection of low-density structures in a given volume

Note 1 to entry: The algorithm uses all the data in a volume of interest to generate a single two-dimensional image. In other words, it consists of projecting the voxel with the lowest attenuation value on every view throughout the volume onto a 2D image.

3.1.18
Hounsfield value
Hounsfield unit
integer representing the intensity of the image at each image point [*pixel* (3.1.6)] which originates from the x-ray scanning process and in turn represents the image intensity, which depends on the density of the tissue at that location

Note 1 to entry: Hounsfield values rise monotonically with tissue density but are not linearly proportional to density.

Note 2 to entry: The highest range of biological tissue Hounsfield values is for cortical bone, and they can go even higher for image artefacts such as metallic implants, metallic sections of a hospital bed included in the image, etc.

3.1.19
multiplanar reformation
MPR
two-dimensional reformatted images that are reconstructed secondarily in arbitrary planes from the stack of axial image data

Note 1 to entry: Multiplanar reformation (MPR) allows images to be created from the original axial plane in either the coronal, sagittal or oblique plane.

3.1.20
volume rendering
set of techniques used to display a 2D projection of a 3D discretely sampled data set, typically a 3D scalar field

3.2 Abbreviated terms

2D	two-dimensional
3D	three-dimensional
AM	additive manufacturing
AMF	additive manufacturing file format
ANN	artificial neural network
CAD	computer aided design
CT	computed tomography
DICOM	digital imaging and communications in medicine
HU	Hounsfield unit
PACS	picture archiving communication system
QC	quality control
ROI	region of interest
STL	stereolithography
SVM	support vector machine

4 Overview of image processing for the medical industry

4.1 Process flow

4.1.1 3D printing process for medical applications

In general, the medical 3D printing processing flow can be divided into eight phases, as shown in Figure 1.

NOTE Annex A contains a list of recommended items to be noted during the 3D printing process flow.

1) **Image acquisition phase**

In the image acquisition phase, medical images are acquired from medical imaging devices such as CT.

2) **Segmentation phase**

In the segmentation phase, the acquired medical images are segmented to fit the design purpose and are processed to be divided (segmented) to extract a subset that would represent the part(s) of the anatomy under consideration.

3) **3D modelling phase**

In the 3D modelling phase, the segmented data representing the human tissue is converted (reconstructed) into a 3D model optimized for 3D printing.

4) **3D printing phase**

In the 3D printing phase, 3D printing is performed using the 3D model designed. For this phase 3D model is processed for 3D printing by slicing, assigning build parameters, being oriented and placed within the build space, and can have support structures generated.

5) **Post-processing phase**

In the post-processing phase, the 3D printed part is post-processed to become fit for actual medical use.

6) **Quality control (QC) phase**

In the QC phase, the 3D printed part is finally verified to meet all requirements (user/design/quality/risk).

7) **Clinical application and review phase**

In the clinical application and review phase, the 3D printed part is reviewed as applicable to clinical application by the healthcare practitioner.

8) **Post-market phase**

In the post-marketing stage, the 3D printed part is managed based on the post-sale market management policy according to product life cycle issues such as tracking management/recall.

4.1.2 Explanation of a typical use case (cranial implant case)

Computed tomography (CT) is a common imaging modality for medical applications. For instance, for patients with a skull defect visiting a neurosurgical clinic, CT has been known as the gold standard for investigating bone-related problems. Figure 1 shows that the CT images are initially transferred to the PACS server in DICOM file format. DICOM images have been used to reconstruct 3D image through segmentation and 3D modelling by certain software. This 3D modelled image is transformed and exported to design software as a stereolithography (STL) file. After completion and confirmation of 3D cranial implant by designing software, a metal AM machine builds this implant as designed. Post-processing such as heat treatment, machining, cleaning and sanding is performed. Reverse engineering is performed to confirm the completeness of the implant before delivery by 3D scanning and matching to the original digital blueprint. After QC, the implant is packed, sterilized and delivered. An operation is performed to cover the defect with the 3D printed cranial implant. For this medical 3D printing process, accuracy and reproducibility should be considered. The accuracy and reproducibility of the parts (anatomical model, surgical guides, implant, etc.) from medical 3D printed parts are affected by the sum of errors introduced in each step during data flow. These steps can be image acquisition, segmentation and any subsequent post-processing of the segmented images. This document covers processes 1, 2 and 3 as shown in Figure 1, ending with a 3D model of the relevant patient anatomy for use in multiple other later processes. Activities related to items for processes 4 - 8 are addressed by ISO/TC 261.

