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3D Printing for Surgical Planning

IDENTIFICATION OF CANDIDATE PROCEDURES AND RESULTING VALUE

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3D-printed anatomical models for surgical planning and clinical training have a wide array of applications in the hospital inpatient setting. Coupled with the benefits, they have fueled a growing clinical interest in surgical applications, as indicated by the number of published papers addressing 3D printing's use in preparation for surgical cases. A literature review conducted at the end of 2015 revealed that 78.5% of the published papers on this subject were released in 2014 and 2015, with the first paper published in 1998.

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The benefits of 3D printing result from the clarity provided by patient-specific anatomical models that illustrate structure and pathology, which may be vague, obscure or hidden in X-ray, computed tomography (CT), magnetic resonance imaging (MRI) or ultrasound images. The information communicated by a physical model translates to numerous advantages (Figure 1) starting with better insights, which leads to better outcomes, both clinically and economically, for patients, providers and payers.

In case studies without controls, 3D printing's value as a surgical tool has been demonstrated on a case-by-case basis. Advantages commonly cited from the surgical theater involve preparation and communication. Stratasys' review of published literature found three top-level uses of patient-specific 3D models:

Plan

Holding an exact replica of a patient's anatomy allows the surgical team to be better prepared before entering the operating room (OR). The model presents the pathology that may reveal a solution or possible complication that could not be seen when evaluating a 2D representation.

Practice

Depending on a 3D printer's ability to match the clinical environment, the model may be used to practice a procedure that involves one or more medical specialties. Often reserved for complicated cases, this can better prepare the team to address risks and difficulties, resulting in more efficient procedures and improved clinical results.

Determine

Less common today, but potentially more impactful, is the use of patient-specific models to determine the viability of procedure (rule-in/rule-out) and the appropriate selection of a surgical approach and/or device. Using the model, the surgical team may ascertain that an entirely different approach is required or that a more suitable device would better accommodate the patient's anatomy.

The following five cases are examples of 3D printing's benefits for planning and determination in surgical oncology, orthopedic surgery, pediatric cardiac surgery and reconstructive surgery.

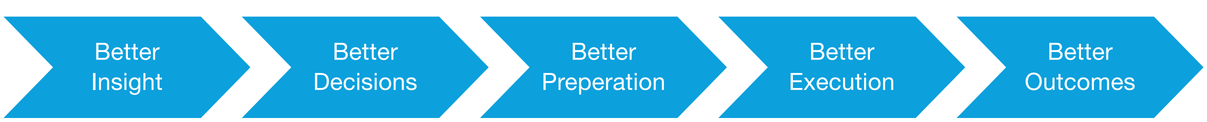

Figure 1: Advantages of 3D anatomical models in healthcare.

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Kidney Tumor (Plan)

Preparing for patient Linda Green's kidney tumor removal[2], Intermountain Medical Center used a 3D-printed model that made the tumor and internal structures visible, something that traditional options could not do. "We could not appreciate the peak of the tumor that was growing up into the drainage system of the kidney until we did the 3D reconstruction and 3D printing," said Dr. Jay Bishoff, director of the Intermountain Urological Institute at Intermountain Medical Center. With this additional information, they successfully removed the tumor while sparing the kidney, significantly improving Linda's long-term prospects.

Scoliosis (Plan)

In the case of 13-year-old Jocelynn Taylor, afflicted with severe scoliosis, Dr. Sumeet Garg, associate professor of orthopedics at the University of Colorado, said, "When you are working with a 3D image on a computer you can spin the image of the spine around. It's not the same as being able to hold it and really appreciate how rotated her spine is."[3] He continued, "Being able to visualize and sort of do the surgery in your head ahead of time, you can anticipate both the perfect surgery but also potential problems when you're working in the OR. If something comes up, it's not the first time you've thought about it." Prior to the surgery, Jocelyn's spine had a curve in excess of 100 degrees. The procedure has been so successful that Jocelynn has grown 4 inches and all restrictions on her physical activity have been removed.

Double Aortic Arch (Plan)

Following the diagnosis of a double aortic arch in young Mia Gonzalez, the challenge was determining a surgical plan to save her life. Dr. Redmond Burke, director of pediatric cardiovascular surgery at Nicklaus Children's Hospital, said that with a 3D model of her complex aortic arch vessels, "We were able to figure out which part of her arch should be divided to achieve the best physiologic result."[5] He continued, "My team could visualize the operation before we started. We knew the safest approach, and confidently made a smaller incision." Burke concluded, "Why experiment? Why go into the operating room and hope? When we have a model, we can test the device and know with certainty this is going to work." Dr. Burke attributes the 2-hour reduction in Mia's procedure to the 3D printed model, and the smaller incision resulted in a faster recovery than is typical in these procedures.

