3D Printing in Healthcare

Technological Context & Applications

Cardiac Anesthesia Grand Rounds, Beth Israel Deaconess Medical Center | August 4, 2021

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TEMERTY FACULTY OF MEDICINE
UNIVERSITY OF TORONTO
Continuing Professional Development

The Lynn & Arnold Irwin
APIL Advanced Perioperative Imaging Lab

UHN
Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

Disclosures - Azad Mashari

Relationships with financial sponsors (APIL research group)

Research & Salary Support:

- **UHN Foundation**
- **UHN-SHS Anesthesia Association**
- UHN-SHS Academic Medical Organization
- Ontario Centers of Excellence (with TME Inc)
- NSERC

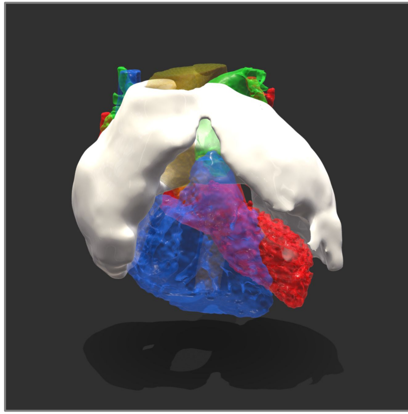
Speakers Bureau/Honoraria: Nil

Consulting Fees: Nil

Research Collaboration:

- Glia Inc. (COVID, other)
- Thornhill Medical Inc. (COVID, other)
- Promation Engineering (COVID)
- General Dynamics Land Systems - Canada (COVID)

Patents: Nil



The Lynn & Arnold Irwin

APIL Advanced Perioperative Imaging Lab

APIL.ca | @APIL_TGH

Project repositories:
https://github.com/tgh-apil

Objectives

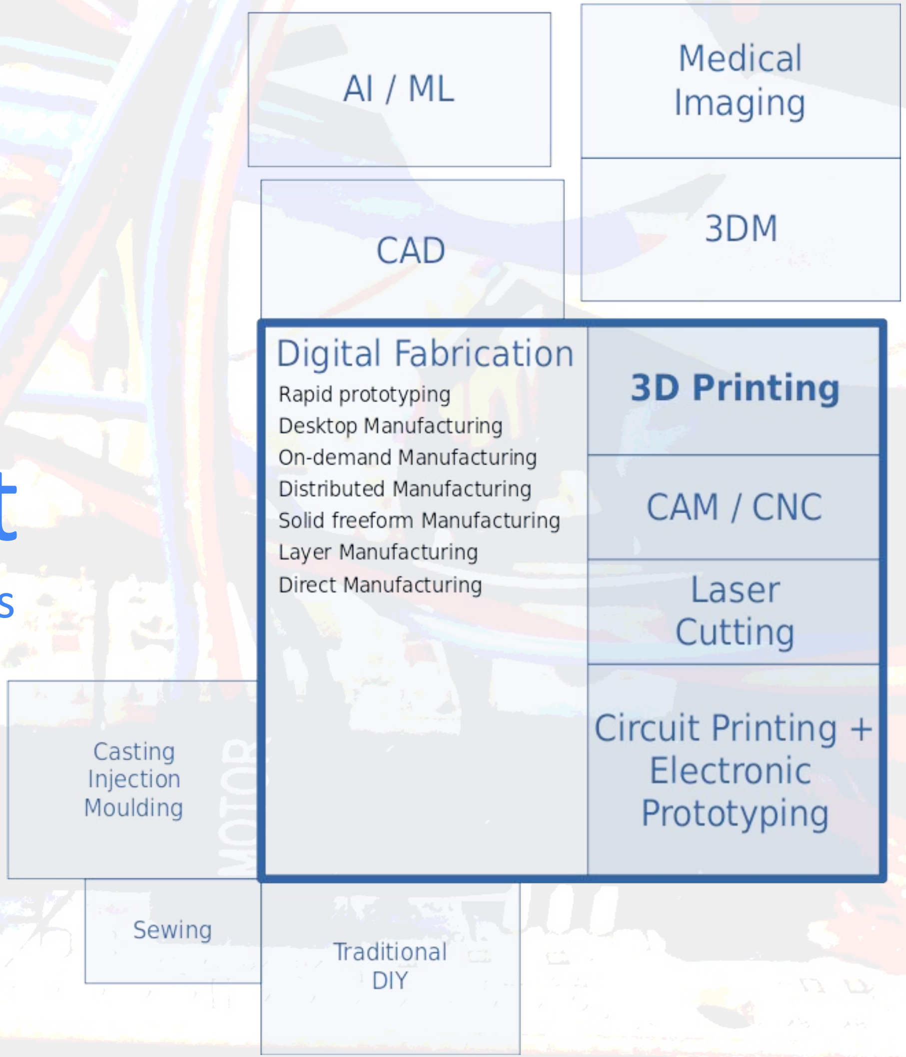
Describe the technical & historical context of Medical 3D printing

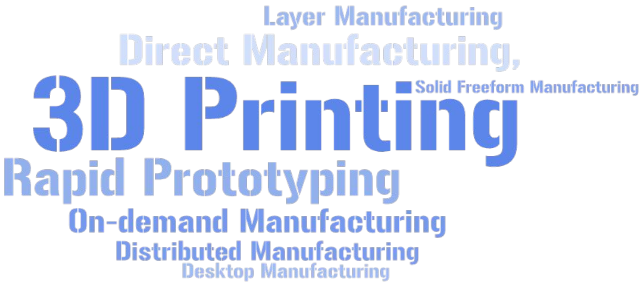
"Critically" discuss potential applications, evidence, guidelines

Discuss limitations, costs, hazards, barriers & future

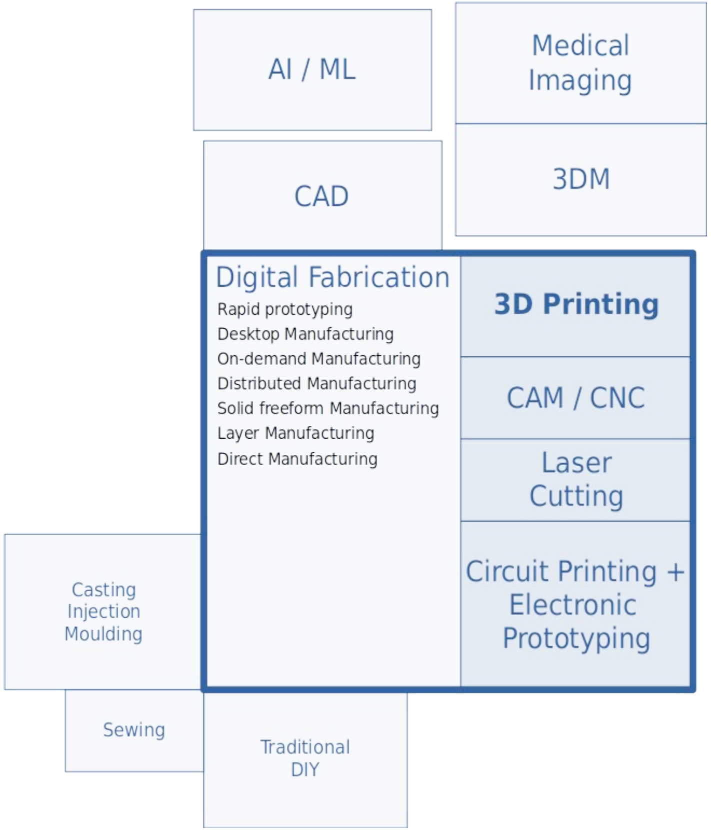
Technical Context

Technical Constellation, History, Drivers





Digital Representation $\xrightarrow{\text{Digital Fabrication}}$ Physical Object



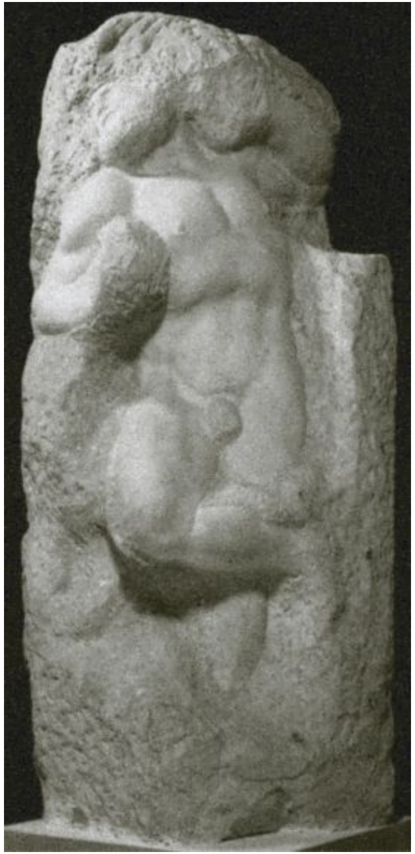
3D Printing: **Layer-by-Layer**

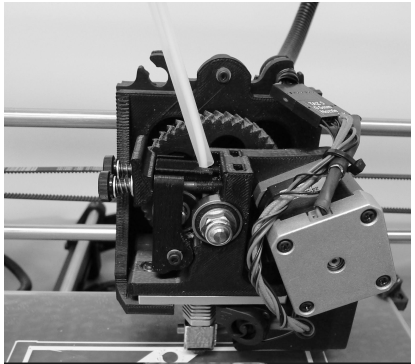
Subtractive vs. Additive Manufacturing

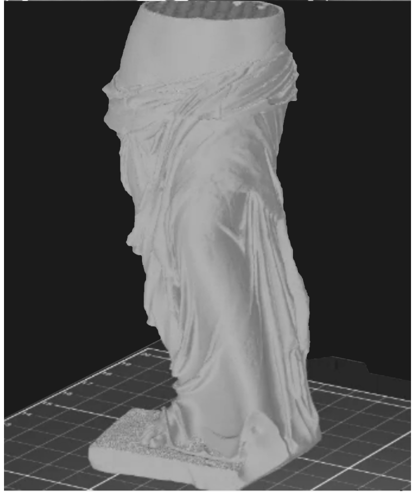
"The sculpture is already complete within the marble block, before I start my work.

It is already there, I just have to chisel away the superfluous material."

-Michelangelo







"Michelangelo had it easy. I make everything from scratch."

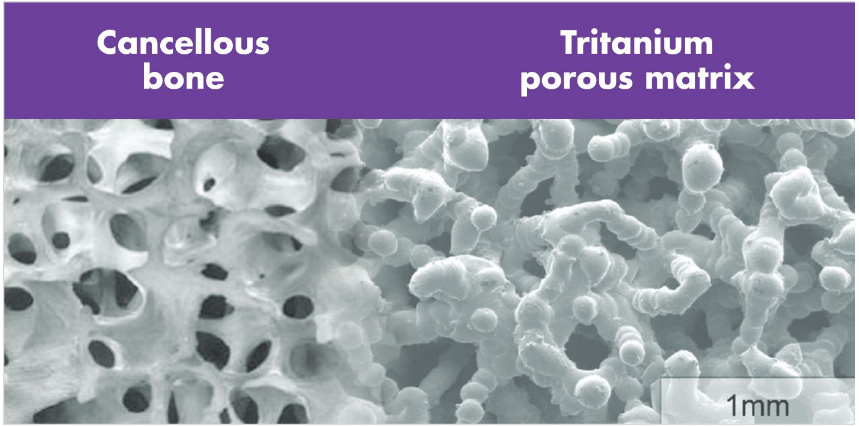
-3D Printer

Layer-by-layer manufacturing: **Technical Implications**

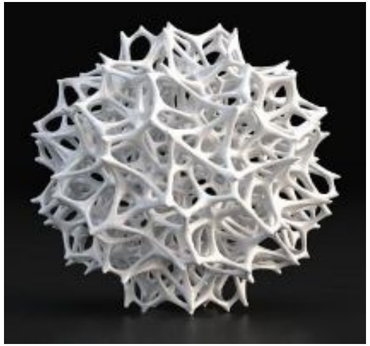
"No" geometric restrictions - Parts that cannot be manufactures any other way

Universal - "can" replace all other DF systems

"Less" material waste



http://az621074.vo.msecnd.net/syk-mobile-content-cdn/global-content-system/SYKGCSDOC-2-48488/3mV0iPvc91l1RRrDBYuvyIP_l2qXtg/TRITAN_WP_1.pdf



https://www.researchgate.net/figure/An-example-of-the-complex-geometry-possible-with-3D-printing_fig5_287512462