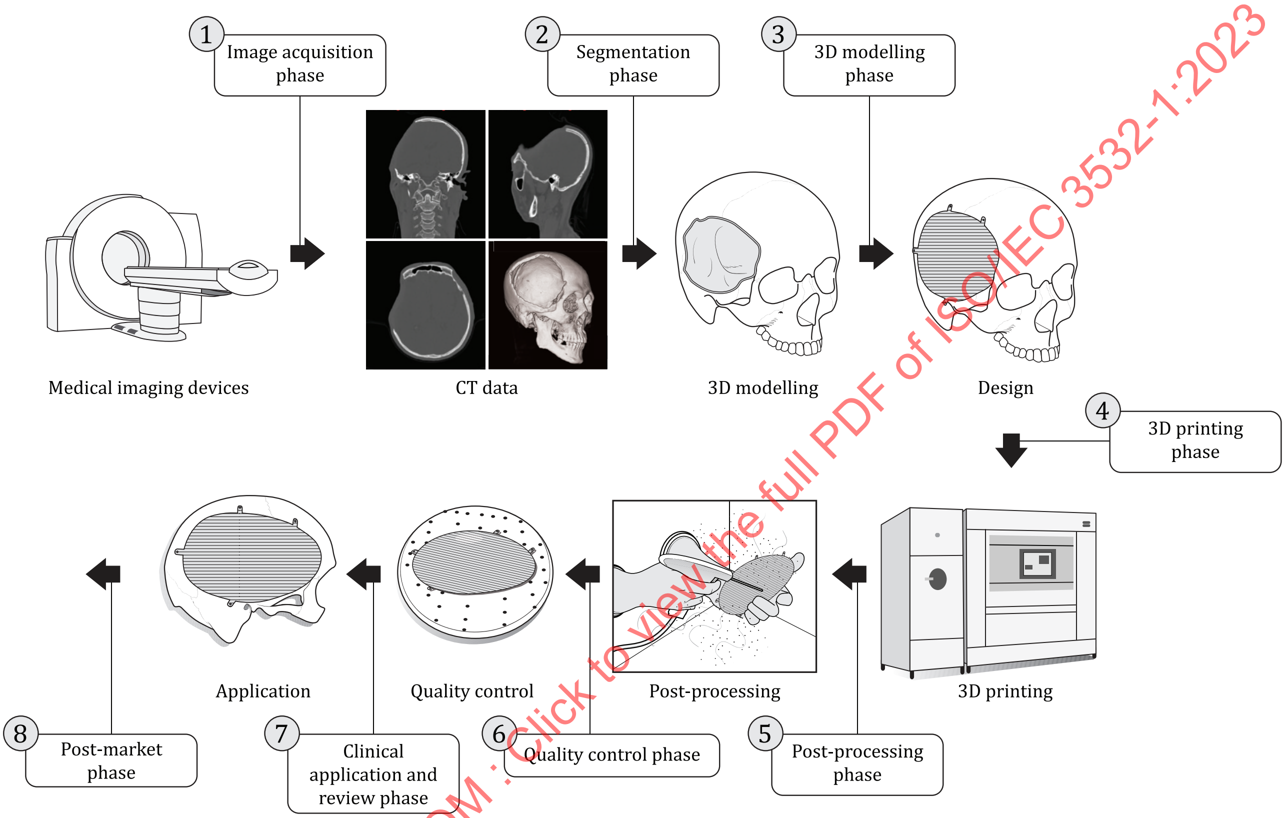


Figure 1 — Typical workflow of medical 3D printing (example: cranial implant case)

5 General requirements

To conform to this document, all of the following items shall be considered and relevant information shall be documented.

— The medical image acquisition protocol by the CT scanner.

— The clinical purpose (bone/hard tissue) of image-based modelling.

— The segmentation method and associated parameters.

