Tutorial

DIGITAL HEALTH
Volume 9: 1–12

DOI: 10.1177/20552076231221899
journals.sagepub.com/home/dhj

3D Printing in a hospital: Centralized clinical implementation and applications for comprehensive care

Samuel Hellman[1], Paul Frisch[1], Andre Platzman[2] and Paul Booth[1]

Abstract

This educational article discusses the use of 3D printing or additive manufacturing in hospitals, not just for rapid prototyping but also for creating end-use products, such as clinical, diagnostic, and educational tools. The flexibility of 3D printing is valuable for creating patient-specific medical devices, custom surgical tools, anatomical models, implants, research tools and on-demand parts, among others. The advantages of and requirements for implementing a clinical 3D printing service in a hospital environment are discussed, including centralized 3D printing management, technology, example use cases, and considerations for implementation. The article provides an overview for other institutions to reference in setting up or organizing their clinical 3D printing services and is applicable to general hospitals or various sub-specialty practices.

Keywords

3D printing, additive manufacturing, personalized medicine

Submission date: 1 May 2023; Acceptance date: 30 November 2023

Introduction

3D printing—also known as additive manufacturing (AM)—encompasses a wide range of technologies that have historically been emphasized for their application in rapid prototyping, however, there has also been a steady increase in adoption of AM for creating end-use products. In the hospital environment, it has become widely adopted both for its traditional prototyping capabilities as well as its ability to produce a range of clinical, diagnostic, and educational tools. While it can be limited in its mass-production throughput, 3D printing is a viable option for low-production numbers and can be vastly more flexible than many traditional fabrication technologies. Particularly in hospitals, it allows for the creation of a wide range of products and devices without the overhead and lead time required for other methods. Furthermore, it can provide the ability to create objects that would be impossible—or very difficult—to make with other manufacturing techniques. One such application is in creating patient-specific builds individually tailored to a patient's unique anatomy and treatment. The flexibility of 3D printing is extremely valuable for the creation of patient-specific medical devices, custom surgical tools, anatomical models, implants, research tools, on-demand parts, and a number of other applications in the medical setting.

Although medical 3D printing in hospitals is a relatively nascent area of development, there is a rapidly growing body of literature discussing specific medical applications, medical subspecialty overviews, general 3D printing technology, and advancements in clinical practice.[1] Although relatively sparse, there is some literature discussing various aspects of regulatory requirements, organizational structure, and considerations for hospital practice surrounding 3D printing.[2–4] It can be difficult when planning implementation of a 3D printing operation to consolidate the relevant information and considerations. There is a need for introductory overviews intended not just for advanced

[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA
[2]Eagle-Picher, Joplin, MO, USA

Corresponding author:
Samuel Hellman, Memorial Sloan Kettering Cancer Center, 1275 York Ave, New York, NY 10065, USA.
Email: hellmans@mskcc.org

medical/technical specialists, but also for others in a hospital organization including administrators, leaders, healthcare providers, and others who may not be as familiar with the details required to adopt this technology. While some articles have taken this comprehensive approach,[5,6] more such resources are needed to provide varying perspectives and examples. This paper is intended to serve as a review which introduces the organization, technology, and related practical considerations (e.g. regulation, quality, facilities) for a hospital-based 3D print lab.

3D printing technology has been in regular use in hospitals since at least 2010 and has rapidly grown from just a few hospitals with localized 3D printing labs in 2010 to over a hundred in 2019[7] and likely over four hundred in 2022.[8] Some hospitals historically leveraged their relationships with affiliated university and engineering programs to supply some of these needs. A range of materials—including engineering-grade polymers, metals, biocompatible materials, and even bioactive cells—provide a plethora of options for clinical applications. There are now many standards of care in clinical operations—for example, anatomical models for presurgical planning, surgical cutting and drilling guides, and boluses for radiation therapy—where a complete workflow for delivery of printed products to the point of care is established.[5] Additionally, the flexibility of 3D printing allows a virtually unlimited number of unique applications on which engineers, radiologists, and other physicians can collaborate to create bespoke, on-demand solutions.

A 3D printing lab in a hospital (along with associated staff, knowledge, and materials) can create new clinical opportunities, research opportunities, and respond quickly to unforeseen clinical and hospital needs. For example, during the initial surge of COVID-19 infections in New York during the Spring of 2020, many medical supplies were unavailable due to rapid spike in demand and supply chain shortages. Hospitals and small businesses were able to 3D print some of the needed supplies such as nasopharyngeal testing swabs, face shields, viral filter adapters, and more.[9–11] Having this technology at the point of care provides the capability to adapt both to standard clinical operations and emergency cases as needed. A 3D print lab is rapidly becoming necessary infrastructure for hospitals to provide advanced healthcare and add resiliency to their operations. As the technology is adopted, hospitals may elect to structure operations in several ways; while printing is often started by many small groups in an institution, a single centralized 3D print lab is becoming more common. Whether adopting a larger, diversified lab or smaller, departmental lab, proper implementation requires input from multiple departments along with resources and expertise that must be developed.

In this review, our comprehensive oncology hospital is used as an example to illustrate some of the practices and considerations needed to implement a 3D printing lab. While our institution is an oncology hospital, the discussion is broadly applicable to general hospitals or other specialty practices. We provide an introductory review of (1) printing technologies, (2) centralized printing operations, (3) printing applications with examples, and (4) a brief summary of considerations when implementing 3D printing. These topics are not exhaustively covered, but rather are intended to provide a basic framework for understanding the needs and uses of 3D printing in a hospital.

3D Printing technologies

3D Printing has developed into a broad umbrella term for several types of technologies that allow the creation of parts by depositing material layer by layer to build an object; hence the term AM is used to distinguish it from traditional subtractive fabrication/machining which removes material from a larger piece. Here we provide a brief overview of the most common technologies, describing some clinical applications, advantages, and drawbacks with respect to use at the point of care in a hospital.

