Medical image processing software

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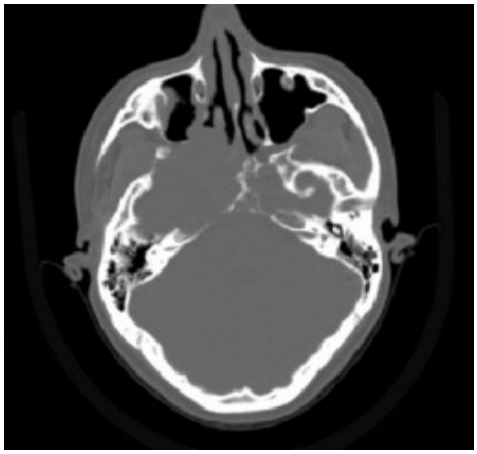
Patient-specific medical devices and anatomical models are almost always produced using radiological imaging data. Medical image processing software is used to translate between radiology file formats and various AM file formats. Theoretically, any volumetric radiological imaging dataset could be used to create these devices and models. However, without high-quality medical image data, the output from AM can be less than ideal. In this field, the old adage of "garbage in, garbage out" definitely applies.

Due to the relative ease of image post-processing, computed tomography (CT) is the usual method for imaging bone structures and contrast-enhanced vasculature. In the dental field and for oral- and maxillofacial surgery, in-office cone-beam computed tomography (CBCT) has become popular. Another popular imaging technique that can be used to create anatomical models is magnetic resonance imaging (MRI). MRI is less useful for bone imaging, but its excellent soft tissue contrast makes it useful for soft tissue structures, solid organs, and cancerous lesions.

Computed tomography: CT uses many X-ray projections through a subject to computationally reconstruct a cross-sectional image. As with traditional 2D X-ray imaging, a narrow X-ray beam is directed to pass through the subject and project onto an opposing detector. To create a cross-sectional image, the X-ray source and detector rotate around a stationary subject and acquire images at a number of angles. An image of the cross-section is then computed from these projections in a post-processing step. With CT, only one contrast mechanism is used because the signal intensity is linearily proportional to the tissue density. CT is considered the method of choice for bone imaging and is typically used to produce medical models of hard tissue structures.

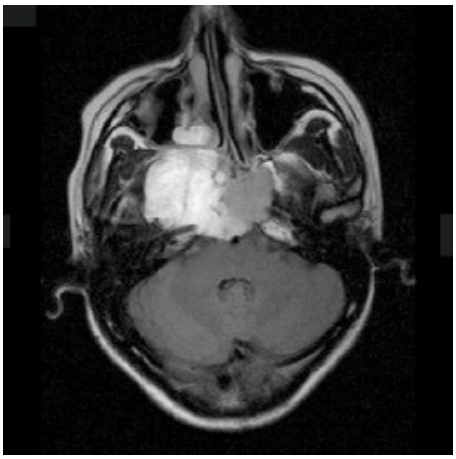


CT scan image depicting a cross section through the head, courtesy of 3D Systems

Cone-beam computed tomography: CBCT operates on the same principle as traditional CT. However, instead of a single, thin X-ray beam making one revolution per image slice, a larger, diverging X-ray beam (a cone beam) is paired with a larger 2D detector array. In this way, CBCT makes it possible to acquire a single image dataset from one revolution of the source–detector pair. This has many benefits in terms of logistics, ease of scanning, and reduced radiation exposure. However, the broader the span of the beam, the poorer the contrast resolution, making segmentation somewhat difficult. Nevertheless, CBCT is very common in clinical use, particularly in

dental specialties, oral and maxillofacial surgery, and ear, nose and throat cases. Ease of installation in a clinical office setting and a low price point make it an attractive technology to use in these areas. It is also being used for patient alignment tasks in radiation therapy and image-guided surgery.

