Open Source Hardware in the Context of Simple and Widely Shared Clinical Applications

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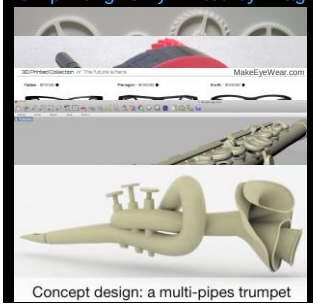
Learning Objectives:

- How does open source apply to 3-D printing applications in radiation therapy?
- What are the main patient safety concerns?
- The Long Tail.

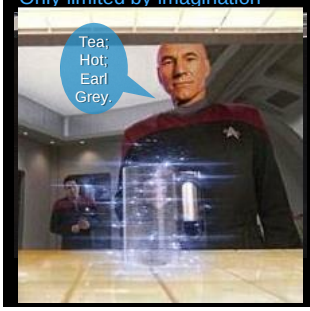
3D printing: Only limited by imagination



Concept design: a multi-pipes trumpet

- 1st 3d printer 1983 but now can get an entry level 3D printer for <$1000
- Small parts
- Integrated gears
- Glasses
- Musical instruments

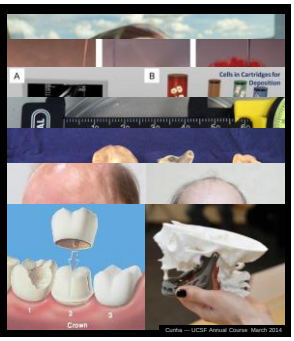
Only limited by imagination



- 1st 3d printer 1983 but now can get an entry level 3D printer for <$1500
- Small parts
- Integrated gears
- Glasses
- Musical instruments
- Cars
- Guns & Drones
- Clothing - print to your custom size
- Food!

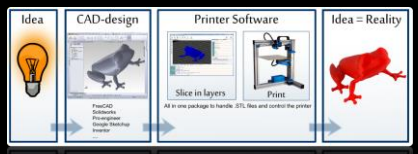
Only limited by imagination

- Acquire US images and 3D print the fetus of your baby-to-be
- Bio-printing can push live cells through the head of the printer onto a gel substrate.
  - create cartelidge, vasculature, etc.
- Biotechs focused on 3D printed biological materials, particularly human tissues.
  - Breast reconstruction (with structure)
  - Hearts (with valves)
  - Hearing aids
  - Prosthetics
  - Bones and teeth

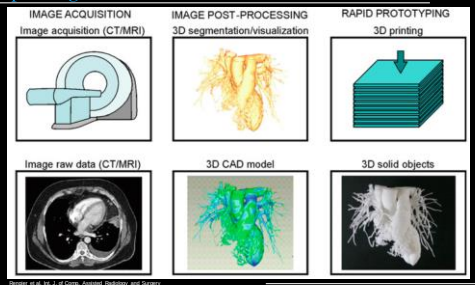


3D printers fabricate digital designs

- Builds up an object from a great many very thin layers
- Extrude substrate from a print head nozzle or lay down thin layer of powder that is fused with a laser.
- Plastics, metal, glass, concrete…
- Digital object storage (online, computer), can be emailed, downloaded, etc.



3D printing workflow in RadOnc.



Rengier et al. Int. J. of Comp. Assisted Radiology and Surgery July 2010, Volume 5, Issue 4, pp 335–341

Biocompatability and Sterilizability

- Biocompatibility of materials is established by the NGO, United States Pharmacopeia (USP).
- The USP classifications of materials and the advertising of these classifications by companies selling products are regulated by the US FDA
- For more details see my talk in the AAPM virtual library from 2015, "Bio-compatibility and Sterilization for 3D printing materials"

Sterilization - CDC Definitions

"Guideline for Disinfection and Sterilization in Healthcare Facilities," Rutala et al HICPAC (2008). www.cdc.gov/hicpac/pubs.html

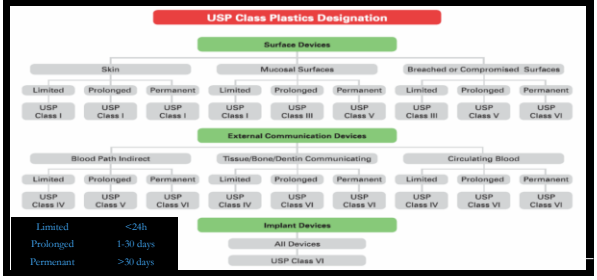
Cleaning: removes visible soil. Use soap and water. Needs to be done before disinfection or sterilization.