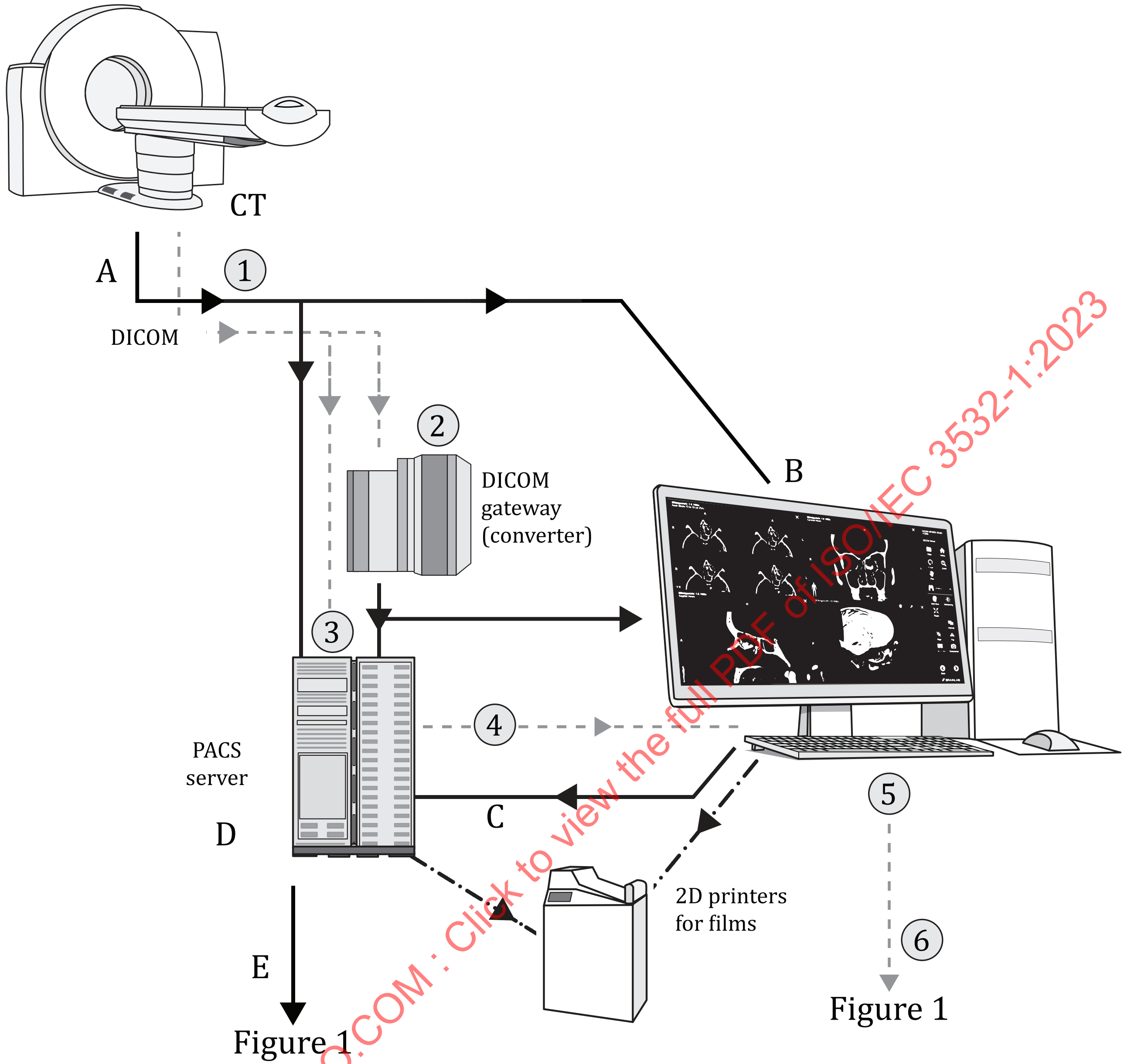
— The processes and parameters for 3D reconstruction.

Major parameters, settings and descriptions of methods used in the processes above shall be recorded.

6 Requirements of data processing

6.1 Medical image data flow

There are usually two medical image data flows involved in data processing: example flow and direct flow. MIP, MinIP, MPRs and volume rendering are used before transporting the medical image to the PACS server. Typically, DICOM files are used to make 3D images. However, many PACS companies provide plugged-in 3D visualization software to reform raw data to 3D images and transport 3D images directly to the PACS server as captured images. These 3D visualizations on the PACS server are 2D projections of a 3D object and are not suitable for 3D modelling. The 2D printers for films prints out 2D images (X ray radiograph, CT, MRI, etc.) or 3D-modelled captured images. See Figure 2.



Key

Example flow (dotted lines)

1 scanned by device
2 convert to DICOM
3 save to PACS server
4 3D visualization
5 transfer to STL or other file formats
6 directs to Figure 1

Direct flow (solid lines)

A scanned by device
B 3D visualization
C save to PACS server
D (transfer to STL)
E directs to Figure 1

Figure 2 — Data flow of medical images (Example)

6.2 Medical image acquisition/computed tomography scan

To make medical 3D models, sequential 2D images are necessary and should be acquired from sectional images. Generally, 2D slice images are acquired from a CT scan of the patient's body at regular intervals depending on the scanning needs. Each CT image set has its own strengths and weaknesses with respect to the different objectives of the observation. Bones are typically clearly identified. Variabilities of output depend on factors such as spatial resolution/voxel size of the images, which in turn depends on the x-ray dosage, the quality of the scanned images, operator capability, and low and high resolution on 2D to 3D conversion algorithms. Features smaller than 0,3 mm cannot be printed successfully with some printing processes if smaller features are needed. This will require special considerations for process selection and post-processing operations. Care should be taken in choosing the appropriate 3D printing technology and the part manufacturers should be requested to consider the required resolutions.

