Unlocking the value of 3D printed medical devices in hospitals and universities

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ABSTRACT

3D printing in Health Care Facilities (HCFs) has evolved from a set of experimental techniques and situational engineering applications employed at leading academic institutions to a relatively mature but expanding field with well-defined workflows and recognition at major medical societies. This project introduces the term 'Final Anatomic Representation' that refers to the final surface mesh files used in patient care. It also introduces the term 'Patient Specific Realization' to characterize how the Final Anatomic Representation is used, for example the creation of a 3D PDF, virtual reality display with shared experiences, augmented reality to include procedure simulation, or 3D printed parts. This project focuses on 3D printing in HCFs, and it includes a wide scope of use cases with literature support. Many intended uses have progressed to guideline support for appropriateness; these are organized by patient presentation or clinical scenario. One benefit of using clinical scenarios is that direct feedback can be translated from the engineering of 3D printed parts to the data generation from those parts used in the medical value equation. Continuing with the direct feedback, established value then supports guidelines for patient care such as clinical appropriateness, and those guidelines can then be applied to realize that value added for future patients who present with the same clinical scenarios.

Keywords: 3D Printing, Radiology, Medical Imaging, Personalized Medicine, Advanced Visualization, Medical Devices, Additive Manufacturing, Rapid Prototyping

1. INTRODUCTION

The potential of 3D printing in medicine was apparent since its inception as a commercially available technology. Publication of this potential was realized no more than 4 years after the 1986 patent [1]. Not long thereafter, patient-specific parts were 3D printed by industry and sold to hospitals and providers. The workflow was established and has been polished by industry and provider stakeholders for decades.

After several key 3D printing technology patents expired, the components necessary for the construction of desktop printers became widely available, more affordable, and therefore more accessible. This was followed by a proliferation of print techniques and 3D printer types. In parallel, medical applications of new advanced 3D printing and visualization techniques were developed, enabling complex preoperative planning for pioneering medical procedures that required high-complexity anatomic visualizations [2]. Many of these procedures would have been difficult or otherwise not possible without 3D printed parts. With increasing clinical applications and more accessible technologies, providers and engineers working in Health Care Facilities (HCFs) began 3D printing to complement 3D visualization using Digital Imaging and Communications in Medicine (DICOM) data alone. Because essentially all patient-specific 3D printed parts are based on medical imaging, radiology became an early home subspeciality for 3D printing in HCFs, although providers in many subspecialties operate 3D printing clinical services.

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As 3D printing firmly entered the armamentarium of advanced medical imaging tools at apex academic centers, the demand for structured educational programs grew and began to be addressed at the 2013 annual meeting of the Radiological Society of North America (RSNA). This expanded the audience and their understanding of the collective technologies [3]. Multiple medical societies have since acknowledged the use of 3D printing in their operations, with some forming subgroups such as the RSNA 3D Printing Special Interest Group. This group published the first set of evidence-based appropriateness guidelines in 2018 [4], rigorously surveying the existing literature at the time to reach expert consensus. Multiple additional guidelines have been published [5-8] by the RSNA group. With these recommendations secured, category III Current Procedural Terminology (CPT) went live in the United States in 2019. 3D printing in a HCF was thus established as a United States medical service, enabling further data collection in support of the formal evaluation of the value of this technology and the associated reimbursement patterns [9].

This project analyzes the value of 3D printing in medicine, focused on parts printed in a HCF. It benchmarks the current (Early 2024) status from the perspective of the provider and hospital-based engineer. Medical 3D printing is inherently 'circular', beginning with patients with a specific, albeit complex, medical problem and ending with established guidelines for the highest value medical care for the next patient who presents with that same medical problem (Figure).

2. UNLOCKING 3D PRINTING VALUE

Scope of 3D printed medical devices under consideration

3D printing enables a vast range of medical devices. Examples include devices used at the point of care outside of the body such as bone cement molds [10]; devices that indirectly interact with patients such as ventilator components [11]; and devices that directly interact with a patient's external surface such as helmet orthoses [12]. Other novel, diverse uses of medical 3D printing include wheelchair cushions [13], adapters for medical sample acquisition [14], external bone fixation devices [15], CPAP masks for newborns [16], precise radiation therapy administration apparatus [17], customized facemasks for burn victims [18], and craniectomy defect helmets [19].