3D Printing: **The Cost of Lunch**

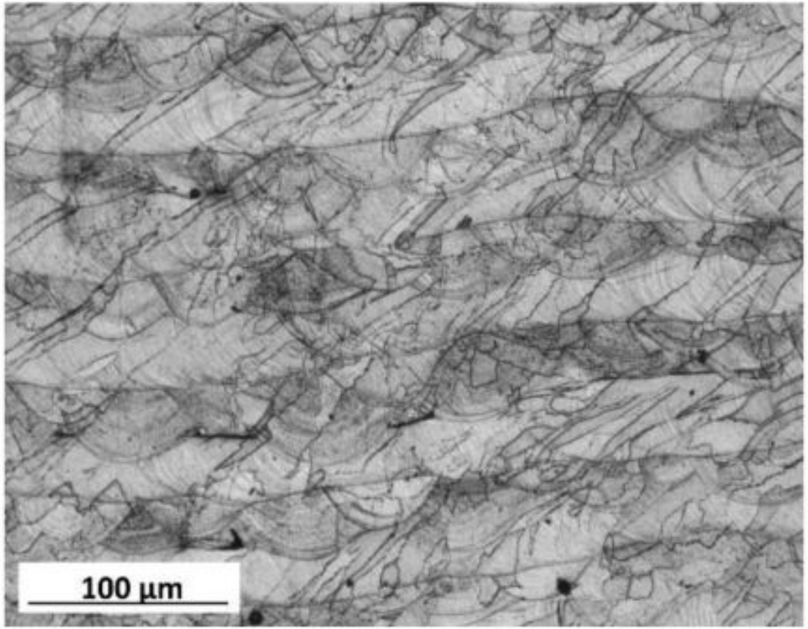
Limited (though wide and growing) range of material options and mechanical properties

Limited control over material microstructure and resulting mechanical properties

Limited part size

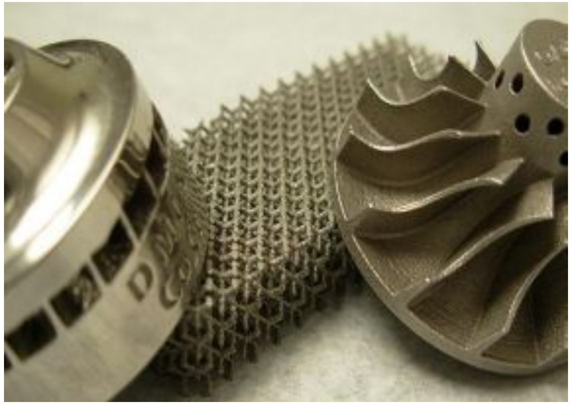
Slow for high volume production

3DP products with “Medical” label ...

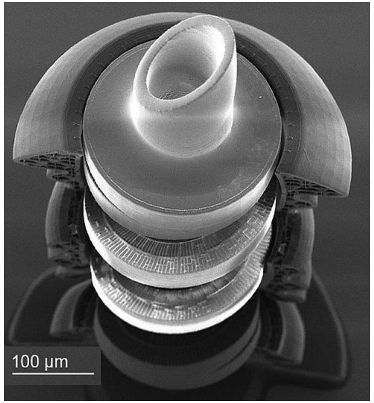


Microstructure of laser powder bed fusion (LPBF) 316 L steel, optical micrograph
(https://3dprint.com/224130/microstructure-stainless-steel/)

Industrial 3D Printers and parts



https://www.dezeen.com/2021/07/19/mx3d-3d-printed-bridge-stainless-steel-amsterdam/



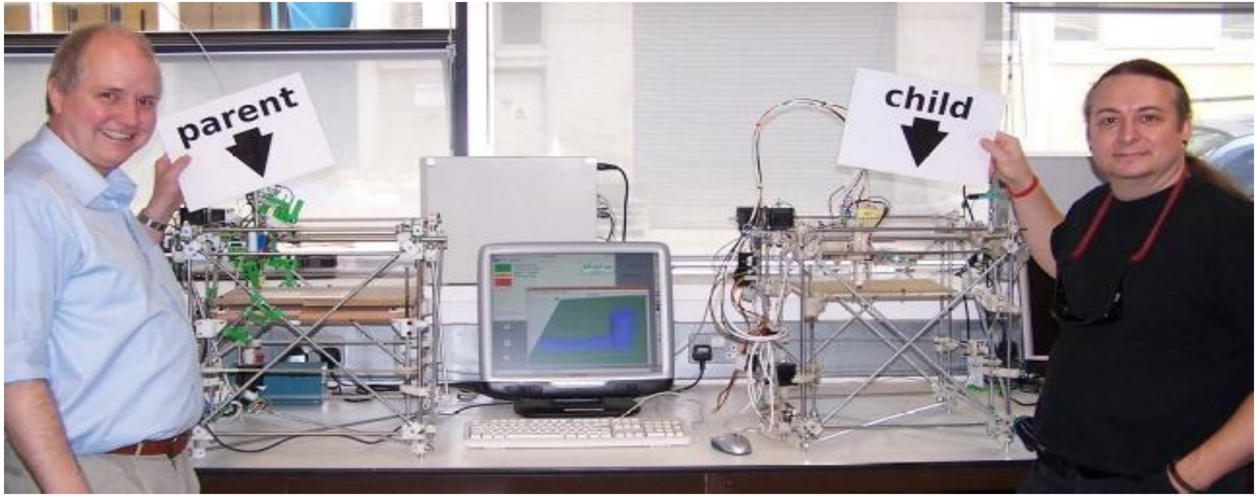
Glaucoma Valve

Desktop 3D Printing: Same Feathers, Different Bird

Not new: First patents 1984. Cost $100K - Millions

Explosion in late 1990's due to **expiry of first patents** on FDM and SLA printers

→ **Open source printer designs** centered around the **RepRap** (Replicating Rapid Prototyper) project



May 2008: First "complete" replication
All of the plastic parts for the machine on the right were produced by the machine on the left.
Adrian Bowyer (left) and Vik Olliver (right)

Source: Wikipedia

The disruptive change

Desktop 3D printing makes it possible for

almost anyone (with basic digital literacy and semi-reliable electricity)

to build complex, functional objects

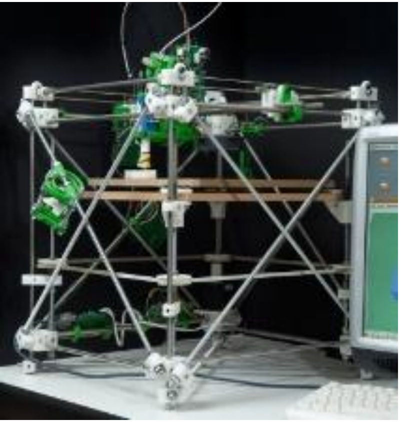
of almost every imaginable shape,

with high quality, at scale,

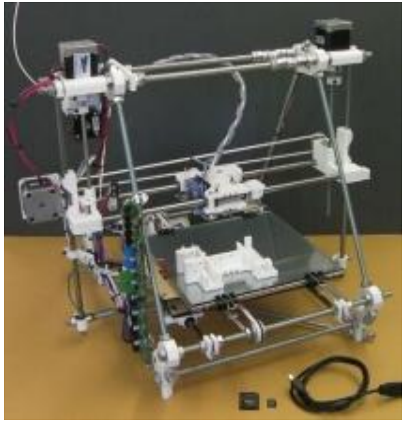
with initial infrastructure costs similar to a new cell phone

Lineage

Makerbot
Ultimaker
Creality
...



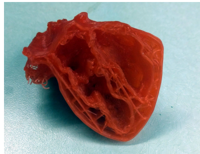
RepRap 1.0: “Darwin”
2008



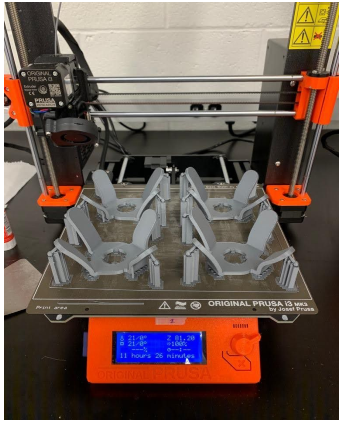
RepRap 2.0: “Mendel”
2009

. . .

Prusa i3
Our first printer.
Built in-house
2015

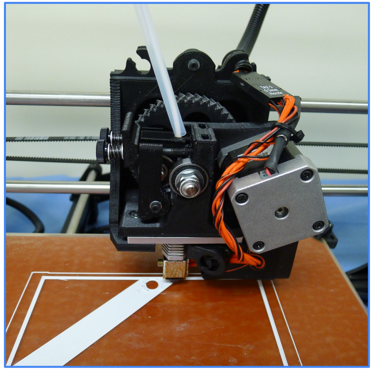


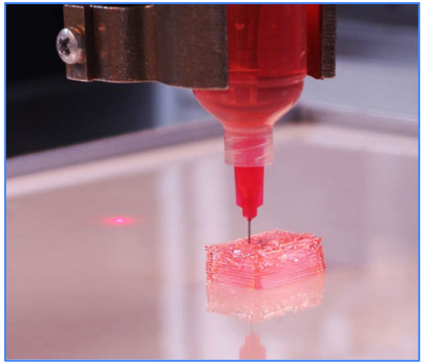
Lulzbot TAZ 5
commercial
open-hardware
Printer
2016

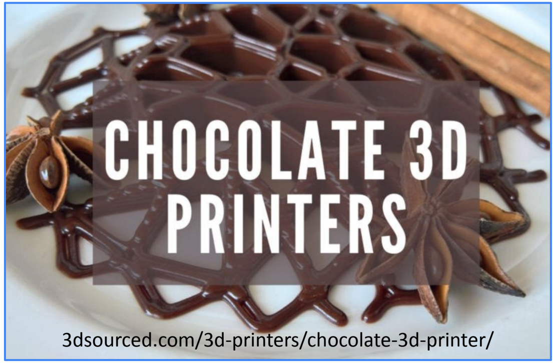


Prusa i3 MK3
Current
Workhorse
2021

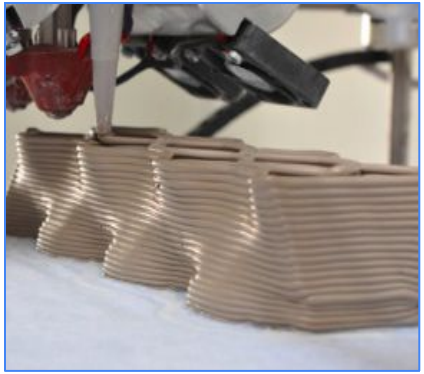
Desktop 3DP spin-offs





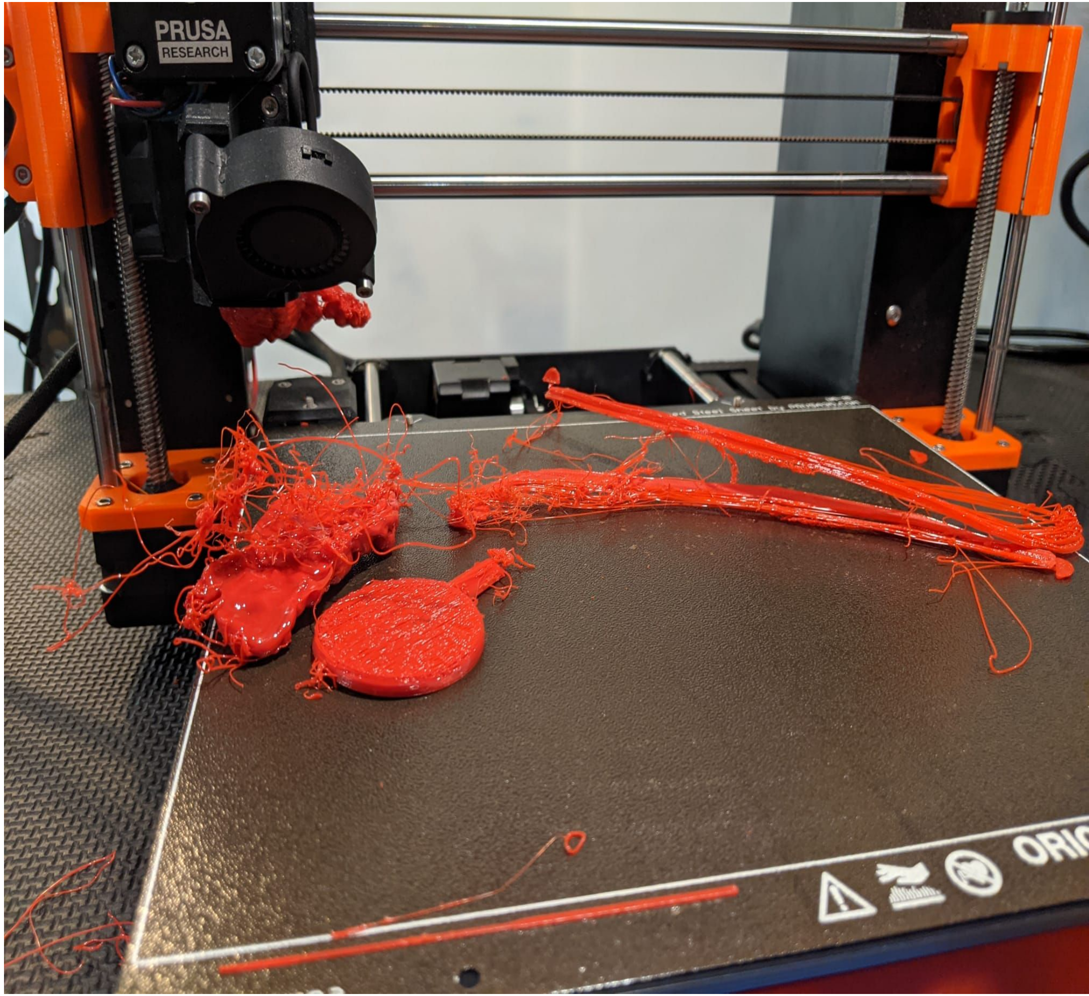


3dsourced.com/3d-printers/chocolate-3d-printer/



3dnatives.com/en/rmit-strengthening-concrete-210120215/


John Moynes
@JohnMoynes
Rage Against the Machine never specified what type of machine they were furious with but I reckon it was probably a printer.
Tweet übersetzen
15:35 · 21.04.21 · Twitter Web App
2.579 Retweets 188 Zitierte Tweets

