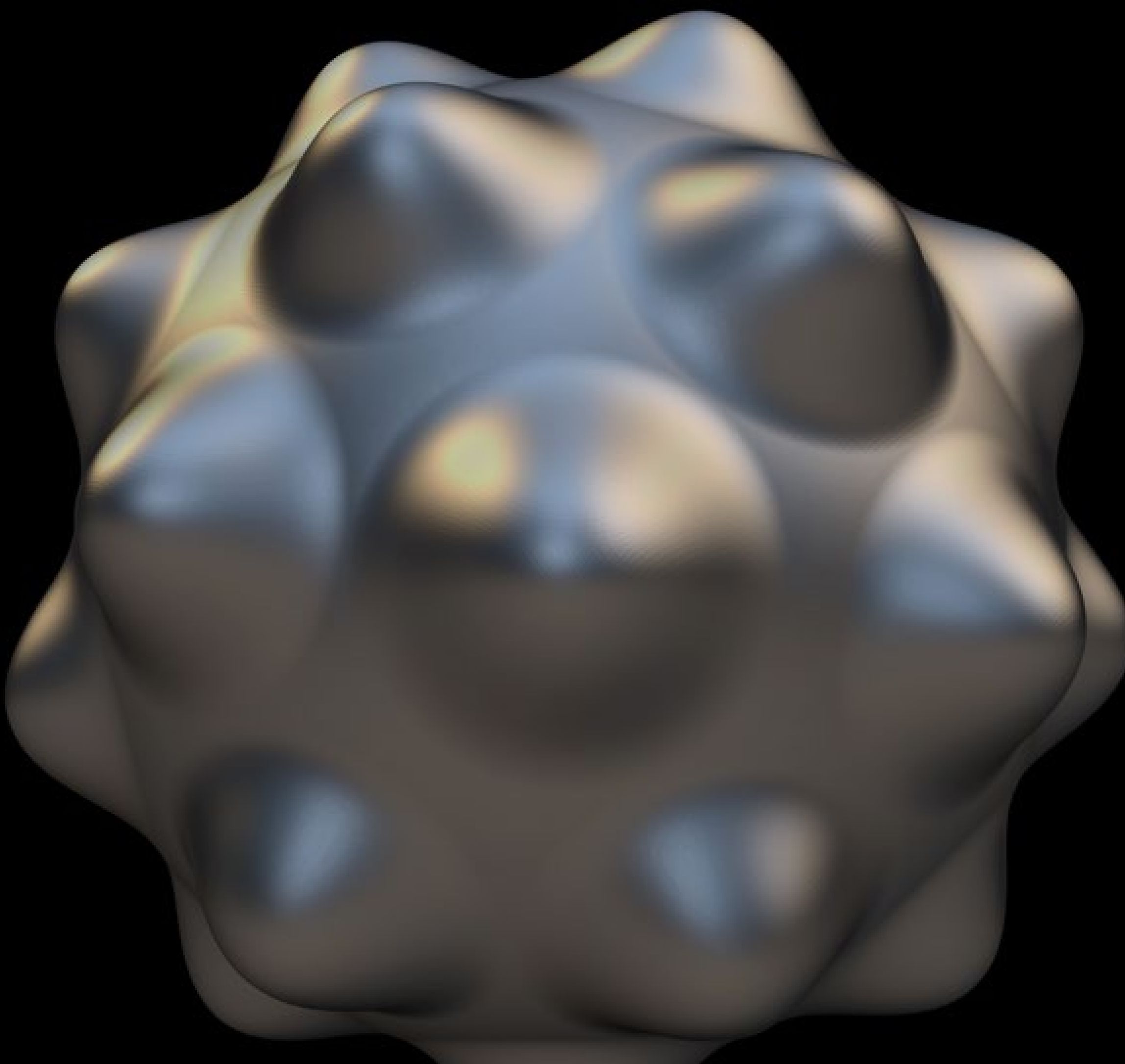
A Roadmap from Idea to Implementation - 3D Printing for Pre-Surgical Applications



1st Edition

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Cover Image: Solid Sphere

The spherical organic form was designed by offsetting a sphere's surface in space in carefully chosen periodic locations defined by a signed distance function. This form was synthesized by a cutting edge modeling technique that uses distance fields instead of boundaries. Learn more here: **http://www.syedrezaali.com/f3-mac-app/**

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Preface

The first time I learned about 3D printing (a.k.a. additive manufacture) for pre-surgical planning was 2012 during RSNA (Radiological Society of North America) in Chicago. As a small box containing pieces of a 3D printed heart from a pediatric patient was passed around the conference room, I could tell that the room stopped breathing. For me it was a sensational moment as a radiologist and as a healthcare provider. Having a patient's disease in three-dimension in my hands was unimaginable. I immediately wanted to learn more about the technology and how I, as a radiologist, could use it to help my clinical colleagues. However, to me, the road to implementation was not simple and almost obscure. The barrier to entrance to adapt such technology seems to require one to be a combination of a designer, a mechanical engineer, and asoftware developer, and lastly a healthcare provider.

Not giving up, I started organizing meetings focusing on learning and discussing healthcare 3D printing solutions in San Francisco called 3DHEALS, hoping to create a community composed of various disciplines to start have more practical conversations to accelerate the adaptation of the technology.

Michelle and I met at an after-work healthcare technology conference, and we instantly hit it off because of our complementary knowledge and interest in healthcare, operational management, 3D printing, and engineering. We are both fascinated with the complex process of integrating promising technologies into healthcare. On top of that, Michelle's background in both operations management and material science and engineering, and mine in medicine and education add unique perspectives to this book.

That said, we both are fully aware of our limitations in various aspects of the subject of 3D printed surgical planning and do not proclaim to be field experts. What we are hoping to accomplish through this writing are as following:

- To initiate a conversation focusing on how to practically implementing a new technology into a healthcare workflow and financial system.

- To provide a framework for future discussions on the subject.

- To inspire more inputs from this new community to add to our knowledge base and future editions.

Acknowledgements

Initially, Michelle and I were only going to write a much shorter white paper focusing on this seemingly narrow niche subject. However, over time, this has evolved into a much larger project than we originally anticipated. While we are excited about writing on something that is incredibly new, we also realize our limitations in multiple areas, and we have to thanks many field experts. In particular, we would like to give special thanks and acknowledgement to the following individuals:

◆**Dr. David Frakes** (Technical Project Lead at Google, Assistant professor at Arizona State University, CSO of EndoVantage) has tirelessly provided us and the 3DHEALS community endless support, time and resources. Among many of his exciting projects, his work in pediatric congenital heart disease has touched many families in a positive and profound way more than any traditional surgical care can ever realize.

◆**Dr. Sanjay Prabhu** (Neuroradiologist at Children Hospital Boston and Havard Medical School, Co- Director BCH SIMPeds 3D print Service) has always been a great example and mentor of mine in radiology and in 3D printing. His passion and perseverance in surgical 3D printing are absolutely infectious. Always humble and patient, Sanjay has always been there to provide us with guidance and knowledge. We are very lucky to have him on board with this project.

We would also like to thank the physicians and great teachers from the **Mayo Clinic** for being the true pioneers in this field and have provided us incredible amount of knowledge.

In future editions of this book, we hope to have more inputs from more experts - combining their insights in business, technology, and healthcare. It takes a village to make it happen.

Additional Individual to thank for their valuable insights and their work in 3D printing surgical planning:

◆**Dr. Parit Patel** (Assistant professor of plastic and reconstructive surgery at Loyola Medicine)

◆**Dr. Elliot Brown** (Assistant professor of radiology and biomedical imaging at Yale University)

◆**Dr. Jose Morey** (Medical scientist with IBM Watson project, adjunct professor of radiology and biomedical imaging at the University of Virginia)

◆**Mr. Glen Jett** from Sutter Health for providing valuable financial insights.

◆**Dr. Justin Ryan** (Arizona State University Post-Doctoral Researcher, Phoenix Children's Hospital Research Scientist) for providing valuable feedbacks and research on 3D printing for pediatric congenital heart cases.

We would like to thank the following individuals, companies, and institutions for providing us amazing graphics/photos for this book:

◆**Dr. Justin Ryan** (Arizona State University Post-Doctoral Researcher, Phoenix Children's Hospital Research Scientist)

◆**Mr. Shannon Walter** (Stanford School of Medicine, Manager of 3D and Quantitative Imaging Laboratory)

◆**Mr. Chris Letrong** (Stanford School of Medicine, 3D Technologist)

◆**Dr. Ben Taragin** (Children Hospital at Montefiore, Director of Pediatric Radiology)

◆**Dr. Joaquim M. Farinhas** (Neuroradiology, Montefiore Medical Center)

◆**Dr. Angela Walker** for providing us with meticulous review/feedback on our drafts of this book

◆**Materialse Inc.**

◆**Whitecloud Inc.**

◆**Stanford School of Medicine**

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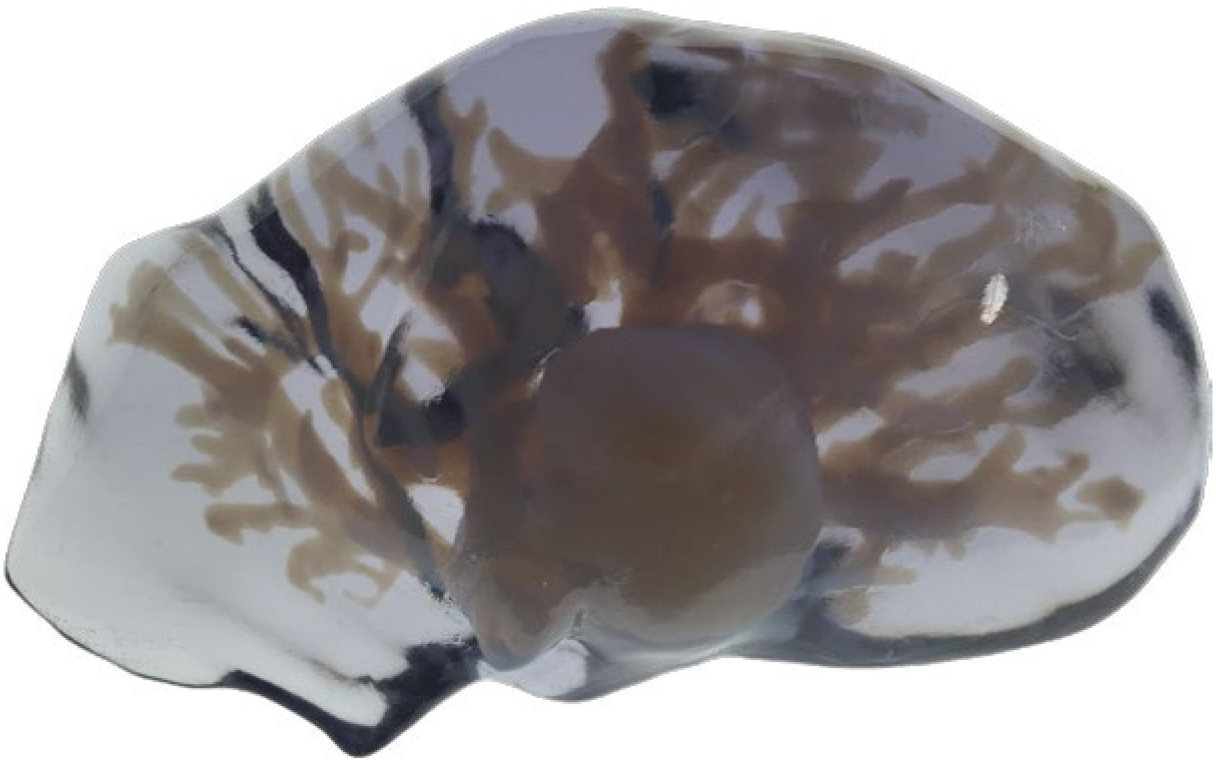
Chapter 1: Introduction



Liver with tumor l Image source: MRI
Multi-Color (Transparent, White) with Rigid Opaque UV Cured Resin l Objet500 Connex3, Stratasys
WhiteClouds, Inc. UT, USA

The healthcare 3D printing sector represents 15% of the global 3D printing industry revenue generated and is growing rapidly at 20-25% Compounded Annual Growth Rate (CAGR). **(1, 33)** While the application of such novel technology in healthcare has generated significant excitement, healthcare 3D printing remains nascent with multiple one-off or low-volume prints except in the areas of hearing aids and dental applications. In addition, there are no established regulatory entities for healthcare 3D printing, either in the U.S or globally, until very recently, despite Obama's recent visible support of the additive manufacture industry through creation of the National Additive Manufacturing Innovation Institute (NAMII) and the recent FDA draft focusing on 3D printed medical device. **(41, 59)**

Further accelerated by the expiration of several major 3D printing patents **(40)**, rapid innovations and emerging applications using 3D printing pose significant challenges to policy makers, the FDA, and the existing legal process. The combination of lack of sufficient clinical data, funding, sound business strategies, and the opaque regulatory/legal landscape presents a significant barrier to entry for many.

Adoption of this technology for pre-surgical applications has demonstrated early, quantifiable clinical benefits on an anecdotal basis, especially in terms of decreasing operating time **(13, 17)**. Increasing interest in adoption of this technology from hospital and surgical centers across the globe is evidenced by a simple Pubmed publication search **(2-8, 10-14, 18,19)**. However, the roadmap to successful implementation of 3D printing for pre-surgical planning remains obscure and disjointed.

This book will first give an overview of 3D printing technology, including its pre-surgical uses. Then, we will focus on operational management issues for implementation of this technology (Table I), including a sample cost analysis. The book concludes with clinical examples illustrating the process from idea to implementation, referencing major published data/papers as well as our interviews with early adopters and industrial leaders.

We are hoping that, by clarifying the challenges and issues in operational management, we can provide a roadmap that will make implementation easier (and perhaps cheaper) for everyone who is interested in exploring the space.

