The Clinical and Economic Promise of 3D Printing for Surgical Planning

MAKING THE CASE THROUGH QUANTITATIVE CLINICAL EVIDENCE

Stratasys engaged Quorum Consulting, experts in health economics and outcomes research, to conduct a comprehensive analysis of the clinical and economic evidence on 3D printing for surgical planning. This white paper, authored by Quorum Consulting, summarizes the result of that analysis.

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The modern emphasis on evidence-based medicine centers on three core tenets:

- Best available research findings
- Clinical expertise
- Patient value

Incorporating cutting-edge technology alongside these principles – often delicately balancing material innovation against scientific rigor, state-of-the-art professional training and experience, and attempts to provide the best care while respecting patient perspectives – is a challenge. 3D printing, however, aligns with the first two tenets, and when appropriately employed, may inform and indirectly influence the third.[1]

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As 3D printing continues to become more widely used in clinical domains, there are many medical use pathways:

- Printing of anatomical objects for medical education and training
- Conducting preclinical verification and validation testing on recreations of human pathology
- Manufacturing custom implantables, prosthetics and surgical instruments
- 3D printing of case-specific models for surgical planning.[2]

This paper focuses on the third pathway, briefly outlining the recent history of 3D printing for surgical planning:

- Indication-specific utilization and evidence-based effectiveness data supporting this technology
- Prospective broad healthcare cost implications for primary and secondary stakeholders

Despite the relative infancy of 3D printing in surgical planning, the technology's potential benefits warrant wider consideration by healthcare providers and other parties with interests in value- and outcome-based care.

BACKGROUND ON 3D PRINTING FOR SURGICAL PLANNING

Surgical planning encompasses the full scope of options for envisioning techniques and anatomies involved in a surgical intervention.[3] Previously, procedural planning was mainly performed using two-dimensional models, often based on computed tomography (CT) or magnetic resonance imaging (MRI) data, with later advances allowing for three-dimensional renderings

Figure 1. Search methodology for peer-reviewed papers on 3D printed models for surgical planning.

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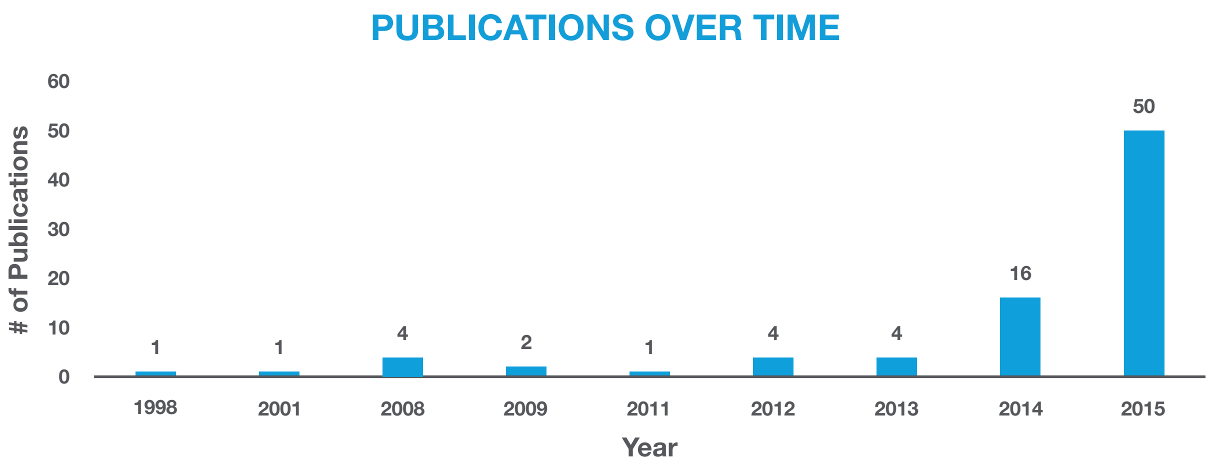

Figure 2. 3D printing for surgical planning peer-reviewed papers by publication year, 1998-2015. Source: Quorum systematic literature review.