A 3D printing lab can range in size and capability depending on the needs of the institution from 1 to 20 or more printers of differing types along with the associated staffing and technical resources. For example, the 3D printing laboratory in Biomedical Engineering (BME) at our institution houses a variety of AM hardware along with software for 3D modeling, digital design, prototyping, manufacturing, reverse engineering, and analysis. As of 2023, the lab has ten printers which employ three types of AM technology: fused deposition modeling, stereolithography (SLA), and material jetting. Each of the printers can be used for clinical, research, or operational applications, the choice of which depends upon the individual requirements of the project. The specific mix of printer technologies and their associated capabilities should be chosen to provide a combination of targeted capabilities for clearly identified clinical use models as well as flexibility to allow for the broadest possible use cases.

Finally, it is important to consider when 3D printing is the appropriate technology to use. Although AM may be thought of first, it can often be the case that more traditional manufacturing may be simpler and/or more cost effective. In our institution for example, BME also has a full suite of traditional subtractive manufacturing/fabrication facilities (CNC mills, lathes forming tools, etc.) and employs engineers, physicists, biologists, technicians, and fabricators. These resources compliment 3D printing technology and allow us to select the best possible technology for each application.

Table 1 presents some of the most common 3D printing technologies. It outlines the technology used to make the print and lists some of their advantages and disadvantages from the perspective of hospital operational needs. It is useful to have access to varying printers and technologies for the wide range of applications we support in our institution. There are more comprehensive guides to the

Table 1. 3D Printing technologies.

Process	Material	Method	Advantages	Limitations
Fused deposition modeling (FDM)	Thermoplastic filament	Heated extrusion	Ease of use, functional prints, inexpensive	Variable durability of print, build orientation affects the end part, long print times, limited spatial resolution, limited surface finish quality
Stereolithography (SLA)	Photo-polymer liquid resin	Scanning beam UV curing	Superior accuracy, superior resolution, excellent surface finish, inexpensive, wide range of material properties	Significant post-processing Support placement considerations Secondary curing Potential for warping
Selective laser sintering (SLS)	Powdered materials	Scanning laser	Strong prints, wide range of materials including metals	Safety/environmental concerns
Polyjet	Photo-polymers	Inkjet printhead UV curing	Mixture of multiple materials, wide range of material properties	Expensive, significant post-processing
Binder jetting	Powdered materials	Binding agent fusing	Fast, can print physically complex parts, color mixing, large parts	Environmental concerns, significant post-processing, fragile prints

technologies[6] available, and a detailed understanding of the printers, materials, and processes is essential to producing successful prints for hospital operations and support. The centralized nature of our printing facility allows for the hardware to be co-located with all the necessary support, safety, processing, and post-processing in one place. For the technologies that we don't currently have in-house, we have networks of partners with the infrastructure and facilities to provide a print as needed using the desired process.

Centralized 3D printing

The decision whether to have a single centralized 3D printing operation in a hospital and, if so, which group or department is responsible for managing it can be a topic of great debate. There is not a clear consensus on the best organization for 3D printing operations, and each institution needs to decide how it will proceed. A recent survey study of hospital 3D printing sites—primarily represented by large, North American, university-affiliated institutions—found that just over half of respondents reported having a single print lab site versus multiple locations, and, of those with a primary administrative department, 67% identified Radiology as the managing group.[3] In our institution, for example, we have adopted a centralized 3D printing lab which is managed by BME. This was chosen due to technical resources within the BME group and strong existing clinical relationships between BME and Radiology, Radiation Oncology, Surgery, and other key users of 3DP technology.

When deciding between operating models, it is important to consider the impact it will have on your institution. While 3D printing technology can be adopted and used independently by specialty groups or individuals within an institution, there can be many advantages to centralizing the operations. For instance, financial resources can be more effectively used to purchase a smaller number of high-quality, centrally managed printers rather than a larger number of lower-cost printers distributed amongst different areas. Additionally, printers may be more efficiently used with higher utilization time and less total staff hours required for maintenance, processing, and other associated costs on a per-print basis. Essentially, a centralized 3D lab can take advantage of economies of scale and a specialized team with more experience to deliver advanced products.

There can, of course, be drawbacks to the centralized model. For instance, a single lab may have competing priorities and/or not be able to serve all groups in a timely manner; a small specialty group may prefer to control its own operation to decrease delivery time or house a printer in a satellite location. Fortunately, having a centralized printing operation does not preclude an individual group with sufficient justification from taking on their own 3D printing operations with the flexibility to coordinate as needed with the central 3D printing lab. For instance, we have several groups who maintain and operate their own 3D printer for specific use-cases; however our hospital has a policy that each request to purchase a new printer outside of BME must be reviewed and approved to help ensure prudent use of resources.

While a centralized 3D printing service may reside within varying individual or collaborative departments for each hospital, it is important that there be a core group responsible for the sustained operations, upkeep, and knowledge required. Input from many areas, including engineers, technicians, surgeons, radiologists, nurses, and others may be required for any given application and the central 3D printing lab can coordinate clinical workflows and communication between the needed departments as applications arise. Establishing these workflows and relationships is equally as important as having the required hardware.

For example, printing of patient-specific anatomical models for surgical planning is an increasingly common application which requires multiple groups to work together.[12] Figure 1 shows a graphic representation of this workflow in our hospital; a request is initiated by the Surgical department and goes first to a surgical review with Surgery, Radiology and, optionally, BME (if engineering/design work is needed). Next, Radiology determines whether existing patient imaging is appropriate or, if needed, new imaging is then completed. Segmentation is then typically done by Radiology, however, it can be done in part or entirely by BME. If additional design work is necessary, BME will do this and then then complete and deliver the 3D printed model(s). Finally, the model(s) must be reviewed and approved by the radiologist and surgeon.