Our target audience includes but is not limited to physicians, hospital administrators, radiology departments, legal experts, additive manufacture industrial partners, and investors. Our book will be one of the first comprehensive writings to cover the operational areas of interest to this audience as outlined in Table I.

Table I. Major Operational Management Considerations

Strategic Issues	Tactical Issues	Financial Issues
◆Clinical trial design ◆Organization and staffing - Multidisciplinary design - In-house versus Outsource ◆Regulatory and legal issues ◆Appendix: sample 3D printing swim-lane	◆Talent allocation ◆Printer/Material selection ◆Software selection ◆Image protocoling and acquisition ◆Quality control and inspection ◆Materials management	◆Reimbursement ◆Revenue strategies ◆Capital considerations for in-house services ◆Sample spreadsheet

Chapter 2: Background

3D Printed brain with tractography I Image source : MRI and diffusion tensor imaging
Multi-color Polyjet Materialise
Leuven, Belgium

A. 3D Printing Techniques and Materials

3D printing techniques have grown since the first stereolithography (SLA) systems were created in 1986. The nomenclature surrounding the printing techniques has suffered from a lack of standardization. Recently, the American Society for Testing Materials (ASTM) designated seven 3D printing processes, each of which is represented by one or more commercial technologies. **(42)** The following table lists the processes, the technologies, the printing resolution of these technologies, and the medical applications that can be produced by each process (Table II). Each process uses specific materials with specific properties that relate to medical applications, which are summarized in Table III. With this general information as a starting point, users should be able to determine what methods and materials could be used for their specific needs.

Currently 3D printers are either high-end or high-performance machines for industrial applications or very low-end and low-capability machines for hobbyists. New mid-priced, good-quality printers have started to emerge. Predictions are that these will be used by small- to mid-sized businesses that will grow the market in 2016. **(34)**

The emergence of these new printers has been driven by the expiration of key early patents for the different technologies, including SLA in 2009 and Fused Deposition Modeling (FDM) in 2011. **(40)** The most recent is Selective Laser Sintering (SLS), whose patents expired in 2014. **(35)**

Table II. Summary of 3D Printing Process

ASTM Designation Additive Manufacturing Process	ASTM Process Description	Techniques	Principle	Medical Use	Resolution	
					XY(um)	Z(um)
Vat photopolymerization	An additive manufacturing process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization	Steriolithography (SLA)	UV initiated curing of defined photoresin layers as platform is raised or lowered	Bone, dental models, dental implant guides, hearing aids	70 - 200	10-Jan
		Digital Light Processing (DLP)				
Material jetting	An additive manufacturing process in which droplets of build material are selectively deposited.	Multijet Modeling (MJM)	UV initiated curing of liquid photopolymer jetted onto a build tray	Medical models, dental casts, dental implant guides	20 – 50	50
Binder jetting	An additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials	Powder Bed & Inkjet Head 3D printing (PDIH)	Colored liquid binding agent is jetted onto a bed of fine powder and selectively bonded	Color models especially color coding of anatomy	20 – 50	50
		Plaster-based 3D printing (PP)				
Material extrusion	An additive manufacturing process in which material is selectively dispensed through a nozzle	Fused Deposition Modeling (FDM)	Extrusion of molten thermoplastics, polymer, or metal onto a build tray	Medical instruments and devices, rapid prototyping, exoskeleton	250	50
		Fused Filament Fabrication (FFF)				
Powder bed fusion	An additive manufacturing process in which thermal energy selectively fuses regions of a powder bed	Selective Laser Sintering (SLS)	Laser or e-beam induced selective heating to fuse or melt small particles of plastic, metal, ceramics, or glass powder on the surface of a powder bed	Models that require a lattice, medical devices such as implants and fixations	50	60-150
		Direct Metal Laser Sintering (DMLS)				
		Selective Heat Sintering (SHS)				
		Selective Laser Melting((SLM)				
		Electron Beam Melting (EBM)				
Sheet lamination	An additive manufacturing process in which sheets of material are bonded to form an object.	Laminated Object Manufacturing (LOM)	Laser/razor cutting of heated, adhesive coated sheet material	Orthopedic modeling of bone surfaces	10	100
		Ultrasonic Consolidation (UC)				
Directed energy deposition	An additive manufacturing process in which focused thermal energy is used to fuse materials by melting as they are deposited.	Laser Metal Deposition (LMD)	Deposits wire or powder material to a location where an energy source is also directed to melt and bond the material	Limited. Commonly used to repair existing parts and build very large parts.	50-1000	

Table III. Summary of 3D Printing Material

ASTM Designation Additive Manufacturing Process	ASTM Process Description	Techniques	Principle
Vat photopolymerization	Steriolithography (SLA)	An additive manufacturing process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization	UV initiated curing of defined photoresin layers as platform is raised or lowered
	Digital Light Processing (DLP)		Safelight initiated curing of defined photoresin layers as platform is raised or lowered
	Continuous Light Interface Production (CLIP)		UV initiated curing of photoresin through an oxygen-permeable, UV-transparent window in a continuous flow
Material jetting	Multijet Modeling (MJM)	An additive manufacturing process in which droplets of build material are selectively deposited.	UV initiated curing of liquid photopolymer jetted onto a build tray
Binder jetting	Powder Bed & Inkjet Head 3D printing (PDIH)	An additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials	Colored liquid binding agent is jetted onto a bed of fine powder and selectively bonded
	Plaster-based 3D printing (PP)		
Material extrusion	Fused Deposition Modeling (FDM)	An additive manufacturing process in which material is selectively dispensed through a nozzle	Extrusion of molten thermoplastics, polymer, or metal onto a build tray
	Fused Filament Fabrication (FFF)		
Powder bed fusion	Selective Laser Sintering (SLS)	An additive manufacturing process in which thermal energy selectively fuses regions of a powder bed	Laser or e-beam induced selective heating to fuse or melt small particles of plastic, metal, ceramics, or glass powder on the surface of a powder bed
	Direct Metal Laser Sintering (DMLS)		
	Selective Heat Sintering (SHS)		
	Selective Laser Melting((SLM)		
	Electron Beam Melting (EBM)		
Sheet lamination	Laminated Object Manufacturing (LOM)	An additive manufacturing process in which sheets of material are bonded to form an object.	Laser/razor cutting of heated, adhesive coated sheet material
	Ultrasonic Consolidation (UC)		
Directed energy deposition	Laser Metal Deposition (LMD)	An additive manufacturing process in which focused thermal energy is used to fuse materials by melting as they are deposited.	Deposits wire or powder material to a location where an energy source is also directed to melt and bond the material

*Composites are defined as - multiple types of materials are combined but do not blend or lose their individual identities. Composite prints can be made with these processes. Composite materials are not used in the making.

Table III. Summary of 3D Printing Material (contd.)

ASTM Designation Additive Manufacturing Process	Medical Use	Materials			
		Polymers	Metals	Ceramics	Composites*
Vat photopolymerization	Pre-surgical models, dental models, dental implant guides, hearing aids	Liquid photopolymers	No	No	No
		Liquid photopolymers	Under development	Under development	No
		Liquid photopolymers	No	No	No
Material jetting	Medical models, dental casts, dental implant guides	Photopolymers, Wax for support & one other material	No	No	Composites
Binder jetting	Color models especially color coding of anatomy	Acrylic	Metal laminates	Ceramic powders, sand	Composites
		No	No	Bonded plaster	Plaster composites
Material extrusion	Medical instruments and devices, rapid prototyping, exoskeleton	Thermo-plastics	Mixed with PLA	Mixed with PLA	No
Powder bed fusion	Models that require a lattice, medical devices such as implants and fixations	Paper, plastic	Metals	Ceramics, glass	Composites
		No	Stainless steel, cobalt chrome, nickel alloy	No	No
		Thermoplastic powder	No	No	No
		No	Stainless steel,tool steel, cobalt chrome, titanium, alumninum	No	No
		No	Titanium powder, titanium alloy, cobalt chrome	No	No
Sheet lamination	Orthopedic modeling of bone surfaces	Paper, plastic	Metal	Glass, Ceramics	Composites
		No	Metal and metal alloys	No	No
Directed energy deposition	Limited. Commonly used to repair existing parts and build very large parts.	No	Metal and metal alloys	No	No

*Composites are defined as - multiple types of materials are combined but do not blend or lose their individual identities. Composite prints can be made with these processes. Composite materials are not used in the making.

Table III. Summary of 3D Printing Material (Contd.)

ASTM Designation Additive Manufacturing Process	Pros	Cons
Vat photopolymerization	High resolution, high accuracy, detailed parts, complex parts, smooth finish	Not durable, sensitive to heat
	High strength and resolution, can build bigger object	More expensive resin
	Fast, flexible elastomer materials possible	Potentially expensive
Material jetting	Fast, Multi-color and material	Not durable, relatively slow build process, range of wax like materials limited
Binder jetting	Simple and inexpensive, fast to build	Fragile, limited accuracy, poor surface finish
	Lower price, high speed, excess powder can be reused	Fragile, limited choice of materials
Material extrusion	Good variety of materials, broadly available to hobbyists, commercial and industrial, strong parts, complex geometries	Poor surface finish quality requires post build processing, slow build compared to SLA
Powder bed fusion	Relatively fast, high heat and chemical resistant	Accuracy limited to powder particle size, surface can be rough, limited colors
	Complex geometries, rigorous prototyping	Needs finishing, not suitable for large parts
	Lower cost than SLS, complex geometries, quick turnaround	New technology with limited track record
	Complex geometry, good for hybrid of solid and lattice, osteointegration	Poor surface finish , weaker prototype, difficult compliance and certification process
	Speed, less distortion of parts, less material wastage	Difficult to clean the machine, caution required when dealing with X-rays
Sheet lamination	Relatively less expensie, no toxic materials, quick to build large parts	Less accurate, non-homogenous parts
	Quick to make big parts, generally non-toxic materials can ultrasonically weld different metals, add wires and electronics due to low heat process	Cannot make complex parts, weld quality is in question, ports with relatively less accuracy and inconsistent quality compared to other 3D printing processes
Directed energy deposition	Open air, large scale, production flexibility	Relatively higher cost of systems, Lower accuracy, not complex, rough finish requires post-processing

*Composites are defined as - multiple types of materials are combined but do not blend or lose their individual identities. Composite prints can be made with these processes. Composite materials are not used in the making.

Table III. Summary of 3D Printing Material (contd.)

ASTM Designation Additive Manufacturing Process	Sterilization	Example
Vat photopolymerization	Y	3D Systems iPro8000
	Y	RapidShape S30, Envision Tec Ultra
	Y	Carbon 3D
Material jetting	Y	3D Systems Projet 3510SD, Stratsys Polyjet
Binder jetting	N	ExOne
	N	3D Systems ZPrinter 850
Material extrusion	Y	*Stratasys Fortus Series/ABS-M30™
Powder bed fusion	Y	Formiga P110, Sharebot SnowWhite
	Y	EOS M 400
	Y	Blueprinter M3
	Y	SLM solutions
	Y	Arcam Q10
Sheet lamination	Y	Mcor ARKe
	Y	Fabrisonic SonicLayer 4000
Directed energy deposition	Y	TRUMPF TruLaser Cell 7040

*Composites are defined as - multiple types of materials are combined but do not blend or lose their individual identities. Composite prints can be made with these processes. Composite materials are not used in the making.

B. Typical 3D Printing Workflow

A typical 3D printing workflow includes the following steps (Figure 1). There are quite a few publications with more comprehensive and detailed discussions on the technical aspects on how to optimize each step **(3, 15,16, 55)**. This section serves as a summary of the process and to familiarize the audience with typical healthcare 3D printing terminologies:

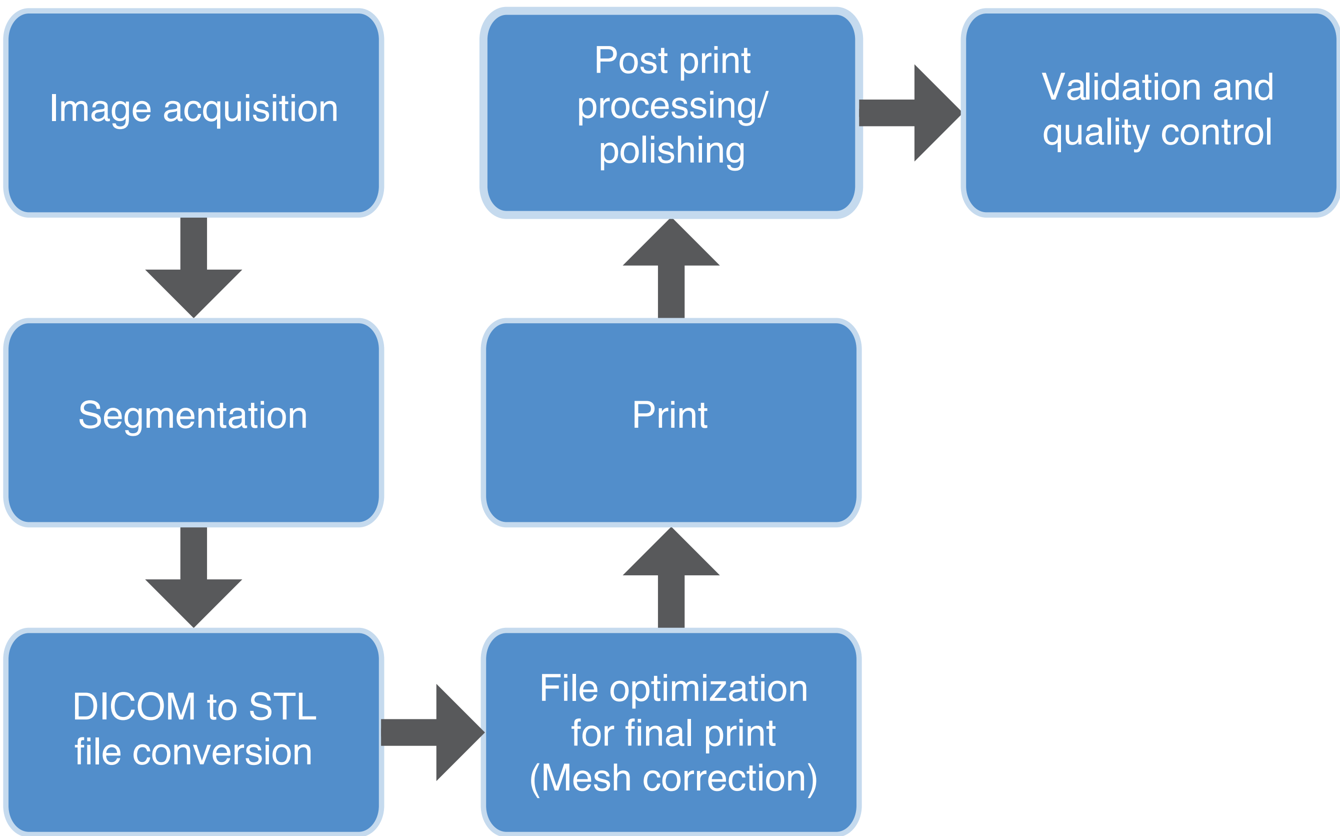


Figure 1. Typical workflow for 3D printing used for pre-surgical planning

1. Image acquisition

Many surgical patients today will have a cross-sectional imaging exam prior to surgery. Cross-sectional imaging exams in general include Computed Tomography (CT), Magnetic Resonance Imaging (MRI), ultrasound (US), and Digital Rotational Angiography (DRA). However, if the surgical team anticipates using 3D printing for surgical planning, suitable imaging protocol becomes the first critical step. **(15,16)** Optimal axial slice thickness depends largely on the anatomic structure of interest, and should around 1 mm to 2 mm. Similar to 3D surface rendering, while it is still possible to construct a 3D object using slice thickness greater than 2mm, a lot of anatomical information will be missing, and the clinicians need to be aware of the degree of inaccuracy in the final print. If vascular structures are of concern, intravenous contrast is needed with adequate bolus timing like any other vascular imaging study. In general, the goal of imaging acquisition is to obtain images with enough structural contrast for later segmentation. Other important factors to consider include kernel selection, CT dosage, and MRI sequence. If 3D printing is considered as part of pre-surgical planning, consulting a radiologist before image acquisition is important to achieve the optimal results. In addition to protocoling, other adverse factors impeding a successful acquisition will need to be considered including motion artifacts, metallic or bony streak artifacts, suboptimal contrast opacification, and unusual body habitus. **(3)**

2. Segmentation

During segmentation, a particular region of clinical interest is outlined/selected on each axial images based on pixel information to construct a three dimensional object. This region of interest (ROI) can be a complex anatomical structure or particular pathology that needs to be surgically treated. This process can be both semi-automated and manually performed. Often, practitioners use a combination of both to achieve a final satisfactory 3D object.

3. DICOM to STL file conversion

All current medical images are stored as DICOM (Digital Imaging and Communications in Medicine). However, most 3D printers only recognize certain file formats, most commonly, stereolithography (SLS) or Standard Tessellation Language (STL) files. It is the most accepted standard file format that interfaces between 3D software and 3D printers. Other commonly accepted file formats, recognized by some but not all software and hardware, include .obj, .wrl, and .zpr, which also have color information. **(3)** Traditionally, medical image Picture Archiving and Communications Systems (PACS) do not have the capability to perform the conversion to 3D printer file formats. An exception to this is the Mac-based DICOM viewer Osirix (http://www.osirix-viewer.com/, Geneva, Switzerland). Although accepted in academia, Osirix is not available as a standard viewer in most U.S. hospitals. Fortunately, major PACS vendors such as GE and Siemens are updating their systems to include this functionality in their future versions. Additionally, many open-source and commercial software packages are available to perform the conversion and often the segmentation also.

4. File optimization for final print (Mesh correction)

Along with the common 3D printable files such as STL, there is associated surface geometry in the form of connected triangles. This geometric information is also known as a “mesh”. The mesh must be mathematically continuous (“manifold”) to be ready for physical 3D printing. **(3)** This involves meticulous mesh correction steps to fix these geometric “errors” without losing significant anatomic accuracy.

With a few exception (e.g. inkjet technology), a mesh with discontinuity ("holes") cannot be printed.

5. Print

This step will construct the physical object based on the corrected mesh. This could be a single-step or multi-step process depending on the size and complexity of the digital design.

6. Post print processing/polishing

After the object is printed, it is often necessary to remove the residual material or supporting structures. Post-print polishing, coloring, reconstruction, or material hardening (infiltration) may also be necessary depending on the use of the print. **(3)**

7. Validation and quality control

Errors can occur during each of the previously described steps. Accumulative errors can be significant. There are a few suggested existing validation/quality control processes, but in general, this is an area of active investigation and improvement. **(7,15,16,20,21)** First, the practitioner can compare the final mesh with the initial imaging study before the file is printed. Second, the surgeons can obtain intraoperative measurements and compare those to the 3D printed object. Third, practitioners can re-image the 3D printed object and compare the images with the patient's images for differences. Others have also developed phantoms to validate the accuracy from digital design to physical print.

C. Values and limitations of 3D printing

Traditional manufacturing methods, like the drill press, lathe, or milling machine, need to be operated by the maker. The work piece needs to be aligned, measured, and machined by the user, which introduces human error into the making of the part. In contrast, 3D printing (a.k.a. additive manufacture) is a hands-off manufacturing process; just by pressing a button, whatever you design will be made.

The benefits of using 3D printing over traditional manufacturing make it suitable for situations requiring:

1. Rapid prototyping
2. Mass customization (e.g. Invisalign)
3. Complex geometries that
    a. Cannot be manufactured by any other method.
    b. Have improved material property (e.g. strength, elasticity, transparency).
    c. Can be manufactured more cost-effectively with 3D printing.

3D printing also has some current limitations that may not lend it to some applications:

1. 3D printers can take hours rather than minutes to complete a piece and thus do not lend themselves to mass production for certain applications, especially in emergent surgical cases.

2. The limited selection of 3D printing material, especially those deemed suitable for medical use (i.e. biocompatible, sterilizable, of good strength, multi-color, and affordable), hinders broader application.

3. The size of the objects intended for printing also limits applications, as printers capable of making larger prints are more expensive and there are fewer options available. In addition, larger prints may take a significant amount of time to print, which would not be acceptable for clinical cases with time constraints

D. 3D printing for pre-surgical applications

Currently, the three main purposes for using 3D printing for pre-surgical applications include:

1. An improvement in pre-surgical planning, including strategy development through improved ability to simulate and manipulate models.
2. A need for haptic feedback.
3. An improvement in communications among multidisciplinary clinical care providers and between clinicians and patients.

These cases can be categorized into the following areas:

1. Pre-surgical strategy development: e.g. surgical approach, device selection, surgical tool selection **(6,10-13,23,26,27,32,50)**
2. Surgical guides **(17,18)**
3. Pre-surgical patient/patient family education **(50)**
4. Pre-surgical training tool **(22, 24)**

For each case, the question must be answered: does 3D printing add value in addition to conventional imaging and computer simulation during the process of pre-surgical planning?

Historically, for the medical community to fully embrace a new technology, supporting evidence based on vigorous scientific methodologies was required. Recent examples of adoption of innovations in healthcare include functional MRI, computational simulation for pre-surgical planning, robotic-assisted surgeries, and a number of other advanced medical technologies. For each of these, methodological collection of clinical evidence was necessary not just for patients and clinicians, but also for the payers to fund their use. In the past several years several major academic institutions such as the Mayo Clinic, Cleveland Clinic, Boston Children's Hospital, and Harvard hospitals have taken the lead and made significant advancements in exploring the technology through clinical trials with larger patient populations - a systematic method acceptable to the scientific community. The trials have often been led by a few highly talented and enthusiastic individuals and funded by the medical group's innovation budget. **(13 ,31, 51)**

Most trials, publications, and advancements have occurred in the fields of orthopedics, pediatric surgery, and maxillofacial reconstruction surgery. For example, the orthopedic department at Cleveland Clinic has recently completed an official clinical trial on how 3D printed surgical guides improved accuracy of acetabular shell placement. **(31)** In the field of pediatric surgery, a publication from Boston Children's Hospital showed significant reduction in operational time based on observations from four surgically treated high-risk intracranial vascular malformation cases. **(13)** Recently, the authors were just informed that there is a new multi-center clinical trial focusing on the benefit of 3D printing in pediatric cardiothoracic surgeries led by Children's National Medical Center, Children's Hospital of Philadelphia, Phoenix Children Hospital. In the field of maxillofacial reconstruction surgery, pre-surgical bending of a mandibular plate over a 3D printed mandibular model resulted in apparent shortening of operating times up to half an hour per case in a series of 20 patients. **(17)**

These early studies are valuable on multiple levels as they not only document meaningful metrics regarding clinical outcomes, but also inspire other researchers in terms of study design and technique by establishing tangible workflows.

At the end of this book, we will provide a few real life examples based on literature review and our direct interviews to demonstrate how certain landmark cases dealt with various operational management issues described in this paper.

Chapter 3: Strategic Issues

Conjoint Twin Skull and Intracranial Vessel Model Pre Surgical Planning
Monteifore Medical Center, NY I Credit: Drs. Benjamin Taragin and Joaquim M. Farinhas, 3DSystem
Printer: 3D System SLA ProX 800 Printer I Material: ClearView (3DSystem)

A. Clinical Trial Design

Clinical trial design should be an important part of the strategic consideration because more clinical evidence, especially in terms of clinical efficacy and outcomes, will strengthen arguments for reimbursement. According to ClinicalTrials.gov **(52)**, a registry for clinical trials maintained by NIH and NML, "a clinical trial is a research study in which human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes."

Good clinical trials serve several major purposes such as:

a) Informing consumers about the values of this technology.
b) Preparing data for new CPT coding and other reimbursement strategies from payers.
c) Inspiring creative innovations.

Data on clinical outcomes is crucial. In recently published studies, researchers have been focusing on the following outcome metrics: operating room time, hospital stay, surgical complication, and post-surgical accuracy. Non-quantitative outcome metrics include patient/family satisfaction.
There are two public clinical trials registered on clinicaltrials.gov for pre-surgical applications (**https://clinicaltrials.gov/ct2/results?term=3d+printing&Search=Search**). The first one is a recently completed randomized controlled clinical trial (**https://clinicaltrials.gov/ct2/show/NCT01791738?term=3d+printing&rank=7**) from Cleveland Clinic, "Acetabular Shell Positioning Using Patient Specific Instruments" which has shown a statistically significant increase in anteversion accuracy when using a 3D printed surgical guide over traditional planning methods in total hip arthroplasty (THA) **(31)**. A limitation to the study is a modest sample size of 36 patients although it is larger than most recently published studies. A second drawback of the study is the lack of information on other clinical outcomes, including hardware loosening and failure as a result of inaccurate placement. This latter issue will require long-term, continuous follow up with the patients.
The second study is currently enrolling (**https://clinicaltrials.gov/ct2/show/NCT02372214?term=3d+printing&rank=1**). It is focusing on 3D printed patient-specific simulations for endovascular aneurysm repair as a pre-surgical training tool.

B. Organisation and staffing

1. Multidisciplinary design:

The creation and use of a 3D printed model is a process that starts with a patient and ends with an operation. The following chart (Table IV) shows the major steps needed to create a 3D printed pre-surgical model for a hypothetical case for cardiac surgery based on best practices of multi-disciplinary collaboration described in the literature. **(3)** Reading the top row of the chart from left to right, the steps are chronologically arranged starting with identifying a need, having a cross-functional meeting, acquiring and processing the image, making and checking the model, and finally using the model. Each row (role) is designed for a specific participant involved in this process including the cardiologist, the surgeon, and the radiologist. The chart details the responsibilities of each of these physicians at every step of the process. This chart can be used to as a basis for understanding the requirements of time and personnel needed to create 3D models for medical applications.

The swim lane version of this can be found in the appendix section of this paper, which demonstrates an actual work flow of a hypothetical case for pre-surgical planning of a cardiothoracic surgery.

Table IV. Roles and Responsibilities in Workflow

Person	Diagnostic Scan	Determine Need	Image Acquisition	Image Post-processing-Define Regions of Interest (ROI) via Multi-disciplinary Strategy session	Image Post-processing-ROI Segmentation	Image Post-processing-Conversion to STL or AMF file format	Image Post-processing - QA	Image Post-processing - CAD/CAM	Model Print	Model QA	Model Post processing	Model Final QA	Deliver Model	Study Model, Multi-disciplinary meeting
Cardiologist	Requests Scan	Calls in surgeon		Presents needs, patient limitations										Study
Radiologist	Interprets Scan		Design 3DP compatible protocol	Presents imaging options and limitations	Thresholding, edge detection, region growing, sculpting	Convert to high fidelity STL or AMF	Corrects for 'closing', holes, inverted normals, smoothing			Checks model against image, corrects errors		Checks model against preoperative and intropertive image		Correlate and validate 3D print with 2D images
Cardiac Surgeon		Reviews needs		Presents needs, proposes and evaluates options								Intraoperative imaging or visual/tactile validation		Study and practice, visual and tactile learning
3D SME/ Radiology Technician/ Technician	Produce 3D visualization post processing for diagnostic purposes		MRI, CT, Ultrasound, DRA	Evaluates methods and feasability	Thresholding, edge detection, region growing, sculpting	Convert to high fidelity STL or AMF	Reviews, corrects	Design additional parts such as supports	Set up machine, transfer file, print model	Machine QA, calibration, phantom	Removes supports, polishes, clean, sterilize	Checks model against image	Handoff to Surgeon	

2. In house v/s Outsource

Depending on existing infrastructure, creating an in-house center can be very expensive and require hard-to-find expertise. Often, it is not a viable initial option for smaller medical centers. Except for imaging acquisition, outsourcing is an option along each of the remaining six steps of the 3D printing workflow. Outsourcing these steps allows the medical center to bypass the initial cost/risk and associated operational challenges of creating an in-house service. Currently, several established companies like 3D System (NC, USA) and Materialise (Belgium) provide such services beyond their core businesses, including services on DICOM conversion, segmentation, and printing all-in-one services. The cost of these services can often amount to thousands of dollars. Although the absolute dollar value appears high for such services, in high-risk, rare, and complex surgical cases, the relative cost of adding a 3D printing step is actually tolerable to most healthcare providers.