displayed on standard 2D screens. While these sources provide some information useful for pre-operative visualization, they are limited in their ability to depict all facets of a procedure, including prospective complicating factors, and cannot offer surgeons tactile interaction with internal structures. [4]

In contrast, 3D printing, using imaging technology to generate a 3D solid object from a digital file, can be used to create highly detailed, patient-specific models for surgical planning. With 3D printed models, surgical planning permits engagement with fully realized models capable of displaying complex articulation. The tactile, physical nature of 3D printed models enables clinicians to conduct thorough preoperative preparation, manipulate accurate relational representations of case anatomies, and identify unusual physiologies and comorbidities whose early discovery can improve surgical efficiency and effectiveness.[5] In addition, with the demand for more accurate custom models and the advent of more sophisticated printers and rendering software, 3D printing offers differentiated, anatomically precise colors and varied textures within a single model, closely approximating individual patients and surgical cases.[6]

In the United States and internationally, leading teaching hospitals and academic medical centers such as Boston Children's Hospital, Cleveland Clinic, Henry Ford Hospital and the Mayo Clinic are employing state-of-the-art 3D printed models to augment surgical planning. Centers are deploying innovative software and protocols, coupled with professional 3D printers, to offer high-quality personalized patient care. Consensus perception of 3D printed models at these and other facilities is overwhelmingly positive, with patients and clinicians responding that they are encouraged by the observed and projected value.

Across a systematic search of peer-reviewed literature, 3D printing for surgical planning has shown expanding utility for several use cases and an accompanying increase in peer-reviewed publications (Figures 1 and 2).[7] In this review, there were more publications in 2015 than all prior years combined. 3D printing was used in surgical planning applications in a wide range of specialties including cardiothoracic, orthopedic, neurological, reconstructive and transplant surgeries, as well as gastroenterology and surgical oncology. When examining these use cases, five general benefits emerge in association with 3D printing for surgical planning:[7]

Patient communication

Over a half dozen publications note that patient understanding and satisfaction is increased by seeing and interacting with models of their anatomy. Anecdotally, clinicians report that increased patient understanding aids in informed-consent discussions and facilitates improved patient cooperation in the procedures.

Anatomic familiarity

Clinicians reported in over 60 cases that 3D printed models promoted increased familiarity and facility with unique anatomies. These models afforded efficient review of individual patient cases during surgical planning and may contribute to reducing operating time costs due to unexpected surgical complexity.

Procedure practice

3D printed models present an opportunity for clinicians to refine surgical techniques and supplementary procedures with precision and realism surpassing that of using animal models or cadavers. Nine published cases were found where 3D models were used to practice a predetermined surgical procedure during planning phases.

Procedure selection

In four published cases covering surgical planning for aortic valve replacement, heart transplant, lung transplant and removal of an adrenal tumor, access to accurate 3D models was noted as valuable for determining the appropriate intervention strategy.

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Patient selection / rule-out

Clinicians noted four published cases involving surgical planning for cardiac lesions, cardiac surgery, liver tumor removal and liver transplant applications, where 3D models were employed in assessing surgical feasibility, aiding decisions to proceed with or rule out planned operations.

While many companies market 3D printers positioned for medical and nonclinical use, 30 peer-reviewed papers outlining 3D printed models for surgical planning identify only 10 individual 3D printer manufacturers. As seen in Figure 3, only four manufacturers were referenced in more than one paper. The most frequently identified 3D printer manufacturer was Stratasys®, which was cited in half of these studies. (This includes units developed by MakerBot Industries, acquired by Stratasys in 2013.)

PUBLICATION SHARE BY PRINTER MANUFACTURER

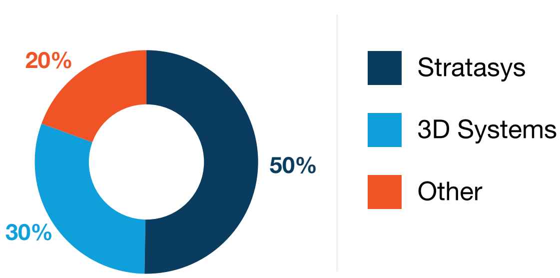

Figure 3. Publication share, by manufacturer, among peer-reviewed literature citing a single 3D printer manufacturer (n=30) Source: Quorum systematic literature review.

