

EDITORIAL

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Stratifying complexity among the widespread use of 3D printing in United States health care facilities

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Introduction

Reimbursement for 3D printing in a Health Care Facility (HCF) is challenging. For a large majority of HCF 3D printing programs, operating expenses are greater than collections. This editorial reviews current knowledge related to the technical component to HCF 3D printing reimbursement, and it provides the rationale for new technology Ambulatory Payment Classification (APC) codes that are intended to fairly reimburse the 3D printing of parts as part of the clinical service. After reporting widespread use of 3D printing in United States Health Care Facilities, three patient levels (Basic, Intermediate, and Complex) of technical complexity are proposed, with the intent on coding based on stepped up technical collections. These proposed complexity levels are benchmarked for a set of expected parameters and for a set of established appropriate clinical scenarios for medical 3D printing.

What is the current knowledge on the topic?

3D printing is commonly used for patient care [1]. For example, 3D printing is central to the care for 10 s of thousands of patients in the United States. Moreover, there are 100 s of thousands of patients for whom the DICOM (.DCM) radiology data must be converted to a surface mesh file format for patient care. This includes nearly all (or all) patients who undergo robotic surgery, all patients who undergo virtual surgery and many additional applications such as analyses of blood flow. The one or more final surface mesh files are termed the Final Anatomic Representation, for which there are many Patient Specific Realizations, one of which is 3D Printing [2].

All patients who need surface mesh files and the subsequent 3D printed parts for care have very challenging and expensive medical problems [3]. Another unique feature is that when a patient is considered for 3D printing, a very high-cost procedure is being either considered or planned. Nearly all, or all major HCFs in the United States purchase patient-specific 3D printed parts from industry. To do so, the patients' .DCM data is exported or uploaded to industry. This is why, to date, there is no published, peer-review data to demonstrate widespread use. This explains why there is an important gap in billing code applications. This publication closes that gap.

Instead of shipping patient data outside the HCF and paying for parts to be delivered by a mail courier, more and more providers realize that 3D printing can remain with the HCF and its digital firewalls. The most important barrier to expanding the use of 3D printing in HCFs is reimbursement. The practice was defined as a medical

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procedure in the United States with the launch of the four category III Current Procedure Technology (CPT®) codes in 2019 [4]. These codes were renewed for an additional 5 years at the February 2024 American Medical Association CPT® meeting. The category III codes are to be used whenever the service is delivered. However, the practical reality over the past 5 years is that providers and hospitals have not championed collections due to inertia. Generally, there are two components to billing and collections: professional and technical. This Editorial focuses on the technical work and recapturing those costs. This requires expertise and coordination between hospitals and payors who work with engineers and HCF finance administrators. Thus, for all but a few hospitals who have both experts and infrastructure to negotiate collections with payors, the amount of money that is reimbursed to pay for the technical aspect of 3D printing falls very short when compared to the expenses to use 3D printing in patient care.

In addition to CPT codes, there is an additional payment infrastructure that is part of the Medicare Hospital Outpatient Prospective Payment System (HOPPS). This reimbursement strategy is called Ambulatory Payment Classification (APC). As the name indicates, payments are for outpatients. A subset of these codes are earmarked to compensate those technical costs that are inherent in implementing new technologies. In general, a classification refers to a group of procedures that have similar traits and use similar resources. The reimbursement depends on the geometric mean of the 'cost' for the group of procedures within a specific classification. To CMS, 'cost' is not the tallied up \$USD that the HCF pays to perform the service [5]. Instead, CMS calculates cost by multiplying two numbers. The first is the hospital charge master charges that are recorded on claims; the second is a Cost to Charge Ratio (CCR) that is based on Medicare hospital cost reports.

What knowledge gap does this editorial address?

Knowledge gap #1: widespread use of 3D printing in US healthcare. To demonstrate widespread use, a survey was conducted by the American College of Radiology. The survey was designed so that a leader of a 3D printing service in a HCF can complete it in roughly 3 min. After widespread use, the secondary goal was to determine the scope of specialists who perform 3D printing, and those who use 3D printed parts in patient care. Among the 195 responses to the survey, 185 indicated that one or more members of the institution performed patient-specific 3D printing.