However, on the other end of the spectrum a larger academic center may be prepared to heavily invest in creating a centralized 3D printing center. The Mayo Clinic was one of the first medical centers to demonstrate its investment **(51)** It has made significant strides in exploring the innovative use of the technology, creating quality standards, and generating global influence in this field. Almost all the surgical departments, from pediatrics, neurosurgery, to orthopedics, are now routinely using their 3D printing service. The widespread acceptance of the technology within the Mayo Clinic has significantly increased the case volume and helped to justify the cost. It is now one of a few go-to institutions for educating clinicians and 3D printing industries about medical 3D printing, which acts as additional revenue stream.

Providers should consider the following questions when making the decision on creating an in-house 3D printing service versus using outside vendors:

What is the existing infrastructure that could be used for 3D printing?

Existing personnel and software may be available to be part of the new service. For example, several larger hospital systems including Cedar Sinai and the Kaiser Permanente groups have existing funding for innovative projects such as simulation programs that include 3D printing services. Medical centers with comprehensive imaging services are often equipped with high-quality imaging hardware that can generate high-resolution medical images required for 3D printing. Some newer scanners (e.g. GE) are already equipped with existing 3D printing protocols from various popular prosthetics or device companies. Additionally, many imaging and medical centers have purchased licenses for popular 3D visualization software packages such as Vitrea (Vital, USA), which contains many similar post-processing functionalities to other 3D printing specific software. Some of the larger companies like GE and Siemens, are already adding 3D printing functionality into their newest software. Highly-trained technicians who are already familiar with post-acquisition imaging processing already have many of the skills required for 3D printing. The learning curve for these centers will be significantly less steep than a center without experienced personnel in 3D visualization software.

What is the turn around time required for the applications?

Turn around time is a critical factor to consider as many surgical cases are urgent and need to occur in a timely fashion. The medical center needs to identify the slowest point among the production steps and investigate if the most time-consuming step can be performed faster if outsourced. Good and effective communication between the requesting clinicians and the 3D printing team is the most important step to quickly conceptualize the best 3D printing strategy. Because many surgical cases require more timely response, a few major academic hospitals, like Boston Children's Hospital and the Mayo Clinic, have officially incorporated 3D printing for surgical planning as part of their Electronic Healthcare Records (EHR). Ineffective initial communication with either in-house or outsourced 3D printing services will prove costly in time and money. The next most time-consuming and labor-intensive step is segmentation and image post-processing. If in-house bioengineering and/or 3D software expertise are already available, then it is much easier to keep this step in-house, since communicating to a multidisciplinary clinical team can be more effective when the engineering step is completed in-house.

On the other hand, some outsource vendors have experienced design/engineering teams who can offer faster printing and shipping/transportation strategies. They may more quickly scale and modify production to shorten turn around time and meet the demand.

What is the equipment needed to achieve the end point?

Software and hardware requirements will highly depend on the goals of the 3D printing center. For example, the resolution and material requirements for creating a pre-surgical educational model for the patients or medical students will be much less than a pre-surgical model intended for a pediatric cardiothoracic surgeon to simulate the intra-operative environment for complex congenital heart disease. Flexible materials which cost significantly more than typically used resins may be needed for pre-surgical models for complex vascular surgery. The size of the model required will also help determine what hardware is needed. For example, a pediatric heart model is small enough to fit inside the popular desktop SLA printer Form 2 (FormLabs , USA) but an actual sized adult pelvis will not fit.

How much does the clinical team want to be involved in the printing process?

In general, when extensive multidisciplinary communication among different clinical and engineering

teams is needed, an in-house 3D printing service is intuitively more efficient and convenient for rapid prototyping and correction of errors and defects in the model. The cost and time of re-designing and reproducing a model will increase significantly with outsourcing.
Again, the steps where clinical team involvement can occur are variable depending on individual cases. For example, in complex maxillofacial cases where the surgeons often want to see a variety of surgical strategies, it may make sense to keep the design/segmentation steps in-house and outsource the final printing with an outside vendor. Models intended for educating patients (patients' families) and students/residents usually do not require extensive in-house multidisciplinary discussion and can be outsourced easily.

What to look for when selecting for an outsource vendor for pre-surgical 3D printing?

Given the promise of the healthcare market, more and more 3D printing companies are now interested in providing services to healthcare providers. Because of isolation from the healthcare facility, it is important for outsource vendors to understand and respect the sensitive nature of the medical record. It is imperative to prepare a HIPAA compliant data transfer process. Currently, some hospitals use LifeImage (MA, USA) as a way to transfer images. For complex cases, the ability to effectively communicate with the radiologist and treating clinicians requires the vendor to have certain healthcare familiarity or clinical experience. Even with experienced vendors, occasional unsatisfactory products may still be produced and it is important that the vendors can provide adequate customer service to either effectively rectify the mistakes or design backup plans in case of such failure. For example, making multiple versions of the prints with different design or structural emphasis is one such strategy.

Table V summarizes the pros and cons for in-house and outsourced solutions. Many facilities will start with a combination of in-house and outsource services. Depending on the clinical needs, medical centers now have many choices in combining the two services to achieve optimal results. There is also a new growing trend of collaborative works between specialized 3D printing companies with large healthcare systems. **(53)**

Table V. In House vs. Outsourcing: Pros and Cons

	PROS	CONS
IN-HOUSE	• Possibly faster • Possibly cheaper • More accessible for experiments and innovations at the facility • More efficient for multi-disciplinary team communication • Staff may already have software experience from 3D visualization software • Potential to sell services to other medical centers	• Will need staff and space to run equipment and learn to use the software, clean and maintain the equipment. • May need special facilities for production, finishing, and cleaning • Will not be able to make all applications – some will still need to be outsourced. • May need a wide variety of machines and materials that would add complexity to the effort
OUTSOURCE	• No dedicated staffing, training or space requirements • Less financial risk • Less time spent on image post processing by technologists or radiologists • More variety of printers and materials to choose from. • Vendors provide expertise.	• Possibly slower than in -house • Possibly more expensive than in-house • May be more prone to error due to added steps and entities involved • HIPPA compliant data transfer agreement and protocol need to be followed

C. Regulatory and legal issues

There are many active discussions in professional societies and across legal forums, but current regulatory, policy, and legal guidelines are very incomplete or non-existent for medical applications of 3D printing, ranging from medical device manufacture to pre-surgical applications. As more healthcare providers and legal experts are getting involved in the field, the final details on regulatory and legal issues for the production process will slowly but surely unfold. In fact, several major law firms are now leading the way in establishing a subspecialty related to medical 3D printing as can be seen in several recent publications. **(45,46)**

Because 3D printing pre-surgical applications are very new, healthcare and service providers can only speculate on potential regulatory and legal issues based on similar scenarios with applications of other new technologies. Therefore, it is foreseeable that regulatory issues may need to be carefully considered every step along the way, from design to production. For example, in the medical imaging post-processing (for example, segmentation and DICOM to STL conversion), there is currently no established software standard. Although a few popular software systems such as Mimics (Materialise, Belgium) and Osirix (Pixmeo, Switzerland) are FDA-approved, it is still debatable if FDA-approved software must be used. Many current users default to FDA-approved software, fearing pending regulatory ruling that could make their new workflow obsolete, but in reality, there is no evidence that using non-FDA-approved software would necessarily produce lower quality products. It is also unclear how extensively the FDA should be involved in software development intended for pre-surgical 3D printing applications. For example, although it is commonly accepted that FDA approval is needed when software is used for diagnostic and treatment purposes, multiple software selections are often involved in the process. Some argue that the CAD component of the workflow need not be FDA-approved, but others will argue that every single design step will ultimately affect the quality of the final printout. Very recently, during the draft of this book, Food and Drug Administration published a new draft laying out a framework to discuss developing more specific guidelines for the industry, signifying the importance of staying up to date on the regulatory rules related to this new technology. **(59)**

Additionally, the associated ownership, patent, and liability issues associated with digital design are also increasingly gaining attention. **(46, 54)** The intensity of the debate on whether a 3D digital file can be patented was demonstrated in a recent case involving Align Technology Inc. (California, U.S.A.) and ClearCorrect (Texas, U.S.A.). **(54)** As another hypothetical example, if a color-coded congenital heart model is proven effective in pre-surgical planning for pediatric congenital heart disease, should and can the color-coding process be patented? Also, if there is an unexpected corruption of 3D Printing digital file for an implant which subsequently causes harm in patients, who should be liable for the mistake and to what degree? Similar questions need to soon be addressed by lawmakers and the legal community.

In the manufacturing process itself, safety guidelines for managing 3D printing material, operating 3D printers, and post-print processing must be followed to OSHA standards. We will cover material management in a later section of this paper. For patient care, more stringent requirements need to be met as the 3D printed product is used in close proximity and sometimes direct contact with the patient. Currently, only a handful of materials are FDA-approved and can be sterilized sufficiently to be within the operating field. An even smaller number of materials can be used for implant production. **(47)** Full understanding of the toxicity and biocompatibility of the 3D printing material used will be critical in compliance with future regulations in pre-surgical applications.

Regulatory concerns have significantly increased the complexity of many 3D printing applications. A 3D printed surgical guide is one such example. A Patient Specific Instrument (PSI), or 3D printed surgical guide can be produced on an in-house 3D printing center within 24 hours. However, due to regulatory concerns, many healthcare providers choose to use outside medical device vendors with regulatory approval. This significantly increases the turn around time to up to weeks, markedly decreasing the appeal of using a PSI.

Chapter 4: Tactical Issues

Trachea/Airway for Simulation I Image Source: Computed Tomography
Vat Polymerization with Shore 40A rigidity in a pink hue I Credit: Chris Letrong -- Stanford University Department of Radiology, 3D & Quantitative Imaging Laboratory.

A. Client Allocation

Currently, most medical centers rely on individuals who are 3D printing enthusiasts. These staff members are motivated and capable of learning new skills, often on their own time without additional compensation. Over time, as the demand for 3D printing increases, many centers will find themselves exhausted of manpower. Ultimately, letting hobbyists man the 3D printing center is not viable for a professional operating facility. To provide reliable 3D printing services consistently, talent allocation needs to be addressed. Typical skills necessary for staffing such center include the following:

a. Basic medical imaging knowledge: Knowing if the quality of the images acquired is adequate for 3D printing is crucial. This will require staff to understand the imaging protocol and why certain images cannot be used for printing

b. Good CAD/3D software understanding: Training staff to use basic (and sometimes open-source) 3D printing processing software is time consuming. Familiarity with 3D visualization software will make the learning curve much lower.

c. Understanding of 3D printing hardware: Basic maintenance is often required when working with 3D printers. Although an engineering degree is not necessary since most commercial printers are fairly user-friendly, understanding the basic mechanics is necessary for troubleshooting.

d. Basic medical knowledge: Having a basic understanding of the clinical case is important to produce high quality prints, with more attention to clinically relevant aspects of the case. This should also lead to better quality control of the final product.

Within the medical community, radiologists and radiological technicians are currently equipped with these professional characteristics and have the lowest barrier to entry to staff a 3D printing center. Due to the high cost of hiring a dedicated physician, the best choice to staff these centers is a highly trained and experienced radiological technician who is well versed in 3D software.

Many larger imaging centers have dedicated imaging post-processing labs (“3D labs”), where the technologist’s main role is to use various visualization tools to create 3D images for various clinical purposes. These staff members are ideal for future 3D printing centers because of their experience with existing post-processing software. If the volume for 3D printed models does not reach a level where a full time technologist is needed, many of the same staff members can also be productive in other areas of the department.

B. Printer/material selection

For comprehensive lists of printing process/printers and materials used for healthcare 3D printing, the readers can refer to Table II and Table IV of this paper.

1. Printers:

Key performance characteristics in selecting printers include the followings **(36)**:

- Speed
- Resolution
- Autonomous operations
- Ease of Use
- Reliability
- Repeatability
- Material/Multi-material capability

Of this list, speed is the most important issue for pre-surgical use since the need for the model may be urgent but printing usually takes hours and sometimes days. Improvement methods vary by process and include changing the printer head movement from a Cartesian to a Delta configuration (which allows for shorter paths from one point to another), optimizing the movements of laser, and using higher quality components. The multi-material and multi-head capabilities are also of particular interest. For example, models of the heart with color-coded parts such as veins, arteries, etc. can be made faster if the sections are not made piecemeal. Models for surgical practice often require materials with different haptic properties and would be made much faster if, once again, the complete model could be made at once and not in a piecemeal fashion.

2. Materials:

There are only a handful of 3D printing materials that are biocompatible and can be readily sterilized. **(47)** A variety of materials with different strength, elasticity, color/transparency will provide additional benefits for pre-surgical 3D prints. In addition to added materials, new sterilization techniques that do not require high temperature or toxic chemicals, and techniques that require less time will all prove useful in the future.

Currently, different 3D printer manufacturers also produce 3D printing materials presumably optimal for their printers. Therefore, the ultimate purchase decision should start with the current and potential future applications for which the printers are intended.