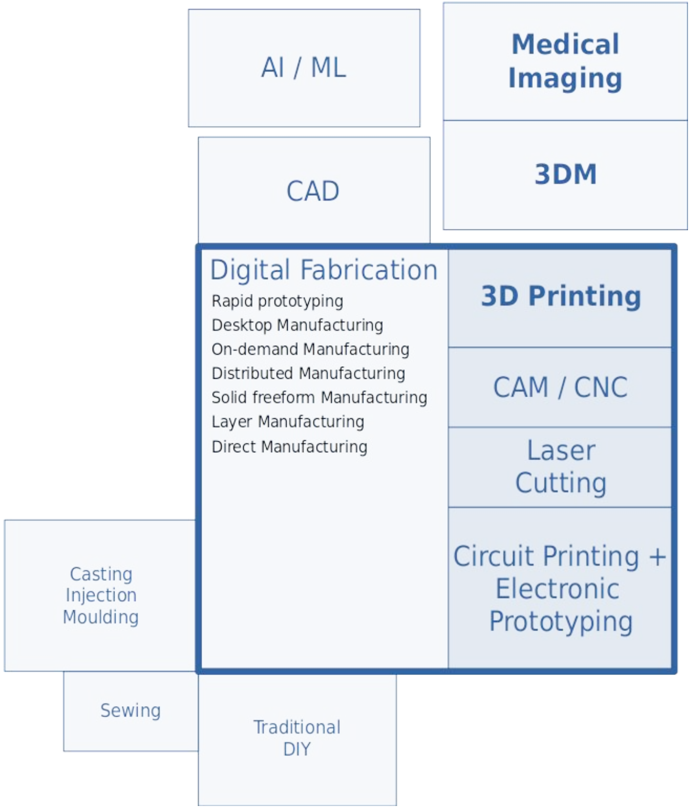

PRUSA
RESEARCH

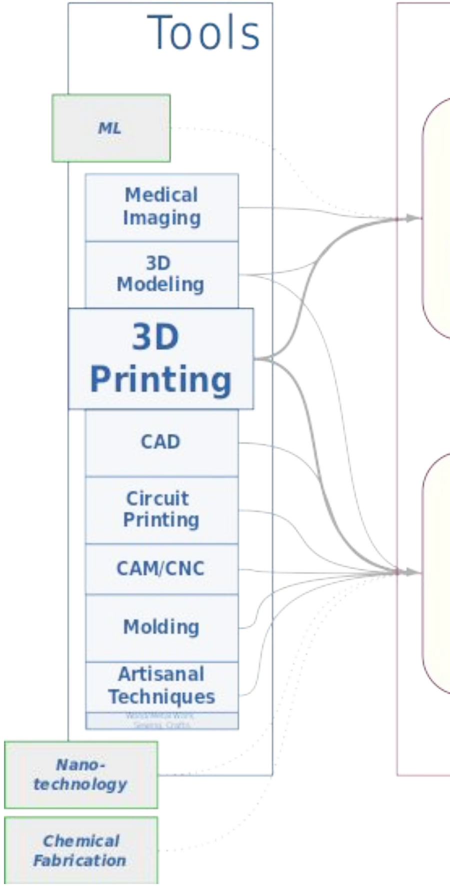
Applications

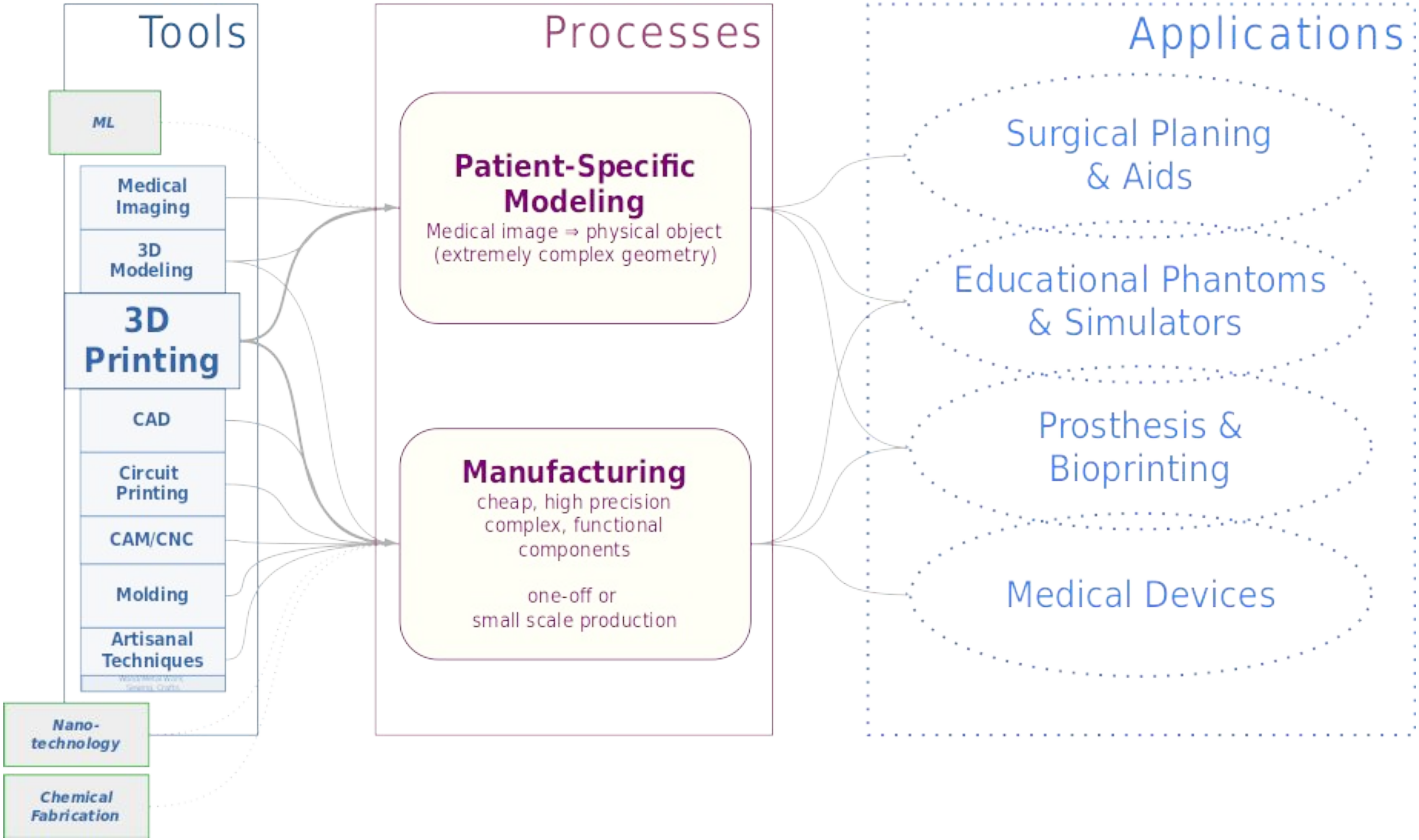
Patient-specific Models

Device Manufacturing

3D Printing - Technical Context






Tools
ML
Medical Imaging
3D Modeling
3D Printing
CAD
Circuit Printing
CAM/CNC
Molding
Artisanal Techniques
Nano-technology
Chemical Fabrication
Processes
Patient-Specific Modeling
Medical image ⇒ physical object
(extremely complex geometry)
Manufacturing
cheap, high precision
complex, functional
components
one-off or
small scale production
Applications
Surgical Planing & Aids
Educational Phantoms & Simulators
Prosthesis & Bioprinting
Medical Devices

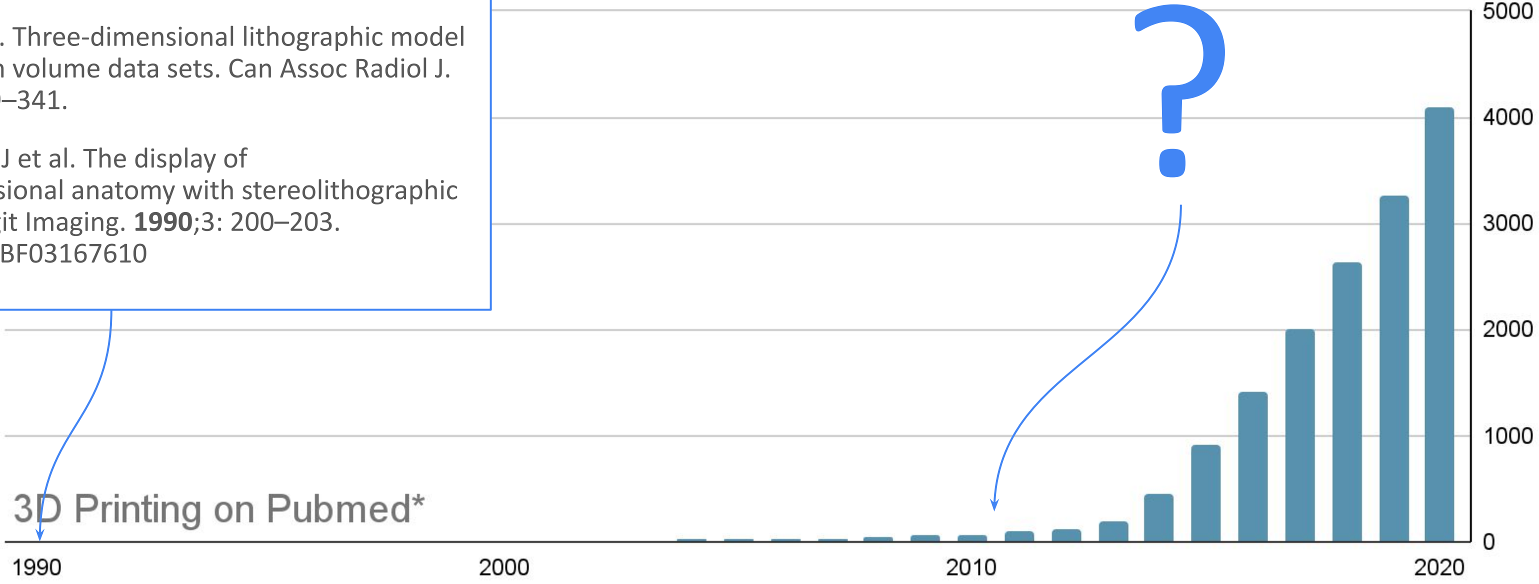
3D Printing in Medicine: History

First medical reports 1990.

Visualization models printed on industrial SLA printers.

Palser R et al. Three-dimensional lithographic model building from volume data sets. Can Assoc Radiol J. **1990**;41: 339–341.