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Frontonasal Dysplasia (Practice)

Before birth, Violet Pietrok was diagnosed with frontonasal dysplasia, a dangerous craniofacial anomaly akin to a cleft pallet that extends up to the top of the skull. Following a nine-hour surgery with a team of seven surgeons supported by anesthesiologists, nurses and caregivers, Violet is now a happy, giggly toddler. Dr. Mark Proctor, a neurosurgeon that practices at Boston Children's Hospital, said, "When you are dealing with such a complex and unique abnormality, it is really hard to conceptualize exactly what you need to do in surgery."[4] His surgical team member, Dr. John Meara, a plastic surgeon, said, "The value of a [3D] model like this is huge. This gives me the ability actually to see on this model better than I will in the operating room, so I can see and feel the trajectory, for example, of where we will have to make certain cuts. And that has never been possible before." Indeed, the team actually performed the planned procedure on the 3D printed parts, making the precise cuts on the model that were going to be performed in the procedure. During the operation, the team referred to the 3D printed model that had been cut to ensure each step progressed as intended.

Dr. Proctor added, "3D printing in some ways has been a natural extension of what we have done in simulation from our very beginning. It saves a lot of the thinking in the operating room. When we get there and the patient is in front of us, we aren't using our brain power to decide what we have to do. We really have that planned going into the surgery, and that makes the whole process quicker, more efficient and safer for the patient."

Lung Tumor (Determine)

In a Mayo Clinic News Network video[1] presenting the case of Michael Slag, who was being treated for a Pancoast tumor, the Mayo Clinic team claimed, "3D printing spared him a much more invasive operation with a far longer and more painful recovery." Based on information gleaned from the model, the surgical team was able to evaluate both open and minimally invasive procedures, determining that a minimally invasive laparoscopic surgery would be a viable option, rather than opening his chest.

The physical model also improves communications with patients, among practitioners and with support staff. Presented with a model of one's own anatomy, patients can see and understand the condition and treatment, yielding truly informed consent. As the focal point for discussion, surgical teams, representing multiple specialties, can clearly convey the methods and the challenges of a procedure.

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When discussing Mia Gonzalez's case, Dr. Burke said, "I hate opening up a textbook and saying, 'This isn't really your baby's heart, but it kind of looks like it, and here is how we are going to do the operation.' That doesn't resonate with them. I showed it [the 3D model] to them and said, 'This is what's choking your baby. This is why she is taking all this medication, and this is why they won't work.' It is very powerful to show a family, 'This is your baby's heart and this is how I am going to repair it.'"[5]

Dr. Shanda Blackmon, thoracic surgeon at Mayo Clinic, said when discussing Michael Slag's case, "We frequently may have a plastic surgeon, an orthopedic surgeon, a vascular surgeon, and myself, all involved in a Pancoast tumor resection. And when that is the case, there is nothing better than having a model for the full team to meet around and plan the case." Patient Michael Slag said, "Knowing that I was more likely to come out with a hand that worked, compared to an arm that wasn't going to do very much, was a big load off of my mind."[1]

The benefits of preparation, determination and communication are clear for Mia, Violet, Jocelyn, Michael and Linda, based on the success of their procedures and their prognoses. Yet, while patient outcomes are of high importance, economic factors also drive decisions.

In Michael Slag's case, the 3D-printed model validated a laparoscopic procedure, which required less OR time (studies have shown OR time to cost $62 per minute in the U.S.) and a shorter hospital stay (estimated at $1,878 per day in the U.S.[6]). Factors like these, influenced by 3D-printed models, may translate to increased procedure volumes and hospital days. These cost savings translate directly into greater profits for the hospital.

Another economic factor emerging from the three case studies is the lack of reported complications, meaningthere were no additional costs and dilution of profits for these procedures. This aspect merits attention and investigation as the healthcare industry transitions between reimbursement structures.

The healthcare system is undergoing a transition from the historical fee-for-service model to value-based-reimbursement approaches. During this transition, more of the financial burden and risk is shifting to hospitals. Improving the efficiency and quality of surgical procedures and minimizing complications takes on increased importance.

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The adoption of value-based-reimbursement systems—affected by quality of care, outcomes and procedure efficiency— may accelerate the acceptance and adoption of 3D printing as a surgical tool.

However, proof of value has yet to be provided through large, controlled trials, as specified by American Medical Association (AMA) Level I criteria. Yet, Level IV evidence, which includes observations and case series without controls, clearly indicates a strong likelihood of a correlation between improved outcomes for patients, practitioners and payers, when 3D printed anatomical models are used to prepare and communicate.

ECONOMICS AND 3D PRINTING

Economically, 3D printing presents many potential advantages that arise from improved performance and efficiency in the OR. Although more robust studies are needed to validate the returns and significance for individual procedures, previous experience indicates that provider profits may be improved in both direct and indirect ways.