This analysis focuses on patient-specific 3D printing in HCFs for specific patient groups; very often this relates to medical devices that serve as surgical or procedural guides. Intraoperatively, these devices have direct contact with exposed tissues – examples include osteotomy devices [20]; devices that are directly implanted, including hip acetabulum prosthesis implants [21, 22] and chest wall reconstruction implants [23]. Because there are specific patient presentations (e.g., pectus excavatum), the value can be tracked from the time the patient presents and undergoes imaging to the determination of 3D printing appropriateness (Figure). Patient-specific 3D printing also continues to prove valuable for planning novel procedures [24] and refining challenging ones [25, 26].

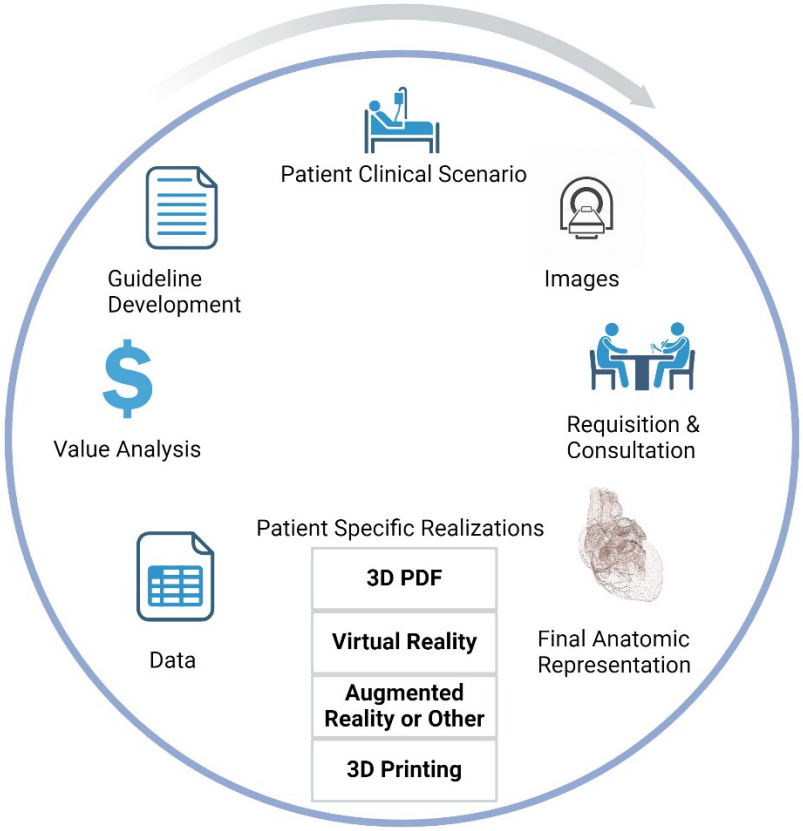

Figure. Unlocking the value of medical 3D printing, emphasizing the circular feedback as data accumulated for a specific clinical scenario can drive guidelines to positively impact future patients. As drawn, the myriad of Patient Specific Realizations (at 6 o'clock) of the Final Anatomic Representation are separated into 4 groups. 3D Printing is unique among these 4 groups because it is the only Patient Specific Realization that ends with a patient specific physical part, and it is the only Patient Specific Realization that is clearly and generally defined as a medical procedure in the United States. The format follows in a clockwise direction, beginning at 12 o'clock with the patient presentation.

Additional 3D printed parts add value, but they fall outside the scope of this analysis because they are educational for patients [27], medical trainees [28, 29], or both. For example, it is difficult to apply benchmarks such as operative time [9] when an anatomic model is printed for educational purposes.

Practical considerations of medical 3D printing

One integrative way of thinking about medical 3D printing and its related value is summarized in the Figure that is intended to be read clockwise, beginning, and ending with the patient. Medical imaging includes segmentation from volumetric CT or MR images that can be fused or replaced with other digital data such as surface scanning [16]. DICOM data is recast as surface mesh files, and these final files are termed the 'Final Anatomic Representation'. There are many 'Patient Specific Realizations'. For illustrative purposes, these are divided into 4 parts.

The Final Anatomic Representation can be seamlessly visualized on 2D monitors via a format such as 3D PDF, placed into virtual or augmented reality setups, used for advanced mathematical modeling such as computational fluid analysis, or it can be 3D printed; this is often the most expensive realization but is often the most valuable. Because the 3D printing literature is more comprehensive than the other realizations, it may appear that this is the most appropriate Patient Specific Realization in most scenarios. However, there are a growing number of clinical applications for which surface mesh files are critical for procedural planning, but alternate analyses such as cardiovascular fluid dynamics constitute the most important output.