Mankovich NJ et al. The display of three-dimensional anatomy with stereolithographic models. J Digit Imaging. **1990**;3: 200–203. doi:10.1007/BF03167610



Query: "Printing, Three-Dimensional"[Mesh] OR (("3D" OR "three-dimensional") AND ("Print" OR "Printing"))

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FDM & SLA Patents Expire

open hardware

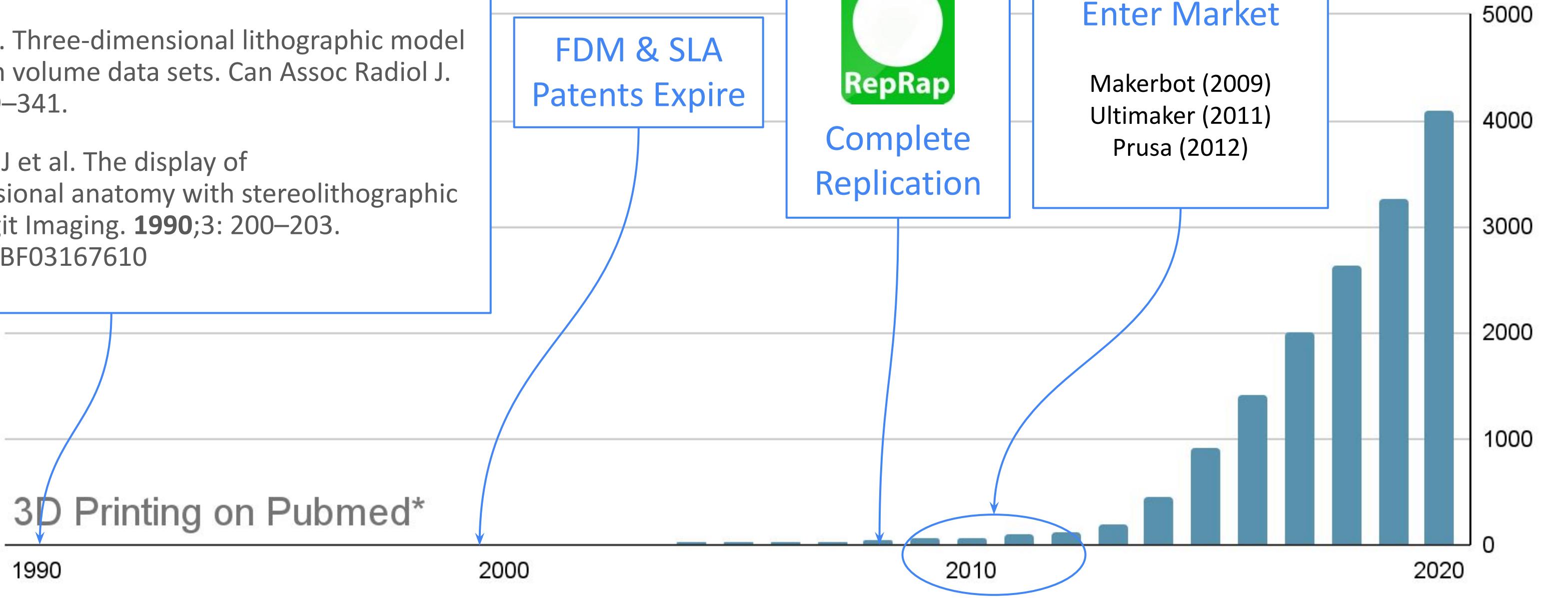
RepRap

Complete Replication

open hardware

Desktop Printers Enter Market

Makerbot (2009)
Ultimaker (2011)
Prusa (2012)



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Applications:

Patient-specific Models

***Marilène Oliver**, Headspace. 2012. From an **MR angiogram** of patient with a brain aneurysm. Ink and drill holes in acrylic plates. marileneoliver.com.*
See also https://www.tedmed.com/talks/show?id=731053

What are Patient-Specific 3D Models?

Digital 3D models created from 3-dimensional medical imaging data (CT, MRI, 3D Ultrasound)

Models can be dynamic or static

Digitally represented as a mesh (vertices & edges)

Multiple file formats (STL, OBJ etc.)