INDICATION-SPECIFIC UTILIZATION AND EVIDENCE-BASED EFFECTIVENESS DATA / RESULTS

The literature review concluded that similar to other emerging medical technologies, quantitative clinical evidence is still accumulating in support of 3D printing for surgical planning. However, data from various smaller studies, case reports and expert anecdotes is available. Below, we summarize some of this evidence and its implications for three therapeutic areas of interest, selected based on their broad adoption of 3D printing technology and potential for impacting patient outcomes.

Cardiothoracic surgery

3D printed models have been used in multiple cardiothoracic indications to improve surgical planning efficiency and operative outcomes. As noted in a May 2016 review published by radiologists and surgeons affiliated with Brigham and Women's Hospital and the University of Ottawa, 3D printed models are well-suited for diverse cardiothoracic procedures and can foster productive collaborations across medical disciplines, to the benefit of patients.[8] In other outcome studies, cardiovascular surgeons report increased patient safety and clinician confidence when they practice and plan routine and relatively novel procedures on 3D printed models, an important factor given the impact of stress and anxiety on patients undergoing surgeries.[9]

In addition to treating adult cardiovascular patients, several reports reflect the advantages of planning with 3D printed models to preoperatively investigate complex therapeutic options for pediatric cases, whose patients often have attendant fine vasculatures and rare congenital defects.[10, 11] Proof of concept publications also indicate that 3D printed models can positively impact planning of reoperation cases. In a 2008 report, Sodian and colleagues noted that for a patient with coronary artery bypass grafting five years prior, a 3D printed model aided aortic valve replacement treatment planning and was also referenced for intraoperative orientation, suggesting potential multi-situational applications.[12]

Neurosurgery

The complexity and risks associated with neurosurgery presents an opportunity for clinicians to use 3D printed models to optimize surgical planning. In light of the delicacy of these operations, clinicians have found the use of custom, patient-specific 3D models "invaluable" in preoperative planning.[13] The high degree of accuracy of current 3D printers allows extremely detailed modeling, with recent publications outlining successful printing of surgical planning models of aneurysms as small as 41 mm^3.[14]

3D printed models have significant adoption potential among neurosurgeons, with several recent reviews and expert opinion articles expressing positive sentiments regarding the technology. In June 2016, Ploch et al. published a case report including results of a multicenter survey distributed among neurosurgery staff at Stanford University, King's College Hospital London and Oxford University Hospitals. Assessing a patient-specific 3D printed brain model, 85% and 95% of survey responders perceived these models as "very useful" for patient illustration and preoperative planning, respectively.[15]

Reconstructive surgeries

As one of the initial specialties of 3D modeling, reconstructive surgery has one of the largest and oldest evidence bases. As early as the 1990s, clinical teams reported discrete advantages of 3D printed models. D'Urso and colleagues (1999) used 3D models to educate their patients and plan complex craniomaxillofacial surgeries in a prospective trial (N=45). In a comparative assessment to standard 2D imaging, clinicians reported that 3D models were associated with improved operative planning (82.21% vs. 44.09%, $p < 0.01$) and diagnosis (95.23% vs. 65.63%, $p < 0.01$), as well as reducing mean operating time by 17.63% and leading to statistically significant less measurement error (7.91% vs. 44.14%, $p < 0.05$). Patients also judged 3D models to be 25% more beneficial in facilitating informed consent.[16]

Subsequent studies have reinforced earlier findings, while also revealing some aspects in which 3D printed models may contribute to comparatively superior treatment. For example, a group of expert spinal surgeons (Izatt et al., 2007) used CT data-based 3D printed models for surgical planning in 26 consecutive patients with complex spinal pathologies[17] In 65% of cases studied, surgeons stated that anatomical details relevant for surgical planning were better visualized with 3D printed models than with 2D models. Additionally, for 11% of evaluated cases, certain anatomical details were only observable using a 3D printed model. Access to 3D models impacted the choice of reconstructive osteosynthetic material used in 52% of cases and led to revised implantation site selection in 74% of cases. Surgeons reported that use of 3D printed models decreased tumor operation time by 8% and deformity reconstruction operation time by 22%.[17]

Overall, 3D printed models have broad utility for planning reconstructive surgeries, particularly in cases where they can inform modified diagnostic approaches and improve efficiency during complex procedures. Continued proliferation of 3D models has the potential to broadly improve confidence and quality of care within this specialty.