For medical image acquisition, the typical slice distance of less than 1 mm is sufficient and the following points shall be addressed.

— Required accuracy and clinical purposes shall be compatible. The CT scanning protocol shall be specified beforehand to achieve the required accuracy of the final models.

— The highest accuracy or resolution of CT scan is not always necessary.

— The time between the acquisition of the patient images and the initiation of image-based modelling shall be minimized.

Other factors which can influence the quality of the final scanned images are as follows.

— Possible patient motion during the scanning process and its implications on the imaging accuracy. Even breathing can cause errors in scanning in cardiovascular applications, for example.

— The use of contrast media during the scanning process to highlight blood or other liquids through various tracers.

— Any digital filtering techniques applied in the data processing at the scanning stage to produce the DICOM data used later for segmentation and reconstruction.

6.3 Segmentation

Image segmentation divides the image into meaningful regions. Segmentation usually extracts one or more subsets of the data from the whole dataset, such that each subset would represent an anatomical part, or tissue of the same characteristics [(e.g. bone having high density versus soft tissue having lower density so a simple threshold can be established based on Hounsfield unit (HU)] etc. Segmentation in medical imaging is generally considered a difficult problem, mainly because of the sheer size of the datasets coupled with the complexity and variability of the anatomic organs.

The situation is worsened by the shortcomings of imaging modalities (such as sampling artifacts, noise, low contrast, etc.) that can cause the boundaries of anatomical structures to be indistinct and disconnected. The segmentation process becomes challenging in the absence of clear distinction in the characteristics desired, such as density ranges overlapping (e.g. very soft bone indistinguishable from calcified cartilage), or blood vessel walls not sufficiently distinguishable from surrounding muscle tissue, etc. The challenge is greater when the target tissue is complex (intermingled or touching) in its location (e.g. small diameter nerves around the orbit and vessels and nerves through skull base foramens, anterior of a distal femur in a highly arthritic patient appearing to be totally connected to their patella, or small complex branched blood vessels.).

Thus, the main challenge of segmentation algorithms is to accurately extract the boundary of the solid organ or region of interest (ROI) and separate it from the rest of the dataset. The notion of boundary starts in a 2D context of an image slice. Boundaries from all images (slices) can help build whole models after segmentation.

For the segmentation of bony structures from CT scans the following relevant segmentation technologies can be selected or combined:

— intensity-based segmentation: thresholding, edge-based (e.g. canny edge detector, sobel edge detector), region-based (e.g. region growing, region splitting and merging), hybrid-based (e.g. watershed transformation);

— deformable model-based segmentation: active contour model, level-set method;

— atlas-based segmentation: active shape model, active appearance models, label fusion;

— machine learning-based segmentation: supervised (e.g. ANN, SVM), unsupervised (e.g. K-means clustering, Fuzzy C-means algorithm).

Segmentation of bony structures from CT scanned image data has therefore benefited from multiple software algorithmic techniques. Several software advancements have emerged stretching from purely image intensity (thresholding) as described above, into more intelligent deformable model versions where a shape is assumed to have been approximately recognized but adjusted based on the data. Even more advanced techniques include the shaper perception to relay on multiple preconceived shape models (from an atlas) and all the way to using the most modern computer learning, Deep Learning and other Artificial Intelligence (AI) methods where a computer smart algorithm itself adds to its own growing database (atlas) and decision processes.

To identify and isolate voxels that represent any anatomy of interest, two implementations of segmentation are:

a) assigning a mask to a dataset indicating active voxels; or

b) deletion/removal of voxels not included in segmentation.

Threshold-based segmentation, commonly used in intensity-based segmentation, uses pixel brightness and patterns throughout the DICOM data to isolate or remove structures. The threshold-based method has been mostly used in 3D modelling software. Most visualization software provides default HU to perform segmentation in semi-automatic fashion. By the adjustment of HU, the extent of segmentation can be changed. Whenever this semi-automatic method cannot cover the whole ROI, manual segmentation will recover the missing part. The boundaries resulting for the ROI or tissue of interest should be checked by the operator on a slice-by-slice level to verify accuracy before the segmentation process is completed to proceed to 3D modelling. In deformable model-based segmentation, the active contour model is a parameterized curve or surface which iteratively evolves toward the desired boundary of the anatomy according to the energy minimization criterion. This model is robust to both image noise and boundary gaps as it constrains the extracted boundaries to be smooth. However, it can severely restrict the degree of topological adaptability of the model if the deformation involves splitting or merging of the anatomy.

