TECHNICAL REPORT

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Additive manufacturing for medical — Data — Optimized medical image data

Fabrication additive dans le secteur médical — Données — Données d'images médicales optimisées

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Foreword

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This document was prepared by ISO/TC 261, *Additive manufacturing*, in cooperation with ASTM Committee F42, *Additive Manufacturing Technologies*, on the basis of a partnership agreement between ISO and ASTM International with the aim to create a common set of ISO/ASTM standards on additive manufacturing. and in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 438, *Additive manufacturing,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

This document has been developed in close cooperation of ISO/TC 261 and ASTM F 42 on basis of a partnership agreement between ISO and ASTM international with the aim to create a common set of ISO/ASTM standards on additive manufacturing.

Digital imaging and communications in medicine (DICOM) image files cannot be used directly for 3D printing; further steps are necessary to make them readable by additive manufacturing system. In particular, as the thickness of the computed tomography slice increases, there is a problem that the error in 3D reconstruction of the anatomical structure increases. Therefore, the focus of this technical report is to automatically reconfigure the slice interval through the application of isotropic conversion technology to utilize the existing dicom file and visualization and editing software as it is. In addition, in order to present a method for optimized medical image data for additive manufacturing, tomography metadata without compression is used by editing and processing the output format file without loss in the AM equipment system, or tomography within the maximum allowable range of radiation. Consider reducing the spacing of slices as much as possible and increasing the resolution per image as much as possible.

This document benefits from the direction of development and high quality additive manufacturing output through the technical optimization of medical imaging for additive manufacturing: medical academics, clinic and industry fields for AM like as anatomical measurements, 3D analysis, finite element analysis and surgical planning or simulation, patient-specific implant and device design. There are many affected stakeholder like as medical AM system manufacturer, AM feedstock manufacturer, AM feedstock supplier and vendor, medical AM hardware manufacturer, medical AM software manufacturer, medical AM system manufacturer, medical AM platform manufacturer, AM based medical device manufacturer, medical 3D scanning and digitizing device manufacturer, surgical simulation AM model manufacturer, AM surgical implant manufacturer, AM surgical guide manufacturer, AM physical model for clinical education and diagnostic treatment, disposable medical AM consumable devices.

Additive manufacturing for medical — Data — Optimized medical image data

1 Scope

This document includes the creation of optimized data for medical additive manufacturing (MAM). These data are generated from static modalities, such as magnetic resonance imaging (MRI), computed tomography (CT). This document addresses improved medical image data, and medical image data acquisition processing and optimization approaches for accurate solid medical models, based on real human and animal data.

Solid medical models are generally created from stacked 2D images output from medical imaging systems. The accuracy of the final model depends on the resolution and accuracy of the original image data. The main factors influencing accuracy are the resolution of the image, the amount of image noise, the contrast between the tissues of interest and artefacts inherent in the imaging system.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in 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
CT
computed tomography
computed axial tomography
radiographic scanning technique that uses a number of CT projections of an object at different angles in order to allow calculation of a CT image

[SOURCE: ISO 15708-1:2017, 3.7]

3.2
MRI
magnetic resonance image
imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ISO 14630:2012, 3.5]

3.3
polygon
planar surface defined by one exterior boundary and by zero or more interior boundaries

Note 1 to entry: Each interior boundary describes a hole in the surface.

Note 2 to entry: A single or group of polygons can be used to define a treatment zone.

[SOURCE: ISO 11783-10:2015, 3.13]

3.4
reconstruction
process of transforming a set of CT projections into a CT image

[SOURCE: ISO 15708-1:2017, 3.25]

3.5
rendering
action of transforming from a scene description to a specific output description/device

[SOURCE: ISO 19262:2015, 3.213]

3.6
ROI
region of interest, sub-volume within an object or a CT image

[SOURCE: ISO 15708-1:2017, 3.26]

3.7
segmentation
method which partitions a surface or volume into distinct regions

[SOURCE: SOURCE: ISO 25178-2:2012, 3.3.6, modified — ISO 25178-2:2012 had “scale-limited surface” in the definition.]

3.8
volume data
data of a volume in a 3D space

Note 1 to entry: The description can be performed on the basis of density differences inside the three-dimensional space.

[SOURCE: ISO 18739:2016, 3.1.42]

3.9
voxel
volume pixel
three-dimensional cuboid representing the minimum unit comprising a three-dimensional image

[SOURCE: ISO/TR 16379:2014, 2.17, modified — "volume pixel" has been added as a second term.]

3.10
2D
geometry in a xy-plane, where all the geometry's points have only x and y coordinates

[SOURCE: ISO 14649-10:2004, 3.1]

3.11
DICOM
digital imaging and communications in medicine
international standard for medical images and related information

Note 1 to entry: It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.

Note 2 to entry: The Medical Imaging Technology Association (MITA), a division of NEMA, serves as the DICOM Secretariat. The current DICOM standard may be found at: https://www.dicomstandard.org/current.

4 Medical images generation for AM

4.1 General medical image data generation

The start for image generation is to collect raw image data. This collects raw information about the inside of the human body and becomes the basic object of all subsequent image processing tasks. In the end, regardless of the image format, the data collection process detects physical factors, pre-processes the collected signals and then digitizes them (see Figure 1).