Digital 3D Model

```
solid ascii
facet normal 0.0927133 -0.0679498 0.993372
  outer loop
   vertex -54.8458 67.1663 -2.49017
   vertex -55.0673 67.1473 -2.4708
   vertex -55.0497 66.8845 -2.49042
  endloop
endfacet
facet normal -0.665674 -0.0996668 0.739557
  outer loop
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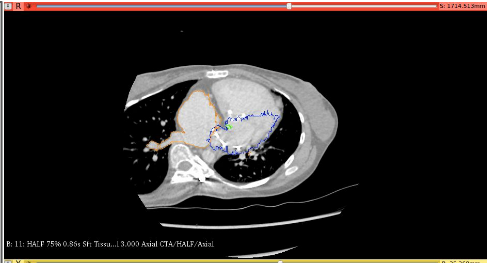
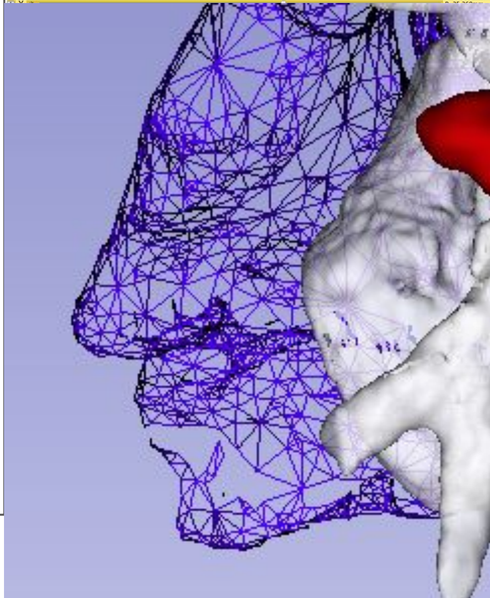




How can you see & interact with them?

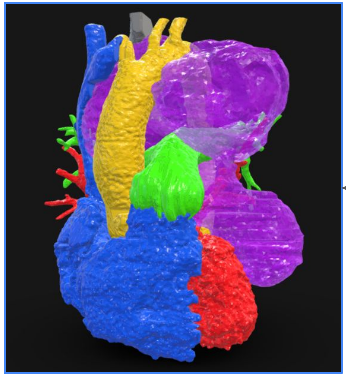
3D rendering (on 2D screen)

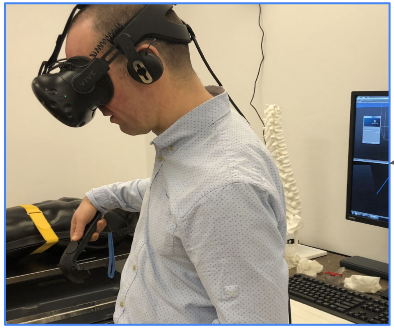
Virtual and Augmented Reality

Stereoscopic & Holographic displays

3D printing

Medical image computation





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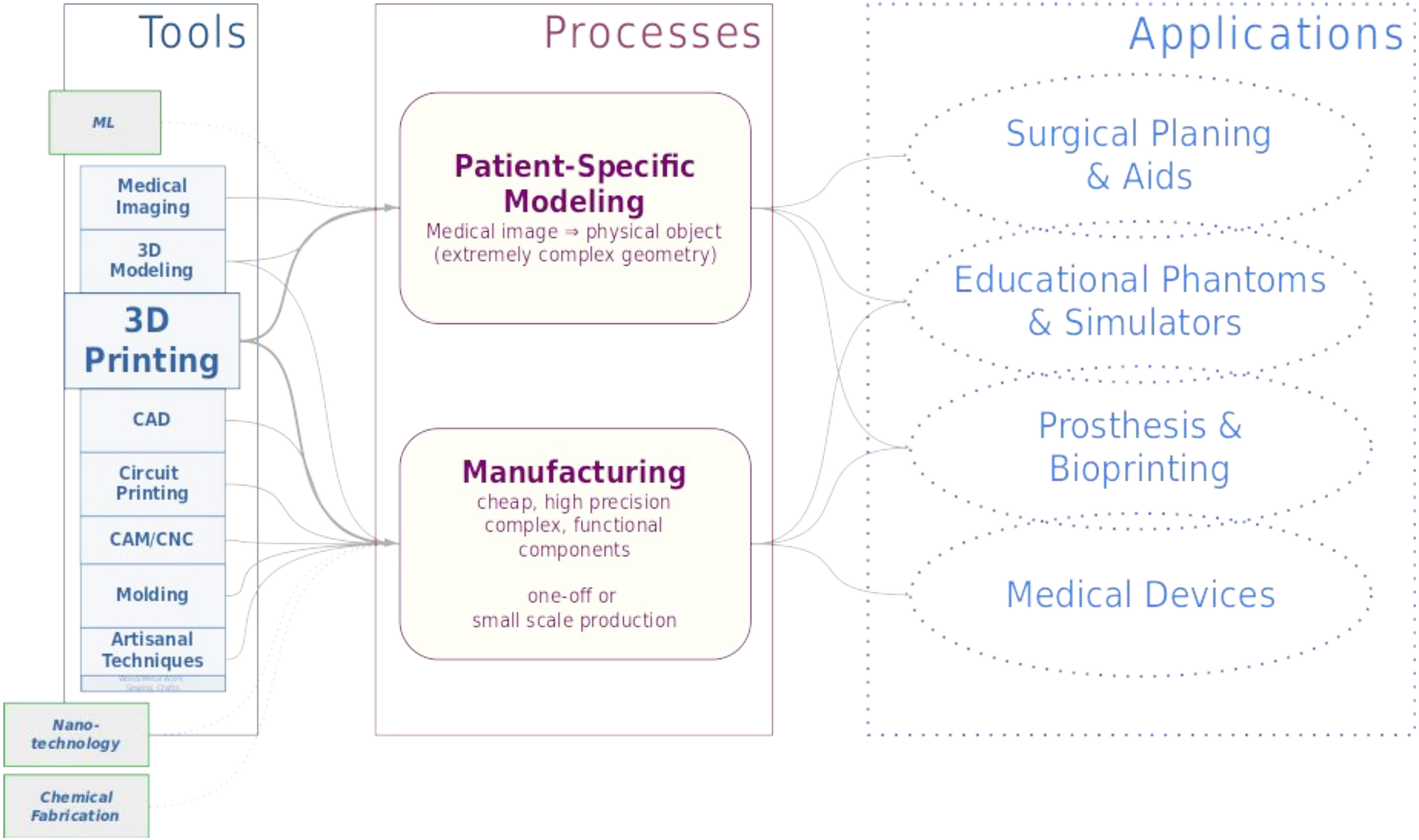

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& Aids
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& Simulators
Prosthesis &
Bioprinting
Medical Devices

Patient-Specific 3D Models: **How are they made?**

Imaging

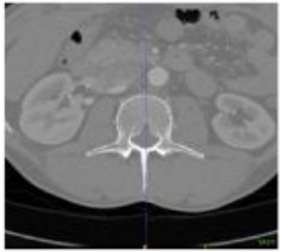
Segmentation of medical image to create voxel model

Manual ⟷ *Automatic*

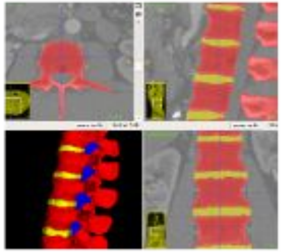
Modeling/Mesh generation from voxel model (Label Map) → **Patient-specific 3D digital model**

Import to visualization system (render; VR/AR …) or

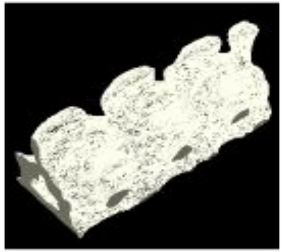
Print: Generating Printer Code (“Slicing”); Send to Printer (cross fingers)



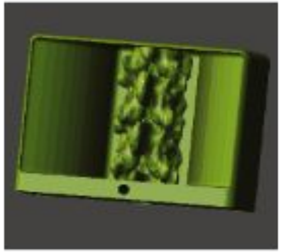
3D Image
CT / MRI / US



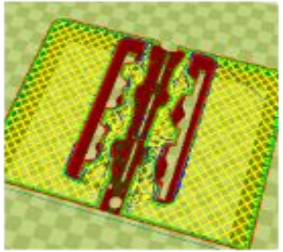
Segmented
Label Map



Raw
3D Model



Edited
3D Model



Printer Code

3D Print

Source Imaging: CT

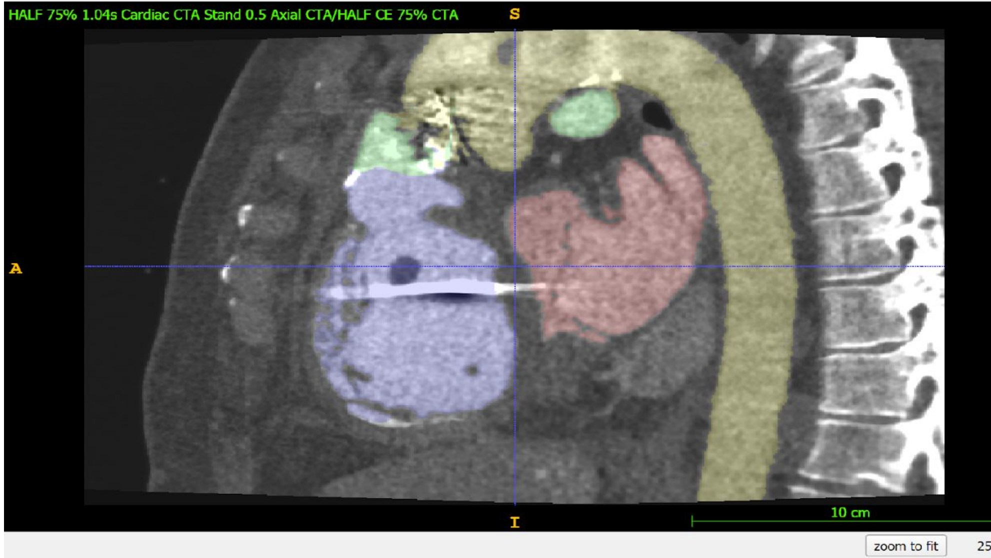
Most common

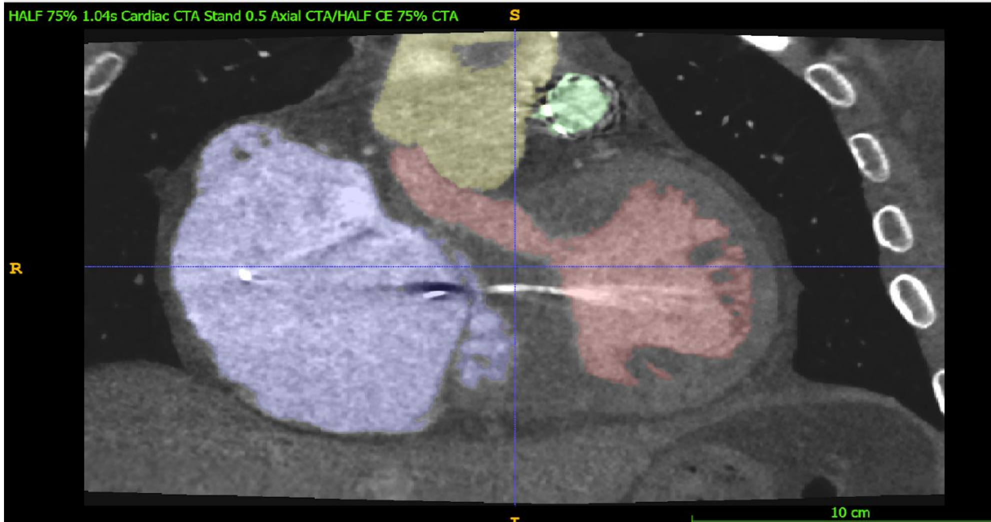
~ 0.5 mm resolution

Ideally cardiac-gated to reduce motion artifact, with contrast

Soft-tissue boundaries can be challenging to model accurately

Dual-energy CT (DECT) can improve soft tissue distinctions but not widely available yet



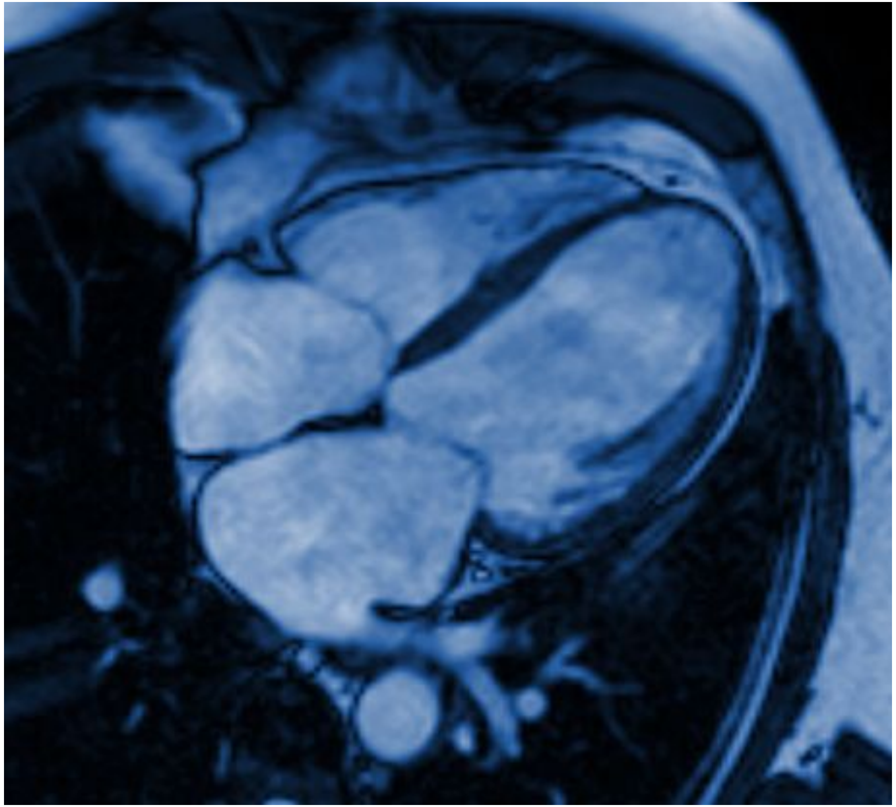


Source Imaging: MR

Best soft tissue contrast

Anisotropic resolution
~0.5 mm lateral & AP but 5-8 axial slice spacing; limited by time, patient tolerance & storage space

Most common in pediatric cases



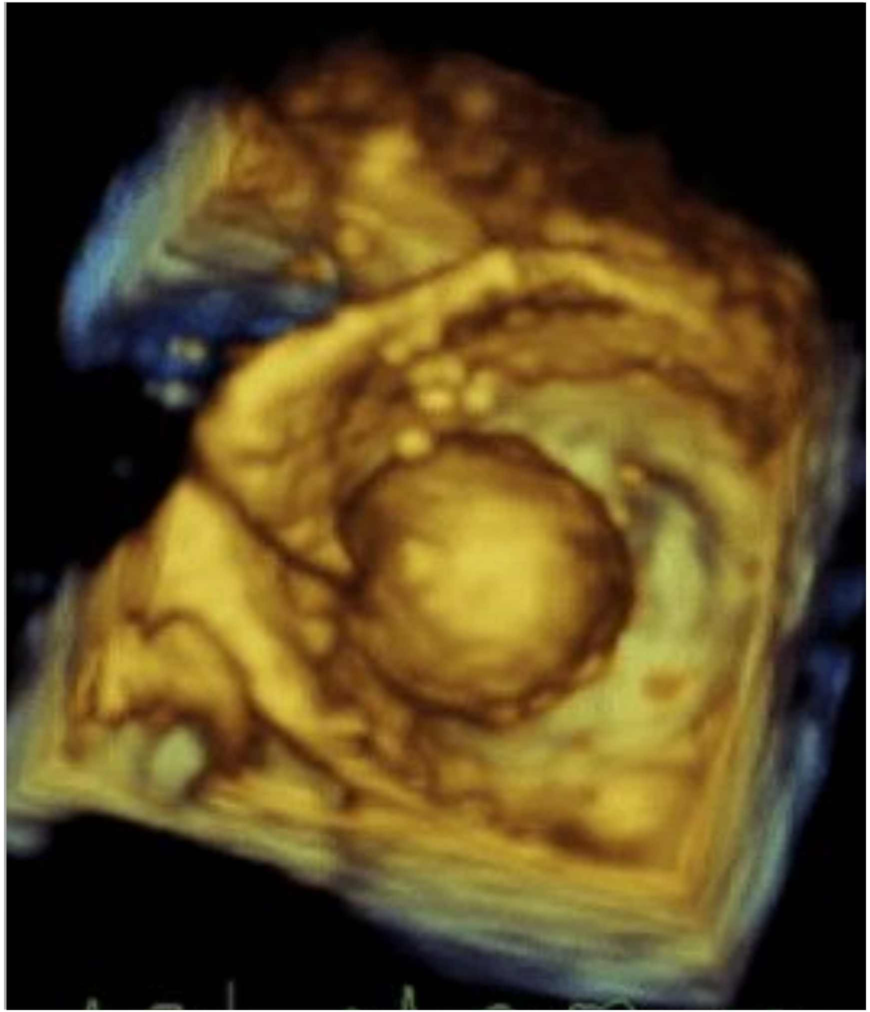
Source Imaging: 3D TEE

Best temporal resolution: Ideal for valves and highly mobile masses.

Limited spatial scope

Frustum anisotropic voxel geometry requires resampling; resolution decreases with depth

Non-standard DICOM format requires vendor-specific software



Voxel Geometry & Resolution: CT vs MRI vs Echo

Isotropic: Same resolution in all 3 axis

CT: Cubic or near-cubic voxels ~ 0.5 mm
No or minimal resampling required

Anisotropic: Varies with orientation

MRI: Rectangular prism 0.5 x 0.5 x 5-8 mm

Echo: Spherical segment voxels which grow with distance from probe

CT

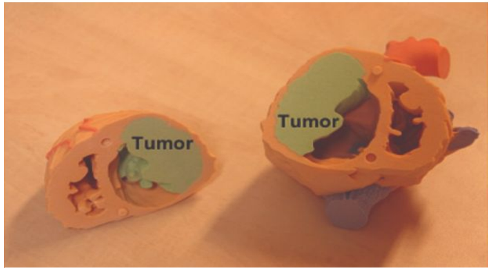
MRI

Echo

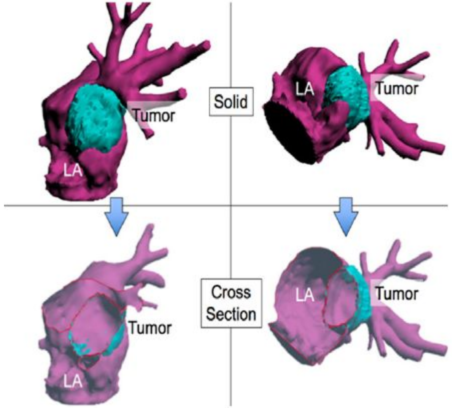
Clinical Planning

Patient-Specific Models:

Clinical Planning



Jacobs et al. Interact Cardiovasc Thorac Surg. 2008;7: 6–9.



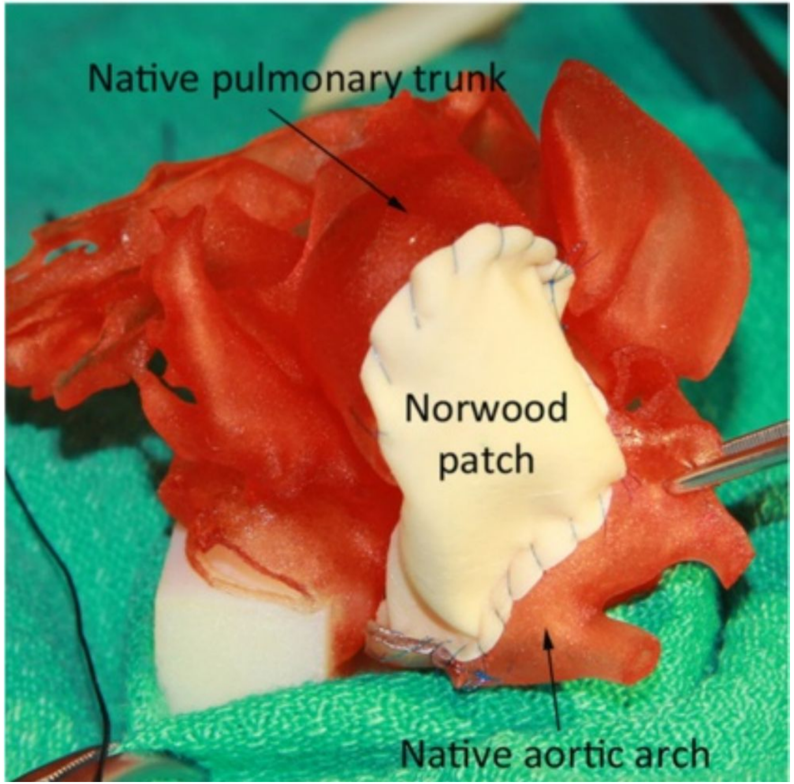
DOI 10.1111/jocs.12812

NEW TECHNOLOGIES

WILEY Journal of Cardiac Surgery

Use of three-dimensional models to assist in the resection of malignant cardiac tumors

Odeaa Al Jabbari, M.D.[1]* | Walid K. Abu Saleh, M.D.[2] | Avni P. Patel, M.E.[1] | Stephen R. Igo, B.S.[1] | Michael J. Reardon, M.D.[1]



Yoo S-J, Thabit O, Kim EK, Ide H, Yim D, Dragulescu A, et al. 3D printing in medicine of congenital heart diseases. 3D Printing in Medicine. 2016 Dec 1;2(1):3. doi:10.1186/s41205-016-0004-x

Case: Cardiac Tumor for Surgical Planning

55M electrician presented to primary care with increasing hoarseness.

Otherwise healthy. No other symptoms on review. Conservatively managed.

2 months later near complete loss of vocalization ⟶ CT Scan

CT: Very large mediastinal tumor encasing the pulmonary artery with “Mickey Mouse” ears compressing SVC, LA + LV.

Deemed inoperable on initial surgical evaluations.

No significant response to 4 cycles Ifosfamide+doxorubicin.

Referred for 3D modeling to

1. Assess feasibility of resection
2. Approach: divide tumor vs. divide great arteries.

Case: Cardiac Tumor for Surgical Planning

Repeat CT to evaluate tumor progression and optimize for modeling