There were 69 United States Health Care Facilities (HCFs) that completed all parts of the survey. When there was more than one HCF within an institution, each

hospital was *not* tallied individually. Instead, the institution was considered unique. Some HCFs had more than one response, reflecting the fact that some large medical centers have more than one 3D printing program. For example, a hypothetical academic medical center can have 3D printing labs, and separate survey responses, from providers in more than one department (e.g. radiology, cardiology, and orthopedic surgery). For these hypothetical institutions, the data would be combined and tallied as a single HCF.

Considering the United States HCFs, the median number of physicians in each institution who perform 3D printing as a service is 8.5. Considering the number of patients treated, 62% of the HCFs used patient-specific 3D printed parts for patient care for more than 50 patients annually.

United States providers who perform 3D printing as a clinical service span multiple specialties (Table 1). The large number of providers who used patient-specific 3D printed parts span many specialties (Table 2).

Knowledge gap #2: Defining complexity for the clinical service of 3D printing. Medical 'complexity' is intuitive, and it is inherent to medical practice. Perhaps the most common, current use of complexity in reimbursement is Evaluation / Management (E/M) codes. Accurate selection of an E/M code for an outpatient visit is now based on the complexity of the medical decision making, or the total time spent in patient care.

Table 1 Specialties represented by 20 or more providers who participated in 3D printing (3D printing physicians) and who completed the ACR 3D printing survey before September 2024

Specialty	Number of Providers
Radiology	61
Cardiology – Pediatric	48
Congenital Cardiac Surgery	41
Craniomaxillofacial surgery	35
Orthopedic Surgery – Adult	34
Orthopedic surgery – Pediatrics	33
Plastic Surgery	32
Cardiology – Adult	30
Thoracic Surgery	28
Plastic and Reconstructive Surgery	28
Surgery – General	26
Otolaryngology—head and neck surgery	25
Neurological Surgery	22
Surgical Oncology	21
Vascular Surgery	20

Table 2 Specialties represented by 20 or more providers who use 3D printed parts for patient care and who completed the ACR 3D printing survey before September 2024

Specialty	Number of Providers
Craniomaxillofacial surgery	63
Congenital Cardiac Surgery	62
Orthopedic Surgery—Adult	58
Radiology	56
Cardiology – Pediatric	56
Orthopedic surgery—Pediatrics	53
Cardiology – Adult	52
Neurological Surgery	48
Plastic and Reconstructive Surgery	48
Plastic Surgery	46
Thoracic Surgery	45
Otolaryngology—head and neck surgery	44
Surgical Oncology	41
Surgery – General	40
Urology	32
Vascular Surgery	31
Radiation Oncology	25
Colon and Rectal Surgery	21
Transplantation/Transplant Surgery	21

Many commonly used radiology codes span variations in complexity. For example, consider the procedure ‘chest CT without contrast’. From a technical perspective, some patients are relatively simple to scan; and some (high body mass index; immobile; the presence of support lines and tubes) are more complex. However, having one code that spans this complexity is reasonable based on the high volume of these studies that effectively normalizes complexity over many patients.

3D printing is inherently different from the imaging services used to generate the .DCM data that forms the basis of the physical parts. All patients who benefit from 3D printing have complex medical problems, and 3D printing provides an essential new technical strategy to extract the additional data that is not available with 3D visualization, defined as the portfolio of digital manipulation followed by 2D display of data [2]. The number of times the 3D printing service is performed is many orders of magnitude smaller than the number of times a patient is imaged with a .DCM output. This limits the ability to average 3D printing complexity over many patients. Moreover, the complexity of the 3D printing itself varies widely, and more complex patients require 3D printing that uses more resources.

Because 3D printing is expensive and there is a continuous learning curve, the technical service of HCF 3D printing is launched with relatively modest resources; for this reason, budding programs are best suited for the less complex patients. Then, as the program grows to include more expensive hardware (3D printers), more patients who require these additional resources can benefit from a HCF 3D printing service line. If 3D printing APC codes had only a single level of complexity, collections would be negatively skewed for mature 3D printing in a HCF. In short, HCF programs must invest substantially in the physical, physician, engineering, and hospital (to include quality management systems) resources to secure the infrastructure and expertise to 3D print the most challenging and expensive anatomic models and patient-specific surgical guides. For example, very complex patients would include oncologic and non-oncologic digital planning and patient specific osteotomy guides.