- Pre-operative
  - Reduce procedure cost from:
    - Optimum method selection
    - Optimum device selection
  - Avoid unnecessary intervention
- Inter-operative
  - Improve physician effectiveness
  - Reduce:
    - OR time
    - Anesthesia time
    - Time on ischemia
    - Complication frequency
- Post-operative
  - Accelerate recovery
  - Reduce length of stay (LOS)
  - Reduce readmission rate
  - Improve outcomes

- Other
  - – Avoid Centers for Medicare & Medicaid Services
  - – (CMS) penalties
  - – Increase procedure volume from:
- Faster OR turnover
  - Improved patient satisfaction
  - Improved regional/national ranking
- Increase available hospital beds from:
  - – Reduced LOS

3D printing can improve surgical planning, which can lead to improved physician effectiveness, producing better outcomes that impact profits. However, according to a JAMA article[7] published May 2016, "…the body of literature relating cost to quality is underdeveloped." Investigating the potential effect of policy changes that incentivize high-quality care, Healy, Mullard, Campbell and Dimick evaluated the costs and financial burden associated with surgical quality in a paper titled "Hospital and Payer Costs Associated with Surgical Complications."

From the authors' study of 5,120 episodes of surgical care, they report that hospital costs for patients with complications were 119% higher ($19,626) than those without complications while reimbursements increased by 106%. The result is that after applying risk adjustments associated with value-based payments, the profit margin for patients with complications decreased to just 0.1%, compared to 5.8% for those without complications. The authors concluded, "Both hospitals and payers appear to currently have financial incentives to promote surgical quality improvements."

When considering 3D printing, hospitals will need to examine both the potential financial advantages and the expense. There are two increased cost components to consider: data creation and model building.

3D printing requires a well-defined, digital, 3D model that is not directly available from imaging technologies. Skilled personnel with biomedical and/or radiology backgrounds translate DICOM (digital imaging and communications in medicine) files using specialized software, often with feedback and collaboration from the clinicians. The 3D-printed models then require hardware, software and some technician time to print, clean and prepare for use by clinicians.

Depending on the complexity and printer capability, the models may cost several hundred to several thousand dollars. This cost is then weighed against the financial benefits of reduced OR time, avoiding complications, reducing LOS and other aspects that can be improved through better surgical planning.

IDENTIFYING CANDIDATE PROCEDURES FOR 3D MODEL-BASED PLANNING

The circumstantial case for 3D printed anatomical models is intriguing and compelling. However, the evidence to support the case, in clinical and economic measures, is limited and dispersed across many surgical procedures. The limited procedural direction and evidence may create a challenge for hospitals to make informed decisions as to when, where, why and how to apply the technology.

To fill this information gap, Stratasys conducted an investigation into the applications and outcomes presented in published research. The intent was to offer hospitals insight into the most advantageous surgical procedures and a framework for decision-making criteria. Stratasys generated a prioritized list of surgical opportunities after reviewing the landscape of clinical applications, gauging the quality of the evidence, evaluating the cited outcomes and investigating the economic drivers. The company also consulted with expert clinicians on specific procedures to better understand the potential for 3D models to impact surgical outcomes.

The first step in the investigation was a literature review. The research began with a keyword search that yielded 1,100 candidate publications. The abstracts and full text of the paper were then manually reviewed to identify those papers that address surgical procedures, excluding implant procedures, dental surgery, regenerative medicine and tissue engineering.

Of the 200 published papers that fit the search criteria, 84 were directly related to surgical planning. After categorization, the research revealed seven medical specialties and 31 procedures to which 3D printing had been applied and investigated (Table 1).

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SPECIALTY	PROCEDURE
Cardiac Surgery/ Interventional Cardiology	Annuloplasty (mitral valve repair)
	Repair Coronary Aneurysm
	Replacement of Aortic Valve
	Stent Insertion
	Repair Congenital Heart Defects
Gastroenterology	Endoscopy of Esophageal Lesion
	Splenectomy
Neurosurgery	Repair Aneurysm
	Transsphenoidal Excision of Pituitary Gland
	Remove Brain Tumor
Orthopedic Surgery	Repair Scoliosis
	Repair Clavicle Fracture
	Hip Repair
	Repair Intervertebral Disc
	Hip Replacement Revision
	Repair Leg Fracture
	Osteotomy
Reconstructive Surgery	Hand Reconstruction
	Facial Reconstruction
	Breast Reconstruction
	Mastoidectomy
	Cleft Palate Correction
Surgical Oncology	Removal of Adrenal Tumor
	Removal of Liver Tumor
	Endoscopic Removal of Cardiac Lesion
	Thoracic Removal of Lung Tumor
	Removal of Renal Tumor
Transplant Surgery	Heart Transplant
	Liver Transplant
	Lung Transplant
	Kidney Transplant

Table 1: Procedures, listed by specialty, presented in published literature.