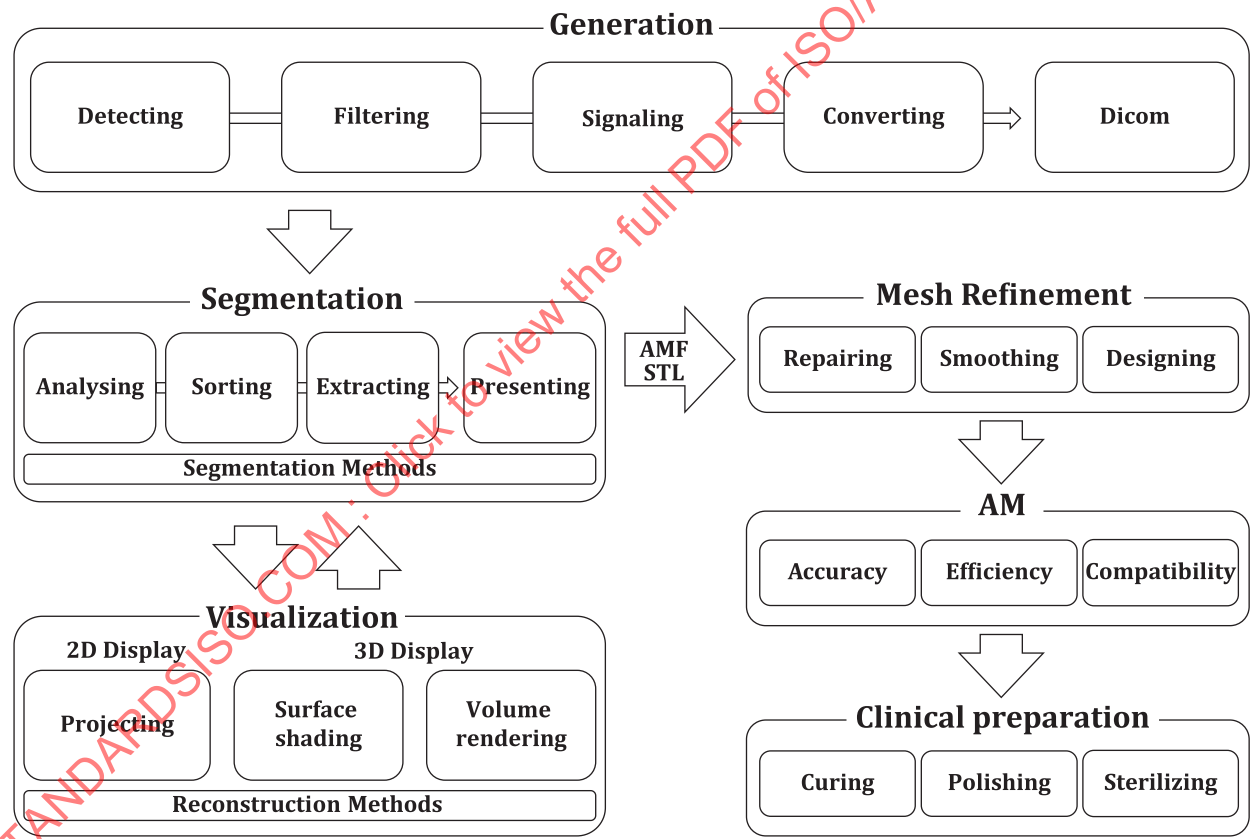


Figure 1 — Process from medical image to medical additive manufacturing

4.2 General error occurrence steps in medical images generation

With gradual technological advancement, many solutions for medical additive manufacturing are emerging. However, research into the cause for resolving errors in medical additive manufacturing output is still ongoing. The cause of additive manufacturing accuracy error occurs in the process of converting the raw data to medical images and the process of converting 3D model data. Error generation factors that occur during this conversion process are described in 4.3 for the most common tomography systems.

Additional errors may be generated by the process of converting DICOM or PACS data to the computational formats used within segmentation editing software and saving the STL 3D mesh format for use in additive manufacturing systems. When saving a customized STL file, all meta data that defined colour, material, surface textures are lost. The lack of accuracy and precision for 3D data from the scan systems, editing and modelling software can reduce the quality of an additive manufactured medical device.

NOTE 1 There can be other factors in creating errors when utilizing other image capture modalities, such as ultrasound, digital microscopy, etc. not covered in 4.3.

4.3 Medical image extraction

4.3.1 Introduction of medical image extraction

The quality of a medical image depends on the degree to which the microscopic structure of the human body can be accurately represented. According to the needs of the medical professional who requested the tomography, the layer spacing between the cross-sectional images is adjusted and photographed. Based on the captured meta data, reconstruction through 3D visualization is performed to extract the data of the region of interest. In this process, the medical imaging tomography technology, imaging conditions, and data conversion process will continue to affect the medical additive manufacturing output resolution.

4.3.2 CT image error generation factors

CT modality images use absorption coefficient parameters that visualize the density of an image. The contrast of hard tissue is more clearly expressed than soft tissue. Since sequential image layers are output as a series, 3D reconstruction is possible. The important factors that determine the image quality are the accuracy of the CT reduction coefficient, which expresses the degree of attenuation of a substance, noise, uniformity, spatial resolution, contrast resolution, and radiation dose. It is recommended that the patient's exposure dose is small, but it is very difficult to control the exposure dose and image quality because it is directly related to image noise and density resolution. Adjustment of radiation dose for each body part according to the patient's condition follows the clinical experience and medical recommendations of the radiologist. This is an external factor that affects the medical image data homogeneity.

— CT matrix size: The digital medical image is stored as 2D pixels, and each pixel is converted into the number of bits matched by the number of gray levels and represented. The CT image size depends on the anatomy being examined. Typically, CT images have a matrix size of 512 pixels × 512 pixels × 8 bytes (12 bits), and gray levels range from 512 pixels (28 bits) to 4 096 pixels (212 bits). A single CT section requires 512 pixels × 512 pixels × 2 bytes = 524,288 bytes of storage on the computer.

— CT reduction coefficient: The tissue weighting factor (W_T) is a relative measure of the risk of stochastic effects that might result from irradiation of that specific tissue. It accounts for the variable radiosensitivities of organs and tissues in the body to ionizing radiation. To calculate the effective dose, the individual organ equivalent dose values are multiplied by the respective tissue weighting factor and the products added. The sum of the weighting factors is 1.

— Based on the values of tissue weighting factors, tissues are grouped into following to assess the carcinogenic risk:

high risk (W_T = 0,12): stomach, colon, lung, red bone marrow;

moderate risk (W_T = 0,05): urinary bladder, oesophagus, breast, liver, thyroid;

low risk (W_T = 0,01): bone surface, skin.

— Spatial resolution: Ability to image small objects that have high subject contrast, CT has moderate spatial resolution 20 lp/cm.

— Contrast resolution: Ability to distinguish between and image similar tissues, CT has excellent low contrast detectability 0,25 % to 0,5 % difference in tissue attenuation.

4.3.3 MRI Image error generation factors

MRI uses a magnetic field that is harmless to the human body and radio frequency, which is non-ionizing radiation. The principle is to image the density and physicochemical properties of the atomic nucleus by causing nuclear magnetic resonance phenomenon in the atomic nucleus inside the human body. The advantage and difference are that it has several imaging parameters compared to CT. Four factors, such as the density of the hydrogen atom nucleus, T1 relaxation time, T2 relaxation time, and blood flow, are important parameters that determine the shading of the image. However, not only the distribution of the hydrogen atom nucleus, but also the molecular state of the contained tissue or the physical state of the image varies. The MRI image looks at the distribution of spin density and is further affected by the T1 T2 relaxation time associated with the NMR (Nuclear Magnetic Resonance) phenomenon. However, due to parameter elements for each MRI device, standard parameter settings are different for each MRI imaging personnel and are external factors affecting image data homogeneity.

MRI image quality depends on resolution (matrix, field of view, slice thickness), signal noise ratio, contrast, artefacts. Especially contrast depends on the MRI scan parameter.

MRI resolution is the size of an individual pixel, the smaller it is, the higher the resolution. The MRI matrix size is the number of pixels in the images. To improve the MRI resolution, increase the matrix, decrease the FOV, and decrease the slice thickness.

In the field of orthopedic surgery, MRI scan parameters are applied in the following ranges of maximum and minimum values of FOV, slice thickness, interslice gap, and matrix size.

Table 1 — Musculoskeletal MRI scan parameters

Parameters	Scan section					
	Shoulder	Elbow	Wrist	Hip	Knee	Ankle
Field of view (cm)	≥16	10 to 16	6 to 12	16 to 20	≥16	≥14
Slice thickness (mm)	≥3	3 to 4	≥3	3 to 4	≥3	≥3
Slice gap (%)	≥10	≥33	≥33	≥33	≥10	≥10
Matrix size (pixel)	≤ 256 × 192	≤ 256 × 256	≤ 256 × 192	≤ 512 × 384	≤ 256 × 192	≤ 256 × 192

— Signal noise ratio: The signal noise ratio is a measure that compares the level of a desired signal to the level of background noise. For data acquired through magnetic resonance imaging, this quantification is typically used to allow comparison between imaging hardware, imaging protocols and acquisition sequences. In this context, the signal noise ratio is conceptualised by comparing the signal of the MRI image to the background noise of the image. Mathematically, the signal noise ratio is the quotient of the signal intensity measured in a region of interest and the standard deviation of the signal intensity in a region outside the anatomy of the object being imaged or the standard deviation from the noise distribution when known. For example, field of view, scan parameters, magnetic field strength and slice thickness, the signal noise ratio of MRI images can be increased because these parameters influence the background noise.

— Image contrast: The repetition time (TR) and Echo time (TE) are basic pulse sequence parameters and stand for 'repetition time' and 'echo time' respectively. They are typically measured in milliseconds (ms). The echo time represents the time from the centre of the RF-pulse to the centre of the echo. For pulse sequences with multiple echoes between each RF pulse, several echo times may be defined and are commonly noted TE1, TE2, TE3, etc. The repetition time (TR) is the length of time between corresponding consecutive points on a repeating series of pulses and echoes.