Disinfection: eliminates many/all pathogenic microorganisms, including bacterial spores, viruses, and fungus

Sterilization: destroys or eliminates all forms of microbial life by physical or chemical methods. Common agents in healthcare: Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities.

Biocompatibility - Classes of Materials

Need to be aware of the biocompatibility of materials you are using.



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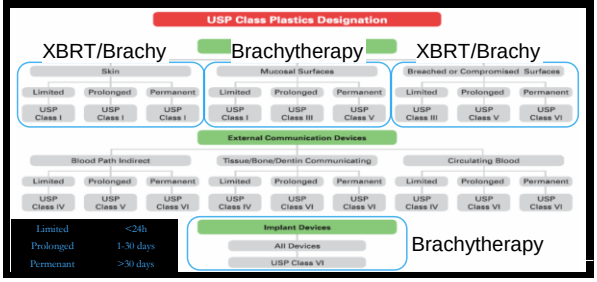
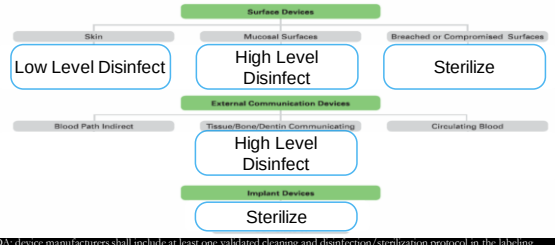


Sterilization requirements

Minimum Requirements - Your hospital may require more



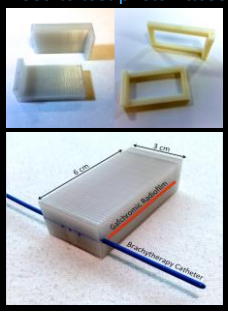
FDA: device manufacturers shall include at least one validated cleaning and disinfection/sterilization protocol in the labeling for their devices.

Sterilization validation for some common materials

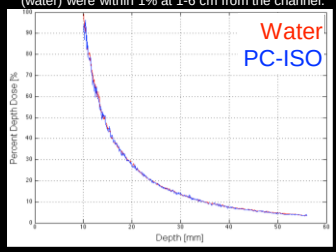
Perez et al. Sterilization of FDM-manufactured parts. Presented at the Twenty-third Annual International Solid Freeform Fabrication Symposium – An Additive Manufacturing Conference, 6-8 August 2011. Austin, TX

	Autoclave			Flash Autoclave			Ethylene Oxide Gas			Hydrogen Peroxide Gas Plasma			Gamma Radiation		
Material Type	Control	Test Samples	Success Rate	Control	Test Samples	Success Rate	Control	Test Samples	Success Rate	Control	Test Samples	Success Rate	Control	Test Samples	Success Rate
ABSi	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
ABS-ESD7	+	5-	100%	-	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
ABS-M30	+	4-1+	80%	+	5-	100%	+	4-1+	80%	+	5-	100%	+	5-	100%
ABS-M30i	+	3-2+	60%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
PC	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
PC-ABS	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
PC-ISO	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
PPSF	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%
Ultem 9085	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%	+	5-	100%

Need to test photon absorption and scatter

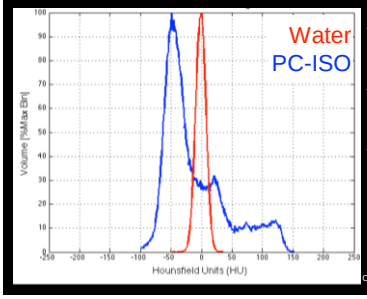


- Radial dose function for PC-ISO and control (water) were within 1% at 1-6 cm from the channel.