DETERMINING 3D PRINTING'S VALUE

The consensus of the papers was that 3D printing plays a positive role in these 31 procedures, but the relative value of 3D printing across these specialties was unclear. To further identify the optimum near-term procedural targets, Stratasys conducted a multi-factor analysis of each procedure to assess research interest level, potential clinical benefit, potential economic benefit and 3D printing's role. The evaluation criteria were as follows:

- Research Interest and evidence
  - Number of published papers
  - Clinical and economic outcomes cited
- Clinical benefit (potential)
  - Inpatient mortality rates
  - Inpatient length of stay (LOS)
  - Procedure complexity and/or OR time
- Economic benefit (potential)
  - Procedure volume
  - Procedure profitability

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- Physician payment (per Medicare Physician Fee Schedule (MPFS))

- Application
  - Role of the 3D-printed model

For potential clinical and economic benefits, four data sources were consulted:

- Healthcare Cost and Utilization Project (HCUP), ©2013
- Physician Supplier Procedure Summary (PSPS), ©2014
- Medicare Physician Fee Schedule (MPFS), © 2015
- Truven Analytics, ©2013

Applications

For surgical procedures, the 3D-printed models were used in three modes: plan, practice and determine. The number of publications for each mode is shown in Figure 2.

Plan

By far, the most studied application is using 3D printing to create a physical model of patient anatomy for review and analysis prior to a procedure. Preparing for an upcoming surgery was cited in 78.5% of all papers. The popularity of this application is assumed to be a natural progression from the established practice of preparing with 2D radiographs. Additionally, this application has historical precedence since it was the first use of 3D printing for surgical planning.

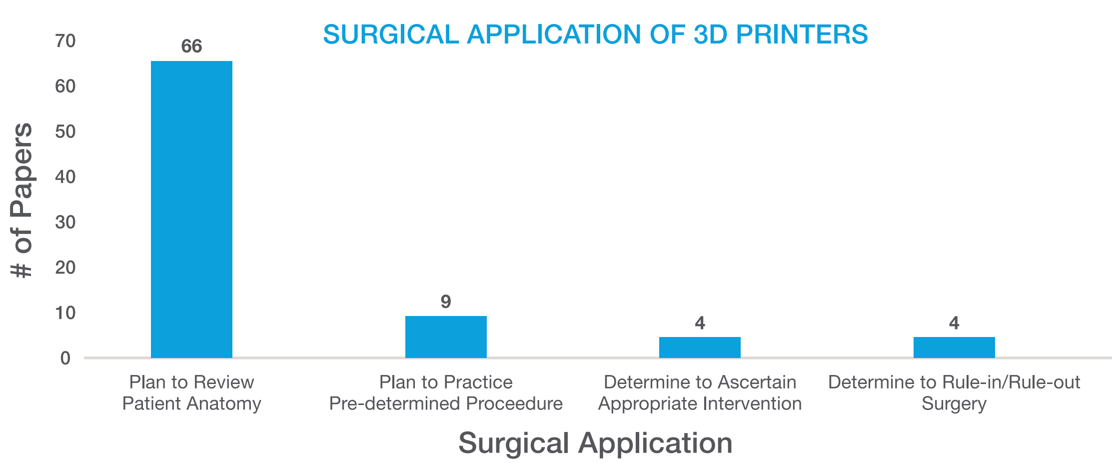

Figure 2: Published research papers by application mode.

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Practice

The second most common application, represented by 10.7% of the papers, involves using 3D models to practice a procedure prior to entering the OR. The number of papers reflects that this application is relatively new and reserved for the most complex patient cases, often when the procedure involves multiple specialties. An additional barrier to this application may be limited access to printers that can create dissectible, flexible models. Many printers are only able to create rigid models that cannot be used for practice.

Determine

Currently, there is far less published research on the use of models to decide on optimal outcomes or rule in/rule out patients from a procedure. These cases represented just 9.5% of the reviewed papers. This may be a reflection of the relative novelty of the application and conservatism among physicians to rely on the models to make critical surgical decisions.

One-half of the decision making applications used 3D printing to investigate the viability of the procedure. The anatomical model is used as a tool to rule-in or rule-out a procedure. The balance discussed the use of the anatomical models to ascertain an appropriate intervention that increases effectiveness and improves outcomes.