Variations in the value of TR and TE have an important effect on the control of image contrast characteristics. Short values of TR (less than e.g. 1 000 ms) and TE (less than e.g. 25 ms) are common in images exhibiting T1 contrast. Long values of TR (greater than e.g. 1 500 ms) and TE (greater than e.g. 60 ms) are common in images exhibiting T2 contrast. Middle TR values (e.g. from 1 000 ms to 1 500 ms) and middle TE values (e.g. from 25 ms to 60 ms) are common for density weighted contrast.

— Artifacts: Most common MRI artifacts were movement, Gibb's, metal and slice overlap artifacts.

— Movement artifact correction: Breath holding, sedation, anesthesia, electrocardiographic trigger, spatial RF pre-saturation, flow compensation.

— Gibb's Artifact (truncation, ringing, spectral leakage artifacts) correction: Softening filters, larger acquisition matrix, smaller FOV.

— Slice overlap Artifact correction: Avoid sharp angle changes between slice groups, increase a gap between slices, apply different storage processes for images.

5 Image segmentation

5.1 Introduction of segmentation

Image segmentation is the process of partitioning an image into multiple labelled regions locating objects and boundaries in images. It can be used to create patient-specific, highly accurate computer models of organs and tissue. There are a number of image segmentation techniques, which each have advantages and disadvantages, but there is no single segmentation technique which is suitable for all images and applications. Basic segmentation approaches rely on the principle that each tissue type has a characteristic range of pixel intensities. Hence, it is possible to distinguish between tissues and identify boundaries.

Image segmentation refers to a process of grouping connected pixels having similar characteristics among pixels constituting a given whole image. However, despite the many image processing methods, there are not many differences in the image attribute information values of the anatomical human structures, so there are many results that appear to be unclear or disconnected. If a modification is made to improve image quality, data corruption problems occur. In the end, it is necessary to improve the segmentation algorithm that can extract all ROI (Region of Interest) boundaries.

5.2 Segmentation techniques

In the 2D medical image, the region of interest needs to be accurately divided so that the desired region of interest can be 3D visualized. As a measure of image segmentation grouping, feature elements such as contrast, colour components, edges, texture, motion, and depth information are used. Many types of segmentation algorithms are applied based on these indicators, and the image segmentation methods. Thresholding-based algorithms, clustering-based algorithms, region-based algorithms, and level-set-based algorithms are representative.

5.2.1 Thresholding algorithm

It is a method to divide into a thresholding range using a histogram. In this case, when a characteristic of a pixel is a pixel value, a set of pixels with a result of 1 is called an object, and a set of results with a result of 0 is called a binary image partitioning method. After determining the general threshold values for bones and muscles, segments of all pixels larger or smaller are divided into groups, and segments are sequentially processed. However, if there is no spatial characteristic of the image to make the noise stronger, there is a method of segmentation using information associated with the local intensity.

5.2.2 Region growing algorithm

The region growing segmentation is a method of finally dividing the entire image by gradually integrating and growing regions with the same characteristics from adjacent small regions. This is an algorithm that regards the starting point of region growth as a seed, and if the similarity is greater than a certain threshold, it is regarded as the same region. In the case of an image in which adjacent pixel values change very little continuously, an incorrect segmentation performed. Therefore, by using the average feature of the entire integrated area to date, a boundary area larger than a threshold value can be determined by comparing with the information of the next integrated object pixel.

5.2.3 Morphological image algorithm

In image analysis, expressing the region shape uses the concept of mathematical morphology as a tool to extract useful image elements. The language of mathematical morphology is set theory, and it provides an intensive and useful method for image processing problems. Frequently used logical operations are AND, OR, NOT, and they are executed between pixels based on the corresponding pixels of the image. Useful methods in binary morphology are dilation and erosion opening and closing. In the application stage, it serves to extract image components useful for expression and description of the form. In the image component extraction step for application, it is used together with the morphological algorithm to extract the boundaries, the connected elements, and the skeleton of the region. For example, boundary extraction, area filling, and connection element extraction.

5.2.4 Level-set algorithm

The level set processing is a segmentation method that creates contour lines by connecting pixels of the same characteristic in a 2D image surface with a curve and maintains the natural shape through grouping and connection algorithms of the same area. This method distinguishes more accurate pixel values and enables easy division by implementing grouping easily. This can be implemented easily and smoothly when the polygon is applied to a 3D model through an extended application.

5.2.5 Other partial segmentation algorithm

There is a method of directly displaying an area (clustering) on the input image. Conversely, there is a method of moving to a specific space, dividing, and then extracting back to the original image. In addition, there is a method of subdividing a region in which features are not uniform, using the entire image as a starting point, and finally stopping the division in a region in which all pixels are uniform. Finally, there is a method of defining a uniform region after extracting a closed curve using only the extracted edge information.

6 Reconstruction

6.1 Introduction of reconstruction

It is difficult to distinguish the anatomical correct structure or the location of the lesion inside the human body by using only the basic data obtained by the medical tomography equipment and the two-dimensional cross-sectional image. Therefore, it is necessary to reconstruct in three dimensions to accurately grasp the location and structure of the lesion, the structure and size of each organ, and the treatment site.

6.2 Reconstruction process

Reconstruction is a series of processes to scan the 2D medical image through CT MRI equipment to check the lesions in the human body and visualize and extract the segmented data of the obtained 2D medical image series in a 3D shape. In particular, it is defined as a process of removing the cause affecting the sample shape measurement result from the image and obtaining an estimate of the measured sample surface topography. Specifically, it is composed by filling the three-dimensional surface with triangular polygons according to the phase difference, when the outline of the section of the visually divided region is connected in the vertical direction, and the quality of the digital shape is determined. This implies that it is necessary to perform a proper division process in multiple steps in the previous step, and the visualization output process for confirming the result also be performed multiple times. However, it is needed to be distinguished from image reconstruction in 2D medical imaging and 3D reconstruction of 3D models.

7 Smoothing

7.1 Marching cubes

The 'marching cubes' is a simple iterative algorithm for creating triangular surfaces for a 3D function (in our case the 3D function is defined point wise and is called voxels). It works by "marching" over the whole 3D region which has been divided into cubes. The vertices of the cube are the voxels.

The algorithm then computes whether a triangular surface passes through this cube or not. Through the marching cubes algorithm, the extracted region of the medical image consisting of voxels can be converted into a mesh-type data structure.

7.2 Mesh smoothing

In general, since it was converted to a mesh through DICOM voxel, it basically maintains the shape of a hexahedron. Therefore, it is necessary to apply a method of representing a smooth surface through the specification of a coarse polygon mesh. Smooth surfaces can be computed from coarse meshes as a limitation of the iterative process of subdividing each polygon face into smaller faces closer to the smooth surface (see Figure 2).

a) Before mesh smoothing

b) After mesh smoothing

Figure 2 — Reconstruction of a) before and b) after by mesh smoothing

8 3D visualization method

8.1 Surface rendering

8.1.1 Introduction of surface shaded rendering

The surface shaded rendering technique visually reconstructs the perspective of the anatomical elevation of a shaded object through the reflection of light from the model surface, based on shape, position, light source, and viewpoint information. By analysing a combination of Hounsfield ranges and segmentation techniques it calculates the location of surfaces separating anatomic tissue types. The surface information is then used to calculate a perspective visualization based on selectable observer position and light source positioning. With the development of virtual lighting and shading technology, it has been possible to create realistic anatomic images in real time.

8.1.2 Surface shaded rendering feature

Since specific scalar values are displayed as basic shapes on the volume data and rendering is partially applied to the generated surface, the amount of data to be processed is not large and the speed of 3D reconstruction proceeds rapidly. However, in displaying useful information of the entire cross-sectional image data, surface rendering limits only specific scalar values to basic shapes. Therefore, the external surface information is implemented, but it causes loss of information that cannot simultaneously express the independent shape of the interior, resulting in a reduction in the overall volume.