Cardiac-gated; Contrast; Enlarged window.

Semi-automated segmentation with manual editing (ITK-snap, 3D Slicer)

Segmentation confirmed by radiologist.

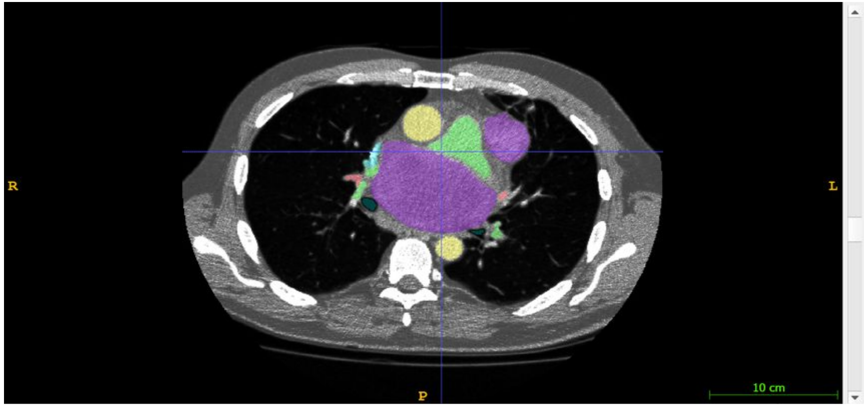
12 hours of labour (two rounds of modeling based on two CTs)

3D renderings (https://skfb.ly/6TOK6) and modular 3D print (Prusa MK3, Formlabs Form 2) used in planning approach and communicating plan to team and patient.

85 hours total printing time

Photo by Tim Fraser. https://uhnfoundation.ca/stories/3d-vision

Cardiac Tumor: Segmentation (ITK-Snap, 3D Slicer)



Cardiac Tumor: Mesh model editing (Meshmixer, 3D Slicer, Blender)

Cropping

Smoothing; Editing drop-outs

Removing erroneous pixels

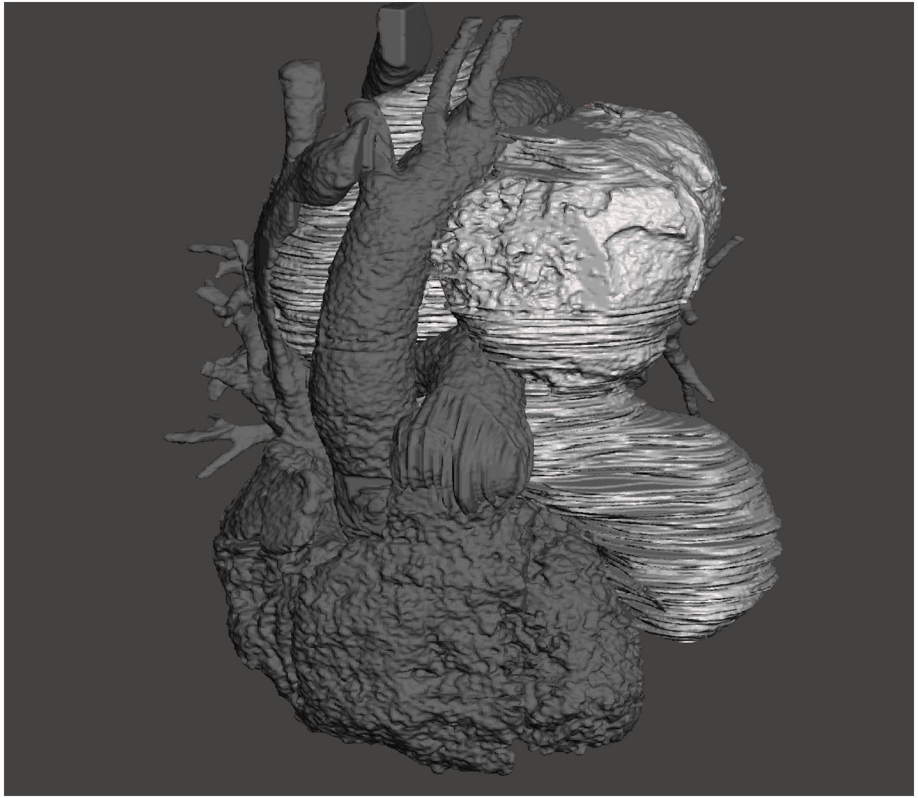
Reducing triangle count

Rendering:

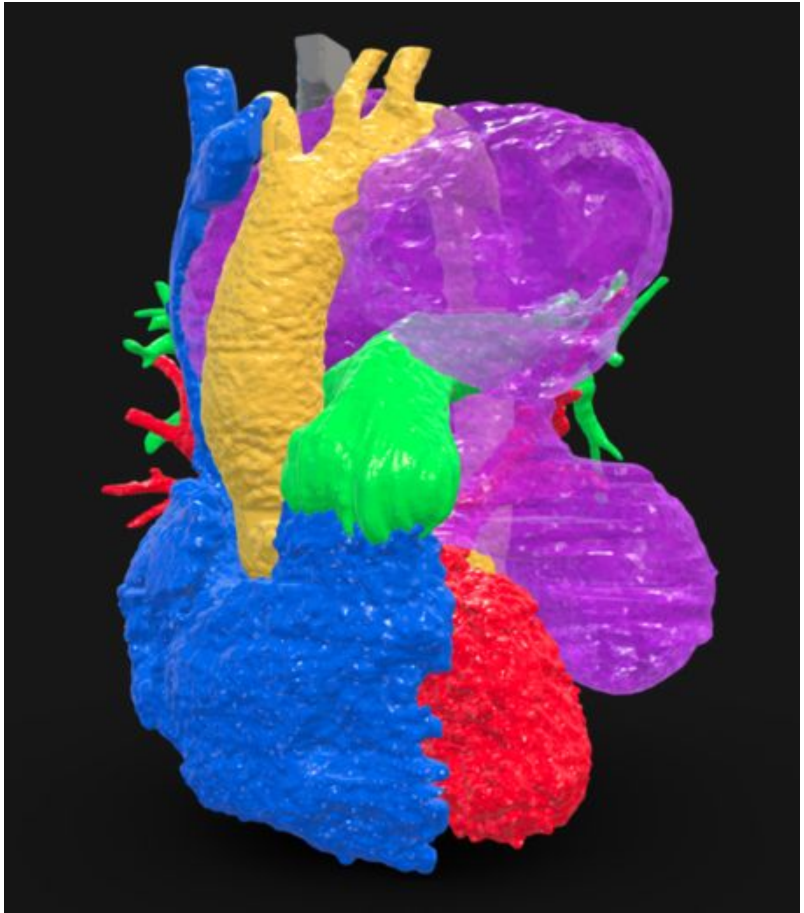
- Texturing (assigning colours)
- Sketchfab (on-line service)

Printing:

- Divide large parts into sections.
- Export as STL to Prusa Slic3r which generated printer g-code.



Cardiac Tumor: Rendering & Print (Prusa MK3; Formlabs Form 2)



Cardiac Tumor for Surgical Planning: Outcomes

Tumor resected successfully.
Spindle cell Sarcoma. 4kg.

6h skin-to-skin. 3.5h on CP support
1.5h central VAECMO; 2h CPB (RA>Fem)
Bilateral clamshell
1 minute warm circ arrest (Aortic injury, rapid switch from ECMO to CPB; Cooled to 30°C.

EBL: 4 L. cell-saver used.

Tumor was not cut.
No division of aorta.
Pulmonary artery divided + anastomosed.
Phrenic n. Preserved x 2
RLN could not be identified.

A small posterior extension (?separate piece, ?LN) not captured in model. Not clearly captured on imaging.

Model reduced resection time by half (Surgeon feedback); supported intra-op decision not to cut tumor

Post-op
Generally smooth course.
No neurologic deficit.
Adjuvant radiation 52GY. Small positive margin.
VC medialization.

Back to work (Electrician). 18 months post-op.
No evidence of recurrence.

Cardiac Tumor for Surgical Planning:

Item	Unit Cost	Quantity	Total (CAD)
Print Time-FDM (/hour)	*$4.00*	58.5	$234.00
Print Time-SLA (/hour)	*$6.00*	26	$156.00
Material-FDM: PLA (/kg)	*$30.00*	0.6225	$18.68
Material-SLA: Clear FLGPCL02 (/L)	*$226.00*	0.2535	$57.29
Resin Tank	*$79.10*	12.7%	$10.03
Post-processing Supplies	*$4.00*	5	$20.00
Software Fee	*$5.00*	1	$5.00
Technician Time (/hour)	*$45.00*	12	$540.00
Subtotal			$1,040.99
Lab Overhead (%)	*10%*		$104.10
Hospital Overhead (%)	*15%*		$156.15
Total			**CAD $1,301.24**
			USD $1,040.99

Cardiac Tumor for Surgical Planning: Lessons

At best only as good as the imaging.

Unable to clearly identify subtle tissue invasion but can define areas of concern which influences surgical approach.

If tumor had to be cut computational model could potentially suggest cuts to minimize exposed tumor surface.

3D print may not be necessary for planning once surgeons are more used to VR/AR, unless surgical rehearsal required.

Procedural Planning ACHD

SHD Procedure Planning: >30 cases to date

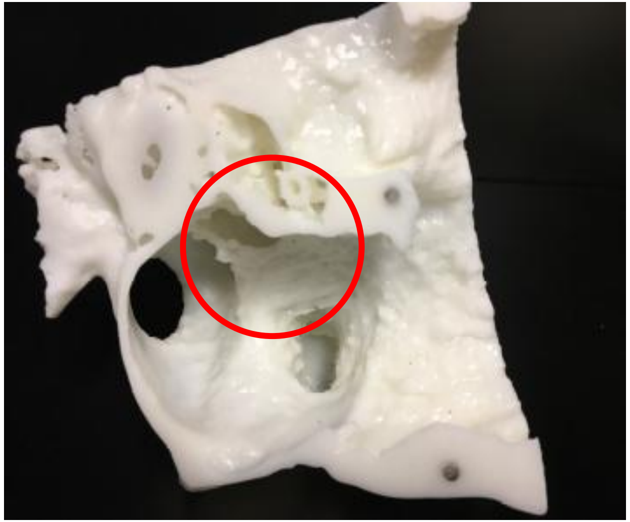
E.g. dTGA s/p Mustard with baffle leak for percutaneous closure

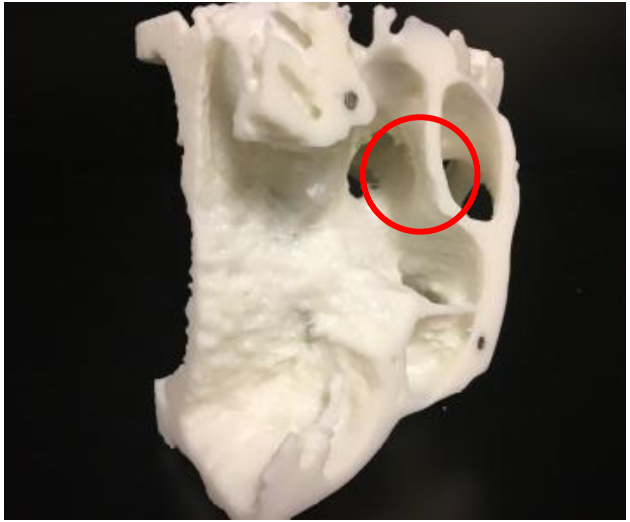
Source: Cardiac-gated CT

Segmentation: 3DSlicer / ITK Snap; Reviewed by radiologist and cardiologist

Post-processing: Meshmixer

Print: Form 2, White resin, Full scale





ACHD Procedural Planning & Simulation

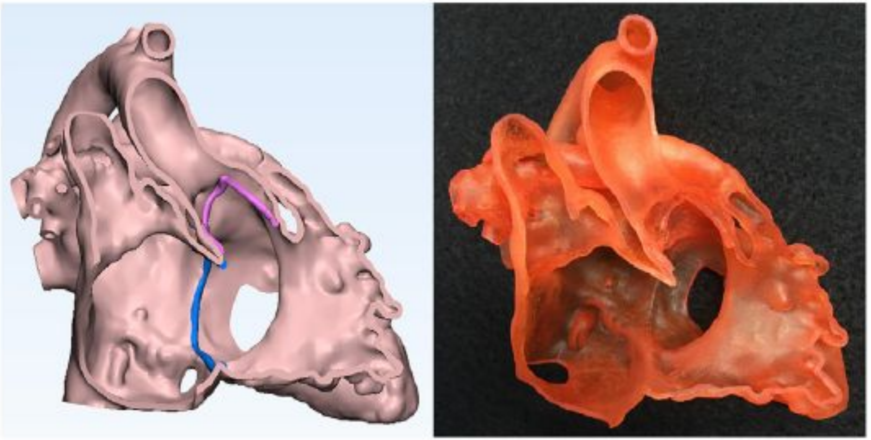
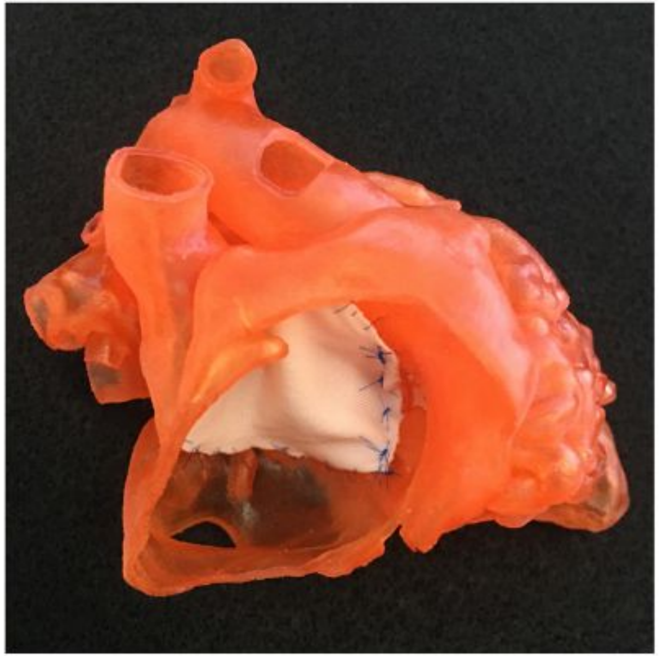


FIGURE 3 | Graphic representation and photograph of the endocardial surface anatomy model made of soft material (TangoPlus, Stratasys Ltd., MN, USA) of the right ventricle of the case shown in **Figure 1**.

3D Printing in Surgical Management of Double Outlet Right Ventricle

Shi-Joon Yoo[1,2] and Glen S. van Arsdell[3]*



Three-dimensional printed models for surgical planning of complex congenital heart defects: an international multicentre study

Israel Valverde[a,b,c,d,*], Gorka Gomez-Ciriza[a], Tarique Hussain[c,e], Cristina Suarez-Mejias[a],

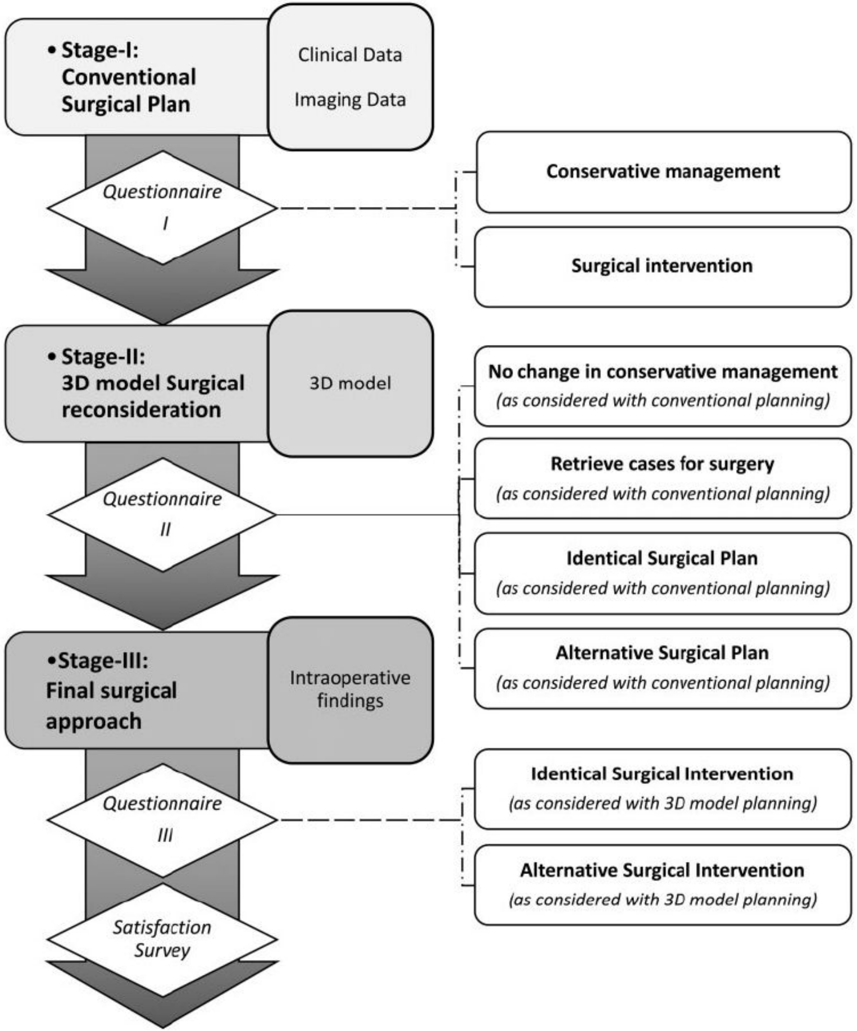