Three questions need to be answered:

a) Primary applications of the 3D printing – the requirements in terms of resolution, color, and texture of a model for conceptual purpose or device prototyping are significantly less than a model intended for hands-on practice before a complicated surgery. If the model were to be extensively used in close proximity to the surgeon intra-operatively, then selecting a system that avails more options in sterilizable material selection would be important.

b) Size of the print – this could be related to the specialty for which the setup is intended. For example, the print size capability of a system dedicated for craniofacial reconstruction will be very different from a system dedicated to Orthopedics. A printing system shared among different specialties will require a large enough platform for everyone, and therefore, it will be more expensive.

c) Other future healthcare related 3D printing activities – other than pre-surgical applications, there are a variety of existing and future healthcare applications, from medical training, rapid prototyping, research, to patient specific implantable devices. If one was to invest in a 3D printing system, calculations for potential future revenue stream may be necessary during the selection process. A 5- to 10-year revenue strategy may be necessary. We will elaborate more on this in the financial section.

C. Software Selection

1. Cost to use – open vs. commercial software.

“Free” may not be “cheap”. The cost of using free open source software includes lack of documentation or instruction, lack of technical support in case of dysfunction, lack of continuous development or updates. Although this is a viable option for users with a small 3D printing budget and technological savvy, be prepared to invest a great deal of time at the beginning to learn to use the software. Lack of time is often prohibitive for busy clinicians to learn the software themselves. Commercial software like Mimic (Materialise, Belgium) has very expensive annual licensing, discouraging many who only want to experiment with 3D printing. Nonetheless, these commercial options have more intuitive designs and great technical support and often offer personalized education/instruction time for users to fully grasp 3D printing within a very short period of time.

2. Future trend – automation and streamlined workflow.

Segmentation is the most time-consuming step of DICOM to STL conversion. Anecdotally, one radiologist can spend up to 13 hours to segment a complex heart model. Others have spent less time but still often in hours of magnitude. Automated segmentation will be a significant future development in the software area and will prove to be extremely valuable for cost-saving improvements. Additionally, more streamlined workflow from imaging acquisition to 3D prints from a software perspective is also what many users are hoping for. According to recent interviews with field experts, many larger PACS vendors are now developing DICOM to STL conversion capability with their newer software versions. Segmentation tools are also included in these newer versions. Many existing 3D printing companies are also actively developing products that are more user-friendly especially to the healthcare industry. Examples of these include Autodesk (CA, USA), and 3D System (NC, USA).

D. Imaging protocoling and acquisition

High-quality imaging acquisition is extremely important to produce a high-fidelity 3D printed model. In theory, any cross-sectional imaging modality can be protocoled to produce images compatible for 3D printing. This would include traditional adult CT, MRI, but now also includes 3D US, fetal MRI, and DRA. **(9, 25, 49)** Typically, the maximum slice thickness for any cross-sectional imaging study should be less than 2 mm. However, there is an existing publication on new reconstruction algorithms that can be used to create adequate STL files from thicker slices (~ 5mm), such as in the case of fetal MRI. **(3, 6, 14, 49)**

E. Quality control and inspection

As it was discussed earlier in this paper, errors can occur during each of the six described steps, with the accumulative error even more significant. **(7, 16, 21)** There is currently no agreed upon standard, and establishing such standard may be challenging as each clinical scenario may require different quality control processes. For example, a model that is used for patient education may not require high accuracy or verifiable labeling (i.e. right vs. left, mirror image, scale, and etc.) as much as a model that is used for surgical strategy intra-operatively. That said, certain calibration processes to verify the accuracy of the conversion from digital file to physical print will be necessary. Additional quality control steps using digital files or intraoperative measurements may also take place. However, a regulatory entity may need to be established to provide guidance on quality control for a variety of clinical cases and circumstances. Licensure may be necessary to ensure the quality of a 3D printing center similar to the American College of Radiology accreditation process of U.S. medical imaging centers.

Especially with centers responsible for larger number of prints, correct patient and anatomical identifications on the print will also be important, as avoiding errors from transforming a digital file into a physical object that is supposed to simulate reality will be critical.

F. Material management

Choosing the material to use for making a 3D printed model can seem overwhelming as there are many choices available and factors to take into consideration. (Table III) The first decision is based on the requirement for the use. For pre-surgical applications, a variety of polymers are used whereas metals and ceramics are often used for implants and other applications. The next consideration is the environment in which the model will be used. If the model will be taken into the operating room, it must be made of a material that is sterilizable such as nylon. The exact heat and chemical nature of the sterilization process will also affect the specific choice of material.

1. Safety

Powder materials have special material handling requirements to prevent explosions, fires, and inhalation of hazardous materials. In 2014, Powderpart Inc, a 3D printing company, experienced an explosion, fire, and injury of workers due to improper handling of metal powders. **(37)**
Airborne emission particles are potential health safety issues. A study released in 2013 by the Illinois Institute of Technology measured the emissions of Ultra Fine Particles (UFPs) by desktop 3D printers using extrusion of thermoplastics and found levels and particle sizes similar to that reported during grilling food on gas or electric stoves at low power. **(38)** The paper recommends caution should be used when operating some commercially available 3D printers in unvented or inadequately filtered indoor environments. **(38)** Carnegie Mellon University (CMU) has also published a 4-page document on 3D printing safety. **(39)** It warns of the emission of nano particles during the extrusion process and recommends that exhaust ventilation, filtration devices, and the placement of printers be considered when setting up the devices. **(39)**

Airborne aerosol emissions are another environmental safety issue to plan for. A study released in January 2016 documented Volatile Organic Compounds (VOCs) from filament extrusion process printers including a styrene, a known cancer causing agent, from ABS. Once again, proper ventilation is required.

Post-printing processing introduces more areas of safety concern. The removal of support material, which is used in applications where the model has an overhang that must be supported during the printing process, can use caustic chemicals. If the material for the supports is considered hazardous waste it must be disposed of appropriately. The mechanical polishing for the post-print finishing introduces air borne particulates into the environment.

CMU also lists four additional safety hazards to be aware of **(39)**:

- Hot surfaces – Print head block and UV lamp
- High voltage – UV lamp connector, electric outlet safety certified and ground wire
- Ultraviolet radiation – UV lamp. Don’t look at the lamp and make sure the UV screen is intact.
- Moving parts – Printing assembly

The latest product safety standards address these potential hazards, so is important to ensure the equipment has been tested and certified by an established third-party certifier.

2. Storage

The space required for material storage and any special environmental conditions need to be evaluated before purchasing materials. Can the materials be purchased in small quantities? Metal powders are generally only available in industrial-sized quantities. Some materials have expiration dates; so smaller quantities should be purchased to avoid waste. Are there specific storage requirements? For example, nylon needs to stay in an airtight container. Otherwise, it will absorb moisture, which will cause bubbles during printing. Many factors must be considered when planning for the purchasing and storage of the print materials.

Chapter 5: Operational Financial Issues

Normal healthy vertebrae l Image source: MRI
Multi-color Rigid opaque UV Cured Resin l Objet500 Connex3, Stratasys
WhiteClouds, Inc. UT, USA

A. Reimbursement

Healthcare is a highly regulated industry. Understanding local healthcare market and reimbursement strategy is essential to the survival and growth of any new medical technology. In order to be eventually viable financially, most U.S. 3D printing service providers need to answer two questions:

- How is the service paid now?

There is currently no established stand-alone reimbursement process for pre-surgical planning 3D printing service. Occasionally, services provided by established 3D printing companies such as 3DSystem/Medical Modeling (Denver, U.S.A.) can get paid indirectly by their contracts with a medical device company, who bills third-party payers for the cost of the medical device which includes 3D printing services.

For example, craniofacial reconstruction surgeons will use the pre-surgical planning 3D printed models and/or cutting guide made by Medical Modeling, Inc. (3DSystem, Denver, U.S.A.), who has a contract with Stryker. Stryker bundles 3D printing services under a single medical device fee, and the hospital bills third-party payers for it. (Figure 2)

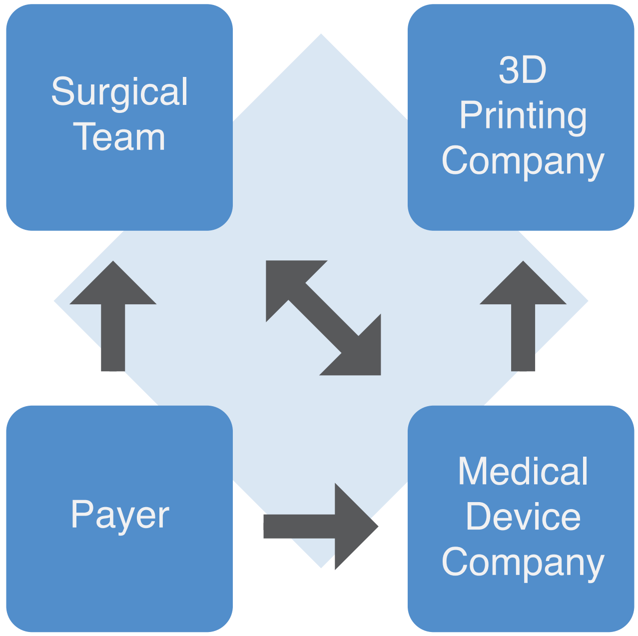


Figure 2. An example of current 3D printing reimbursement process (arrows represent direction of payment)

The result of such bundled billing is a lack of cost transparency. As the interest in 3D printing for surgical planning grows, however, more providers are now willing to pay out-of-pocket either at full price or at a negotiated price with 3D printing companies directly for similar services, bypassing any third-party (Figure 3). There is a trend towards more existing commercial 3D printing service providers venturing into the pre-surgical 3D printing arena. For example, Anatomics (St Kilda, Australia), 3D Ops (Tennessee, USA), and Whitecloud (Utah, USA).

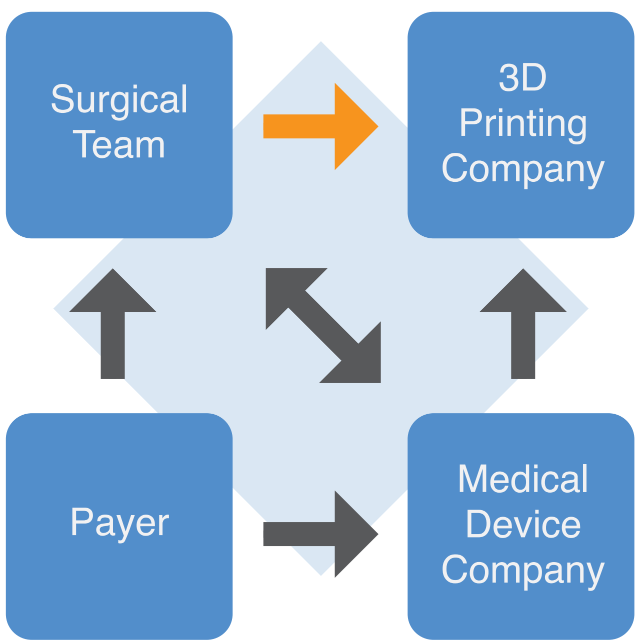


Figure 3. An example of future 3D printing reimbursement process (arrows represent direction of payment)

Additionally, a growing number of larger healthcare organizations and academic hospitals, such as the Harvard hospitals, Mayo Clinic, and Cleveland Clinic have dedicated significant internal research and development grants to develop in-house 3D printing centers. However, payers currently do not reimburse expenses for 3D printing at all if performed “in-house” or “in-office”. Thus, currently, 3D printing service appears to add costs to the overhead of health care facilities. Some have suggested potential cost savings for the hospital to provide 3D printing service as part of the surgical care, but these remain to be anecdotal **(27)**.

- How will the service be paid in the future?

For either “in house” and “outsourced” 3D printing services to be paid consistently, future work must be done to a have a procedural terminology (CPT) code created and the associated professional and facility fee assigned. The reimbursement for the physician and hospital services would then need to be negotiated with payers, insurance groups and the Centers for Medicare and Medicaid Services (CMS). **(27)** To achieve such “code-able” status by the AMA (American Medical Association) **(48)**, the procedure must be officially recognized as part of patient care, which has demonstrated sufficient clinical evidence that the procedure improves patient outcomes.

Although many recent papers have documented significant improvements associated with multiple outcome metrics including reducing operating time and surgical accuracy **(13)**, the results are still too early and too little to convince the payers. Another added challenge also includes lack of an advocacy entity for this purpose. However, this will likely change as the field matures.

B. Revenue Strategies

Although payers currently do not directly reimburse hospitals for the cost of 3D printed models, the use of 3D printing can reduce costs and increase revenue. Increasing income with 3D printing services is not a simple selling/buying transaction. Rather, revenue could come from many sources such as increased efficiencies, increased number of patients served, and increased Medicare reimbursements.

1. Patient Satisfaction

Improving patient understanding of their disease has direct benefits not only to the patient but also to the hospital bottom line margins. Via the 2016 Hospital Value-Based Purchasing program **(57)**, Medicare will adjust hospitals’ payments based on their performance on 4 domains that reflect hospital quality. The patient experience of care domain is weighted as 25% of the Total Performance Score (TPS). That score encompasses 8 important aspects of hospital quality. One of these that is directly relevant is Communication with Doctors, shown as the percentage of patients who reported that their doctors “Always" communicated well. This means doctors explained things clearly, listened carefully, and treated the patient with courtesy and respect. In addition, a second aspect that may be affected by use of 3D printed models is the Overall Rating of the Hospital.

The use of physical 3D representations to significantly increase patients' understanding of their disease and treatment options can lead to higher patient experience of care ratings, which would lead directly to increased payments to hospitals. The high scoring and improved reputation of a hospital will also drive more patients to choose it over other competing medical centers.

2. Improved patient throughput

Clinical cases continue to show that training, strategizing, and practicing with 3D printed models increases the speed of operations. This can lead to improved throughput in the operating room, which would lead to additional revenue for the hospital.

There is anecdotal evidence that the improved patient understanding of their disease through the use of the 3D printed models reduces the amount of time the doctor spends answering follow-up questions. This frees up doctor time to see additional patients.