8.2 Volume rendering

8.2.1 Introduction of volume rendering

Volume rendering is a visualization technique that creates an internal image of a medical tomography image using a volume data set, which is a set of 3D scalar intensity based on voxels. Voxels are small cuboid shapes in a three-dimensional space and have a colour density in that space. The volume information is a three-dimensional matrix structure of these voxels. Data obtained by CT, MRI, CAD (Computer aided design), CAM (Computer aided manufacturing), and simulation can be transformed into volume information.

8.2.2 Volume rendering feature

Volume rendering goes through the pre-processing stage of data extraction, gradient application, resampling to perform 3D interpolation, classification to emphasize the boundary by applying opacity, and sequential synthesis process to combine numerous samples that assign colour to data into one. As a method of compositing, when a ray passes through each pixel and samples pixel values and positions, there is a ray casting method, which is an image order that generates images by synthesizing the opacity and intensity of voxels in which each ray lies in a straight line. In addition, there is an object order method in which voxels are searched in the order in which the volume data is stored and synthesized into pixels corresponding to each voxel. The basic unit on the 3D image, the voxel includes coordinate information on the X, Y, Z axis, colour value information, density value, and opacity information. By assigning opacity and shading to each voxel, and projecting and compositing these values, they are expressed in a three-dimensional image plane.

8.2.3 Ray casting techniques

Ray casting is a technique in which a virtual ray is shot at each pixel of the viewpoint plane in a space where volume information is located, and the result of blending voxels that the ray meets is stored in the pixel where the ray is started to generate the entire image. In this case, since the entire voxels are compared for each ray in order to determine which voxels the ray meets, the amount of work to be performed is very large. Also, the larger the resolution of the image to be generated, the more the amount of work is rapidly increased.

8.2.4 3D texture mapping techniques

This is a technique of applying a colour value corresponding to a 3D texture to a polygon in the space when texture information about the 3D space is given. It uses a 3D texture mapping unit built into the hardware. This creates a section at regular intervals in the space where the volume information is located, and after mapping the volume information to the section in three-dimensional texture, it is possible to obtain the final image alpha-blended the entire sections from behind.

The general method of execution is as follows. First, the volume information is stored in the graphic memory as 3D texture data, and cross sections parallel to the viewpoint plane are generated at regular intervals in the space where the volume information will be located. The generated cross-section is mapped to a 3D texture stored in memory through a mapping unit. After that, the alpha-blended cross sections of the mapped sections are stored in the frame buffer and the contents of the buffer are displayed on the screen. However, there are disadvantages in that the size of physical memory required and the bus bandwidth inside the graphics hardware are very large, and it is difficult to apply a real-time shading and early ray termination, anti-aliasing performance improvement technique.

9 Additional processing for additive manufacturing

In order to maximize the merits of medical additive manufacturing, it is necessary to convert, edit, and process visualization data. For patient-specific AM prosthetics, it is essential to design a 3D shape based on visual data inspection and consultation by medical experts. During the entire process of generating medical image-based data, data corruption is inevitable in the editing process. Data corruption is due to the gap between the technician's clinical anatomy knowledge and the medical professional's data transformation knowledge. Data transformation can continue to provide clinical anatomy data and data transformation optimal algorithms to examine how to solve them with machine learning.

10 Methods

10.1 Image isotropic conversion

Theoretically, getting more CT image enhances the quality of reconstruction since each CT data represents information in the human anatomy. But, getting more data from CT scan is impractical due to the fact that human body has the dose of x-ray radiation. Therefore, in most cases, CT images have different depth dimension, called anisotropic. This problem makes the voxel size not in a cubic shape, which causes:

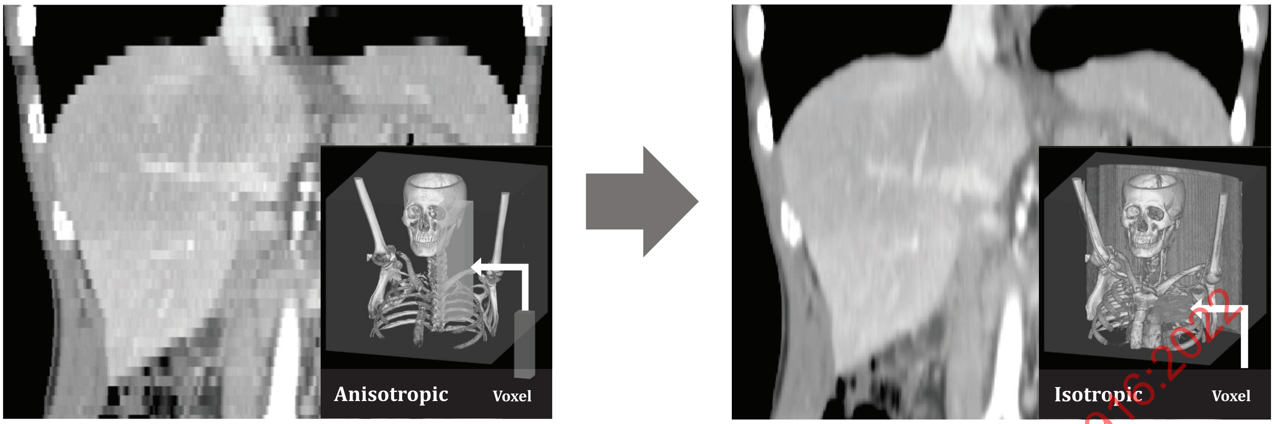
a) stair-step artifact reconstruction;

b) wrinkled surface reconstruction;

c) degradation of original anatomy size, etc.

Isotropic conversion is the method to normalize the CT volume voxel size. In order to make the same image spacing of CT data, this method is basically using a sampling method, by adopting specific interpolation method such that the resulting volume has isotropic volume. In other words, this method is adding more data in between each slice such that the whole spacing size is the same. There are several interpolation algorithms for isotropic conversion such as 1D nearest neighbour, linear, cubic, 2D nearest neighbour, b-spline, bilinear and bicubic interpolation. We use b-spline interpolation because it provides more accurate interpolation in CT cases other than other interpolation methods.

Figure 3 and Figure 4 shows some examples of isotropic conversion. In Figure 3, the left image is an anisotropic CT data. However, after isotropic conversion, as shown on the right of Figure 4, the resolution of the image is increased, resulting smooth reconstruction from coronal view. In Figure 4, it is possible to see that isotropic conversion also increases the surface smoothness of 3D modelling since the isotropic data depth is larger than anisotropic one.



a)

Resolution: 512 pixels × 512 pixels × 94 images

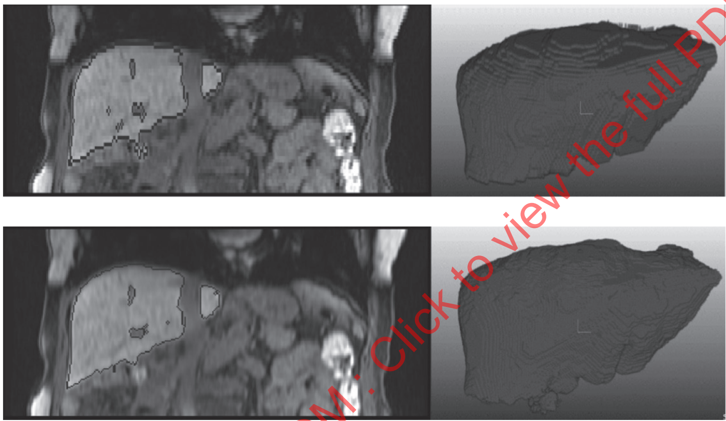
Spacing: 0,7 mm × 0,7 mm × 5,0 mm

b)

