Medical image processing software

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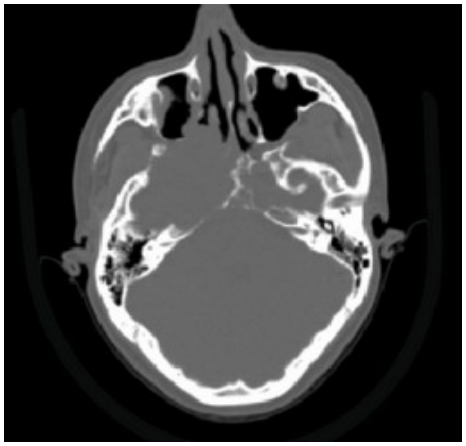
Patient-matched medical devices and anatomic models are almost always produced using radiological imaging data. Medical image processing software is used to translate between radiology file formats, most commonly Digital Imaging and Communications in Medicine (DICOM) and various AM file formats. Theoretically,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

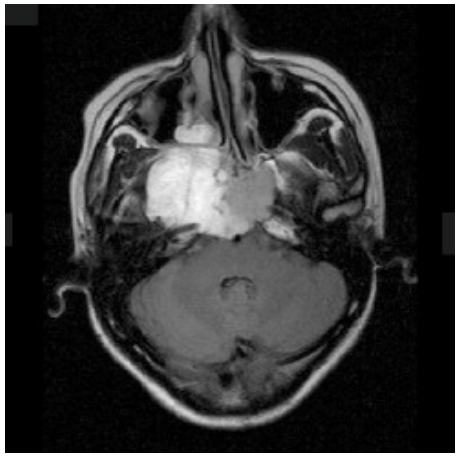


CT scan image depicting a cross-section through the head, courtesy of 3D Systems

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.



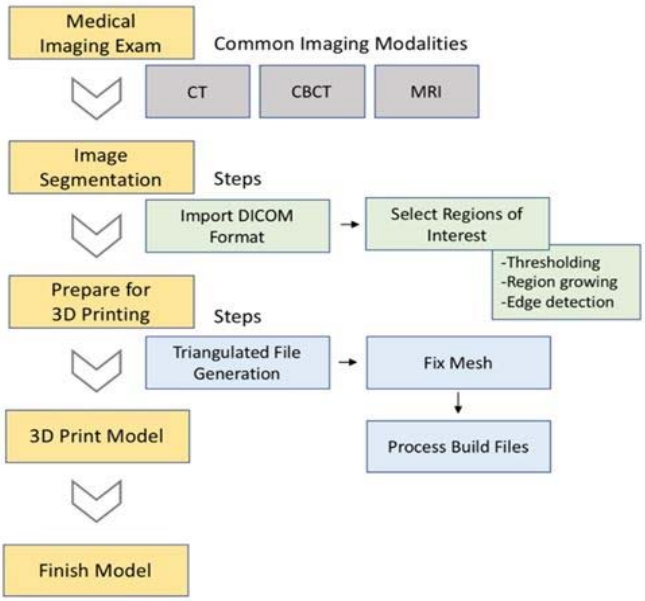
MRI image showing the same cross-sectional anatomy as the previous CT scan image with enhanced resolution of the tumor near the center (light area), courtesy of 3D Systems

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 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 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 draft technical guidance was made final on December 5, 2017 (Ref 2) and is now 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 additively manufactured medical devices over the last 10 years (Ref 5).

Radiological Society of North America (RSNA) Special Interest Group (SIG): In November 2016, the RSNA launched its SIG on 3D Printing (Ref 3). It marked a significant milestone for the technology and its use in clinical care. In its first two years of existence, the SIG has reached several important milestones including 1) publishing the first clinical consensus guidelines document (Ref 6) 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 (Ref 7), and 3) collaboration with the American College of Radiology (ACR) on establishment of new Category III CPT codes for anatomic models and guides (Ref 8).

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 and elaborated on the FDA's views concerning medical image processing software in preparation for 3D printing (Ref 4). The FDA currently views medical image processing software marketed 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. Three categories exist after the FDA established a "new" category of software, which is intended to produce diagnostic-use anatomic models at the FDA/RSNA meeting in 2017 (Ref 4). 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 table highlights some of the software products available for medical image processing. They have received FDA clearance to be used for advanced visualization of medical images in 3D (on-screen only and not 3D printed). Note that Mimics inPrint from Materialise has received FDA clearance for "diagnostic-use," including 3D-printed anatomic models.

Product	Company	Website	Relative cost
Amira	Thermo Fisher Scientific	www.fei.com/software/amira-3d-for-life-sciences	$$$
AW VolumeShare	GE	www.gehealthcare.com/en/products/advanced-visualization	$$$
D2P	3D Systems	www.3dsystems.com	$$$
Dolphin 3D Surgery	Dolphin/Patterson Dental	www.dolphinimaging.com	$$
F.A.S.T.	Fovia	www.fovia.com	$$
IntelliSpace Portal 10	Philips	www.usa.philips.com/healthcare/product/HC881102/intellispace-portal-10-advanced-visualization	$$$
iNtuition	TeraRecon	www.terarecon.com	$$$
Mimics inPrint	Materialise	www.materialise.com	$$$
OsiriX MD	Pixmeo	www.osirix-viewer.com	$
Synapse 3D	Fuji	www.fujifilmusa.com/products/medical/medical-informatics/radiology/3D/	$$$
Syngo.via Frontier	Siemens	www.healthcare.siemens.com/medical-imaging-it/advanced-visualization-solutions/syngo-via-frontier/use	$$$
Vitrea	Vital Images/Toshiba	www.vitalimages.com/product-information/3d-printing	$$$

The following table provides medical image processing software that has not received FDA clearance. The software 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	Collaoration with 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	$
Seg3D/Biomesh3D	University of Utah	www.sci.utah.edu/cibc-software/seg3d.html	$
Sliceomatic 5.0	Tomovision	www.tomovision.com/products/sliceomatic.html	$

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
Ref 5. Ricles LM, Coburn JC, Di Prima M, Oh SS. Regulating 3D-printed medical products. *Sci. Transl. Med.* 10, eaan6521 (2018).
Ref 6. Chepelev L, Wake N, Ryan J, Althobaity W, Gupta A, Arribas E, Santiago L, Ballard D, Wang K, Weadock W, Ionita C, Mitsouras D, Morris J, Matsumoto J, Christensen A, Liacouras P, Rybicki F, Sheikh A, and RSNA SIG for 3D Printing. Radiological Society of North America (RSNA) 3D Printing Special Interest Group (SIG): Guidelines for Medical 3D Printing and Appropriateness for Clinical Scenarios. 3D Printing in Medicine 2018; 4:11.
Ref 7. FDA/CDRH - RSNA SIG Joint Meeting on 3D Printed Patient-specific Anatomic Models, August 31, 2017
Ref 8. New ACR-Sponsored CPT Codes approved by the AMA. November 1, 2018.