With the rationale for complexity secure, there is one key principle and one key question. The key principle is cost containment; this is addressed in 3 parts. First, if a patient does not need 3D printing as the Patient Specific Realization, the surface mesh file should not be 3D printed. 3D printing uses extensive human and physical resources. For example, it may be the case the simply presenting the surgeon with a 3D PDF of the surface mesh file is sufficient, or that virtual or augmented reality is sufficient or even superior to 3D printing for a specific clinical scenario [2].

The second part of cost containment uses clinical appropriateness as guidance when 3D printing is being considered. Experts have published appropriate clinical scenarios for 3D printed anatomic models, loosely modeled after the American College of Radiology Appropriateness Criteria™ [6]; guidance [7–14] includes comprehensive literature review and assessment of the strength of evidence. Representative, usually appropriate clinical scenarios are divided into ‘Basic’ (Fig. 1), ‘Intermediate’ (Fig. 2), and ‘Complex’ (Fig. 3) regarding the 3D printing (Table 3) using an algorithm defined below. Table 3 is intended to be representative, but it is not exhaustive. For example, a surgeon typically requests patient-specific 3D printed parts related to a challenging procedure, and that procedure may be a common medical problem that is not listed in Table 3. Moreover, listing of a scenario in Table 3 does not imply that all patients with that diagnosis will require 3D printing; the opposite is more likely. Specifically, 3D printing will be requested and performed only for those patients in the clinical scenario with the most atypical anatomy or those for whom the procedure has highest risk.

The third part of cost containment is the technology used – there are a wide variety of 3D printers, and



Fig. 1 Elderly gentleman with atrial fibrillation being evaluated for left atrial appendage occlusion using a transcutaneous catheter-deployed device: example of 'Basic' 3D printing. CT data (not shown) was segmented, after which computer aided design was used to arrive at a Final Anatomic Representation surface mesh file (not shown). Transparent, flexible 3D printed part as the Patient Specific Realization of the surface mesh file. The left atrial appendage occlusion device is shown near the orifice of the appendage. Anatomic models have high utility for this clinical indication when compared to 3D visualization alone. Ravi P et al. *J Am Coll Radiol.* 2023 Feb;20(2):193–204. Reproduced from Rybicki, F.J., Morris, J.M., Grant, G.T. (eds) *3D Printing at Hospitals and Medical Centers: A Practical Guide for Medical Professionals.* Springer, Cham. Switzerland. DOI: <https://doi.org/10.1007/978-3-031-42851-7>

desktop 3D printing is ubiquitous in HCFs. For most clinical scenarios, there is more than one combination of 3D printers (hardware) and materials (resins) that can be used for patient care. The least expensive technology should be used to solve the clinical problem.

The key question becomes, "How is complexity defined?" The first step is to identify those parameters (variables) that contribute to complexity. On one hand, if too many parameters are introduced, the analysis becomes too granular, and it can quickly become too complicated to settle on complexity categories. On the other hand, too much "lumping" leads to too few