Workflows such as this exist for each clinical application within the hospital, and each must be coordinated to allow collaboration and communication between the appropriate groups. In each case, the central 3D print lab is responsible for the operation and management of the 3D printing work, materials and hardware, while the associated tasks (design, clinical work, approval, etc.) may fall to one or more external groups depending on how the workflow is arranged.

It should also be mentioned that it is possible to outsource some or all printing externally. Depending on the operational needs of the institution, it may not be viable or desirable to operate a 3D print lab in house. There are an increasing number of companies who specialize in delivering 3D printed medical devices as well as many companies who are not specifically limited to medical applications who can provide these services. For instance, we employ external services for several applications; currently this includes all permanently implanted devices and several proprietary device types which are incorporated by third party companies into predefined clinical workflows. Smaller hospitals may find it more advantageous to outsource the printing parts of the workflow or start with a smaller set of printing hardware in house as it is justified by business or operational needs.

3D printing application areas and examples

Much of the existing literature on medical 3D printing describes specific applications or clinical specialties. Often, the focus is on the technology or medical details. In the present article, we are focused on the organizational needs of these applications and have categorized print types by operational parameters rather than clinical type. The application examples presented here are not intended to be exhaustive or comprehensive nor are they intended to be complete technical/medical descriptions. Rather, the examples are intended to provide context for how the technology is used in our hospital for each category. While there are many technological and clinical areas where 3D printing can be used in the hospital environment, we broadly organize these applications into four operational categories:

- Standard Clinical Cases
- Nonstandard Clinical Cases
- Research and Development
- Hospital Support Services

These categories provide a rough outline which is useful for organizing the workflows required to implement 3D

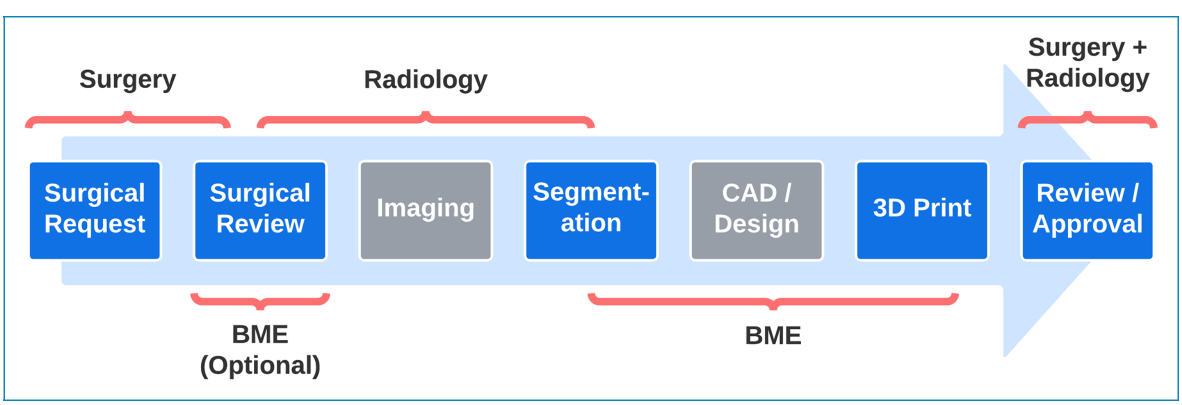

Figure 1. Example workflow graph for presurgical anatomical model. Tasks to produce 3D printed anatomical models are shown left to right with responsible group shown above/below each task with orange brackets. Gray tasks are optional depending on application.

printing services. Each area requires a different level of planning, regulation, auditability, quality control (QC), and so on. In the following sections, we provide some use-case examples which fall under each of the categories and a few comments on future directions.

Standard clinical cases

These are clinical applications with defined workflows and procedures. They may consist of the same part printed many times or custom-made/patient-specific devices which fall under standard operations. In either case, there is ideally a set of standard operating procedures which define how and when the prints are ordered, fabricated, post-processed, sterilized/disinfected (where applicable), delivered, and used. Some examples are as follows:

Anatomical models. One of the most common applications for this type of 3D print in hospitals are anatomical models used for presurgical planning and—in some cases—intraoperative reference. Research has shown that the use of 3D anatomic models for surgical planning can enhance tumor localization,[13] decrease operating room time and cost,[14–16] increase surgeons' confidence,[17] and improve patient outcomes.[18] Figure 2 shows an example of a 3D rendering and 3D printed pelvic model with osteosarcoma. Here, the 3D model can help visualize the complex physical relationship between the tumor and surrounding bone, nerves, arteries, and veins. This type of model can help to plan surgical approach, reduce surgical time, and avoid complications.

Surgical guides. Dental surgical guides are a prime example of clinically used guides in medicine. Patient-specific anatomy is segmented and modeled, and precise clinical guides are created to facilitate reconstructive procedures. Dental procedures are particularly well suited for this type of modeling as the teeth provide an accurate and reproduceable set of landmarks to ensure proper positioning. Figure 3 shows an example of a surgical guide used to properly align drilling locations and depths for dental implants. Here, a biocompatible resin is used and the guide snuggly fit to existing teeth for proper positioning. Press-fit metal bushings are inserted into the 3D printed model to guide the drill bit.

Typically, bone or teeth are required for use of a surgical guide, however other landmarks could potentially be used. Depending on the specific application, 3D modeling software is used to effectively create the appropriate model for the clinical application in question. Once completed, the surgeon can use these guides to position for cutting and/or drilling. These guides can optimize operations like drill placement, angle, and depth all while helping the clinician conform to a digitally planned surgical procedure.