METHODS: A prospective case-crossover study involving 10 international centres and 40 patients with complex CHD (median age 3 years, range 1 month–34 years) was conducted. Magnetic resonance imaging and computed tomography were used to acquire and segment the 3D cardiovascular anatomy. Models were fabricated by fused deposition modelling of polyurethane filament, and dimensions were compared with medical images. Decisions after the evaluation of routine clinical images were compared with those after inspection of the 3D model and intraoperative findings. Subjective satisfaction questionnaire was provided.

RESULTS: 3D models accurately replicate anatomy with a mean bias of -0.27 ± 0.73 mm. Ninety-six percent of the surgeons agree or strongly agree that 3D models provided better understanding of CHD morphology and improved surgical planning. 3D models changed the surgical decision in 19 of the 40 cases. Consideration of a 3D model refined the planned biventricular repair, achieving an improved surgical correction in 8 cases. In 4 cases initially considered for conservative management or univentricular palliation, inspection of the 3D model enabled successful biventricular repair.

CONCLUSIONS: 3D models are accurate replicas of the cardiovascular anatomy and improve the understanding of complex CHD. 3D models did not change the surgical decision in most of the cases (21 of 40 cases, 52.5% cases). However, in 19 of the 40 selected complex cases, 3D model helped redefining the surgical approach.

Eur J Cardiothorac Surg. 2017;52: 1139–1148.

Valverde et al. Three-dimensional printed models for surgic
planning of complex congenital heart defects: an internatio
multicentre study. Eur J Cardiothorac Surg. 2017;52:
1139–1148. doi:10.1093/ejcts/ezx208



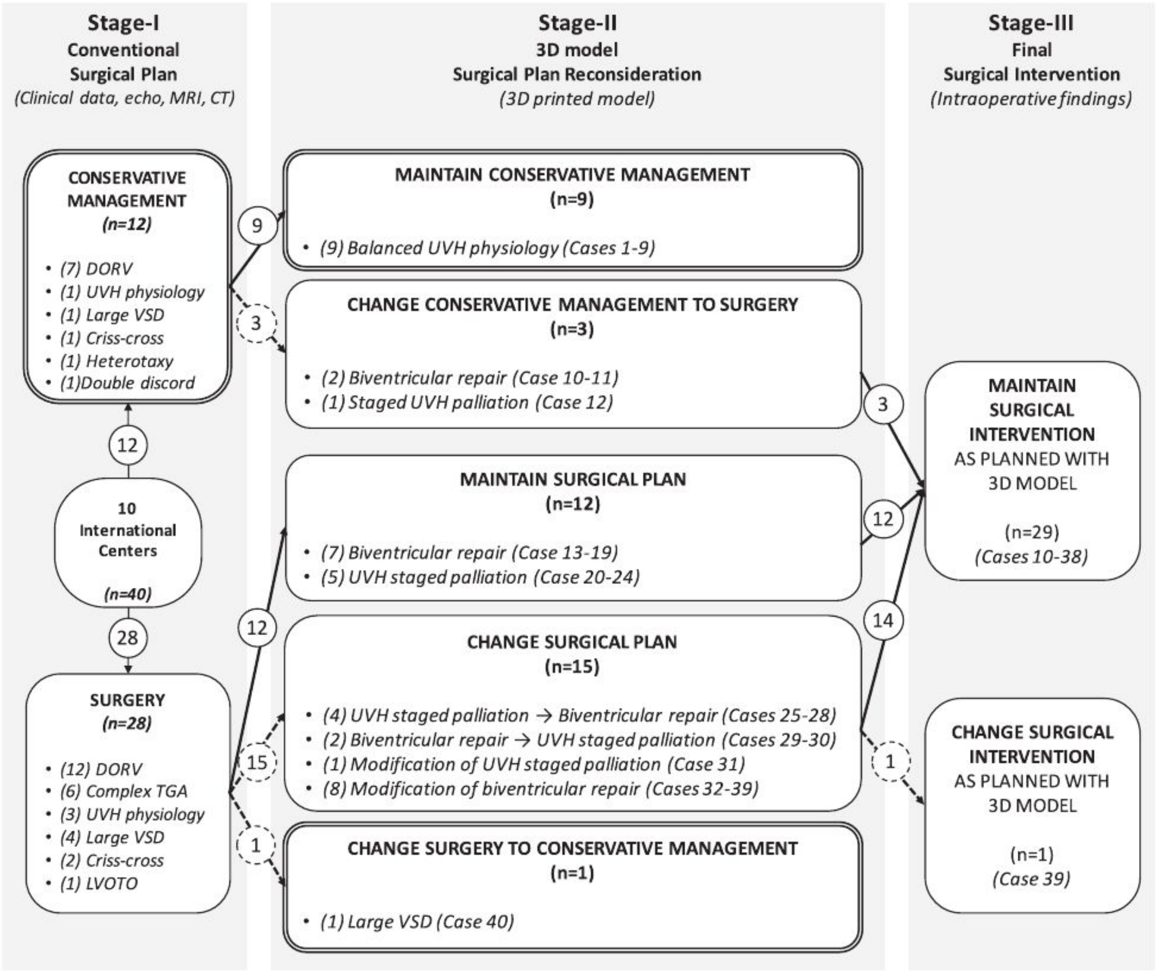


Figure 5: Surgical management decision. Continuous arrow: no change in management decision. Dotted arrows: change in management decision. Conservative management showed in double line box. Surgery management showed in single line box.

Patient-Specific Guides - Typical Studies

Cecchinato et al. Pedicle screw insertion with patient-specific 3D-printed guides based on low-dose CT scan is more accurate than free-hand technique in spine deformity patients: a prospective, randomized clinical trial. Eur Spine J. 2019;28: 1712–1723. doi:10.1007/s00586-019-05978-3

Improved accuracy; reduced radiation dose (including additional low-dose CT for modeling)

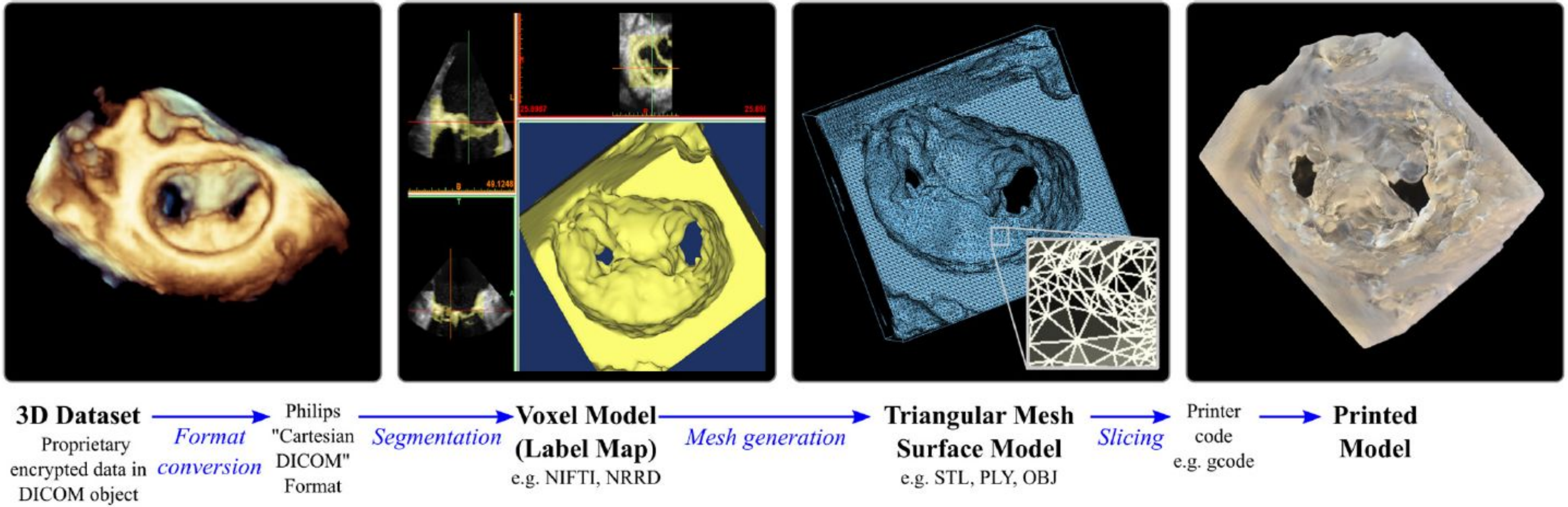
Hu et al. Clinical application of individualized 3D-printed navigation template to children with cubitus varus deformity. J Orthop Surg Res. 2020;15: 111. doi:10.1186/s13018-020-01615-8

<u>Non-randomized</u> controlled trial. 50% reduction in time for key surgical step and angle error of 1° vs 4° but no difference in elbow function.

Wake et al. 3D printed renal cancer models derived from MRI data: application in pre-surgical planning. Abdom Radiol. 2017;42: 1501–1509. doi:10.1007/s00261-016-1022-2: Simulated decision making on 10 retrospective cases by 3 surgeons. Imaging alone then imaging+3D model one week later.

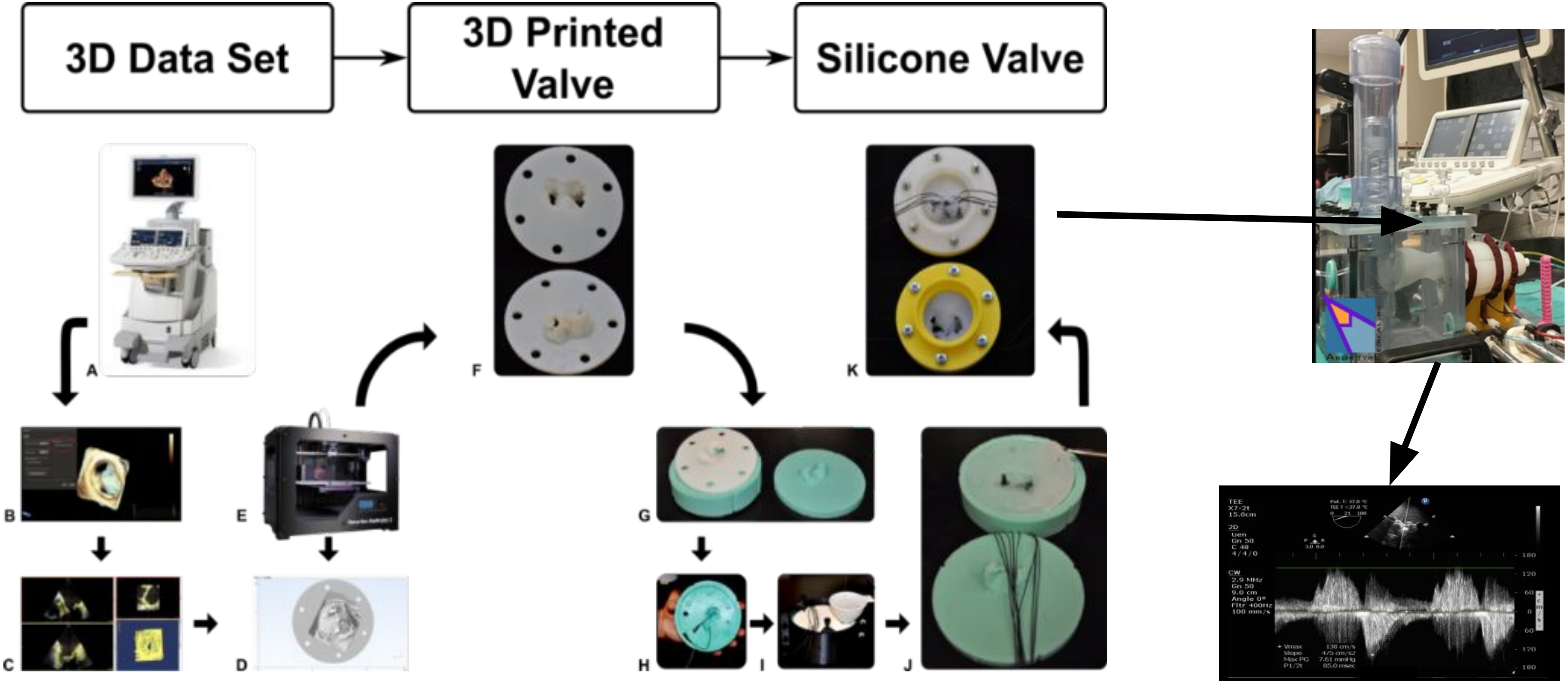
Retrospective study, small local sample.

Patient-Specific Functional Simulation (3D Echo)



Mashari et al. Echo Res Pract **2016**, 3 (4), R57–R64. https://doi.org/10.1530/ERP-16-0036.

Functional Simulation for Procedural Planning



Mashari et al. Hemodynamic Testing of Patient-Specific Mitral Valves Using a Pulse Duplicator: A Clinical Application of Three-Dimensional Printing. J Cardiothorac Vasc Anesth. 2016;30: 1278–1285. doi:10.1053/j.jvca.2016.01.013

Functional Simulation for Procedural Planning

Physical simulation is very limited

model based on single 3D image frame; good for “static” pathologies (e.g. stenosis)

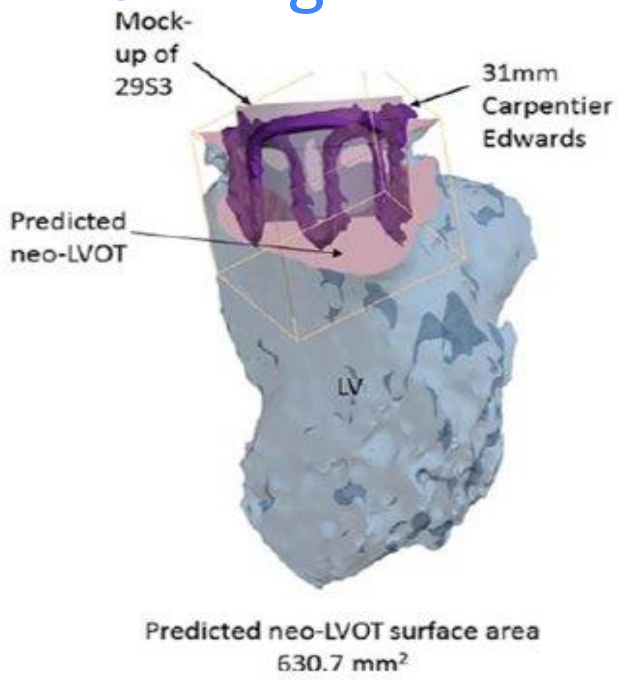
Mobile pathologies (e.g. regurgitation) require high mechanical fidelity, not currently feasible.

Not ready for clinical application.

May be useful for procedure simulation and prediction of adverse effects for SHD interventions (e.g. mitral stenosis post clip)

The future is likely digital

- Xu et al. A framework for designing patient-specific bioprosthetic heart valves using immersogeometric fluid–structure interaction analysis. International Journal for Numerical Methods in Biomedical Engineering. 2018;34: e2938. doi:10.1002/cnm.2938



Catheter Cardiovasc Interv. 2018;**92**:379–387

Validating a prediction modeling tool for left ventricular outflow tract (LVOT) obstruction after transcatheter mitral valve replacement (TMVR)