Ongoing research, including collaborative work at Cleveland Clinic , and a hospital-wide pilot efficacy study at Erlanger Health System, will continue to add to this evidence base and provide further confirmation of the benefits of 3D printed models for surgical planning in these and other indications.[18] Proposed large clinical studies, such as one being organized by several leading pediatric hospitals intending to demonstrate the benefit in treating congenital defects, are also attempting to further demonstrate the positive impact of 3D printed models on supporting ideal care and patient outcomes. These initiatives have already captured the support of leading clinicians who see the merits in the technology and are advocates for standardized use and third-party payer coverage of 3D printed models for planning complex surgical procedures.[19]

PHARMACOECONOMICS OF 3D PRINTING FOR SURGICAL PLANNING

In addition to the literature search, public and proprietary repositories were used to collect healthcare cost and resource data for 28 surgical specialties identified in the published literature of 3D printing for surgical planning. Sources include the Healthcare Cost and Utilization Project (HCUP) database, national Physician-Supplier Procedure Summary (PSPS) files, and Medicare Provider Analysis and Review (MedPAR) datasets.[7] Aligning with studies demonstrating 3D printing for surgical planning as a clinically effective tool, financial data also resonates its influence on direct profitability factors such as procedure cost and reimbursement, as well as patient outcome-driven cost components. For providers concerned with margins of profitability, particularly among complex procedures, our analysis shows several pressure points where integrating 3D printed models could offer rapid impact.

Figure 4 shows relative value units (RVU), a comparative measure of clinicians' work and expended effort for various services, and per-procedure operating times for six specialty surgeries for which published evidence, fee data, and detailed procedure characteristics are available. RVUs were derived from the Medicare physician fee schedule. The analysis shows that relative to average facility throughput, several procedures including annuloplasty, facial reconstruction, repair of brain and coronary aneurysms, and congenital heart defects can benefit from the improved efficiency offered by incorporating 3D printed models into standard surgical workflow.

Anecdotally, comprehensive utilization of 3D printed models for surgical planning leads to significant time savings without negatively affecting quality of care. In studies such as Liu et al. (2014), which contrasted standard surgical management against 15 cases using surgical planning 3D models, researchers calculated that optimized surgical plans based on 3D models decrease operating times by 20% or more compared with conventional methodologies for mandibular defect repair procedures.[20] Reflected across an entire institution or healthcare system,

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PERFORMANCE METRICS BY PROCEDURE (LINEAR TRENDLINE)