When used to ascertain an intervention, the 3D printed models validated a novel, non-traditional

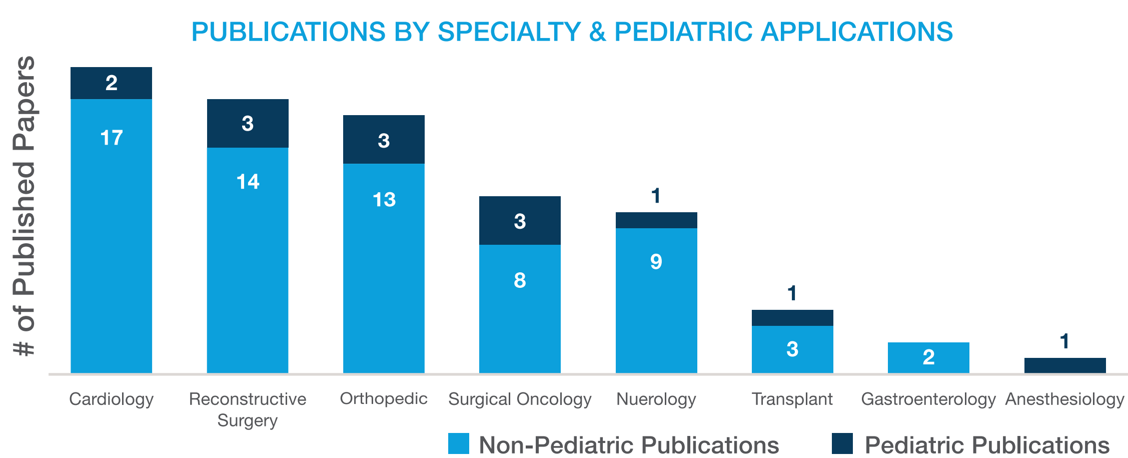

Figure 3: Count of published papers by specialty.

approach, confirmed an intended procedure and aided in procedure selection when the best alternative was unclear. When used to rule-in/rule out procedures, the models demonstrated that surgery was unsuitable and would not produce a desirable outcome in several cases. In others, the procedure was deemed viable.

Interest

Assuming that the volume of published papers is a proxy for the interest level in and potential value of 3D printing, the specialties with high research interest are cardiac surgery, reconstructive surgery, orthopedic surgery, surgical oncology and neurosurgery, listed in order of the number of occurrences (Figure 3). Collectively, these specialties represent 89% of the reviewed papers.

Outcomes

While published outcomes were informative, they were generated in randomized, controlled clinical studies and should only serve as guidance for future evidence generation. The papers reported observed (AMA Level IV criteria) or potential impact rather than definitive outcomes produced under a control (Level I criteria).

3D Printing Economic Outcomes

PROCEDURE	CLINICAL	ECONOMICAL
Annuloplasty	Patient case study showed reduction in mitral regurgitation after surgery (-.04 cm2)	
Stent placement		Patient cast study illustrating that the stent size selected during pre-operative planning was found to be anatomically correct during the operation
Removal of pituitary		16 novice surgeons experienced reduced operation time compared to 2D image planning
Brain Aneurysm		• 10/10 pre-planned microcatheters matched the intra-operative vessel • 2 cases using 3D printed surgical planning showed a 30-minute reduction in operative time
Scoliosis	Blood loss was reduced by~182 ml (n=126)	Operating time was reduced by ~28 minutes (n=126)
Intervertebral disc	Blood loss was reduced by~126 ml (p<0.001) (n=37)	
Cleft palette		Decreased clinical visits (author conclusion, no p-value not provided)

Table 2: Published outcomes.

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Just 8.3% of the published papers cited specific measures that quantify the outcomes (Table 2), either in economic or clinical terms. Additionally, the sample sizes were small, ranging from 1 to 126 patients, with the majority being two or fewer.

The most common clinical measure reported was blood loss. For example, in orthopedics, a reduction in blood loss of 126 ml and 182 ml was reported in two spinal repair procedures. For cardiology, mitral regurgitation was decreased with a change in effective regurgitant orifice of 0.04 cm2.

For economic impact, the most-used measure was decreased OR time. Using a national average of $62/minute[8], the papers revealed savings of $1,550 to $1,860 with an average of $1,695. Perhaps more significant is the increased throughput that reduced OR time yields, but this economic factor was not included as an outcome in any of the papers. Other non-monetized results included correct selection of stents and microcatheters during pre-operative planning,

Economic Analysis

Since the papers included limited economic impact data, Stratasys conducted its own economic analysis. The intent was to investigate 3D printing's potential for a significant impact on profitability across all constituents: hospitals, doctors and payers, with a primary focus on hospitals' financial impact.

The premise for this analysis is that complicated procedures with high volumes (relative to those in the study) represent those where 3D printing may have the largest impact, and therefore, would be the most attractive targets. The logic is that there is potential to increase annual profitability by improving the factors that have measurable impact on total cost. To quantify complexity, data for each procedure was collected for AMA relative value units (RVU), LOS, patient mortality and intraoperative time.

Additional weight was then applied to the procedures for which the published papers cited actual economic outcomes, in terms of the profitability, with and without 3D printing.