Regardless of the intended use for a 3D printed device, it is imperative to maintain an appropriately staffed and compliant 3D printing laboratory with a well-defined quality control system and a laboratory data management system capable of patient anonymization, safe storage of patient data, and packaging the data for further forwarding for preservation for medicolegal purposes. Such a laboratory is also expected to host imaging software appropriate to the task of advanced segmentation, with commercial and open-source AI-assisted solutions currently available. All segmentation must be reviewed by an imaging physician familiar with the anatomy in question. There should be a physician-guided process for referral to the 3D printing clinical service line, and a triage algorithm that considers existing appropriateness guidelines. Sufficient manufacturing expertise and oversight should exist locally with competence to ensure that all devices coming in direct contact with exposed patient tissues are 3D printed using biocompatible materials and should be sterilizable to minimize or eliminate intraoperative infection risks [30]. Additionally, all devices should be subject to printing technology-specific optimizations to ensure that the expected structural and functional parameters are successfully achieved [31].

Towards establishing conventional medical value

Widespread acceptance and reimbursement for medical 3D printing requires well-defined appropriateness criteria. Systematic reviews [9, 32-34] have established overall cost savings, decreased surgical times, decreased blood loss, and overall utility and effectiveness. To further expand the evidence base, the American College of Radiology and the Radiological Society of North America have established a 3D Printing Registry [35]. Registry data includes information on clinical indications, intended use of 3D printed parts, images used in model creation, effort of the providers and engineers for medical 3D printing in a HCF, and the clinical impact.

A major challenge in establishing clinical value is the absence of precedent or control groups into which patients can be randomized. Several key procedures are not possible in their modern form without 3D printed parts. Thus, it is not possible to compare '3D Printing' versus 'Control' groups in a randomized trial to show improved surgical time, blood loss (short term metrics) or quality of life, disease-free survival, and mortality (long term metrics). For example, consider a 3D printed patient-specific cutting guide for free fibular flap orthognathic reconstruction or anatomic models for planning congenital heart surgery. The value is indisputable, even though it is impossible to randomize since it would not be ethical to establish a control group where 3D printing was withheld. Despite these limitations and challenges, there remains a general optimism regarding the formal recognition of the substantial value of 3D printing through reimbursement of 3D printing as a medical procedure.

Unexpected value of medical 3D printing

In addition to the direct, conventional value of 3D printing in medicine through the collection of evidence, this technology holds enormous potential that is only now being realized. The pandemic and resultant global medical supply chain disruption wrought havoc on medical operations internationally, endangering lives and resulting in deaths due to shortage of critical equipment. An unexpected value of medical 3D printing arose from enthusiasts and professionals alike banding together to rapidly develop numerous solutions, both for personal protective equipment, and for the development of last-ditch medical device replacements [36]. These efforts included a wide spectrum of devices, from laryngoscopes to ventilator components and entire ventilators designed *de novo*. Although in many cases the parts were not needed, the pandemic brought out the versatility of this decentralized manufacturing technology and demonstrated the latent capabilities that were available.

The second potential value of medical 3D printing rests not in direct device generation or 3D printing itself, but rather in the impact the field has had on medical image segmentation, and by transfer, on advanced visualization. With the relatively recent development of AI-assisted image segmentation, the 3D printing community has been eager to adopt this technology. As virtual reality and augmented reality have become more accessible, providers and engineers focused on 3D printing have worked to adopt these technologies while maintaining the necessary degree of caution regarding image accuracy and quality [37-38]. The goal is to find synergies between the many uses for the surface mesh Final Anatomic

Representation, and to arrive at the highest value and most cost-effective Patient Specific Realization for each clinical scenario.

3. CONCLUSIONS

3D printing in Health Care Facilities (HCFs) continues to advance and to demonstrate value. The maturation includes well-defined quality control procedures, appropriate guidelines, and an ecosystem of hardware, software, personnel, and professional society support. The field is responsible for the development and prototyping of a vast array of applications and devices, sometimes enabling interventions that were not possible previously. The wide range of benefits are demonstrated through case studies, reviews, meta-analyses, and a patient registry.

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