3. Specialty focus

Specialty surgeries targeted towards the rare, complex, and often deadly diseases benefit the most from 3D printing, because the technology has provided new insights and opportunities to the surgeons before these high-risk and high-cost surgeries are performed. Some of the examples are well-documented cases in cardiothoracic surgeries. **(30,31,51)** However, a simple literature search in Pubmed (http://www.ncbi.nlm.nih.gov/pubmed) on 3D printing surgical applications can show the enormous creativeness demonstrated in every surgical sub-specialty from plastic surgery to interventional/vascular radiology. The number of published cases has compounded in the last few years.

4. Cost Reduction and Avoidance

The case for cost reduction to the medical facility is less clear for pre-surgical applications than it is for applications such as prosthetics and surgical implants.

Payers will be interested in reduced operating time, which can cost up to $180 per minute. Clinical cases demonstrate reduction of operating room time and length of hospital stay, leading to a decrease in risk for hospital acquired infections which are not only detrimental to the patient, but also no longer being reimbursed by Medicare **(28).**

C. Cost consideration for in-house services

Capital costs are one-time, fixed set-up costs incurred on the purchase of equipment or construction after which there will be only recurring operational or running costs. Operational costs include fixed costs, which recur every year, and variable costs, which are volume dependent. All of these costs must be examined when reviewing a proposal for creating an in-house 3D printing facility.

Accumulation of high-quality data on costs is difficult since without a CPT code there are multiple reimbursement pathways and no reliable, repeatable process to collect costs. For example, sometimes, the cost can be bundled in an outsourced pre-surgical process by medical device companies, with a significantly elevated price tag. (Figure 2) However, more often, researchers, providers, surgical centers, and some industrial partners have to absorb the costs of creating the 3D print. Methods to collect and document costs for every case should be employed, as each case can be considered a potential data point in a future larger scale (and possibly multicenter) clinical trial.

1. Capital Costs

The cost of providing 3D printing service can range from a few hundred dollars to millions, depending on the goal of the medical/surgical center in providing such service. Modest setups for simple models for patient education could have a capital expenditure under $10,000. On the high end of the spectrum, the authors have seen a proposal for a Veterans Association facility requesting $1 million for a fully equipped in-house 3D printing service with high-capacity printers and software. This facility would be performing in-house prosthesis work with significant cost savings that would offset this high initial cost.

Although it may be simple for a hobbyist to set up a printing machine at home, in a medical facility there are many factors to consider. Utilization of this technology is relatively new. Thus, there are many potential environmental, regulatory, and legal issues yet to be properly addressed. For example, certain steps of the 3D printing process may potentially involve or create hazardous materials or work environments. Thus, upgrading facilities to handle power requirements, and ventilation and chemical handling for post-processing operations may cause a significant increase in capital funds required.

Capital costs include the hardware, software, and built out facilities. For a frame of reference, some sample costs to be included in a proposal for capital funding are provided:

- 3D printer
- Imaging software
- Segmentation software

- CAD/CAM software
- Standard computer for administrative functions
- High powered computational computers
- High resolution monitors
- Fume hood/Ventilation setup

Funding is required to pay for these capital costs. Most academic hospitals can allocate existing research grants to create 3D printing service without expecting any near-term return.

2. Fixed Costs

Fixed costs remain constant within a range of activities but vary per unit. For example, a technician's salary is fixed for the year. If there were two technicians, the salary fixed cost would double. The salary is not changed if the facility makes 100 or 1000 3D models.

Fixed costs to maintain a 3D printing facility include personnel salaries, equipment maintenance contracts, facility costs, training costs, cost of material, and the labor involved in creating a final clinical acceptable print.

Ongoing costs of maintaining a 3D printing facility include personnel salaries, equipment maintenance contracts, facility costs, training costs, cost of material, and the labor involved in creating a final clinical acceptable print.

The following are sample fixed costs:

- Technician and Engineer salarie
- Equipment maintenance and vendor service agreements
- Training
- High bandwidth network for file transfer

3. Variable Costs

Variable costs change in direct proportion to volume.

For 3D printing, the materials are variable costs. The choice of material is huge, and the costs vary widely also. (Table III) The amount of material used will also vary with each application.

If specific clinician time is charged to a project, that expense can be considered to be variable. If hourly labor was used to make the print vs. a salaried technician, it would be considered a variable cost.

D. Sample spreadsheet

To demonstrate a financial analysis, we have created spreadsheets, which you can use as a basic framework to construct a financial plan for setting up a 3D printing service (**www.3d-heals.com**). **(29,30)** The following is a discussion of two hypothetical scenarios to demonstrate how the spreadsheet works. Please be aware that the values used could vary widely and should not be used as reference numbers. For example, construction of a dedicated area for a 3D printer is highly variable depending on geography, type of machine, regulatory requirements, etc.

In Hospital 3D Printing Service Financial Plan (Table VI):

Scenario ("Worksheet" part of Table VI):

A community based subspecialty hospital wants to justify setting up a 3d printing center for cardiothoracic surgeries. They want to expand this service to other specialties but want to start with the cardiothoracic department, using 3D printed models for as part of patient education and pre-surgical planning. For this service, they plan to charge such that after all Medicare and other discounts, they are receiving $4000 per print in net revenue. The hospital has determined that 30 patients out of 300 patients per year would benefit from the model and that the new service will attract two new patients as a result. Thus, the hospital will start their planning calculations for the first year at 32 prints at $4000/print leading to $128,000 in revenue. The two new patients per year each increased additional $40000 surgical revenue to the hospital. Total net revenue is $168,000 for the first year.

Next they determine what equipment is to be purchased based on their application and needs. Since this is used in pre-surgical planning, precision/accuracy, good resolution and sterilizable material are all important. In cardiac cases, time is often of the essence where turnaround time needs to be in 1 or 2 days. Thus, a high speed printer is required. Multicolor is extremely useful in showing complex anatomies including the vascular structures. A typical machine that meets these requirements would be Stratysys Objet500 Connex 3, which costs roughly $300,000 including a maintenance contract.

The hospital has a well-developed radiology team who is versed in 3D imaging. To make the 3D print, a radiologist will spend on average 4 hours more than their usual time, at $200/hr to perform the detailed segmentation. Approximately $26,000 will therefore be spent on radiology time.

The technologist requirement is estimated to start and remain at one half person for 10 years. Their salary is estimated $60,000 per year so the technologist cost is $30,000 per year.

The installation fees (including transportation) is $1000. Remodeling costs are estimated at $400 per square foot in a 150 square foot room, for a total of $60,000. Cost of training is estimated at $5000. It is assumed that any insurance needs are already covered by the hospital, thus no additional insurance is required. Again, these numbers are highly hypothetical and will vary significantly, depending on existing infrastructures.

Results ("Results" of Table VI):

The "results" spreadsheet (Table VI) looks at the cash flow over 10 years. First the gross revenue is calculated by multiplying the number of procedures by the amount charged per procedure. The revenue is then adjusted to take into account the mix of discounts and patients with Medicare, Medicaid, etc. Added to this is any additional revenue generated, such as from new patients, over and above that from the new procedure. This sum is the net revenue – the additional cash taken in due to the 3D printing. In our example in the out-source model in Year 1, we have 32 procedures at $5000 per procedure for a gross revenue of $160,000. After discounts our revenue drops to $128,000. However, we attract in new patients who have additional procedures. That additional revenue of $40,000 brings our net revenue to $168,000.

Next the costs are accounted for. As described earlier, there are fixed and variable costs, which are seen in the in-house model. For the in hospital model, there is significant cost of acquisition, which amounts to **$367,600**. The annual fixed cost is estimated to be 32,000, assuming an additional half-time technologist is needed. The variable cost is about 800 per print, assuming a total of four hours of post processing time is needed from the radiologists. The total annual fixed cost is therefore, again, 25,600.

The sum of the costs is the net expenses. In our Year 1 case, the costs are what we are paying to set up the 3D printing center and to hire new technologist. In addition, we have additional cost of a radiologist's time at $200 per print, assuming approximately 4-hour post processing time from the radiologist. The total of these costs are the $425,200 of expenses.

The net income is the difference between the net revenue and the net expenses. If the number is positive, you have a profit. If it is negative, there is a loss. Our example shows a loss of $257,200 for the first year.

The breakeven volume is the number of procedures needed to have no profit – where the revenues and the expenses match. In this spreadsheet, the additional revenue comes from new procedures attracted due to employment of the new technology. We assume two new patients will be attracted for year 1. We also assume a subsequent of 10% increase in new patients in subsequent years. Obviously, patients come in integer, and 10% is more of an average annual percentage growth spread over 10-year period. The Year 1 breakeven is 125 prints. Since we only did 32 prints, we end up with a loss, even accounting for additional procedural revenue.

The net present value (NPV) is the value of the 10 years' worth of net income in today's dollars. Due to inflation, $10 today is worth more than $10 a year from now. To determine the total worth of the project for 10 years in today's dollars, the values for Years 2 – 10 need to be discounted. The rate at which they are discounted is decided by the analyst. That rate is filled in on the Worksheet tab and is used to calculate the results. Using a 2% discount rate, which is set on B57 on the "worksheet" section of Table VI , we see an NPV of approximately $ $1,359,600 over 10 years.

Table VI. In House 3D Printing Service Financial Spreadsheet

Financial analysis tool Part A- In House Analysis

This spreadsheet estimates the financial feasibility of physically setting up a new 3D printing equipment in hospital. This is an adapted version of a tool origially developed by Deanna R. Willis, MD, MBA in 2004 "How to Decide Whether to Buy New Medical Equipment," Family Practice Management, March 2004, page 53 (http://www.aafp.org/fpm/20040300/53howt.html).

Assumptions of the numbers of the spreadsheet is based on anecdotal conversations with 3D printing community and hospitals to serve as a reference. These are noted at the bottom of the spreadsheet.

For those readers who want to create their own financial spreadsheet, we have put up an interactive printable spreadsheet online (www.3d-heals.com) for your convenience.

Table VI(a). In House 3D Printing Service Financial Spreadsheet

Estimate the number of procedures you will perform with the new medical equipment:

How many of your current patients go to another facility to have pre-surgical 3D printing done?	0
How many of your current patients who otherwise would not have had 3D printing done at all will now have that done?	30
How many new patients will you attract by offering the service?	2
On average,how many 3D printing planned surgeries will each of these patients have per year?	1
What growth percentage do you expect each year in the number of procedures performed?	10%
Estimated number of procedures for the first year:	**32**

Estimate the additional net revenue you expect to receive from the new procedure:

How much will you charge for the procedure?	$5000
What percentage of your practice is Medicare?	30%
What is your discount rate for Medicare?	20%
What percentage of your practice is Medicaid?	15%
What is your discount rate for Medicaid?	20%
What percentage of your practice is capitated managed care?	10%
What is your discount rate for capitated managed care?	20%
What percentage of your practice is discounted fee for service?	25%
What is your discount rate for fee for service?	20%
What percentage of your practice is self pay?	15%
What is your discount rate for self pay?	20%
What percentage of your practice is some other payer?	5%
What is your discount rate for those payers on average?	20%
Payer mix:	**100%**
Estimated gross revenue:	**$160,000**
Estimated adjustments to revenue:	**$32,000**
Estimated total net revenue:	**$128,000**
Estimated net revenue per procedure:	**$4,000**

Estimate the lost revenue per year:

What is the amount of revenue you will lose by doing this procedure instead of what you normally do?	$0
Estimated lost revenue per year:	**$0**

Additional Assumptions:
1. Net revenue for each surgical procedure is 20,000 This will of course vary greatly depending on the kind of procedure
2. Half of the 3D printing staff salary will be paid else where (e.g. CT department)
3. Training courses cost about 5K including traveling and time

Table VI(a). In House 3D Printing Service Financial Spreadsheet

Estimate the equipment acquisition costs:

What is the purchase price of the equipment (including any interest paid) and software?	$300,000
What is the transportation cost of obtaining the equipment?	$1,000
What are the remodeling costs associated with installation of the equipment?	$60,000
What are the maintanance costs associated with the purchased 3D Printer?	$0
What are the costs associated with material? (assuming $50 per case)	$1,600
What are the costs associated with personnel training?	$5,000
Estimated acquisition costs:	**$367,600**

Estimate the fixed costs of the equipment:

What is the cost of additional salaried personnel you will hire to use the equipment?	$30,000
What is the cost of additional space you will acquire to use the equipment (including rent, property tax, opportunity cost)?	$0
What is the additional cost of insurance associated with the equipment ?	$2,000
Estimated fixed costs per year:	**$32,000**

Estimate the variable costs of the equipment:

What is the additional wage and benefit cost for technologist associated with each procedure?	$0
What is the additional cost of additional time spent by radiologist to perform this procedure?	$800
Estimated variable costs per procedure:	**$800**
Estimated total variable costs per year:	**$25,600**

Estimate the rate of return on your alternative investments:

What percent return do you expect to make on your other investments during the duration of the analysis?	**2%**

Additional Assumptions:

1. Net revenue for each surgical procedure is 20,000 This will of course vary greatly depending on the kind of procedure
2. Half of the 3D printing staff salary will be paid else where (e.g. CT department)
3. Training courses cost about 5K including traveling and time

Table VI(b). In House 3D Printing Service Financial Spreadsheet

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
No. of procedures per year	32	35.2	39	43	47	52	57	62	69	75
Gross revenue	$160,000	$176,000	$193,600	$212,960	$234,256	$257,682	$283,450	$311,795	$342,974	$377,272
Adjustments to revenue	($32,000)	($35,200)	($38,720)	($42,592)	($46,851)	($51,536)	($56,690)	($62,359)	($68,595)	($75,454)
Yearly net revenue	$128,000	$140,800	$154,880	$170,368	$187,405	$206,145	$226,760	$249,436	$274,379	$301,817
Additional procedure revenue	$40,000	$44,000	$48,400	$53,240	$58,564	$64,420	$70,862	$77,949	$85,744	$94,318
Total revenue	$168,000	$184,800	$203,280	$223,608	$245,969	$270,566	$297,622	$327,384	$360,123	$396,135
Lost revenue per year	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Acquisition costs	$367,600	$0	$0	$0	$0	$0	$0	$0	$0	$0
Additional fixed costs	$32,000	$32,000	$32,000	$32,000	$32,000	$32,000	$32,000	$32,000	$32,000	$32,000
Additional variable costs	$25,600	$28,160	$30,976	$34,074	$37,481	$41,229	$45,352	$49,887	$54,876	$60,363
Yearly Expenses	$425,200	$60,160	$62,976	$66,074	$69,481	$73,229	$77,352	$81,887	$86,876	$92,363
Net profit (loss) per year	($257,200)	$124,640	$140,304	$157,534	$176,488	$197,337	$220,270	$245,497	$273,247	$303,772
Cumulative cash flow	($257,200)	($132,560)	$7,744	$165,278	$341,766	$539,103	$759,373	$1,004,870	$1,278,118	$1,581,889
ANALYSIS										
Break-even volume	124.9	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Years before recovery	2									
Net present value	$1,359,600									

Additional Assumptions:
1. Net revenue for each surgical procedure is 20,000 This will of course vary greatly depending on the kind of procedure
2. Half of the 3D printing staff salary will be paid else where (e.g. CT department)
3. Training courses cost about 5K including traveling and time

Outsource 3D Printing Service Financial Plan (Table VII):

Scenario ("Worksheet" part of Table VII):

A community based subspecialty hospital wants to justify setting up a 3D printing center for cardiothoracic surgeries. They want to expand this service to other specialties but want to start with the cardiothoracic department, using 3D printed models for as part of patient education and pre-surgical planning.