Radiotherapy boluses. For high energy radiation therapy in cancer patients, it is often desirable to achieve higher accumulated radiation dose near the surface of the skin or with a small penetration depth. In these cases, bolusing (tissue-equivalent material placed on the skin) is used to achieve the desired dose. Standard sheets of bolus material do not conform well to complex anatomical surfaces and generally leave air gaps which are filled with wet gauze.

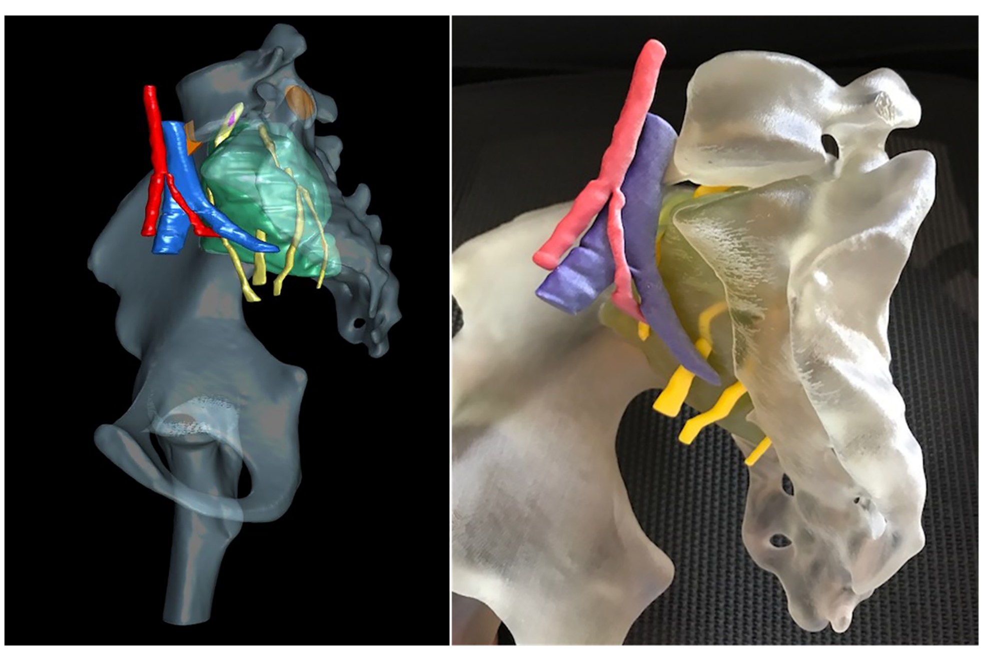

Figure 2. Pelvic osteosarcoma 3D model. Left, 3D rendering. Right, printed model.

3D printing these boluses with an appropriate material allows patient scans (optical, CT, MR, etc.) to be used, and provides for excellent fit with reduced/eliminated air gaps. Figure 4 shows an example of a nasal cancer case where a 3D printed bolus was used to provide proper dosing at the disease site while reducing the dose delivered to deeper tissues (in this case brain). The bolus is printed using a flexible biocompatible (skin contact) resin using an SLA printer.

Brachytherapy applicators. For rectal and vaginal/cervical cancers, brachytherapy is an important tool to treat disease with local high dose radiation. There are standard commercially available applicators which allow for multiple treatment modalities but do not offer patient-specific adjustment. 3D printing these applicators allows us to tailor the applicator size and shape (to account for anatomical differences or abnormal physiology) as well as needle trajectory (for optimal tumor coverage). Figure 5 shows an example of a 3D printed vaginal brachytherapy applicator. Here, custom configured lumens provide proper positioning of radiation source for treatment and the applicator is designed to fit a specific patient's anatomy. Both the main applicator as well as the collets and set screw are 3D printed from biocompatible (mucosal and breached surface contact <30 days) resin using an SLA printer.

Nonstandard clinical cases

These are clinical applications which can be carried out on an as-needed basis. Typically, these are unforeseen/unique situations and non-standard cases which do not get repeated (frequently) and thus do not necessarily have a defined workflow. This can also include educational tools used to train health care providers.

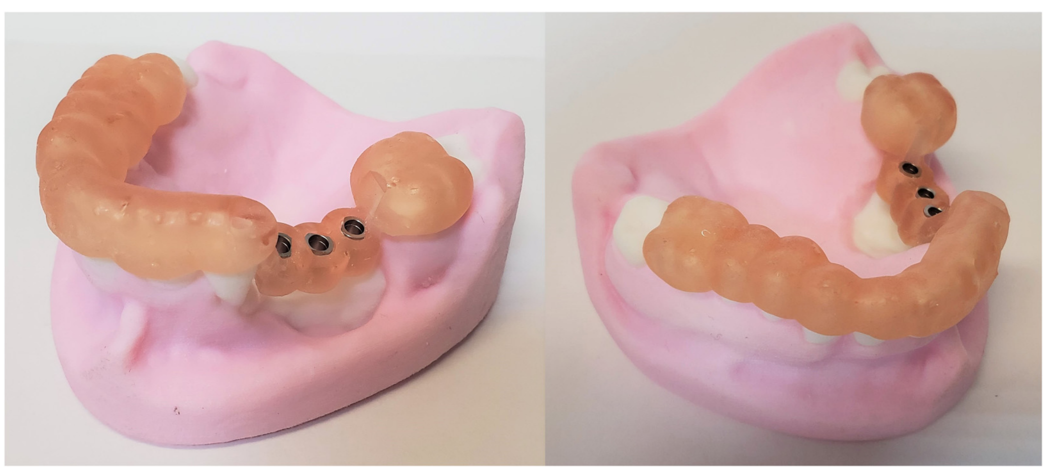

Figure 3. Dental surgical guide on 3D printed mandible model. The 3D printed guide sits on the teeth and metal bushing inserts guide drilling location and depth for dental implants.