Figure 4 graphically presents the results of the economic analysis. The most promising procedures are those with the most significant potential economic impact on hospitals. Generally, the target procedures have RVUs greater than 20, OR times greater than 3 hours, mortality rates greater than 2% and LOS days greater than 3. The procedure volumes range from less than 2,000 to 88,000 per year.

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SPECIALTY	PROCEDURE	COMPLEXITY (RVU)	OR TIME (HOURS)	MORTALITY	LOS (DAYS)
Cardio.	Annuloplasty	Low	Low	High	High
	Coronary Aneurysm	Moderate	High	High	High
	Rep. Aortic Valve	Moderate	Moderate	High	High
	Stent Insertion	Low	Moderate	Moderate	High
	Congenital Heart Defect	Moderate	High	High	High
Gastro.	Splenectomy	Moderate	Moderate	*	High
	Endo. Esophog.	Low	Low	High	Moderate
Neuro.	Rem. Pituitary	Moderate	High	Low	Moderate
	Rep. Aneurysm	High	High	High	High
Orthopedic	Scoliosis	Moderate	High	Low	Low
	Clavicle Fracture	Low	Low	*	Moderate
	Hip Repair	Low	Low	Low	Moderate
	Rep. Interver Disc.	Low	Moderate	Low	Low
	Rev. Hip	Low	Low	Low	Low
	Rep. Leg Fracture	Low	High	Low	Moderate
	Osteotomy	Low	Moderate	*	Moderate
Plastic/Recon.	Rec. Hand	Low	Low	*	Low
	Rec. Facial Bones	Moderate	High	*	Moderate
	Rec. Breast	Moderate	Moderate	*	Moderate
	Mastoidectomy	Moderate	High	*	High
	Rep. Cleft Palete	Low	Low	*	Low
Oncology	Rem. Adrenal Tumor	Moderate	High	*	Moderate
	Rem. Liver Tumor	High	High	Moderate	High
	Rem. Cardiac Lesion	High	High	Low	Moderate
	Rem. Lung Tumor	High	High	Moderate	High
	Rem. Renal Tumor	Moderate	High	*	Moderate
Transplant	Heart Transplant	High	High	High	High
	Liver Transplant	High	High	High	High
	Lung Transplant	High	High	*	High
	Kidney Transplant	High	High	Low	High

Figure 4: Potential economic impact by procedure.
* Data unavailable

Key	*Complexity (RVU)*	*OR Time (hours)*	*Mortality (%)*	*LOS (days)*
Low Potential	<=15	<=1	<=1	<=3
Moderate Potential	16-30	1-3	1-2	4-5
High Potential	>30	>3	>2	>5

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Results

Considering the interest level, evidence and profitability potential, 11 procedures (Table 3), representing six specialties, were identified as prime candidates for 3D printing applications. These were selected for significant merit and then subjected to further analysis.

The procedure selection listed in Table 3 includes three exceptions to the stated guidelines. Transplants did not satisfy the criteria of a large number of published papers. However, transplantation represents the most complex procedures and are accompanied by the longest LOS and OR times. These factors outweighed the published-papers metric. Both brain tumor removal and pediatric congenital defect repair were not specified in the published papers. However, they fall in specialties of interest (cardiac surgery and neurosurgery) and represent complex procedures. The decision to include them was based on observation of 3D printing applications within hospitals that use Stratasys technology.

SPECIALTY	PROCEDURE
Cardiac Surgery/ Interventional Cardiology	Coronary aneurysm (repair)
	Aortic valve (replacement)
	Mitral valve (repair)
	Congenital defect (repair)
Reconstructive Surgery	Facial (reconstruction)
Orthopedic Surgery	Scoliosis (repair)
Surgical Oncology	Liver tumor (remove)
	Lung tumor (remove)
	Brain tumor (remove)
Neurosurgery	Neurovascular aneurysm (repair)
Transplant Surgery	Liver (transplant)

Table 3: Prime candidates for 3D-printed models.

To illustrate components of the decision-making framework and the significance of any improvement that 3D printing could offer, Table 4 presents the results for four high-ranking procedures. The data was compiled from MPFS, HCUP and Truven Analytics.

		DISCHARGE VOLUME (THOUSANDS)	LOS (DAYS)	OR TIME (HOURS)	INPATIENT MORTALITY (%)	COMPLEXITY (RVU)
Valve Replacement	Aortic	88.3	7	2	14	25
	Mitral	13.1	11	1	3	6
Aneurysm Repair	Coronary	<2.0	7	3	14	21
	Cerebral	13.7	10	4.5	6	53

Table 4: Average values for key decision-making factors in valve replacement and aneurysm repair procedures.

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Valve Procedures

Aortic valve replacement is a common, yet complex, procedure with a very high mortality rate and long hospital stays. Mitral valve repair (annuloplasty) is far less complex and has a significantly lower annual volume, but LOS is one of the largest of the selected procedures.