Dee Dee Wang, MD[1] | Marvin H. Eng, MD[1] | Adam B. Greenbaum, MD[1] |

“Guidelines”

1. Chepelev et al. Radiological Society of North America (RSNA) 3D printing Special Interest Group (SIG): **Guidelines for medical 3D printing and appropriateness for clinical scenarios**. 3D Print Med. 2018;4: 11. doi:10.1186/s41205-018-0030-y

2. Ali et al. Clinical situations for which 3D printing is considered an appropriate representation or extension of data contained in a medical imaging examination: **adult cardiac conditions.** 3D Printing in Medicine. 2020;6: 24. doi:10.1186/s41205-020-00078-1

3. Ballard et al. Clinical situations for which 3D printing is considered an appropriate representation or extension of data contained in a medical imaging examination: **abdominal, hepatobiliary, and gastrointestinal conditions.** 3D Printing in Medicine. 2020;6: 13. doi:10.1186/s41205-020-00065-6

Chepelev *et al. 3D Printing in Medicine* (2018) 4:11
https://doi.org/10.1186/s41205-018-0030-y
3D Printing in Medicine

RESEARCH **Open Access**

Radiological Society of North America (RSNA) 3D printing Special Interest Group (SIG): guidelines for medical 3D printing and appropriateness for clinical scenarios

Leonid Chepelev[1†], Nicole Wake[2,3†], Justin Ryan[4†], Waleed Althobaity[1†], Ashish Gupta[1†], Elsa Arribas[5†], Lumarie Santiago[5†], David H Ballard[6], Kenneth C Wang[7], William Weadock[8], Ciprian N Ionita[9], Dimitrios Mitsouras[1], Jonathan Morris[10], Jane Matsumoto[10], Andy Christensen[1], Peter Liacouras[11], Frank J Rybicki[1*], Adnan Sheikh[1] and RSNA Special Interest Group for 3D Printing

1–3, red, rarely appropriate: There is a lack of a clear benefit or experience that shows an advantage over usual practice.
4–6, yellow, maybe appropriate: There may be times when there is an advantage, but the data is lacking, or the benefits have not been fully defined.
7–9, green, usually appropriate: Data and experience shows an advantage to 3D printing as a method to represent and/or extend the value of data contained in the medical imaging examination.

Table 1 Ratings Summary: Appropriateness Guidelines (scoring system defined in Methods) for patients who present with a variety of medical conditions, and for whom 3D Printing is often considered

Scenario	Rating	References
Congenital Heart Disease		
Atrial Septal Defect, Large	2	1-7
Atrial Septal Defect, Small or Spontaneously Closed	3	
Ventricular Septal Defect, Complex	5	8-16
Ventricular Septal Defect, Large Noncomplex	3	
Ventricular Septal Defect, Small	3	
Atrioventricular Canal	4	-
Aortopulmonary Window	6	-
Truncus Arteriosus	9	-
Partial Anomalous Pulmonary Pulmonary Venous Connection (PAPVR)	8	-
Total Anomalous Pulmonary Venous Connection (TAPVR)	8	-
Cor Triatriatum	6	-
Pulmonary Venous Stenosis	3	-
Tetralogy of Fallot, NOS	6	11,17,18
Tetralogy of Fallot, with major aortopulmonary collateral arteries	7	
Tricuspid Valve Disease and Ebstein's Anomaly	4	-
RVOT Obstruction and/or Pulmonary Stenosis	4	12,16
Hypoplastic Left Heart Syndrome	5	9-11,19-24
Shone's syndrome	5	-
Double Inlet Left Ventricle	7	-
Double Inlet Right Ventricle	7	-
Mitral atresia	5	-
Tricuspid atresia	4	-
Unbalanced AV canal	7	-
Single ventricle (general)	6	25-27
Congenitally Corrected TGA (levo-TGA)	7	23,28
Transposition of the Great Arteries (dextro-TGA)	7	29
Double Outlet Right Ventricle	9	9-12,19, 20,23, 24,30
Double Outlet Left Ventricle	9	-
Craniomaxillofacial		
Skull Fractures, Simple	1	31-43
Skull Fractures, Complex	7	

3D Print Med. 2018;4: 11.
doi:10.1186/s41205-018-0030-y

Clinical Planning Models: Limitations & Challenges

Only (at best) **as accurate as source** imaging

Illusion of certainty: Margins of error and uncertainty in image interpretation difficult to capture in 3D Print

Multi-step process = **multiple sources of error**: verification of critical details against source or other imaging is crucial

Mechanical properties poorly captured

Limited access, frequently on experimental basis

Limited evidence base. Lack of **guidelines / appropriate use criteria***.

Infrastructure needs to be developed for **integration into regular clinical workflows**: Organizational model of modeling services; PACS/EMR integration; cost recovery