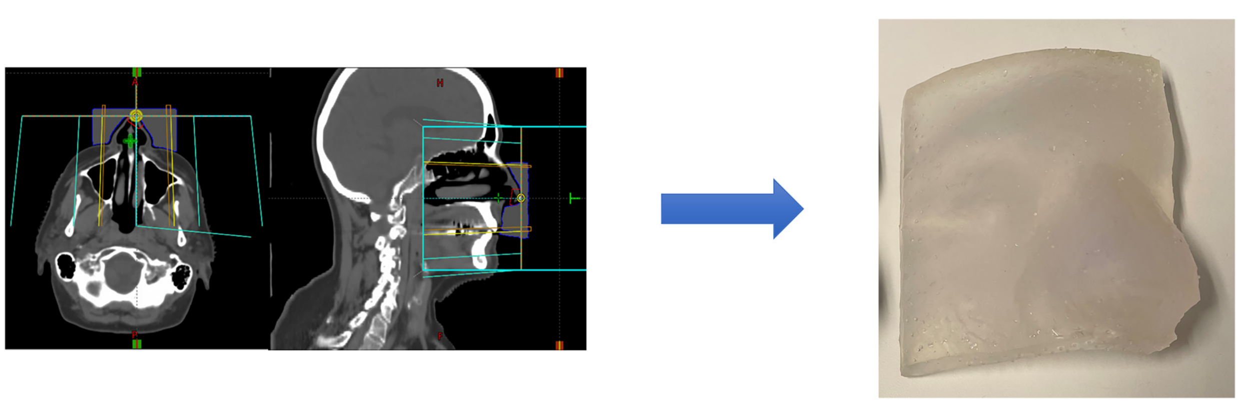

Figure 4. Left, CT scan of nasal cancer patient used for planning and creation of 3D bolus. Right, 3D printed bolus using flexible material which is approximately tissue equivalent.

Examples of non-standard applications can range from a rare infant cardiac defect[19] to aiding in the separation of conjoined twins.[20] While many of these prints are similar to anatomical models, tools, and guides in standard workflows, there are typically alternate requirements, uses, or post-processing needed to complete them. Below are some examples of such cases at our institution.

Oral prosthesis with trismus. Patients with oral cancers that have been surgically removed often have a resulting void in the oral cavity. Typically, a prosthetic is specifically created for them by first using a molding material which conforms to the defect and then using that model to create a patient specific prosthetic that accurately fills the void. Patients who develop trismus can have limited access to the oral cavity and, as a result, some molds may not be accurately formed (or access is virtually impossible). Attempting a mold in these cases can result in a suboptimal prosthesis that doesn't fit and can present a dangerous choking hazard. However, not having the prosthesis has clinical and social impacts for the patient as well; speech and swallowing can suffer and result in a host of negative outcomes like social isolation and unhealthy weight loss. In rare cases such as this, we are able to 3D print the oral cavity of the patient suffering from this condition. First, we obtain a CT of the patient post-surgically and segment the relevant anatomy into a 3D model, as shown in Figure 6. We then 3D print the model and use it to accurately mold and create a standard prosthesis.

Mandibular model for pre-bending fixation plate. Another example of a non-traditional application is employing a 3D model to pre-bend surgical fixation plates. These plates are used to rigidly connect adjoining bone segments with screws. In a specific case at our institution, a fracture in the mandible occurred in weakened bone as a result of surgery and subsequent radiation treatment. The fracture was identified both by the patient and confirmed through CT imaging. A corrective procedure needed to be performed using metal fixation plates which are bent to conform to the specific bone pieces in question and screwed into the mandible on both sides of the fracture. The result of this process is a bone segment that is fused together and maintains its orientation. Typically, the fixation plate is chosen and bent during the procedure. Depending upon the complexity of the case and the experience of the practitioner, the surgical time taken to bend these plates accurately can be in the tens of minutes. While this doesn't seem like much, every minute of anesthesia time for the patient, operating room time, and surgical team time represents both a clinical and financial cost for the patient and hospital. An existing CT scan of the patient was used to segment and reproduce the broken mandible and it was then digitally manipulated to bring the broken segments back into their intended locations/alignment. A 3D printed model (Figure 7) was made that allowed the clinicians to pre-bend the fixation plate, taking as much time as they needed without the pressure of having to do this with an anesthetized patient. The fixation plate was