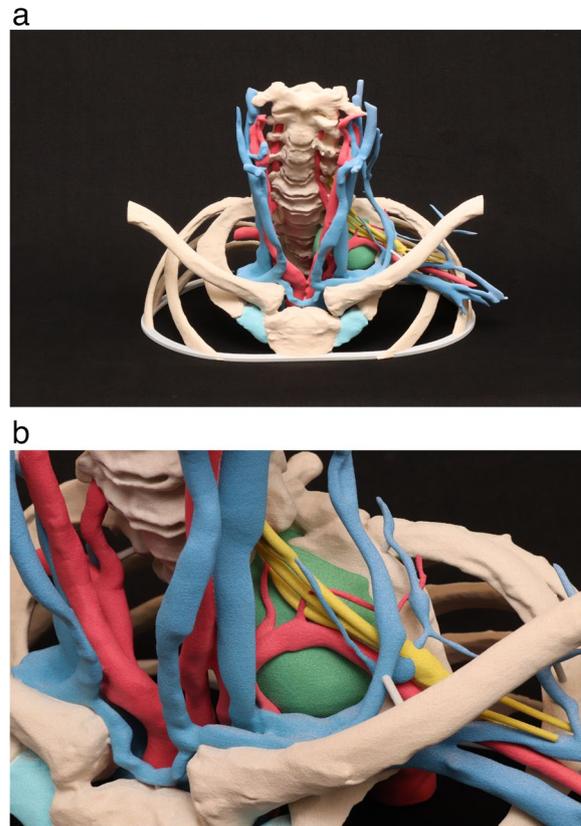


Fig. 2 Superior sulcus (Pancoast) tumor successfully resected: example of 'Intermediate' 3D printing. Traditionally, a complex resection for this patient population would require an open procedure, if surgery was attempted. Video Assisted Thoracoscopic Surgery (VATS) has lower surgical exposure when compared to procedures with much broader skin incisions. A key tenet of 3D printing is that it has increasing utility for less, or minimally invasive procedures because there is less surgical exposure in the operating room. **A** anterior view of anatomic model showing left sided tumor at the lung apex; **B** coned down view showing the relationship of the tumor with surrounding structures that must be preserved at the time of resection. Published with kind permission of © Mayo clinic. All Rights Reserved. Reproduced from Rybicki, F.J., Morris, J.M., Grant, G.T. (eds) *3D Printing at Hospitals and Medical Centers: A Practical Guide for Medical Professionals.* Springer, Cham. Switzerland. DOI: <https://doi.org/10.1007/978-3-031-42851-7>

parameters that limit the ability to distinguish complexity. The methods for determining technical complexity considered 7 parameters (Table 4). There are no absolute rules. However, patients who require material jetting generally require more complex parts. Also, desktop machines inherently have a smaller build tray, are less expensive, and have lower complexity than their counterparts.

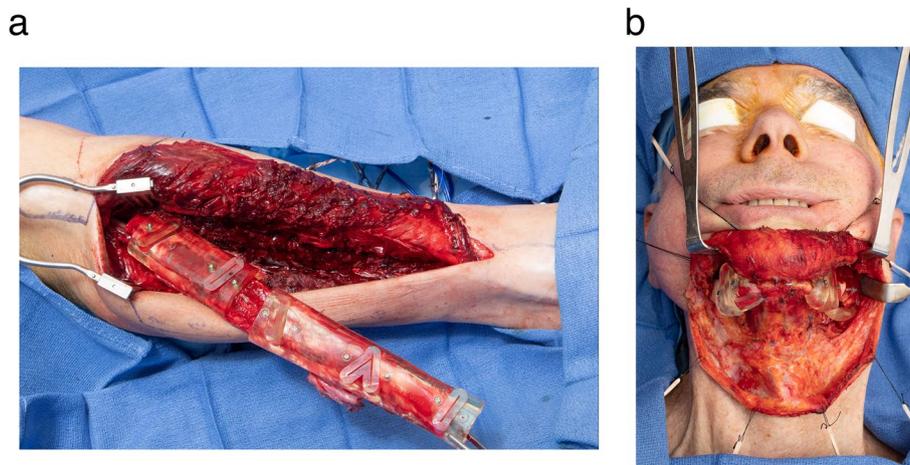


Fig. 3 Bilateral mandibulectomy with fibular free flap reconstruction using 3D printing: example of ‘Complex’ 3D printing. A 50-year-old man with aggressive squamous cell carcinoma centered in the mandibular region was evaluated for surgical intervention. 3D printed parts of the patient anatomy were created from Computer Aided Design (CAD), based on the segmented CT data for digital planning of the procedure. The final anatomic representations for both the mandible and fibula (used for the graft) were created to fit with a custom 3D printed titanium plate. That titanium plate was fabricated by industry, for this patient by KLS Martin (Jacksonville, FL). All other parts of the clinical service were performed in the Health Care Facility (HCF). The digital surgical plan performed in the Health Care Facility (HCF) conceptualized the fixation of the osteotomized fibula to the remaining symphysis. This requires the placement of cutting planes in the region of interest providing a 1-to-2-cm margin of normal bone. The HCF engineer then designed the cutting guides to fit the underlying anatomy with screw holes to secure to bone and slots made for each size oscillating saw blade. For the fibular free flap vascular graft, in the HCF, the length and shape of segments of the fibula required for reconstruction are translated directly from the planned mandibular reconstruction and are marked in color. The planning also uses CT angiography to assure that the leg vessels are patent, and to identify their position. Adequate perforators are also assessed to optimize flap survival. After the segments from the mandible are transferred to the fibula, the engineer created patient specific osteotomy guides similar to the mandible by subtracting the underlying fibular geometry to assure a perfect fit. Labels were digitally added to ensure proper orientation when the fibula is transferred into the defect. In addition, a 3D printed sterilizable model was autoclaved to use as reference on the back table in the operating room (not shown). The fibula was harvested leaving the blood supply connected to the parent artery while the sterilized osteotomy guides are attached with fixation screws. Osteotomy was performed while the vascular pedicle was attached; that is, the clock on the ischemia time had not started until the flap was finally harvested. Because harvesting the FVFG depends on the peroneal vessels, the periosteum was kept intact to ensure vascular supply to all fragments. Submental incision was placed and the mandible is exposed (not shown). **A** the HCF 3D printed mandibular cutting guide was secured in place with screws. The surgeon then performed the osteotomies in the preplanned trajectories. Resection of the osteoradionecrotic segments of the mandible was performed. 3D printed, sterilizable fixation trays (not shown) were designed in the HCF to secure the mandibular section into place and to allow the custom titanium plate to be affixed in the proper location efficiently, limiting ischemia time. Posts for the future mandibular prosthesis were placed at this time; **B** the titanium plate and fibular flap were then transferred into the operative defect in one piece further limiting ischemia time and replicating the surgical plan. Finally, using the standard microsurgical technique, the artery and vein were then anastomosed with lingual-facial vessels. (Published with kind permission of © Mayo Clinic. All Rights Reserved). Reproduced from Rybicki, F.J., Morris, J.M., Grant, G.T. (eds) 3D Printing at Hospitals and Medical Centers: A Practical Guide for Medical Professionals. Springer, Cham, Switzerland. DOI: <https://doi.org/10.1007/978-3-031-42851-7>