Similarly, for this service, they plan to charge such that after all Medicare and various discounts, they are receiving $4000 per print in net revenue. However, hesitant to invest significant capital up front, they decided to use a third party vendor to both design and manufacture the 3D prints. This vendor has a minimal turn around time of one week for each procedure, therefore limiting usage to less emergent cases that would require a 1-2 day turn around time.

Subsequently, the hospital has determined that 20 patients out of 300 patients per year would benefit from the model and that the new service will attract two new patients as a result. Thus, the hospital will start their planning calculations for the first year with 22 prints at $4000/print leading to $88,000 in revenue. The two new patients per year each increased additional $40,000 surgical revenue to the hospital, assuming each surgery will generate 20,000 in revenue. Total net revenue thus is $128,000 for the first year.

The hospital will pay $4000 per print with the outside vendor.

Results ("Results" of Table VII):

The "results" spreadsheet (Table VII) looks at the cash flow over 10 years. First the gross revenue is calculated by multiplying the number of procedures by the amount charged per procedure. The revenue is then adjusted to take into account the mix of discounts and patients with Medicare, Medicaid, etc. Added to this is any additional revenue generated, such as from new patients, over and above that from the new procedure. This sum is the net revenue – the additional cash taken in due to the 3D printing. In our example in the out-source model in Year 1, we have 22 procedures at $5000 per procedure for a gross revenue of $110,000. After discounts our revenue drops to $88,000 however, we bring in new patients who have additional procedures. That additional revenue of $40,000 brings our net revenue to $128,000.

Next the costs are accounted for. As described earlier, there are fixed and variable costs, which are seen in the in-house model. For the outsource model, there is no cost of acquisition. The sum of the costs is the net expenses. In our Year 1 case, the costs are what we are paying a vendor for the prints, which totals $4050 per print. In addition, we have the cost of a radiologist's time at $200 per print, assuming approximately 1-hour design time from the radiologist. The total of these costs are the $93,500 of expenses.

The net income is the difference between the net revenue and the net expenses. If the number is positive, you have a profit. If it is negative, there is a loss. Our example shows a profit of $33,500 for the first year.

The breakeven volume is the number of procedures needed to have no profit – where the revenues and the expenses match. In this spreadsheet, the additional revenue comes from new procedures attracted due to employment of the new technology. We assume two new patients will be attracted for year 1. We also assume a subsequent of 10% increase in new patients in subsequent years. Obviously, patients come in integer, and 10% is more of an average annual percentage growth spread over 10-year period. The Year 1 breakeven is 23 prints. Since we only did 22 prints, we should have a loss. The additional revenue brought in gives us a positive result.

The net present value (NPV) is the value of the 10 years' worth of net income in today's dollars. Due to inflation, $10 today is worth more than $10 a year from now. To determine the total worth of the project for 10 years in today's dollars, the values for Years 2 – 10 need to be discounted. The rate at which they are discounted is decided by the analyst. That rate is filled in on the Worksheet tab and is used to calculate the results. Using a 2% discount rate, which is set on B57 on the "worksheet" section of Table VII, we see an NPV of approximately $523K.

Table VII. Outsourced 3D Printing Service Financial Spreadsheet

Financial analysis tool Part A- Outsource Analysis

This spreadsheet estimates the financial feasibility of physically setting up a new 3D printing equipment in hospital. This is an adapted version of a tool origially developed by Deanna R. Willis, MD, MBA in 2004 "How to Decide Whether to Buy New Medical Equipment," Family Practice Management, March 2004, page 53 (**http://www.aafp.org/fpm/20040300/53howt.html**).

Assumptions of the numbers of the spreadsheet is based on anecdotal conversations with 3D printing community and hospitals to serve as a reference. These are noted at the bottom of the spreadsheet.

For those readers who want to create their own financial spreadsheet, we have put up an interactive printable spreadsheet online (www.3d-heals.com) for your convenience.

Table VII(a). Outsourced 3D Printing Service Financial Spreadsheet

Estimate the number of procedures you will perform with the new medical equipment:

How many of your current patients go to another facility to have pre-surgical 3D printing done?	0
How many of your current patients who otherwise would not have had 3D printing done at all will now have that done?	20
How many new patients will you attract by offering the service?	2
On average,how many 3D printing planned surgeries will each of these patients have per year?	1
What growth percentage do you expect each year in the number of procedures performed?	10%
Estimated number of procedures for the first year:	**22**

Estimate the additional net revenue you expect to receive from the new procedure:

How much will you charge for the procedure?	$5000
What percentage of your practice is Medicare?	40%
What is your discount rate for Medicare?	20%
What percentage of your practice is Medicaid?	15%
What is your discount rate for Medicaid?	20%
What percentage of your practice is capitated managed care?	10%
What is your discount rate for capitated managed care?	20%
What percentage of your practice is discounted fee for service?	15%
What is your discount rate for fee for service?	20%
What percentage of your practice is self pay?	15%
What is your discount rate for self pay?	20%
What percentage of your practice is some other payer?	5%
What is your discount rate for those payers on average?	20%
Payer mix:	**100%**
Estimated gross revenue:	**$110,000**
Estimated adjustments to revenue:	**$22,000**
Estimated total net revenue:	**$88,000**
Estimated net revenue per procedure:	**$4,000**

Estimate the lost revenue per year:

What is the amount of revenue you will lose by doing this procedure instead of what you normally do?	$0
Estimated lost revenue per year:	**$0**

Additional Assumptions:
1. Net revenue for each surgical procedure is 20,000 This will of course vary depending on the kind of procedure.
2. Imaging center is NOT equipped with neither 3D printer nor 3D staff for post processing

Table VII(a). Outsourced 3D Printing Service Financial Spreadsheet

Estimate the outsourced printing costs:

What is the average cost of per 3D printing model for this procedure?	$4,000
What is the transportation cost of obtaining the equipment?	$50
What are the remodeling costs associated with installation of the equipment?	$0
What are the maintanance costs associated with the purchased 3D Printer?	$0
What are the costs associated with material? (assuming $50 per case)	$0
What are the costs associated with personnel training?	$0
Estimated acquisition costs:	**$89,100**

Estimate the fixed costs of the equipment:

What is the cost of additional salaried personnel you will hire to use the equipment?	$0
What is the cost of additional space you will acquire to use the equipment (including rent and property tax)?	$0
What is the additional cost of insurance associated with the equipment (i.e., malpractice insurance, property insurance for the equipment, business hazard/loss of use insurance)?	$0
Estimated fixed costs per year:	**$0**

Estimate the variable costs of the equipment:

What is the additional wage and benefit cost for hourly personnel associated with each procedure?	$0
What is the per-procedure cost of additional radiologist time?	$200
Estimated variable costs per procedure:	**$200**
Estimated total variable costs per year:	**$4,400**

Estimate the rate of return on your alternative investments:

What percent return do you expect to make on your other investments during the duration of the analysis?	**2%**

Additional Assumptions:
1. Net revenue for each surgical procedure is 20,000 This will of course vary depending on the kind of procedure.
2. Imaging center is NOT equipped with neither 3D printer nor 3D staff for post processing

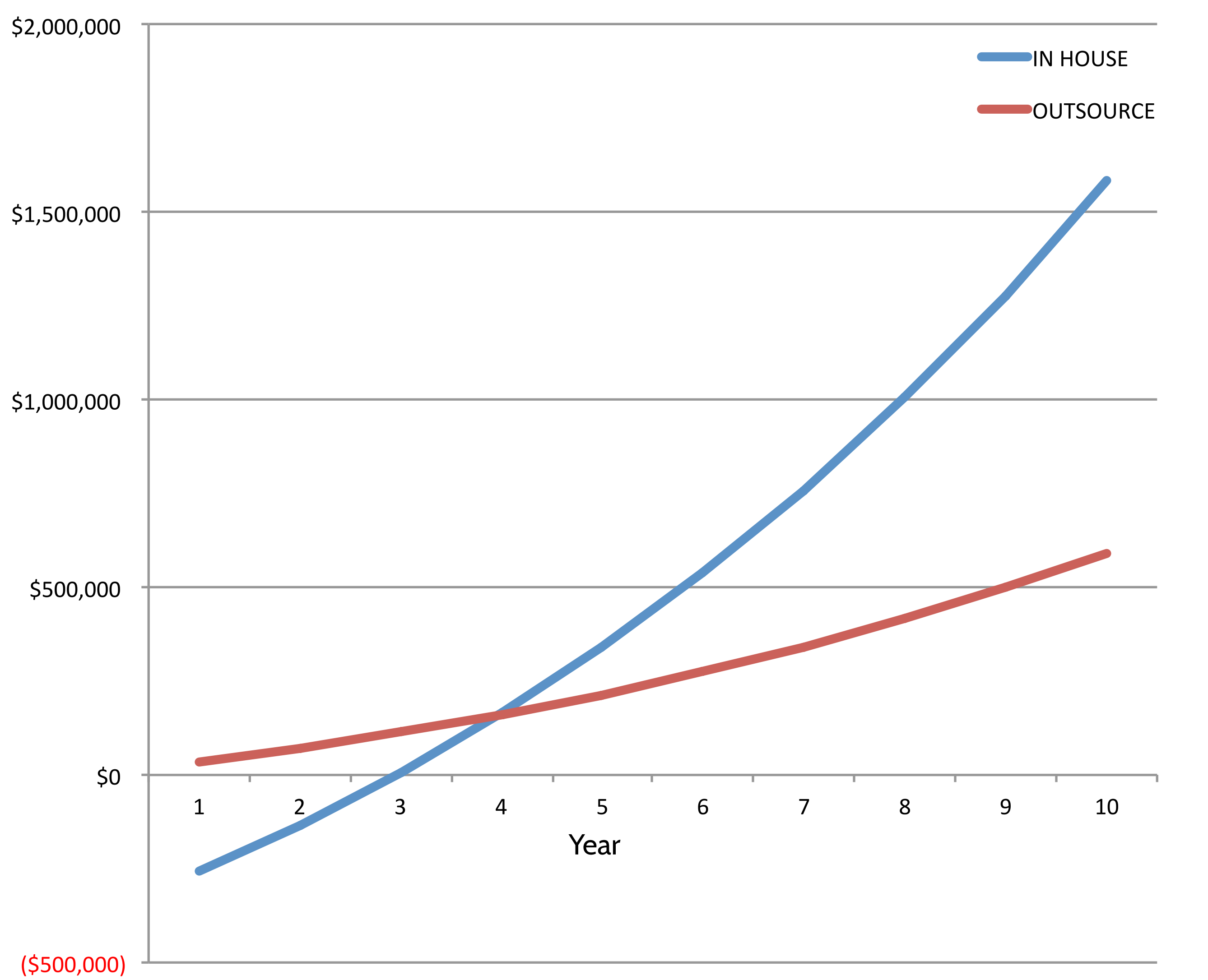
Table VII(b). Outsourced 3D Printing Service Financial Spreadsheet

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
No. of procedures per year	22	24	27	29	32	35	39	43	47	52
Gross revenue	$110,000	$121,000	$133,100	$146,410	$161,051	$177,156	$194,872	$214,359	$235,795	$259,374
Adjustments to revenue	($22,000)	($24,200)	($26,620)	($29,282)	($32,210)	($35,431)	($38,974)	($42,872)	($47,159)	($51,875)
Yearly net revenue	$88,000	$96,800	$106,480	$117,128	$128,841	$141,725	$155,897	$171,487	$188,636	$207,499
Additional procedure revenue	$40,000	$44,000	$48,400	$53,240	$58,564	$64,420	$70,862	$77,949	$85,744	$94,318
Total revenue	$128,000	$140,800	$154,880	$170,368	$187,405	$206,145	$226,760	$249,436	$274,379	$301,817
Lost revenue per year	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Acquisition costs	$89,100	$98,010	$107,811	$118,592	$130,451	$143,496	$157,846	$173,631	$190,994	$210,093
Additional fixed costs	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Additional variable costs	$4,400	$4,840	$5,324	$5,856	$6,442	$0	$0	$0	$0	$0
Yearly Expenses	$93,500	$102,850	$113,135	$124,449	$136,893	$143,496	$157,846	$173,631	$190,994	$210,093
Net profit (loss) per year	$34,500	$37,950	$41,745	$45,920	$50,511	$62,649	$68,914	$75,805	$83,386	$91,724
Cumulative cash flow	$34,500	$72,450	$114,195	$160,115	$210,626	$273,275	$342,189	$417,994	$501,379	$593,103
ANALYSIS										
Break-even volume	23.4	25.8	28.4	31.2	34.3	35.9	39.5	43.4	47.7	52.5
Years before recovery	0									
Net present value	$523,151.37									