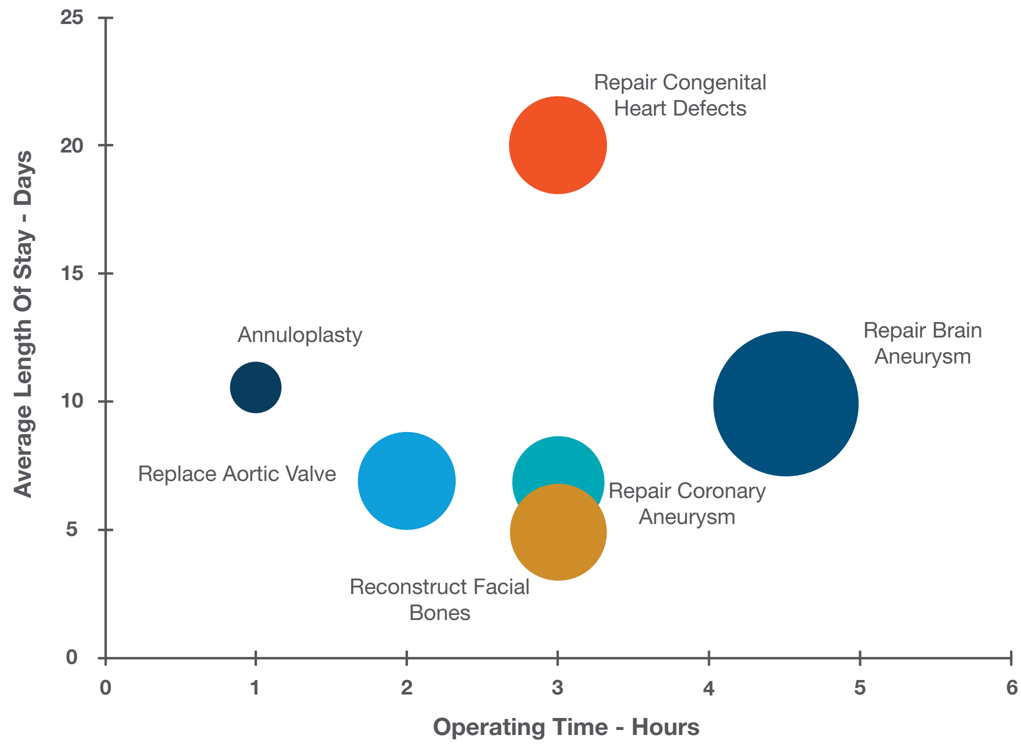

Figure 4. Multivariate analysis of facility throughput, based on work RVUs, for selected procedures with published reports using 3D printed models for surgical planning. Trendline represents average length of stay and operating time across 29 evaluated procedures. Source: 2014 AMA CPT survey and 2013 Healthcare Cost and Utilization Project data.

these reduced operating times would translate to substantial cost savings and decreased capital resource use, while also enabling additional throughput. This dual benefit is a valuable financial incentive for incorporating 3D printed models into surgical workflow. For instance, at a nationwide average operating room cost of $62 per minute, 3D printed models could lead to savings of $2,232 or more per procedure for facial bone reconstruction surgeries (based on a 2015 American Medical Association Current Procedural Terminology survey list operating time of 3 hours).[20, 21]

In a secondary analysis, these specialty procedures plotted in Figure 4 were examined for their corresponding adverse procedure outcomes (inpatient stays and patient mortality

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ADVERSE PATIENT OUTCOMES BY PROCEDURE (LINEAR TREADLINE)

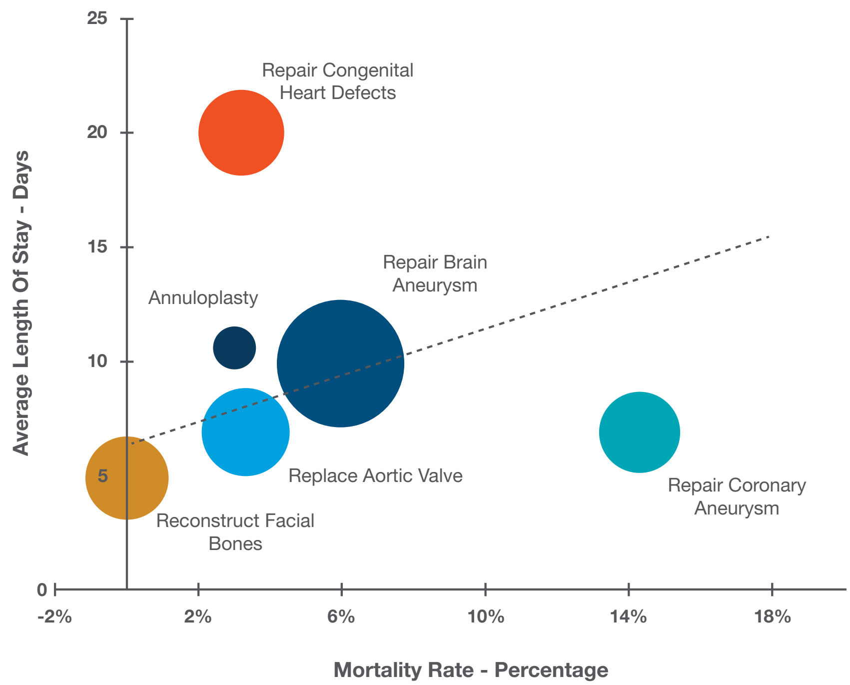

Figure 5. Multivariate analysis of adverse treatment outcomes for selected procedures with published reports using 3D printed models for surgical planning. Bubble size represents proportional work RVUs for each procedure. Trendline represents best-fit line across 28 evaluated procedures cited in published literature of 3D printing. Source: 2013 Healthcare Cost and Utilization Project data.