Atlas-based segmentation uses a database of images and anatomic structure labels and attempts to register and fuse this information to the current DICOM dataset.

In machine learning-based segmentation, as an example, K-means clustering is a way to identify groups in an image, where K represents the number of groups. It works repeatedly to assign each pixel (or voxel) to one of the groups according to features similarity to form a group, and similarity measures include distance. K-means clustering and Fuzzy C-means clustering are similar in approaches. The main difference is that in Fuzzy C-means clustering, each pixel (or voxel) has a weight associated with a particular cluster, which means that there is a weak or strong association in that cluster.

The minimization of errors during segmentation of body parts of interest is critical. There are several known critical issues, and therefore a verification process shall be made before proceeding further. Not just single segmentation techniques but also combinations of those techniques should be adopted for accurate extraction of a target area. However, this process greatly depends on the operator. Semi-automated segmentation which is provided by a default HU does not completely recover true bony structure. The operator shall further adjust the extent of the segmentation manually. A common problem is undersegmentation. However, oversegmentation is also problematic for designing implants for covering defects as the implant is not fitted.

Methods of segmentation are automatic, semi-automatic and manual.

For medical image segmentation, the following points shall be addressed:

- for minimization of errors during this job, operators should know which segmentation technique is mostly used in their imaging software and be qualified in that technique;
- a communication step included in the process where the physicians review the segmentations/ surface models prior to manufacturing can greatly help to control the risks and errors;
- the operator should address the feasibility of original images to proceed to further segmentation;
- the choice of segmentation techniques shall be appropriate to applications and verifiable;
- verification processes for each step of segmetation shall be addressed;
- the results of segmentation shall be reproducible and verifiable.

6.4 3D reconstruction and visualization

This step is about creating a 3D model which can either be a surface model or a volumetric model from the segmented image data. A 3D volume model is created. 3D models can be made by stacking serial segmented images. These can be created as follows: each segmented image is expanded onto the next image to build several small volume models, referred to as volume reconstruction. Finally, all volume models are combined. From the combined volume models, a surface model is extracted, referred to as the surface reconstruction. The resulting shape can be a triangulated surface model and is hollow. That would be considered a surface model, and can be stored in STL file format. Generally, the volume and surface reconstructions are performed simultaneously by reconstruction software. The surface model consists of the original stacked outlines and numerous triangular surfaces between the outlines as a facet model.

Some techniques produce a volume model which is not hollow, and comprises voxels; then it is called a volumetric model. There are many methods (computational algorithms) for reconstruction to develop 3D models from slice image data. One traditional method is called the “marching cubes” with many variations and improvements since, and multiple other methods. The details of all those methods are not in the scope of this document.

As DICOM is a bitmap-based image format and the STL file format is triangle tesselation surface mesh file format, there is a reconstruction problem. To convert segmented images from DICOM, "smoothing" and "averaging" are mostly essential. Most of the software for 3D conversion of 2D images provides "smoothing and averaging" functions for removing "step ladders" which are a critical defect from the stacking 2D images. This can frequently produce smoother surfaces with improved appearance, without step ladders. However, such step ladders are inherent in the segmented data input to the reconstruction algorithm and they represent the true reconstruction based on the input which is by nature not smooth (e.g. there is no data between the slices from the imaging), so the boundaries from one image slice to the next can change in what looks like an abrupt manner. While doing segmentation and 2D to 3D conversion there is a risk that the shape and the true edge of the structure will be lost. If modest and reasonable smoothing was desired, consideration shall be taken of the possible errors in terms of how much loss or addition of the surface model can occur due to the smoothing. The edge of the defect site is a critical structure to be fitted by implant or surgical guide. 2D to 3D conversion can change representations of portions of body parts, especially edges of a bone or bony defects. However, there is no clear predictability for how much these processes (smoothing and averaging) are going to impact the change.

The 3D surface model can also end up with unintended holes (missing triangles) and therefore ambiguity about the edge and on which side of the edge triangles are facing outwards (direction of the normal). It is good practice to always patch a surface model to make sure that the surfaces are essentially closed and no triangulate edges are left unconnected with other triangles.

Volume and surface 3D models have different file formats according to the software used, so exchanging data and using other software can be difficult. If the outlines are exported then the format used shall be a standard one. The volume models, too, shall be exported in a standard format.