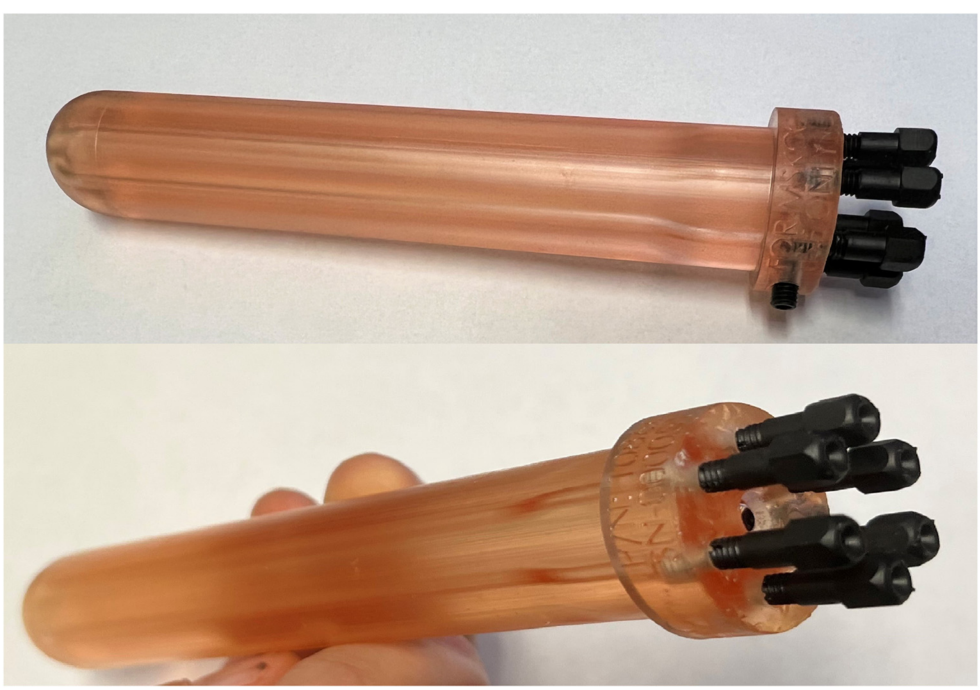

Figure 5. 3D printed vaginal brachytherapy applicator.

Figure 6. Workflow for 3D print of oral cavity to aid in prothesis molding. Left, CT scan. Center, 3D rendering. Right, printed model.

Figure 7. Mandibular model for pre-bending of fixation plates. The mandible is repositioned, but the fracture is still visible.

accurately positioned, bent, and sterilized for clinical use in the patient. This is an excellent use of 3D printing technology to reduce operating room time and potentially improve outcomes. Furthermore, these applications are able to use the most cost-effective printers to accomplish this as there are no requirements for advanced material properties.

Research and development

This category describes the multitude of applications which fall under a hospital's R&D or training activities. These can be devices made for training, testing, experimentation, prototyping, and so on. For research or teaching hospitals, 3D printing is proving to be a critical technology which has become an integral part of the development process. The range of applications in this space is quite broad; from simple mounts/adapters/jigs in experimental setups to full anatomical models used to train nurses, residents, and fellows.

An example of an experimental setup print is shown in Figure 8. Here, a test was needed to quantify the effect of a source light emitter's angular position on the signal intensity seen by the imaging system. A custom rotating mount was made which holds the light source in place and can be rotated to specific angular positions for testing.[21] Multi-material polyjet technology was used here to allow integral markings in the print.

As a cancer research and treatment center, our institution has a large focus on development work for radiation therapy and testing. We create many custom radiation shields (patient- or application-specific) which can be 3D printed hollow and then filled with appropriate shielding material. Shielding material can be, for example, small metal spheres such as stainless steel, copper, or tungsten, or alternatively filled with Cerrobend (a low-melt temperature lead alloy). These can be, for example, a small patient-specific eye shield, or a relatively large enclosure for sensitive electronics. These prints allow incorporating

Figure 8. Rotating mount for testing angular dependence of light emitter.

shielding along with other features needed in a custom testing setup.

Another application which is advancing quickly within the Radiation Oncology and Medical Physics space is 3D printing of imaging phantoms. Phantoms are used regularly in radiation oncology for testing, quality assurance (QA), and plan checking. There are materials which can be 3D printed that have variable properties when imaged by CT and/or MRI and these materials can be used to create custom-configured CT or MR phantoms. Commercially available phantoms are often very expensive and are available in a limited set of configurations. 3D printing allows custom phantoms to be made to suit exactly what is needed for a given test.

For teaching hospitals, one of the leading applications for 3D printing is in creating training models for medical staff. Even with existing technologies, models can be used to simulate various procedures. Rapid advancements in material properties are allowing increasingly realistic models which can now supplant use of cadavers, animal models, or practicing directly on patients. For example, 3D printed models can be used to simulate a complex airway (e.g. specific tumor physiology) and allow prior practice of intubation or bronchoscopy. Realistic tissue materials provide tactile feedback and allow development of approach techniques to handle these complex scenarios. As of early 2023, nearly every field of surgical practice is currently exploring applications for these kinds of models.

Hospital support services

This broadly describes the applications which address operational needs of the hospital but are not necessarily medical devices or used directly in clinical treatment. Some items which are used in a clinical setting but do not directly influence patient care and/or patient risk can also fall under this category. While the clinical and R&D applications are currently more suited to large research hospitals, these support services are finding use even in smaller hospitals throughout the world.

Having 3D printing capabilities in a hospital allows flexibility both under normal operations and in the case of emergencies or supply chain issues. We have found many applications to improve workflows and patient care by filling in the gaps where commercial solutions are not available. For example, custom holders have been printed to keep wires organized at patients' beds or unique ultrasound probe holders printed to place it in a more accessible location for our room layouts. These kinds of applications are often too time consuming or expensive for typical hospitals to fabricate (usually requiring outsourcing) but become relatively simple once 3D printing is available. In times of crisis, 3D printing provides the ability to respond to unforeseen needs with flexibility and speed. For example, during supply chain shortages seen in the early stages of the COVID pandemic, our institution used 3D printing to make face shields, nasopharyngeal test swabs, viral filter adapters, and respiratory fittings in addition to other applications.[11]

Future use-cases

3D printing technology is a rapidly evolving field with significant investment into both refining existing processes as well as innovating new technologies. Areas like bioprinting, electronics printing, MEMS (micro electromechanical systems) sensors and actuators, life-like materials, and entire printed systems that combine some or all of these technologies are being investigated and are at varying stages of maturity. In the materials space, new materials with focused properties that take advantage of existing printing processes are introduced into the market on a regular basis.

In the 3D printed electronics space, research is moving from simply printing conductive traces for connectivity between different components, to printing complete embedded systems and components down to the transistor level. Printable displays and sensors are some of the targeted areas for development that will take advantage of the unique abilities that 3D printing affords. It is allowing designers to think outside of their traditional processes and limitations, and potentially allow for more robust designs and applications.