rates). Two of the six identified procedures (annuloplasty and congenital heart defect repair) have associated inpatient stays significantly exceeding the expected values based on all quantified procedures, while one procedure, coronary aneurysm surgery, had a high mortality rate relative to procedures with similar inpatient stay lengths (Figure 5). Notably, cardiovascular and neurological surgeries also have relatively high malpractice RVUs, indicative of perceived procedural risk and corresponding high reimbursement rates. As a result, these and other similarly positioned procedures stand to reap the largest profitability gains from efficiency increases associated with 3D printed models (see sidebar).

Because 3D printed models enable robust surgical planning and strategic assessment, providers may also view their use in terms of adverse patient outcomes including mortality and extended hospital stays. Not only could 3D models reduce overall adverse patient outcome rates, using models for nontraditional or complex cases is likely to minimize variability among patient subsets and individual cases. Easing variance will lead to improved standardized care and allows for more reliable financial forecasting, adding invaluable stability for healthcare administrators, particularly when considering procedures that are characteristically high-risk and require longer inpatient times (Figure 5).

CONCLUSION

In a healthcare environment continuing to shift towards value- and outcome-contingent systems that penalize providers for inefficiencies and suboptimal outcomes in rendered care, 3D printed models for surgical planning – with their ability to facilitate procedural efficiency, improve treatment outcomes, and reduce downstream re-intervention costs – offer high potential value. Patients, clinicians and hospitals all have a vested interest in quality, affordable patient care and service, and surgical planning with 3D models appeals to each of these stakeholders. Accordingly, results and trends from published literature and healthcare data support the effectiveness of 3D printing for surgical planning. As shown for several surgical procedures, clinicians with access to 3D printed models are able to provide better, more efficient care likely to improve patient outcomes and reduce the need for additional surgical interventions. Procedures that would most justify the financial and resource cost in creating 3D printed patient models are those with long operating times, high RVUs, greater

A Brief RVU Primer:

Relative Value Units (RVUs) are used by Medicare to determine reimbursement rates for a given service:

- For each service, Medicare determines the cost value of three primary components – physician's work, practice expenses and malpractice insurance.
- These three components are then adjusted based on differences in living and business costs nationwide, using a factor called the Geographic Practice Cost Index (GPCI).
- The adjusted values are multiplied by an annual conversion factor, established by the U.S. Congress, and totaled to calculate final reimbursement rates.

risk and uncertainty, and risk of complications. Concurrently, this quality care is also potentially less costly and more profitable to providers.

Amidst the growing commercial market for 3D printers and related technologies, there are some key differentiators when evaluating utility for surgical planning. As reflected in clinician surveys, the most effective 3D models should capably depict complex, fine anatomy with high fidelity to actual patient physiologies. This degree of fidelity crosses several characteristics:

- Accurate depiction of a variety of colors
- Simulation of multiple textures
- Manipulability, including the ability to be dissected or probed with surgical instruments.[22]

Given these real-world requirements, next-generation multi-material and multi-color 3D printers likely represent the best option for facilities and clinicians.

Viewed objectively, additional data addressing the quantitative impact of 3D printed models is needed. Preferably, this data will be generated from well-designed, patient outcome-oriented studies. However, in the interim, the tide of evidence favors 3D printed models for surgical planning, particularly for leading-edge clinicians and healthcare administrators who are able to recognize its value.

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ABOUT QUORUM CONSULTING

The mission of Quorum Consulting is to help medical innovators improve people's lives by enabling payment for their products and services. Quorum's capabilities are in payer and provider health economics, pricing, and reimbursement. For nearly 20 years the firm has provided expertise in coverage and reimbursement, health economics and outcomes research, provider impact analyses, and strategic product planning. In addition to commercial projects, firm members regularly present and publish novel healthcare and pharmacoeconomics research for national and international professional meetings and peer-reviewed journals.

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