What are the recommendations from this editorial?

This Editorial recommends 3 categories to span the complexity of patient specific 3D printing: Basic, Intermediate, and Complex. To show how patients may be distributed into these complexity categories if they were approved, all combinations of the 7 parameters were considered. Many of these combinations were nonsensical or unexpected, leaving 216 feasible combinations that were then assessed by the authors and categorized into “Basic” ($n=47$), “Intermediate” ($n=83$), and “Complex” ($n=86$). The distribution suggests that if 3 individual APC codes were assigned to each level of complexity, there would be substantial numbers of patients that would be coded for each level. To generate the groupings in Table 3, clinical

scenarios [9–14] were aggregated into the 63 descriptors, and each of the 7 parameters for the typical patient who would undergo 3D printing was considered for the assignment into the Basic, Intermediate, and Complex categories.

There are important additional details and limitations. First, no set of billing codes perfectly captures all patients. Codes are designed and used to capture typical patient populations, with the understanding that there will be exceptions. Second, the analysis was initiated for 3 categories; this was a logical compromise between more and fewer categories. The analyses included substantial vetting among experts in coding, payments, and 3D

Table 3 Summary of clinical scenarios first aggregated from those considered usually appropriate [9–14], and second separated into ‘Basic’, ‘Intermediate’, and ‘Complex’ with respect to the 3D printing component of patient care. Within each clinical scenario, the word “complex” does not refer to 3D printing. For example, “Congenital Cardiac—ASD (Additional Complexity)” refers to the fact that 3D printing will not be appropriate for, and will not be performed for, the large majority of patients (primarily neonates and infants) who present with (are born with) an Atrial Septal Defect (ASD). However, some patients have ‘additional complexity’ related to the ASD itself, making 3D printing a relative or absolute prerequisite before corrective surgery. The 3D printing itself for this clinical scenario was considered ‘intermediate’ in the literature (see scenario #6 in the ‘Intermediate’ group)

Basic (n = 25)

1. Olfactory Groove Meningioma: Complex
2. Tuberculoma Sella/Planum Sphenoidale Meningioma: Complex (Class III-IV)
3. Esthesioneuroblastoma: Kadish Group C
4. Sinonasal tumors: Complex
5. Pituitary Macroadenoma: Complex (Knosp 3–4 or Hardy 4, D-E)
6. Craniopharyngioma: Adamantinomatous
7. Craniopharyngioma: Papillary
8. Sphenoid Wing Meningiomas: Complex or Group II, Cavernous Sinus involvement
9. Cerebellopontine Angle: Vestibular Schwannoma: Complex (Koos Grade III–IV)
10. Petroclival Meningioma
11. Myeloma/Plasmacytoma: Complex
12. Fibrous Dysplasia: Complex
13. Hemangioma: Complex
14. Complex Aneurysms: Thoracic Aortic Aneurysm
15. Complex Aneurysms: Abdominal Aortic Aneurysm
16. Complex Aneurysms: Visceral Aneurysm/Pseudoaneurysm
17. Complex Acetabular Fracture
18. Fracture Malunion
19. Hip Dysplasia
20. Urolithiasis, Surgical Management
21. Coronary Artery Disease—bypass grafting with minimally invasive approach
22. Myocardial Infarction – pseudoaneurysm repair surgical planning
23. Cardiac Transplant
24. LVAD, pediatric with sizing considerations
25. Left Atrial Appendage Occlusion, Complex or redo