Resolution: 512 pixels × 512 pixels × 651 images

Spacing: 0,7 mm × 0,7 mm × 0,7 mm

Figure 3 — Reconstruction of a) before and b) after 3D medical data generated by isotropic conversion



a)
Modality: MR
Resolution: 320 pixels × 320 pixels × 94 images
Spacing: 1,19 mm × 1,19 mm × *3,0* mm
Interpolation Method: None

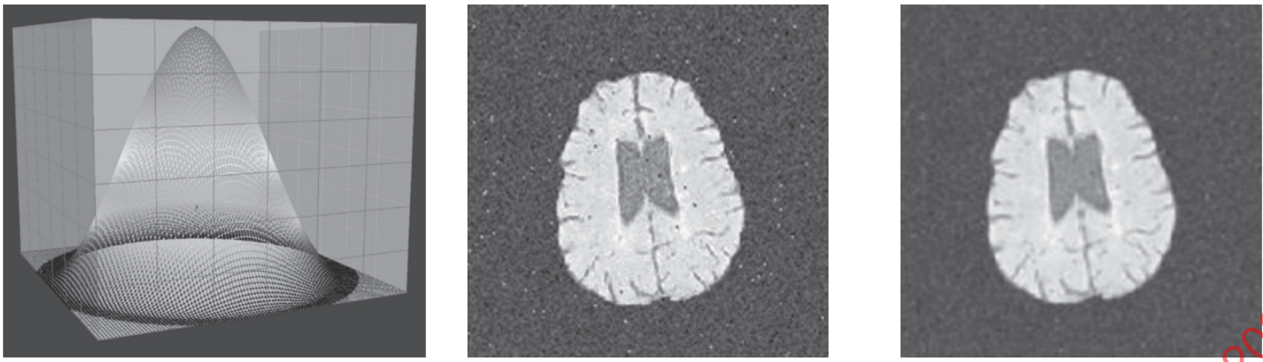
b)
Modality: MR
Resolution: 320 pixels × 320 pixels × *141* images
Spacing: 1,19 mm × 1,19 mm × *1,19* mm
Interpolation Method: *B-Spline*

Figure 4 — Isotropic 3D modelling result a) before and b) after

10.2 Image enhancement

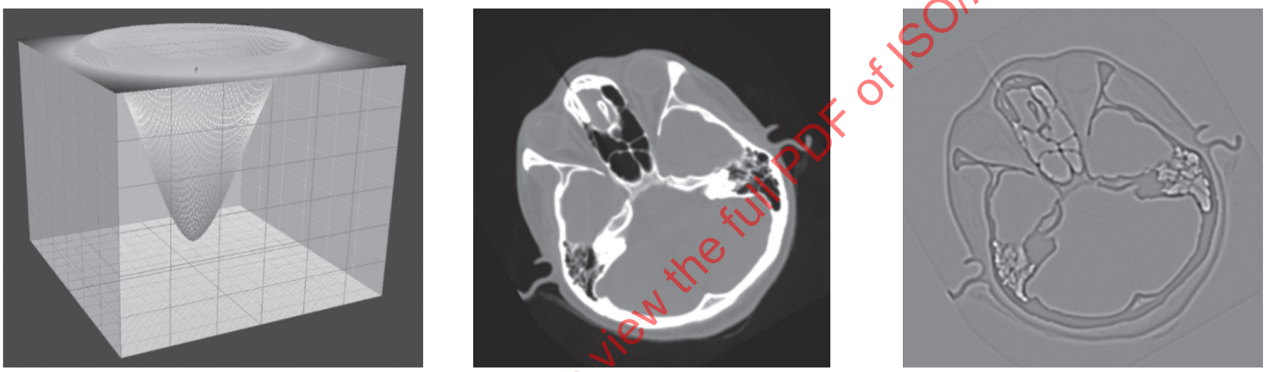
In medical imaging tomography, the noise is inevitable due to different imaging principles. Therefore, it is necessary to remove these noises before segmentation to ensure a good quality segmentation result.

Gaussian low pass filter uses a normal distribution function to remove noise from the image, while the Laplacian of Gaussian filter is a filtering method that highlights the edges of the images. By doing so, you can either remove the noise in the medical image or pre-processing the techniques that emphasize certain areas to increase the quality of the final segmentation result.



a) b) c)

Figure 5 — Gaussian low pass filter a) visualization of 2D kernel b) before applying c) after applying

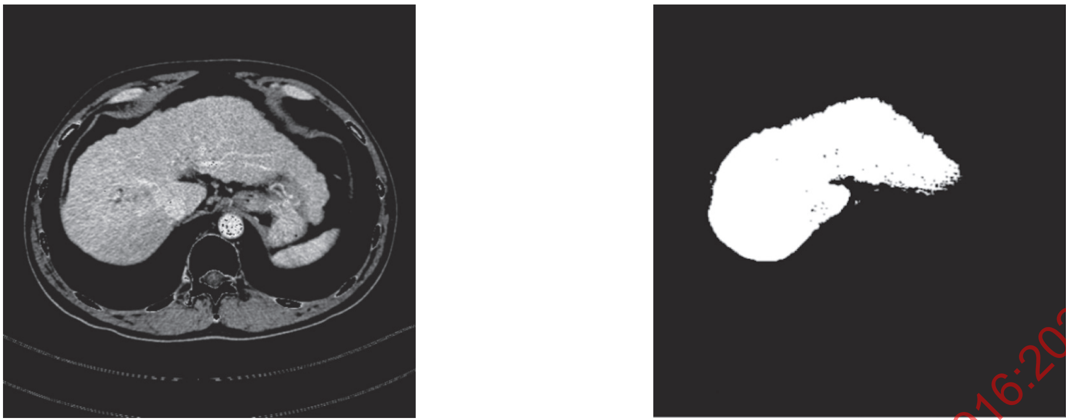


a) b) c)

Figure 6 — Laplacian of Gaussian filter a) visualization of 2D kernel b) before applying c) after applying

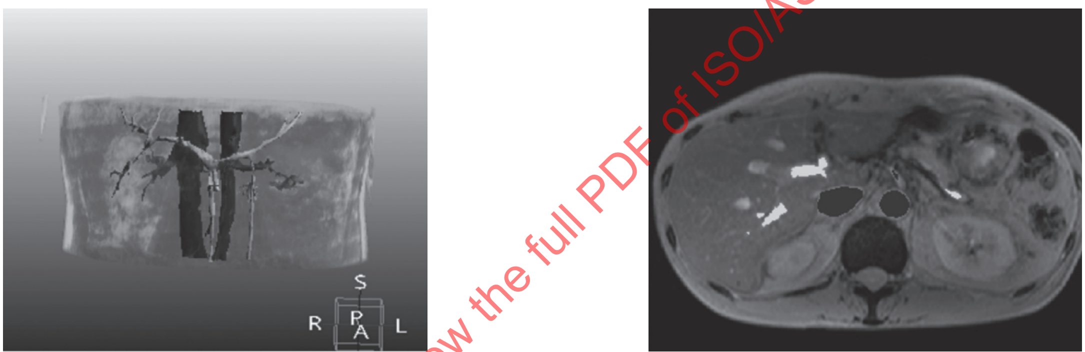
10.3 Image segmentation

Image segmentation is the process of partitioning a digital image into multiple segments. The goal of medical image segmentation is to simplify and change the representation of an image into something that is more meaningful and easier to analyse.



a) b)

Figure 7 — Soft tissue segmentation a) CT image b) Liver region of CT image



a) b)

Figure 8 — Soft tissue segmentation a) 3D visualization b) segmented vessel region of MR image

Extraction results inevitably include false positives (FP). Removal of these FP is necessary, which may require different methods depending on the extraction algorithm.