Magnetic resonance imaging: MRI is based on the principle of nuclear magnetic resonance and employs strong magnetic fields and radio waves. Hydrogen protons in water molecules become aligned in the strong primary magnetic field. Radio waves at a specific frequency, which can be calculated from the strength of the magnetic field, are introduced to perturb protons from their alignment within the magnetic field. When the radio waves are removed, protons return to their alignment within the magnetic field at different rates, depending on the surrounding molecules (i.e., tissue type), and emit an echo signal that can be measured. The echo signal is used to determine relaxation times, which is the time required for hydrogen nuclei to return to their alignment in the magnetic field. Local relaxation times are used to reconstruct cross-sectional images.

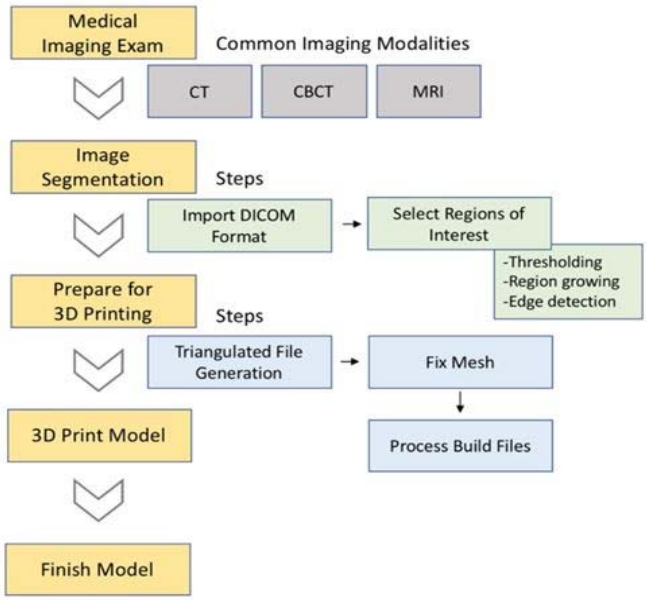


MRI image showing the same cross-sectional anatomy as the previous CT scan image with enhanced resolution of the tumor near the center (light area), courtesy of 3D Systems

Image acquisition: Most medical imaging technologies used for medical modeling produce data in serial section format in the form of 2D images. These images represent a finite thickness of data taken at increments along the axis of an object being scanned. Think of them as stacked 2D images that together form a 3D volume. For example, a CT scan can be taken using a slice thickness of 1 mm (0.039 inch) and repeated (slice spacing) every 1 mm (0.039 inch). In this case, an object that is 20 mm (0.79 inch) in length would have 20 slices. Within these 20 slices, data is available for the entire object being scanned. However, image processing tools are needed to "extract" the areas of interest, such as bone structure or a tumor. In-plane resolution for most medical imaging studies of all types can be in the range of 0.1–1.0 mm (0.004–0.039 inch).

Once an imaging dataset has been acquired, the images are typically stored in a hospital patient archiving communition system. The most common format found today for medical imaging is the open-source standard Digital Imaging and Communications in Medicine (DICOM) 3.0. The DICOM industry format is to medical radiology what the JPG format is to general photography.

Medical image processing: To efficiently and accurately handle medical image data, specialized software is needed to read the DICOM format and enable what is called "image processing." The export of this medical image data to a suitable AM format is also crucial to the accuracy of the workflow. Primary tasks within the field of medical image processing for AM include 1) import of native medical images, 2) image segmentation, 3) slice/volume editing, and 4) STL file generation. The following chart shows some of the major steps involved when producing an anatomical model of bone structure.



Overview of the process of using medical imaging data to produce a 3D-printed anatomical model, courtesy of Andy Christensen

Medical image processing software: The following tables highlight some of the software products available for medical image processing. In the U.S., medical image processing software that is marketed for patient care (i.e., clinical care or diagnostic use) requires FDA clearance. Outside the U.S,. regulations vary and the user must determine what the regulatory compliance requirements are for a particular application.