Aneurysm Procedures

Repair of coronary aneurysms shows the potential for significant improvements due to high complexity, LOS, OR time and mortality. These factors overshadowed the relatively low discharge volume. That potential impact is even greater for brain aneurysm repair since it is among the most complex procedures that require more OR time and longer hospital stays.

While Table 3 presents the prime candidates for 3D printing, exclusion from the list is not an indication that 3D-printed anatomical models lack value in clinical or economic terms. This listing is presented for initial guidance to direct attention to the most impactful applications of 3D printing. Additionally, the data represents national averages that will be different from those of an individual provider. The 11 procedures are a starting point from which a hospital can, and should, evaluate 3D printing's impact on a case-by-case or procedure-by-procedure basis within the context of an individual institution's performance measures.

DETAILED ECONOMIC ANALYSIS

As previously noted, the 11 procedures listed in Table 3 warranted further investigation. In light of the published papers' limited evidence of derived value, the research sought to characterize the potential benefits as they relate to improved surgeon effectiveness, reduced complications and decreased readmission rates.

The research consisted of additional literature searches and an analysis of Medicare claims in the contexts of peri- and post-operative complications and procedure costs and profits. For complications, the rate of incidence and the ability of 3D printing to affect the outcome were evaluated. For economic impact, ICD-9 diagnostic procedure codes were profiled and claims analyzed. The analysis concluded with a comparison of factors such as profit and LOS, for procedures with and without complications.

Because the link between financial performance and factors such as mortality and patient satisfaction has not been fully developed (per the previously cited JAMA article7), these factors were excluded.

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Additionally, Stratasys consulted clinical specialists to better understand which complication reductions or clinical improvements would be possible with better planning using a patient-specific 3D printed model. These specialists represent Jacob's Institute and Hasbro Children's Hospital. Other resources for this phase of the investigation included:

- Truven Analytics, © 2013
- MedPAR (Medicare Provider Analysis and Review), © 2014
- SAF (5% Standard Analytic File), © 2014

SPECIALTY	PROCEDURE	COMPLICATION
Cardiac Surgery/ Interventional Cardiology	Aortic valve (replacement)	Paravalvular leak
		Residual aortic regurgitation
		Aortic root rupture
	Mitral valve (repair)	Mitral regurgitation
Orthopedic Surgery	Scoliosis (repair)	Neuro problems
		Fusion failure
Surgical Oncology	Liver tumor (remove)	Pleural effusion
	Lung tumor (remove)	Bronchopleural fistula
		Acute kidney injury
Neurosurgery	Neurovascular aneurysm (repair)	Intraoperative rupture
		Neuro problems
		Stroke
Transplant Surgery	Liver (transplant)	Nonanstomotic biliary stricture
		Incisional hernia

Table 5: Procedures and corresponding complications selected for further analysis.

Readmission Rates

The impact of readmissions is that in many circumstances, the cost is born by the provider, under 90-day global periods. Presuming that surgical planning with 3D printed models improves care quality and reduces complications, financial gain potential exists by reducing readmissions.

90-DAY READMISSION RATES BY HIGH PRIORITY PROCEDURE [1,2]

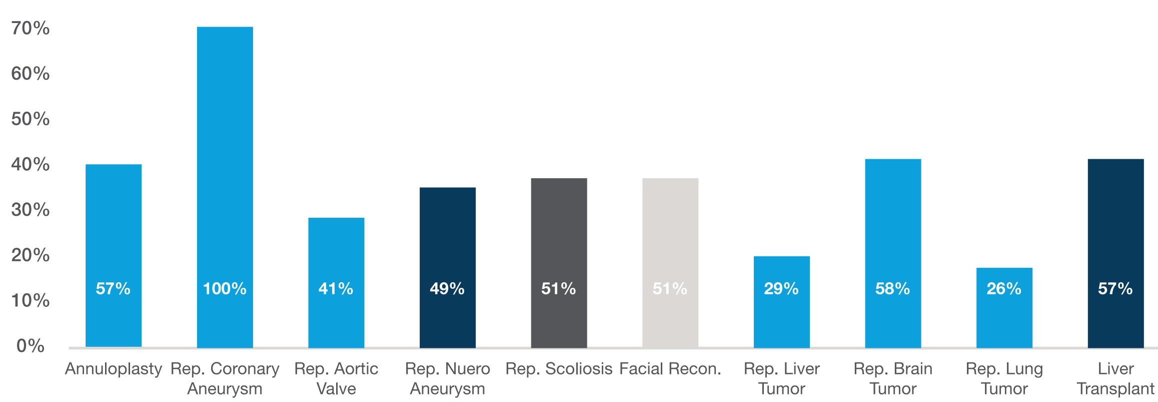

Figure 5: 0-day readmission rates by procedure.