For instance, in the graphic to be shown the black area on the left a) is the FP area of the extraction of the bronchi, and the results b) are effectively removed by tests. The importance of the FP removal process can be found in this example.

a) b)

Figure 9 — Reduction the over segmented artifacts a) before applying b) after applying

11 Minimizing error of software and equipment

11.1 Introduction of software and equipment error

Medical CAD data obtained by segmentation and cloud point formation of image data such as CT and MRI images are dependent on the resolution of the original image (see Annex A). The errors that occur in reproducing the information on irregular real human body parts with organic inflection points and a plurality of sampled image data are inevitable. Assessing and reducing errors is ultimately related to medical image quality, and therefore, a system that can be used for research and practical purposes needs to be established.

11.2 Software error

11.2.1 Background

Image processing that utilizes an interpolation algorithm is applied to a section of an image composed of several intervals; the algorithm is applied at intervals of no information. To interpolate a specific section, the method of application of geometric information and slope or curve characteristics depends on the number of shear and trailing slides referenced. The error in interpolation without image information is the highest among the errors. However, when there is no singular point within the slide interval and while referring to the front and rear information, this error can be reduced to a negligible level. Singularities need to be examined by medical image analysis experts or doctors. Errors are mainly due to the uncertainty of the image information itself that occurs during image acquisition and image processing. As image processing is performed during thresholding for segmentation, an error occurs in this process. The 3D data creation software of commercialized medical image data has been commercialized at an advanced level and it is being used for the simulation medical operation for evaluating preoperative surgical treatment option with continuous research and development, manufacturing design of surgical medical device and implant. Thus, the behaviour of the operator becomes a variable. In the segmentation process, there is a need for segmentation method that varies depending on the type of the anatomical structure and a structure profiling that can optimize the image processing algorithm.

11.2.2 Verification method using main inflection

In order to correct a problem related to critical error or scale, verification can be performed by designating a main inflection part as a reference point in the already generated mesh data by referring to a higher resolution image and an X-ray image. The section profile is used as a verification reference. By applying the guidelines according to the characteristics of the anatomical structure to the certification criteria of the software created by the medical image enterprise, a basis for improvement of the quality of 3D medical care can be provided. Methodically, it is possible to define error images by type and to evaluate the quality through dimensional trueness evaluation between the result of correcting the input of such error images and the actual standard data. The evaluation methods are based on volume difference, maximum error of coordinates, average error, for intended of use and so on.

11.2.3 Improving accuracy and precision

An additional class of software errors is generated by the act of converting the image data from a source capture system to DICOM PACs format to segmentation software to modelling software to print preparation software to the MAM system software.

Lack of an automated method for recording and sending resolution, precision, colour, surface texture, material and other key meta data affecting image quality from image source through the software conversion process degrades MAM medical device quality. There is a need for an automated method to maintain accuracy and precision as close to the original image accuracy and precision as possible.

The following methodology can be used to optimize accuracy and precision of MAM produced medical devices:

Replace use of the STL format with ISO/ASTM standard AMF format. Utilize the format's extensible XML meta data support to provide an integrated, accurate and reliable means of recording and transmitting all relevant meta data from the image source system and each software application used to create, store, segment, edit and output the completed 3D image file to the MAM system.

Use segmentation and modelling software that can output the file and all related resolution, accuracy, precision and functional parameter settings saved as meta data tags in the AMF file. Use modelling software applications to assign colours, materials, surface textures, multi-part assembly orientation, software parameter settings, application version history and any additional meta data created by each software application that may aid in improving the quality of the medical device.

The MAM system technician can utilize this meta data to optimize print preparation software parameter settings, select the most appropriate MAM system for producing the medical device and configure the MAM system parameters to align with the meta data integrated within the image file. The MAM system service provider can use this file meta data as input to its quality management system (QMS) required by the FDA and EU for verifying and validating accuracy, precision and reliability of MAM produced medical devices.

11.3 Equipment error

11.3.1 Background

Software error correction rate cannot reduce the error rate in an AM process. Even if the same equipment has different characteristics, it is necessary to have guidelines on individual calibration methods for the equipment. The calibration is performed by the phantom which the amount of X-ray absorption is closely similar, it is needed to calibrate the evaluation of each phantom model (metal phantom and simplified measurement drawing).

11.3.2 Standard computational mesh model data creation for an evaluation method

The printing result obtained through a series of processes is used as the phantom model entity from the medical image data (CT and MRI) generated in the foremost input step. After obtaining the final output of the 3D data creation process and AM process and scanning this output and comparing it with the phantom mesh data, the final matching rate can be confirmed. In addition, the phantom model can confirm the accuracy for data generation of medical imaging devices and optical scanning apparatus. Therefore, calibration of equipment based on phantom model is also possible.

11.4 Tolerance error situations

Although the tolerance with regard to errors that may occur during the acquisition of the medical image data and the allowable range from the AM device are described, in actual applications, dimensional tolerance is also important with regard to the material and post-processing.

— data creation (segmentation);

— AM processing (mechanical tolerance);

— deformation and shrinkage (material properties);

— post-processing (polishing tolerance).

Annex A
(informative)

Medical CAD for additive manufacturing tolerance

A.1 Purpose

The measurements of Medical AM (additive manufacturing) output can provide a database of reliable dimensional errors for each process. In order to perform it, it obtained a database by comparing and analysing 3D model, AM model (scan data) and real model (scan data). Based on the database, it developed a standard phantom model for medical 3D printing not only to provide the opportunity for the equipment or products of service provider but also to gain credibility (see Figure A.1).

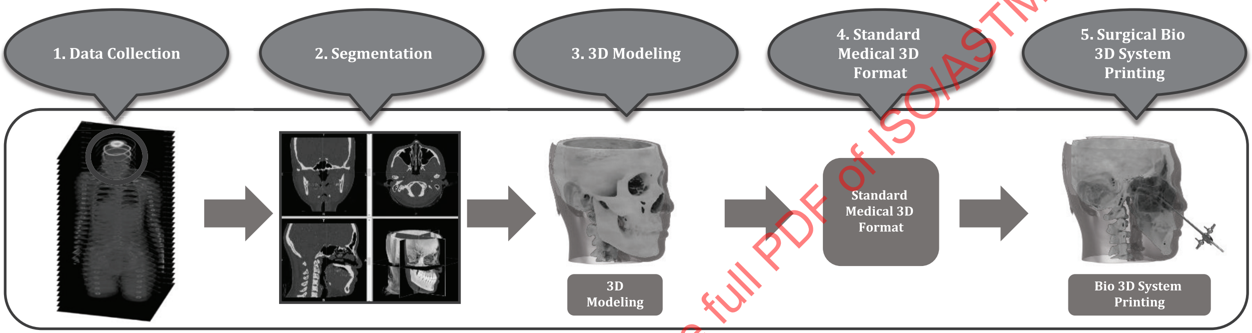


Figure A.1 — Standardization of medical CAD for additive manufacturing

A.2 Procedure

A CT scan was performed to acquire DICOM data of an Anatomy class's real bone. By using the high-precision scanning with the slice of 0,01 mm, it obtained a standard model data of real bones to be compared. We printed medical 3D model data from two types of data, which are CT scan and real bone scan as shown in Figure A.2.

The phantom model, which can be a standard model, can be used with real human bones. Two types of model was prepared for the phantom model from the actual human bone in the anatomy classroom. One type of model is converted to STL by high-precision scanning of bone, and the other type of model is converted from the bone's CT into STL by software.

Errors occur between the real bone and the data generated by software during the transformation process, and deformations due to shrinkage occur in the material and equipment.