Product	Company	Website	Relative cost
Amira*	Thermo Fisher Scientific	www.fei.com/software/amira-3d-for-life-sciences	$$$
D2P	3D Systems	www.3dsystems.com	$$$
Dolphin 3D Surgery	Dolphin/Patterson Dental	www.dolphinimaging.com	$$
F.A.S.T.*	Fovia	www.fovia.com	$$
iNtuition	TeraRecon	www.terarecon.com	$$$
Mimics, Mimics InPrint	Materialise	www.materialise.com	$$$
OsiriX MD	Pixmeo	www.osirix-viewer.com	$
Vitrea	Vital Images/Toshiba	www.vitalimages.com/product-information/3d-printing	$$$

Medical image processing software products for clinical/diagnostic use, courtesy of Andy Christensen

Footnote:
* Software is part of other larger "system" products cleared by the FDA

Product	Company	Website	Relative Cost
Analyze/Analyze Pro	Analyze Direct	www.analyzedirect.com	$/$$
AnatomicsRx	Anatomics	www.anatomics.com/anatomicsrx/ordering-software	$$
NemoFAB	Nemotec	www.nemotec.com/en/software/fabsoftware	$$$
Seg3D/Biomesh3D	University of Utah	www.sci.utah.edu/cibc-software/seg3d.html	$
Ossa3D	Conceptualiz	www.conceptualiz.com/products_ossa.html	$
3D Slicer	Brigham and Women's Hospital	www.slicer.org	$
MeVisLab	Mevis Medical Solutions AG	www.mevislab.de	$
Itk-SNAP	Collaoration with University of Utah and University of Pennsylvania	www.itksnap.org/pmwiki/pmwiki.php	$
4DICOM	Unknown	www.4dicom.com	$

Medical image processing software products for research use, courtesy of Andy Christensen

The U.S. Food & Drug Administration has been more vocal in the past three years regarding the regulatory landscape for additively manufactured medical devices. In 2014, the FDA held a public workshop (Ref 1) attended by more than 500 industry attendees on the subject. In May 2016, the FDA published a draft guidance document entitled Technical Considerations for Additive Manufactured Medical Devices, which outlined their collective thinking on the topic.

The FDA's thinking included not only the outcomes of the public workshop, but also its experience in clearing more than 100 additively manufactured medical devices over the last 10 years. The draft technical guidance was made final on December 5, 2017 (Ref 2) and is now the "law" for medical device manufacturers to consult when working on a 3D-printed medical device from a regulatory and quality assurance standpoint.

In November 2016, the Radiological Society of North America (RSNA) launched its first ever special interest group (SIG), on 3D printing (Ref 3). It marked a significant milestone for the technology and its use in clinical care. The RSNA SIG and the FDA collaborated on a joint meeting held in August 2017 at the FDA's White Oak Campus in Silver Spring, Maryland. The focus of the meeting was on patient-specific anatomical models and the use of 3D printing in a hospital environment for provision of such models.

At the meeting, Nooshin Kiarashi (FDA/CDRH/Division of Radiological Health) presented on FDA Current Practices and Regulations and elaborated on the FDA's views concerning medical image processing software in preparation for 3D printing (Ref 4). The FDA views medical image processing software to be used for "diagnostic use" as a medical device and regulates those who would sell such software for this purpose in the U.S. as medical device manufacturers. Premarket clearance through the FDA by either a 510(k) or PMA is required before offering such products on the market.

Ref 1. FDA Public Workshop on Additive Manufacturing held October 8-9, 2014, Silver Spring, Maryland
Ref 2. FDA Guidance Document Technical Considerations for Additive Manufactured Medical Devices released December 5, 2017
Ref 3. RSNA Special Interest Group on 3D Printing launched in November of 2016
Ref 4. Nooshin Kiarashi Presentation August 31, 2017 at FDA and RSNA SIG Joint Meeting, Silver Spring, Maryland