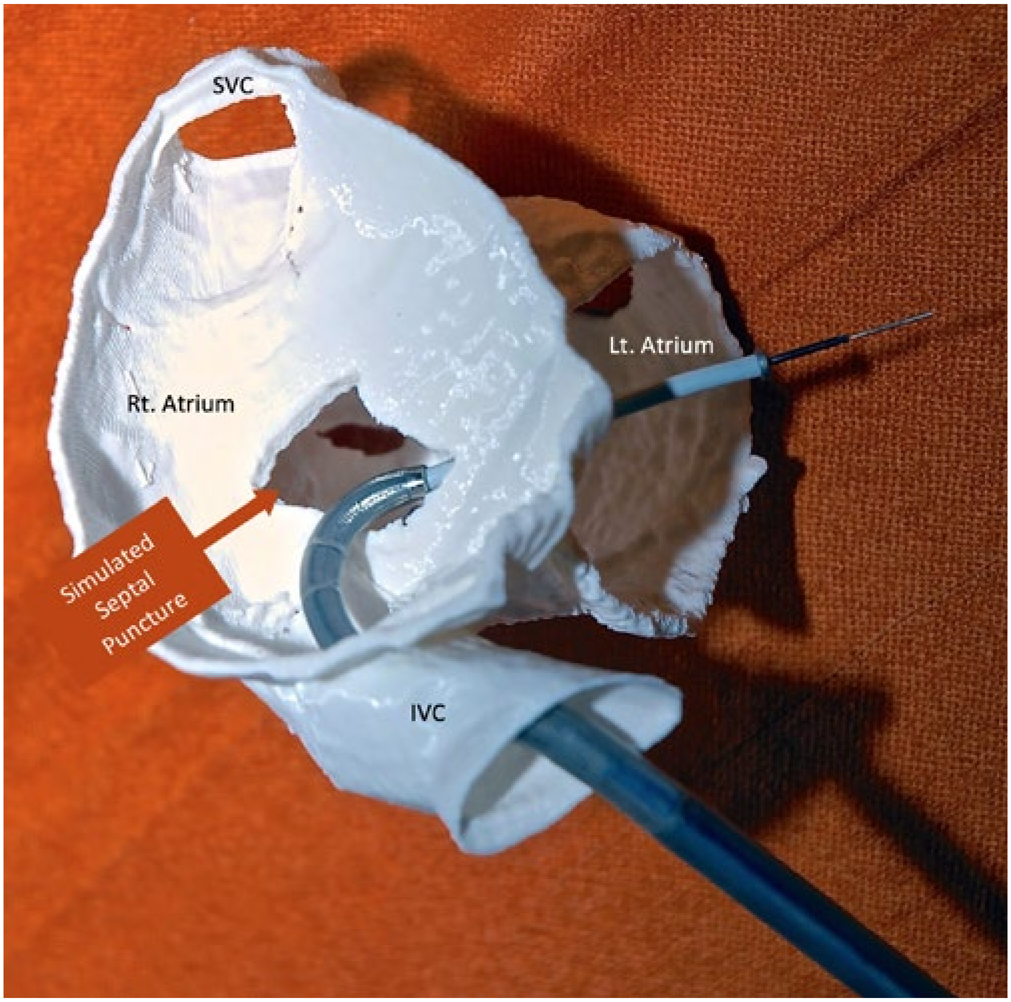
Additional Assumptions:
1. Net revenue for each surgical procedure is 20,000 This will of course vary depending on the kind of procedure.
2. Imaging center is NOT equipped with neither 3D printer nor 3D staff for post processing

With these two hypothetical scenarios, a graph of return on investment over a ten year period can be generated.

Figure 4. In-house VS Outsource



Chapter 6: Conclusion



Mitral Clip Planning simulation l Fused Deposition Modeling (FDM)
Image Source: Computed Tomography l Credit: Shannon Walters -- Stanford University Department of Radiology, 3D and Quantitative Imaging Laboratory.

3D printing technology holds many promises and excitement to the healthcare industry. Although the technology has mainly been used for rapid prototyping, this will soon change as the technology and market are evolving at a very fast pace. Resolution continues to improve, material choices to expand, while patent are expiring, all allowing more market entrants and forcing down prices. New 3D printing applications are being constantly invented in the healthcare field. The latest healthcare drivers of improved customer satisfaction and value-based payments are forcing the healthcare industry to look for innovative solutions. As a new tool, 3D printing technology is providing the innovation opportunity. Pre-surgical planning using 3D printing technology is one of the solutions with many added benefits from providing never-before visual and haptic information to the treating physicians, to improving communications with patients and multi-disciplinary clinical team. As more clinical trial evidence is gathered, we are expecting to see a burgeoning field with more effective and systematic way of adopting the technology in surgical centers worldwide. We hope this book can serve as a good starting point for many venturing into this nascent field.

Chapter 7: Clinical Vignette

Tetrology of Fallot (CTA)
Binder Jetting
Materialise. Leuven, Belgium

Disclaimer: The information presented here may be incomplete since the authors could only directly contact some of the individuals listed as authors for these published cases. Additionally, many clinical cases are not included at this point due to incomplete data.

Table VIII. Clinical Cases

Author/Ref	Anatomy	Modality	Imaging protocol	Segmen-tation	DICOM-> STL (software)	STL->3DP Model (software)
Sanjay Prabhu (20)	Pediatric neurovascular disease	MRI	MRA/MRI, including 1mm volumetric FSPGR T1 post contrast images	Mimics (Materialise, Belgium)	Mimics (Materialise, Belgium)	Mimics (Materialise, Belgium)
Parit Patel (38)	Craniofacial	CT	1.25 mm	Rapid3D (Rapid, Long Beach, CA)	Rapid3D (Rapid, Long Beach, CA)	DeVide (Delft Visualization, GA Delft, the Netherlands)
David Frakes (61)	Pediatric congenital heart disease	CT	Slice thickness: 0.625-mm FOV: includes entire heart & great vessels. Image matrix: 512x512 px Pixel dimensions: 0.313-mm square.	GE Advantage Workstation by radiologist	Mimics (Materialise, Belgium)	Geomagic Studio (Morrisville, NC, USA)

Table VIII. Clinical Cases (Contd.)

Author/Ref	Printer	Material	Validation	Outsource?	Suggested time	Sterilization
Sanjay Prabhu (20)	Objet500 Connex3 (Stratasys)	ABS (Acylonitrile Butadiene Styrene) two color resin, 16 microns	Comparing measurements made based on model photographs and intraoperative photographs taken from the same angle of approach	N	8-22 hours	Autoclave
Parit Patel (38)	MakerBot Replicator (MakerBot Industries, Brooklyn, NY)	PLA (polylactic acid)	N/A	N	12-16 hours	Sterrad (Advanced Sterilization Products, Irvine, CA)
David Frakes (61)	ZPrinter 650 RP machine (3D Systems, Rock Hill, SC, USA),	Gypsum-based powder media	1.Qualitatively by at least two radiologists during and at the end of the printing process. 2.Quantitatively by comparing virtual volume (Mimics) and physical volume (3D System Zprint software)	N	3 hours	N/A

A. Pediatric congenital heart disease

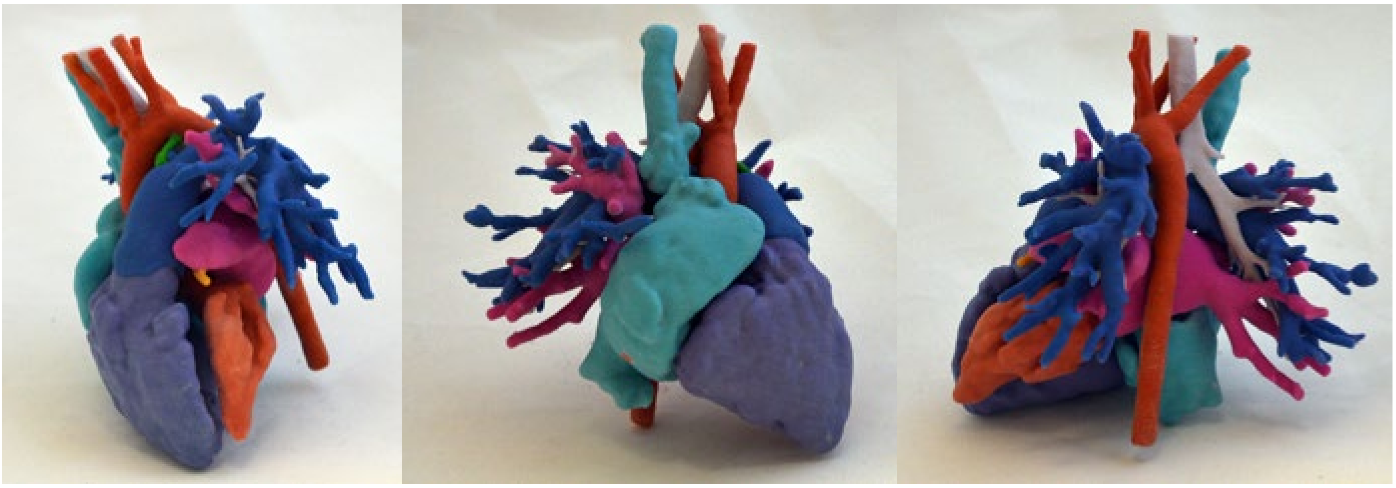


Figure 5. Color-coded Patient-specific Physical Models of Congenital Heart Disease. ProJet x660 by 3DSystems. Gypsum media (z151).

Published source:

Color-coded Patient-specific Physical Models of Congenital Heart Disease Ejaz F1 , Ryan J1 , Henriksen M1 , Stomski L1 , Feith M2 , Osborn M3 , Pophal S3 , Richardson R4 , Frakes DF15 **(50)**

Authors:

A group of researchers and engineers led by Professor David Frakes from Arizona State University, St. Joseph's Hospital and Medical Center, and Phoenix Children Hospital.

Experience:

The group has worked on 3D printed models of pediatric congenital heart disease for nearly a decade. They have accumulated experiences from 300+ cases.

Case Summary:

A library of 36 life-sized, pediatric congenital heart disease (CHD) models was created using 3D printing with standardized color-coding systems. The study showed significant effectiveness in promoting understanding of complex pediatric CHD anamolies, and therefore potentially adding value to pre-surgical planning. Specifically, the researchers showed significantly higher score in terms of identifying the correct anatomy by a group of pre-medical students with 3D printed models over virtual simulation models.

Tactical Issues:

The group has a dedicated "in-house" 3D printing lab through their association with Arizona State University. Researchers themselves are the main operators from design to production. The technical aspects of the printing process are listed in Table VI. Medical experts including radiologists also participated in imaging acquisition, segmentation, and quality control processes.

The printer and materials are handled within a dedicated engineering lab fit to industrial safety

Strategic Issues:

The researchers did not receive any dedicated grants or reimbursement for this project. The project was essentially funded by the principle investigator's (Dr. David Frakes) research grants from multiple sources for his other research activities unrelated to this project.

The project has received significant public/parental attention and support, including establishment of a nonprofit organization named Opheart.org, which primarily advocates for 3D printing surgical planning for complex CHD.

However, the benefit of 3D printing with pediatric CHD remains anecdotal and there is no established funding process for either research or clinical care. Currently, the group is a participant in a new multi-center clinical trial focusing on the benefit of 3D printing in pediatric congenital heart disease surgeries led by Children's National Medical Center.

Financial Issues:

Currently, the 3D printing activity is considered a cost center to both the hospital and the researchers.

B. Pediatric Neurovascular disease

Published source:

Weinstock, P., Prabhu, S. P., Flynn, K., Orbach, D. B., & Smith, E. (2015). Optimizing cerebrovascular surgical and endovascular procedures in children via personalized 3D printing. Journal of Neurosurgery: Pediatrics, 1–6 **(13)**

Authors:

A multidisciplinary team from Boston Children's Hospital and Boston Children's Hospital Simulator Program (SIMPeds) led by Dr. Sanjay Prabhu.

Experience:

The SIMPeds 3D printing center led by Dr. Sanjay Prabhu has worked on surgical planning 3D printing since September 2013 and produced about 280 models.

Case Summary:

In this paper, four cases of pediatric vascular malformations were used to assess the potential clinical benefit of surgical planning using patient specific 3D printing. The authors suggest potential benefit through shortened operative time.

Tactical Issues:

The group has a dedicated in-house 3D printing center through their association with Boston Children's Hospital's SIMPeds program. SIMPeds' radiologists, engineers, and technicians are the main operators from design to production. The technical aspects of the printing process are listed in Table VI. Medical experts including radiologists, neurosurgeons, and a team of clinical collaborators are also participants in design and quality control processes.

The printer and materials are handled within a dedicated engineering lab fit to industrial safety standards. While CHB handles most of the 3D printing projects in-house, there have been a few occasions when the projects were outsourced due to demand of ultra-realistic simulators. However, even with the outsourced projects, each step was closely monitored by SIMPeds' staff and engineers.

Strategic Issues:

The 3D printing center is a part of CHB's simulation program, SIMPeds, which receives multiple grants from various CHB departments. The 3D printing center itself did not receive dedicated grants. Additionally, 3D printing is now officially incorporated in the EHR system, so that clinicians can more effectively communicate their order to have 3D printing service.

Financial Issues:

Although also started as a cost center, the SIMPeds 3D printing center has generated positive revenues from providing 3D printing services to outside entities and hospitals. This allows the center to price their internal services as well, and is subsequently becoming revenue-neutral according to Dr. Prabhu during our interview.

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3D Printing Swimlane available at **www.3d-heals.com**

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