3D Printing for Surgical Planning

IDENTIFICATION OF CANDIDATE PROCEDURES AND RESULTING VALUE

An analysis of 10 of the 11 targeted procedures shows 90-day readmission rates of 26% to 58% for those with sample sizes greater than three (Figure 5). With a 100% readmission rate, coronary aneurysm repair was the highest, but it had only one sample within the dataset.

This early research concluded that there is significant room to improve readmission rates for facial reconstruction, liver tumor removal and lung tumor removal. These procedures had cumulative non-rehabilitation-related readmission rates of 17% to 75% for the top three complications. The remaining procedures are less likely to benefit from surgical planning with 3D printed models because the primary cause for readmission was rehabilitation services.

Complications

The economic impact analysis of complications used three parameters to indicate total relative potential: Medicare discharge days, incidence rate of complications and profit penalty. The intent is to identify the procedures with the greatest cumulative financial impact resulting from surgical complications.

Seven of the eleven targeted procedures had meaningful data from the claims analysis. The four that were omitted include coronary aneurysm repair, congenital heart defect repair, facial reconstruction and lung tumor removal. Each had a lack of claims or limited complications data from which to derive valid results. Clinical partners also noted that 3D printing would be unlikely to affect complication rates for coronary aneurysm and facial reconstruction surgeries.

Dr. Albert Woo, Chief of Pediatric Plastic Surgery at Hasbro Children's Hospital, indicated that it would be difficult to correlate 3D printed models with a reduction in the identified surgical complications for facial reconstruction. However, he did add that demonstrating a statistical decrease in operating time could correlate with fewer complications overall.

Physicians from the Jacob's Institute in Buffalo, New York, commented that coronary aneurysm repair is rarely done percutaneously and that when doing a surgical removal, 3D printed models would be unlikely to have an impact on complications.

The seven procedures with sufficient data had a total of 51 complication candidates identified for consideration. The incidence rate for these complications ranged from 0.5% to 90.0%. However, these incidence rates alone did not determine the priority of the procedures. When combined with discharge rates and negative impact on profits, 14 complications and their associated procedures were selected for additional analysis (Table 5).

From this analysis, the procedures with the greatest potential and best financial return from the use of 3D printed models are mitral valve repair, aortic valve replacement and neuroaneurysm repair.

Mitral Valve Repair

Considering the complication of mitral valve regurgitation, physicians at the Jacob's Institute said, "3D printed models may help identify the optimal surgical approach. There is significant potential for it to reduce mitral valve regurgitation."

According to Medicare data, there is a $25,000 (142%) difference between cases with and without mitral valve regurgitation. This complication also adds one day (9%) to the average LOS.

Aortic Valve Replacement

The impact of aortic valve replacement complications were evaluated for both open-heart and endovascular procedures.

The most significant profit improvements, when comparing procedures with and without complications, were for paravalvular leaks and aortic rupture. On a per-patient basis, eliminating paravalvular leaks would improve hospital profits by $23,000 with an open-heart procedure and $17,000 as an endovascular procedure. An aortic rupture that results from an endovascular procedure decreases hospital profits by $67,000. These complications increase the LOS by 0.5 to 5.5 days.

Based on first-hand experience working with 3D models, physicians at the Jacob's Institute believe these models have a significant potential for reduction of these complications, especially for the endovascular approach.

Neuroaneurysm Repair

The selected complications for neuroaneurysm repair — neurological problems, stroke and intraoperative rupture — show hospital profit improvements of $5,300 to $24,300 and LOS decreases of 1.3 to 7.2 days when complications are avoided.

They noted that to reduce intraoperative rupture risk, 3D printing would be especially valuable in complex cases.

Strokes had the largest impact on profit and LOS. Avoiding this complication would improve profits by $24,300 and decrease LOS by six days (74%) for each patient.

Conclusion

Performing claims analysis based on complications provides a measurable, quantifiable approach to gauge 3D printing's potential economic impact. Evaluated in this financial context, cardiac surgery and neurosurgery become the candidates on which to focus efforts, followed by surgical oncology and transplant surgery.

Lacking Level I evidence, providers will need to rely on an evaluation of key economic metrics such as those cited in this document. They provide the framework for determining the value of 3D printing as a surgical tool. Variables such as complications, readmission rates, length of stay and OR time are measurable and directly related to profitability, providing a decision-making foundation.

However, the clinical benefit of improving surgical success, which influences profitability, efficiency, outcomes and patient satisfaction, is the true advantage of 3D printing. In this context, procedures such as those for Violet Pietrok, Mia Gonzalez, Michael Slag, Jocelynn Taylor and Linda Green become viable opportunities to capitalize on 3D printing's ability to communicate patient-specific anatomy when preparing for complex surgical procedures. In this mode, any complex procedure, even those not described in the published literature, becomes a candidate.

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