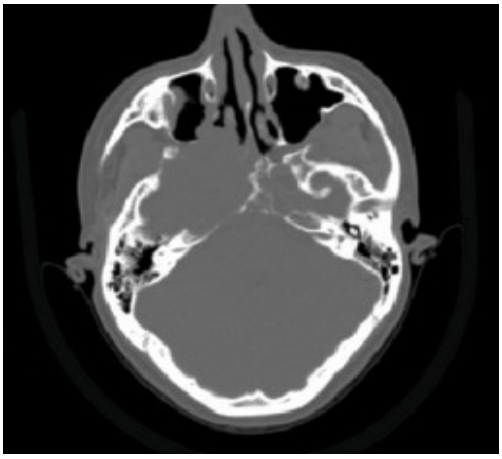
Medical image processing software

by Andy Christensen
and Nicole Wake

Patient-matched medical devices and anatomic models are almost always produced using radiological imaging data. Medical image processing software is used to translate between radiology file formats, most commonly Digital Imaging and Communications in Medicine (DICOM) and various additive manufacturing (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 linearly 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.

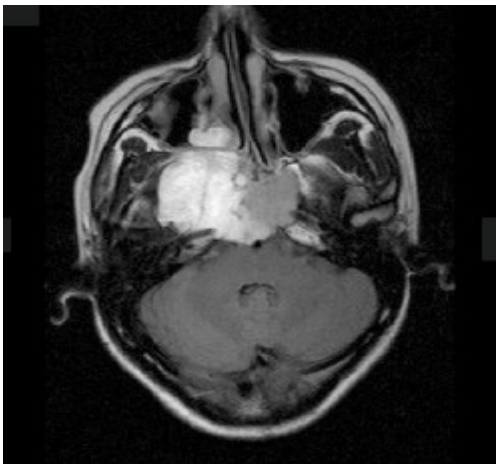


CT scan image depicting a cross-section through the head, courtesy of 3D Systems

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 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 are introduced to perturb protons from their alignment within the magnetic field. The frequency can be calculated from the strength of the magnetic field. When the radio waves are removed, protons return to their alignment within the magnetic field at different rates and emit a measurable echo signal. The rate of return depends on the surrounding molecules (i.e., tissue type). 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.



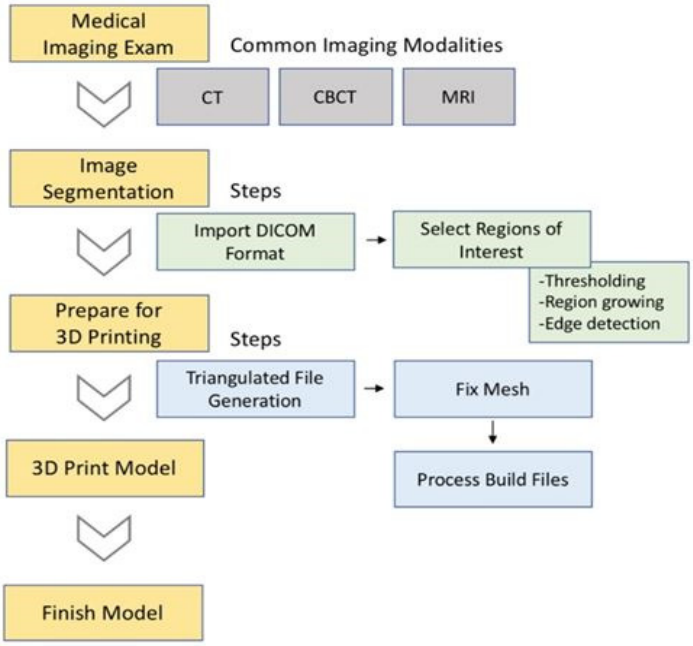
MRI image showing the same cross-sectional anatomy as the previous CT scan image with enhanced resolution of the tumor near the center (light area), courtesy of 3D Systems

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 1.0 mm (0.039 inch) and repeated (slice spacing) every 1.0 mm (0.039 inch). In this case, an object that is 20.0 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 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 picture archive and communication system (PACS). The most common format found today for medical imaging is the open-source standard DICOM. 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 anatomic model.



Overview of the process of using medical imaging data to produce a 3D-printed anatomic model, courtesy of Nicole Wake

The U.S. Food & Drug Administration (FDA): The FDA has been more vocal over the last five years regarding the regulatory landscape for AM medical devices. In 2014, the FDA held a public workshop 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 the administration's collective thinking on the topic. The draft technical guidance was made final on December 5, 2017. It is a formal reference for medical device manufacturers to consult when working on a 3D-printed medical device from a regulatory and quality assurance standpoint. The FDA has reportedly cleared more than 100 AM medical devices over the last 10 years.