The result as shown from Figure A.3 to Figure A.8 that the tolerance of colour contour occurs by merging two data of CT and standard model together. (The standard model achieves the highest level of high-precision scanning possibility.) Green means the exact match part with both of them, the part that gets bigger in size than the real bone will turn red, and the part that gets smaller in size will turn blue.

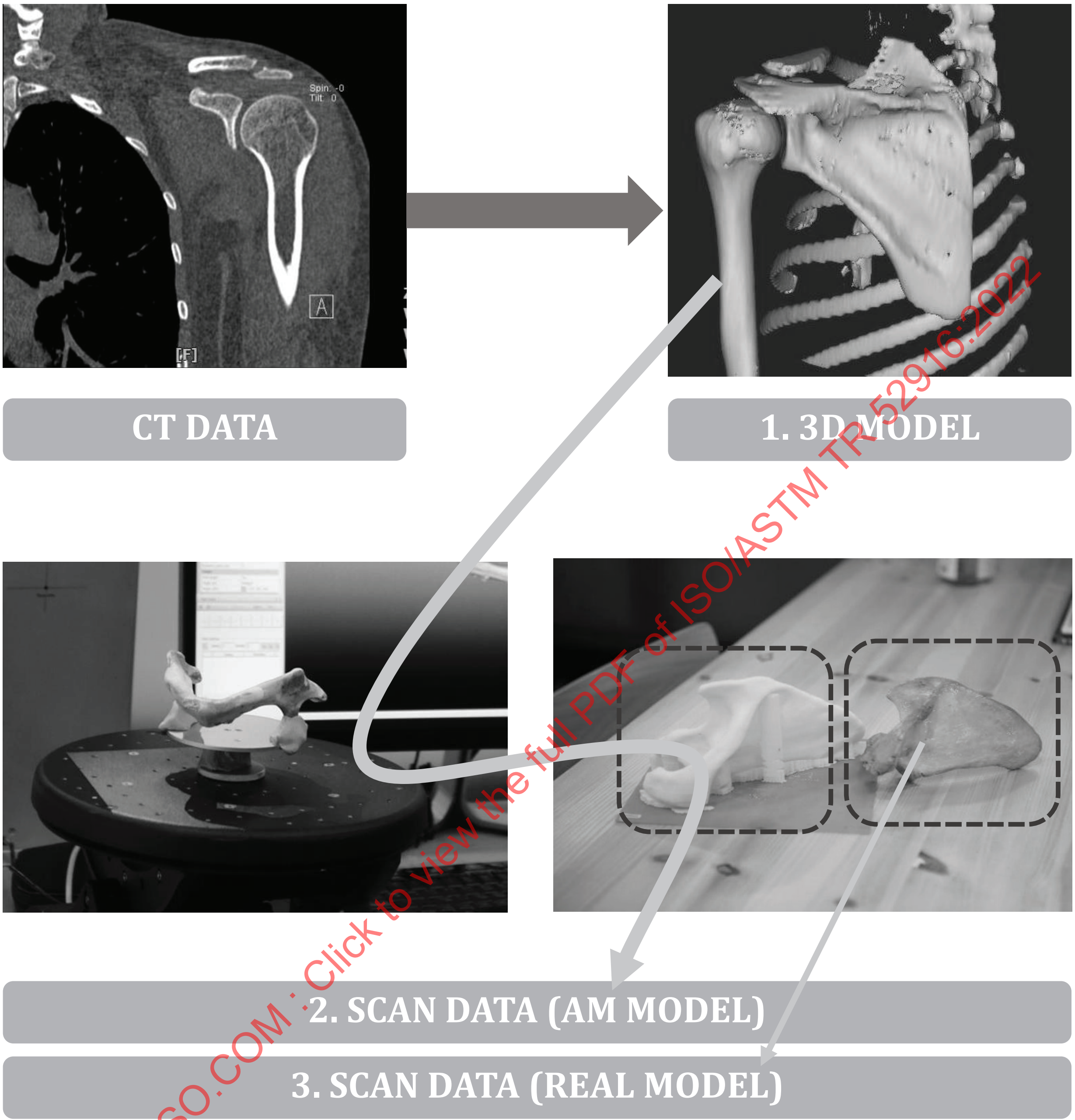
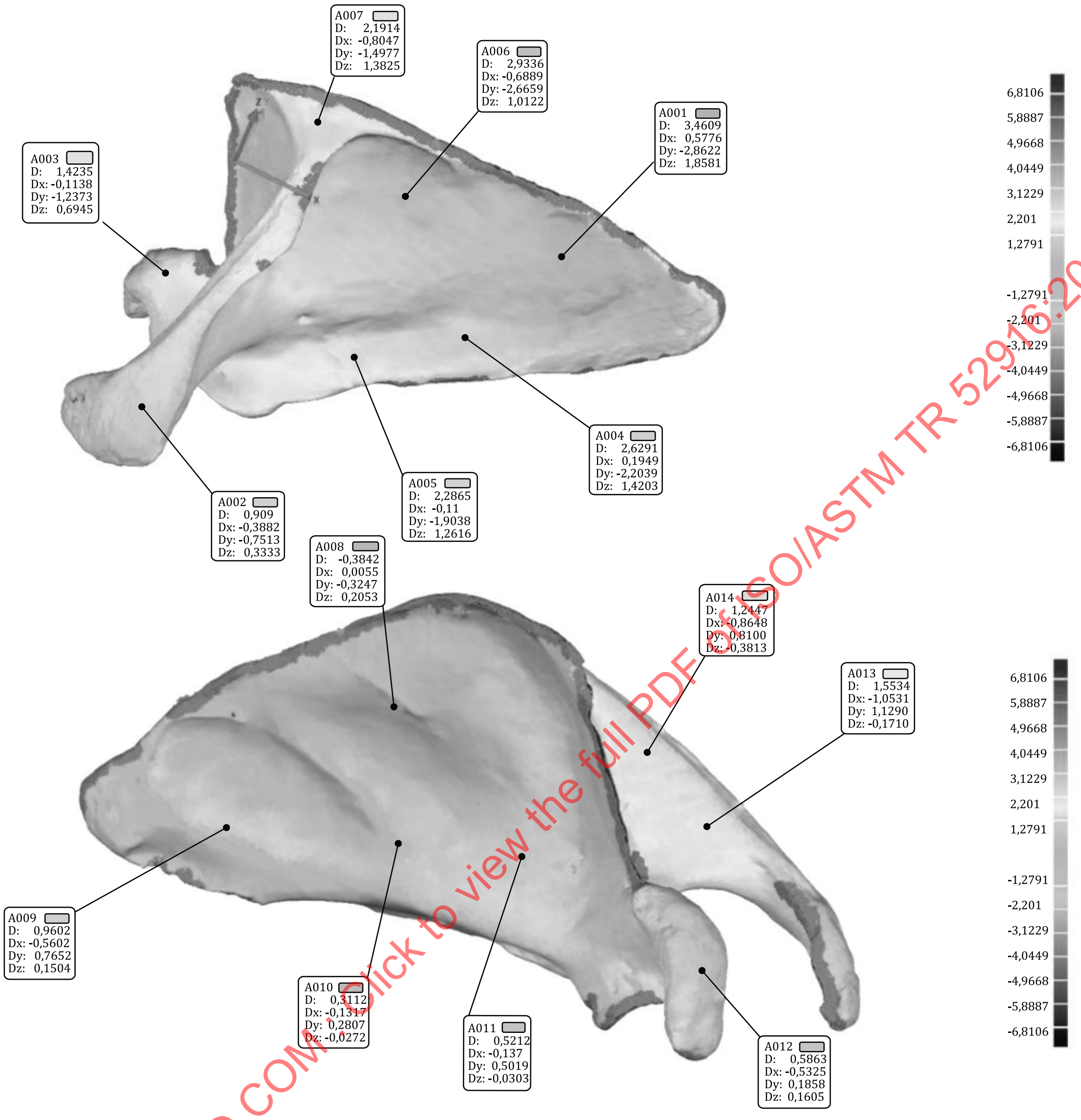


Figure A.2 — Three (3D model, AM model scan data, real model scan data) file comparison analysis process

A.3 Results

The results are atypical because of the difference between the instrument resolution and the image quality of the CT. However, the CT data on the scapula-sized scale can range from 7 % to 8 % of the real bone in general, which can reach to ±4,0 mm in the maximum error area. The maximum error of additive manufacturing is about ±0,5 mm, and the error obtained by CT is much larger than the tolerance of printer. See the figures from Figure A.3 to Figure A.8.