On the medical side of this evolution, we are seeing new materials introduced that mimic the look, feel, and response of actual biologic materials. This is enabling the industry to develop a new range of anatomically accurate models to be used for education, simulation, and more effective training. One of the ultimate goals in the field is to print living biological tissue which can repair or even replace human anatomy; this technology may eventually be able to provide complex systems, including functioning organs.

Considerations

Accuracy and QA

When referencing accuracy in clinical 3D printing, this is most often referring to the dimensional accuracy of a physical 3D print matching the digital 3D model or patient anatomy within specified limits. Alternatively, it may refer to other characteristics which must be controlled: radiopacity, biomechanical properties, chemical composition, and so on. These specifications will depend on the requirements of the use-case and have inherent limitations based on the specifications of printing methodology chosen and the source data. While the same principles apply regardless of what parameters are being controlled, we will discuss dimensional accuracy here for illustration.

The dimensional accuracy requirement in clinical 3D printing depends largely upon the medical indication of the 3D model being used. For instance, applications such as training and education might have less stringent tolerances than clinical uses such as implants and surgical cutting guides. An awareness of where the sources of error are introduced in the system is essential to obtaining the best possible 3D print and is only possible through a fundamental understanding of the entire printing process from idea generation to finalized print.

Error in the 3D ecosystem can be introduced due to human decision factors, information translation from one step to another in the process, and mechanical error with the print. To ensure deliverable quality, there are several quality assurance (QA) and quality control (QC) steps that can be taken to validate that the actual output conforms to the planned output.

The most thorough method is to carry out QC checks on each print; this involves measuring the final printed model/part and comparing to the initial data source. The measurement can be a complete scan (using, e.g. a 3D optical scanner) of the printed part or can entail measurement of critical features of the part using any number of manual or digital tools (calipers, rulers, micrometers, lasers, etc.). Various metrology and scanning technologies can be used to identify areas of discrepancy between the print and the model; however, it is important to note that the scanning/measuring system itself may need to be maintained to ensure QA.

Another approach is (in parallel or on its own) systematic QA, and involves stepwise checks on the work process. For instance, a 3D print created from an optical scanning of a patient could be validated stepwise by **a**. Taking a few manual measurements on the patient if there are sufficient landmarks available, **b**. Checking the accuracy of the 3D scanner by scanning a known reference object, and **c**. 3D printing an easily measurable object (e.g. a cube with round hole features) along with the final 3D print to ensure the printer is working properly. These types of measurements are assessing the performance of the process and help ensure that the final print should be correct.

Systematic QA and part-oriented QC should be part of any robust 3D printing operation since clinical decisions/outcomes will often be based on these models/parts. Allowable error must be determined based on critical areas of the process and a QA/QC program will ensure that produced parts fulfill these requirements.

Sterilization, infection control, and biocompatibility

Some 3D prints are intended to come into physical contact with patients and/or be used in a sterile environment. The safety and sterility of the print must be verified before use in these cases. Again, knowing the application and how the print is to be used will define the requirements. It must be determined whether a part needs to be, **a**. disinfected, **b**. sanitized, **c**. sterilized, and/or **d**. biocompatible (and for which clinical indication). The first step in creating clinical prints which need to meet any of the above requirements is to use a printer and material specifically designed to be used for the purpose. Several printer manufacturers make commercial printers and materials that are designed and intended to be used clinically, but there are widely varying compliance types. It is important to note, for instance, that simply being sterilizable, does not mean that a material is biocompatible and does not automatically allow it to be used in a clinical operation. Users must adhere to the specific limitations that the manufacturer recommends for clinical utilization.

In addition to sourcing the appropriate printer and materials for sterilizable prints, it is critical to follow the appropriate Instructions for Use (IFU) which detail manufacturing and processing steps for the material and for the subsequent sterilization technology. QA/QC procedures need to be established to ensure that all of the steps are followed appropriately, and that the device is safe for patient use. In addition, even when a material is indicated as biocompatible for the specified application type and all IFU's are followed, the final shape and features of the print may require testing to ensure sterile processing. For example, a part with complex features or small lumens may need to be tested to make sure that the cleaning and sterilization process are sufficient.

Biocompatibility can play a significant role in clinical 3D printing and, as with sterilization, the first thing a facility needs to do is to establish the patient safety protocols for the intended use and abide by all regulatory requirements. There are various standards that a material can meet with regards to cytotoxicity, sensitivity, irritation, genotoxicity, hemocompatibility, carcinogenesis, and so on.[22] Material selection is largely a factor of application and availability of materials for the printer type and model being used.

Suitable manufacturers have rigorously tested their media and should be delivered with all of the information and documentation to support a specified clinical use. If a bespoke material is to be used, in-house or third party testing may be required to ensure it is suitable and safe.

Regulatory requirements

It should be noted that devices to be used on patients and/or in a clinical setting must go through all appropriate regulatory steps; this may include internal groups such as Internal Review Boards (IRB), legal counsel and clinical leadership or external agencies such as the Food and Drug Administration (FDA) and the Joint Commission. While point-of-care manufactured medical devices may or may not fall under FDA regulation,[23] it is advisable to adhere to FDA guidelines and common good manufacturing practices[24] when producing clinical 3D prints. It is strongly recommended to create an auditable workflow with tracking of materials and processes along with QA procedures discussed in the previous sections.

The scope and nature of the regulations, like many other areas in medical printing, are largely defined by the intended use of the print itself. While the responsibility for medical use ultimately falls on clinicians, it is the safety apparatus of their institutions and of regulatory agencies which provide the highest levels of protection for the clinical use of 3D prints. As in all areas of medical 3D printing, it is critical to have an in-depth understanding of each step in the process from conceptual model to the final print and ultimately its clinical use.