Intermediate (n = 18)

1. Malignant breast lesions, Complex
2. Breast reconstruction
3. Post Infarct VSD
4. Cardiac Tumors
5. Hypertrophic Cardiomyopathy
6. Congenital Cardiac—ASD (Additional Complexity)
7. Chondrosarcoma
8. Foramen Magnum Meningioma: Complex
9. Meningiomas not related to Skull Base: Complex
10. Craniostomosis Simple Single Suture: Open Repair
11. Craniostomosis Simple Single Suture: Endoscopic Repair

Table 3 (continued)

12. Craniostomosis Complex Multiple Suture: Open Repair
 13. Craniostomosis Complex Syndromic
 14. Congenital Vascular Malformation
 15. Scoliosis, Secondary to Congenital Vertebral Anomaly
 16. Renal Cancer (Including Malignant Cystic Neoplasms)
 17. Prostate Cancer, planning for minimally invasive surgery
 18. Pediatric Retroperitoneal Genitourinary Tumors
- Complex (n = 19)*
1. VSD—Additional Complexity
 2. Atrioventricular Canal Unbalanced
 3. Interrupted Aortic Arch with LVOT obstruction
 4. Truncus Arteriosus
 5. Major Aortopulmonary Collateral Arteries
 6. Heterotaxy, Cardiac Anomaly
 7. D-TGA with Pulmonary Stenosis
 8. Double Outlet Right Ventricle
 9. Atrioventricular and/or Ventriculoarterial Discordance (excluding Single Ventricle, TGA and DORV)
 10. Mitral Valve Repair/ Replacement – Complex, Percutaneous or Endoscopic
 11. Tricuspid Valve Repair/ Replacement – Complex, Percutaneous or Endoscopic
 12. Pulmonary Valve Repair/ Replacement – Complex, Percutaneous or Endoscopic
 13. Cerebrovascular Cerebral Aneurysms/ Arteriovenous malformations
 14. Ameloblastoma
 15. Meningioma: NOS Complex
 16. Basilar Invagination, Platybasia, Craniocervical or Craniovertebral Anomalies
 17. Osteoconductive Implant Placement
 18. Craniostomosis Metopic Bandeau
 19. Bone/Soft Tissue Neoplasms, to include Joint & Neurovascular Involvement and osteotomy guidance

Table 4 Technical components used to classify 3D printing levels of complexity. Three-hundred thirty-five minutes was the mean time spent by the non provider (to include the engineer and other non-physician 3D printing specialists) as reported in the initial data analysis [7] of the RSNA-ACR 3D printing registry [8]. Digital modification was divided into two groups as previously described [15]

Parameter (variable)	Classification
3D Printing Technology	Material Extrusion, Vat Polymerization, Material Jetting
Desktop Machine	Yes, No
Expected non provider effort*	< 335 min, 335 min or longer [7]
Number of parts	1–2, 3–5, 6+
Substantial digital modification [15]	Major, Minor
Biocompatibility	Yes, No
Sterilization	Yes, No

* 92 and 335 minutes were the mean time spent by the provider and engineer [7], respectively, as reported in the initial data analysis of the RSNA-ACR 3D printing registry [8]

printing. Third, only three 3D printing technologies were included. For example, the analyses did not include powder bed fusion. This technology is still commonly used by industry, and while uncommon, there are medical centers that use this technology to 3D print medical parts. Lastly, as noted above, Table 3 was not intended to capture all clinical scenarios for 3D printing. Moreover, Table 3 is not intended to 'lock in' a complexity assignment for any particular patient. Instead, the analyses focused on showing how patients for whom there is published guidance would likely be distributed among the 3 proposed categories.

Authors' contributions

All authors contributed to the study conception or data acquisition, analysis, interpretation, drafting or critical revision, final approval and accountability of this article. The author(s) read and approved the final manuscript.

Declarations

Competing interests

None of the authors has a competing financial interest or personal relationship that could have appeared to influence the work reported in this paper.

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