A.3.1 Scapula: Real (ref) vs CT model



Deviation Distribution

> = Min	< Max	# Points	%
-6,8106	-5,8887	2	0,0089
-5,8887	-4,9668	4	0,0178
-4,9688	-4,0449	8	0,0357
-4,0449	-3,1229	11	0,0491
-3,1229	-2,201	22	0,0982
2,201	-1,2791	141	0,6291
-1,2791	1,2791	11 860	52,9157
1,2791	2,201	4 593	20,4926
2,201	3,1229	4 094	18,2662
3,1229	4,0449	1 670	7,451
4,0449	4,9668	5	0,0223
4,9668	5,8887	0	0
5,8887	6,8106	3	0,0134

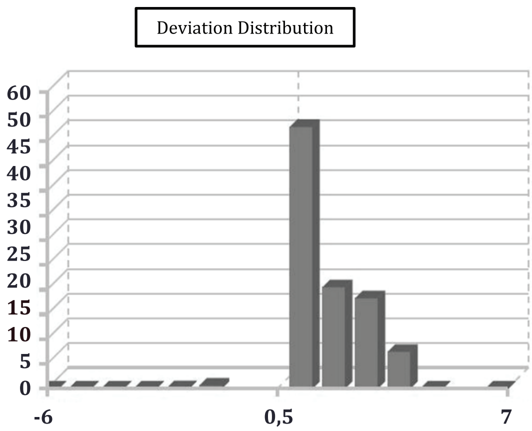
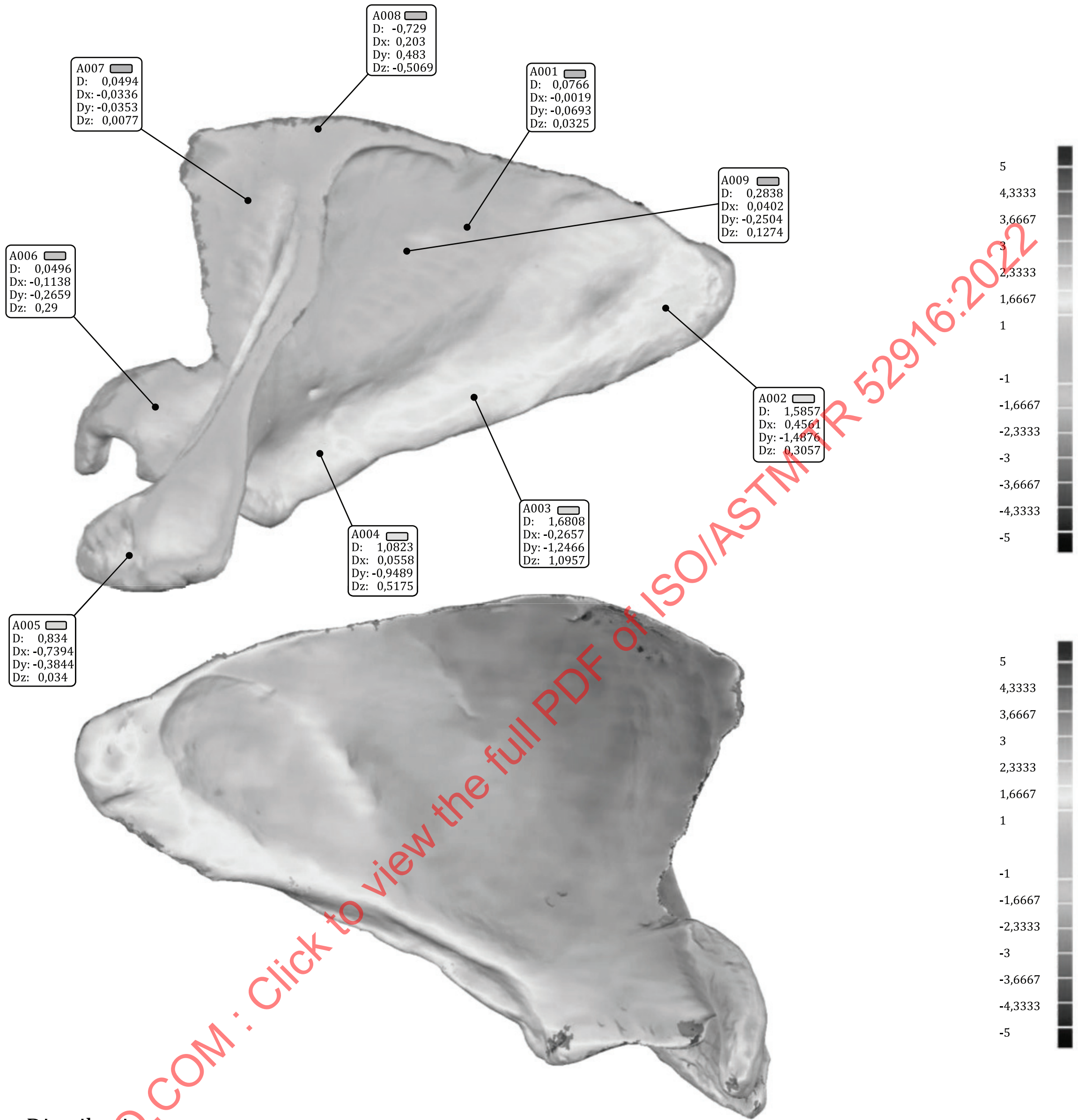


Figure A.3 — Scapula: Real (ref) vs CT model deviation distribution

A.3.2 Scapula: Real (ref) vs AM model



Deviation Distribution

>=Min	<Max	# Points	%
-5	-4,3333	37	0,0139
-4,3333	-3,6667	74	0,0278
-3,6667	-3	66	0,0248
-3	-2,3333	324	0,1217
-2,3333	-1,6667	2 004	0,7526
-1,6667	-1	5 687	2,1358
-1	1	125 666	47,1944
1	1,6667	38 253	14,3661
1,6667	2,3333	27 363	10,2763
2,3333	3	32 071	12,0444
3	3,6667	24 493	9,1985
3,6667	4,3333	10 036	3,7691
4,3333	5	112	0,0421

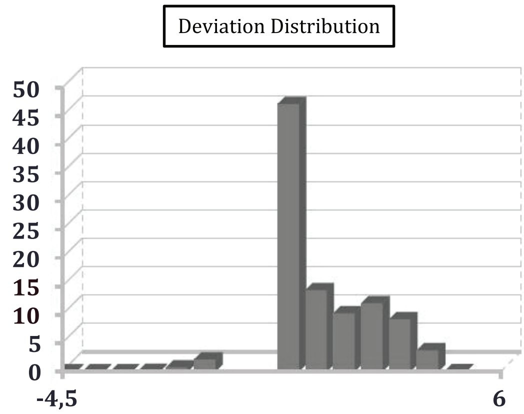


Figure A.4 — Scapula: Real (ref) vs AM model deviation distribution