Cunha et al. JACMP 16;1 (2015)

Hounsfield Unit distribution



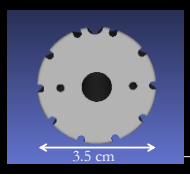
- CT scan showed no visible CT artifacts inside the testing apparatus.
- Distribution of the Hounsfield units shows that PC-ISO is water-equivalent*.
- *Lack of uniformity is due to in-fill effects.
  - Creates a honeycomb internal structure

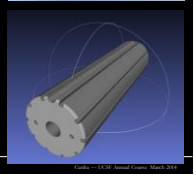
Cunha et al. JACMP 16;1 (2015)

Clinical need 1: Larger vaginal cylinder

- Can we design and 3D print a custom vaginal cylinder applicator, and use it in our current clinical workflow?
- 1st step: Recreate a cylinder in CAD but parameterize dimensions (length and diameter).
- Determine the number and locations of catheter channels.

Cunha et al. JACMP 16;1 (2015)





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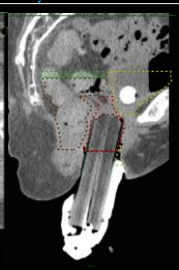
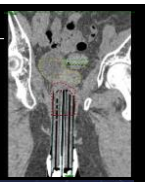
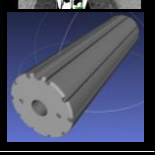


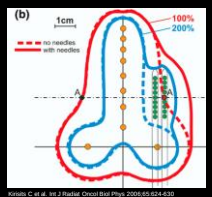




Can now share the files!
More in big reveal later. ☺

Clinical need 2: Cervix interstitial template

- Cervix brachy: tandem + ovoids or ring.
- Gives typical pear shaped dose distribution.
- Wanted to have an applicator that guides lateral interstitial needles.



Kirisits C et al. Int J Radiat Oncol Biol Phys 2006;65:624-630

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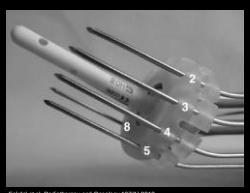
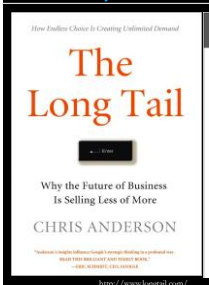


Fokdal et al. Radiotherapy and Oncology 107(1) 2013

Clinical Case X

- Bolus
- Compensators
- Alignment devices
- Phantoms!

Shift away from one-size fits all



http://www.longtail.com/

"With the possible exception of the equator, everything begins somewhere."
— C. S. Lewis

Development of a web sharing platform for Medical Physicists

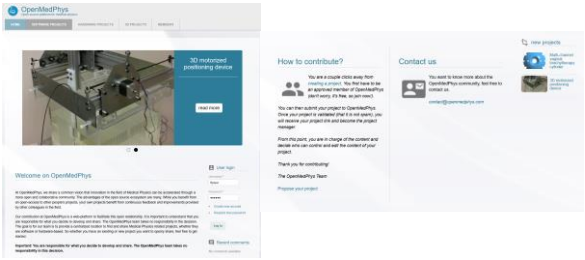
By Thomas Henry, Jacques Henry, and François Therriault-Proulx



Goals

- Develop a go-to place on the web to share open-source software, hardware, and 3d printing projects for Medical Physicists

openmedphys.org



The progression

- 2015: General poster presentation
- 2016: SAMs symposium at AAPM and launch of the website
- 2017 goals:
  - >100 members
  - >20 projects
  - creation of a working group within AAPM…

Questions / Discussion

- Where do you see a fit for Open Source Hardware in the clinic?
- How will industry react to the movement?
- What role can companies play in facilitating such a movement?
- What are your fears about liability issues and how should we address this?
- …