Radiological Society of North America (RSNA) Special Interest Group (SIG) on 3D Printing: In November 2016, the RSNA launched its SIG on 3D Printing. It marked a significant

milestone for the technology and its use in clinical care. In its first three years of existence the SIG has reached several important milestones including 1) publishing the first clinical consensus guidelines document, which is a comprehensive review and vetting of clinical diagnoses and indications for 3D printing, 2) collaboration with the FDA on a joint meeting held in August 2017 at the FDA's White Oak Campus in Silver Spring, Maryland, 3) collaboration with the American College of Radiology (ACR) on establishment of new Category III CPT codes for anatomic models and guides and 4) collaboration with ACR on establishment of a first-of-its-kind Anatomic Model Registry.

*Medical image processing software***:** At the August 2017 FDA + RSNA SIG meeting, Dr. Nooshin Kiarashi (FDA/CDRH/Division of Radiological Health) and others presented on FDA Current Practices and Regulations. They elaborated on the FDA's views concerning medical image processing software in preparation for 3D printing. The FDA currently views medical image processing software marketed for "diagnostic use" as a medical device. It 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. Three categories exist after the FDA established a "new" category of software at the FDA/RSNA meeting in 2017. This is intended to produce anatomic models of diagnostic use. The FDA's definition of the term "diagnostic use anatomic models" generally encompasses all uses of anatomic models that affect patient care. This would include models used for presurgical planning, models used to determine appropriately sized devices for use in surgery, and models used as reference during surgery. Outside of the U.S., regulations may vary and the user should determine what the regulatory compliance requirements are for a particular application.

The following tables highlight some of the medical image processing software that has received FDA clearance. These products can be used to produce 3D-printed anatomic models for diagnostic use.

Product	Company	Website	Relative cost
D2P	3D Systems	www.3dsystems.com/dicom-to-print	$$$
Mimics inPrint	Materialise	www.materialise.com/en/medical/software/materialise-mimics-inprint	$$$
Mimics Medical	Materialise	www.materialise.com/en/medical/mimics-innovation-suite/mimics	$$$
Mimics Enlight	Materialise	www.materialise.com/en/medical/software/materialise-mimics-enlight	$$$

The following table lists medical image processing software which has received FDA clearance for advanced visualization of medical images in 3D. They apply to on-screen visualization and not 3D printing.

Product	Company	Website	Relative Cost
3D Doctor	Able Software Corp.	www.ablesw.com/3d-doctor/3ddoctor.html	$
Amira	Thermo Fisher Scientific	www.fei.com/software/amira-3d-for-life-sciences	$$$
AVIEW Modeler	Coreline Soft	www.aviewmodeler.com	$$$
AW	GE	www.gehealthcare.com/en/products/advanced-visualization	$$$
Dolphin 3D Surgery	Dolphin/Patterson Dental	www.dolphinimaging.com	$$
F.A.S.T.	Fovia	www.fovia.com	$$
IntelliSpace Portal	Philips	www.usa.philips.com/healthcare/product/HC881102/intellispace-portal-10-advanced-visualization	$$$
iNtuition	TeraRecon	www.terarecon.com	$$$
Medical Design Studio	Anatomage	www.anatomage.com/medical-design-studio	$$
OsiriX MD	Pixmeo	www.osirix-viewer.com	$
Simpleware ScanIP Medical	Synopsys	www.synopsys.com/simpleware.html	$$$
Synapse 3D	Fuji	www.fujifilmusa.com/products/medical/medical-informatics/radiology/3D	$$$
Syngo.Via Frontier	Siemens	www.healthcare.siemens.com/medical-imaging-it/advanced-visualization-solutions/syngo-via-frontier/use	$$$
Visage 7	Visage Imaging	www.visageimaging.com/visage-7	$$$
Vitrea	Vital Images/Canon	www.vitalimages.com/product-information/3d-printing	$$$

The following table lists medical image processing software that has not received FDA clearance. These products may be used for research and other purposes.

Product	Company	Website	Relative Cost
3D Slicer	Brigham and Women's Hospital	www.slicer.org	$
4DICOM	Unknown	www.4dicom.com	$
Analyze/Analyze Pro	Analyze Direct	www.analyzedirect.com	$/$$
AnatomicsRx	Anatomics	www.anatomics.com/anatomicsrx/ordering-software	$$
Itk-SNAP	University of Utah and University of Pennsylvania	www.itksnap.org/pmwiki/pmwiki.php	$
MeVisLab	Mevis Medical Solutions AG	www.mevislab.de	$
NemoFAB	Nemotec	www.nemotec.com/en/software/fabsoftware	$$
OsiriX Lite	Pixmeo	www.osirix-viewer.com	$
Ossa3D	Conceptualiz	www.conceptualiz.com/products_ossa.html	$
Rhino3D Medical	Mirrakoi	www.mirrakoi.com/rhino3d-medical/	$
Seg3D/Biomesh3D	University of Utah	www.sci.utah.edu/cibc-software/seg3d.html	$
Sliceomatic 5.0	Tomovision	www.tomovision.com/products/sliceomatic.html	$