Facilities

One of the often-overlooked areas of consideration are the facility requirements for a 3D printing operation. While space and power requirements come to mind first and foremost, careful consideration of other environmental factors is important as well. For instance, it is increasingly becoming apparent that fumes released during printing may be harmful for those working in the area.[25,26] Setting up proper enclosures and/or ventilation is critical to provide safe environmental conditions for operators and nearby workers. For some materials in their raw state (filament, powder, liquid, etc.), there are additional concerns including skin irritation, flammability, and other systemic toxicity. In the case of powdered materials, proper handling and containment during transfer and cleaning is vitally important as they can easily become airborne and present inhalation and flammability risks. For reactive metals such as titanium and aluminum, these powders can also potentially be explosive. The requirements for each printer type and material can vary, but a careful plan must be put in place to ensure safe storage, handling, and operation. All waste materials must also be disposed of appropriately.

Conclusion

3D Printing technology has rapidly gained adoption in the hospital environment due to its ability to create patient-specific medical devices, custom surgical tools, anatomical models, implants, research tools, and other applications. The flexibility of 3D printing provides a wide range of options for clinical applications, enabling engineers, radiologists, and physicians to collaborate and create bespoke, on-demand solutions. With the increasing adoption of this technology, a complete workflow for delivery of printed products to the point of care has been established, creating new clinical opportunities and allowing for quick responses to unforeseen needs, as demonstrated during the COVID-19 pandemic.

Implementing a clinical 3D printing service in a hospital requires establishing proper facilities, legal and medical approvals, proper handling of materials, documentation, QA, and funding/billing. Centralizing the 3D printing operations can offer advantages in terms of cost-effectiveness, higher utilization rates, and more efficient use of staffing and technical resources. The specific mix of printer technologies and their associated capabilities should be chosen to provide a combination of targeted capabilities for clearly identified clinical use models as well as flexibility to allow for the broadest possible use cases.

Overall, the adoption of 3D printing technology in hospitals is becoming increasingly necessary infrastructure to provide advanced healthcare and add resiliency to clinical operations. As the technology continues to evolve, we can expect to see even more innovative and practical clinical applications emerging in the years to come.

Contributorship: SH wrote the first draft of the manuscript. PB and AP carried out literature research and drafted content. PF contributed to the content organization. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Declaration of conflicting interests: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval: This research does not contain any studies involving human or animal participants. Cases reported fall under the practice of medicine and do not require ethical approval.

Funding: The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the NIH/NCI (grant number P30 CA008748).

Guarantor: SH.

ORCID iD: Samuel Hellman https://orcid.org/0000-0002-5519-870X

References

1. Tack P, Victor J, Gemmel P, et al. 3D-printing techniques in a medical setting: a systematic literature review. *Biomed Eng Online* 2016; 15.
2. Beitler B, Abraham P, Gelnnon A, et al. Interpretation of regulatory factors for 3D printing at hospitals and medical centers, or at the point of care. *3D Print Med* 2022; 8.
3. Shine K, Schlegel L, Ho M, et al. From the ground up: understanding the developing infrastructure and resources of 3D printing facilities in hospital-based settings. *3D Print Med* 2022; 8.
4. Lohss M, Hammersley E and Ghodadrs A. Customizable document control solution for 3D printing at the point-of-care. *3D Print Med* 2023; 9.
5. Ganapathy A, Chen D, Elumalai A, et al. Guide for starting or optimizing a 3D printing clinical service. *MEthods* 2022; 206: 41–52.
6. Bastawrous S, Wu L, Liacouras P, et al. Establishing 3D printing at the point of care: basic principles and tools for success. *Radiographics* 2022; 42: 451–468.
7. Pietila T. How medical 3D printing is gaining ground in top hospitals. 11 June 2019. [Online]. Available: https://www.materialise.com/en/blog/3D-printing-hospitals. [Accessed 23 February 2022].
8. Davies S. Standard of care: Why hospital-based 3D printing labs are becoming so prevalent. 31 May 2021. [Online]. Available: https://www.tctmagazine.com/additive-manufacturing-3d-printing-industry-insights/healthcare-medical-dental-and-bioprinting-insights/standard-of-care-hospital-3d-printing-labs-prevalent/. [Accessed 23 February 2022].
9. Choong YY, Tan HW, Patel D, et al. The global rise of 3D printing during the COVID-19 pandemic. *Nat Rev* 2020; 5: 637–639.
10. Longghitano G, Nunes G, Candido G, et al. The role of 3D printing during COVID-19 pandemic: a review. *Prog Addit Manuf* 2021; 6: 19–37.
11. Hellman S, Frisch P and Booth P. Medical devices: responding to a crisis with 3D printing, design, engineering, and production. In: *Leveraging technology as a response to the COVID pandemic*. Taylor & Francis, 2022.
12. Paramasivam V, Sindhu V, Singh G, et al. 3D Printing of human anatomical models for preoperative surgical planning. *Procedia Manuf* 2020; 48: 684–690.
13. Wake N, Wysock J, Bjurlin M, et al. "Pin the tumor on the kidney:" an evaluation of how surgeons translate CT and MRI data to 3D models. *Urology* 2019; 131: 255–261.
14. Ravi P, Burch M, Farahani S, et al. Utility and costs during the initial year of 3-D printing in an academic hospital. *J Am Coll Radiol* 2023; 20: 193–204.
15. Diment L, Thompson M and Bergmann J. Clinical efficacy and effectiveness of 3D printing: a systematic review. *BMJ Open* 2017; 7.
16. Ballard D, Mills P, Duszak R, et al. Medical 3D printing cost-savings in orthopedic and maxillofacial surgery: cost analysis of operating room time saved with 3D printed anatomic models and surgical guides. *Acad Radiol* 2020; 27: 1103–1113.
17. Wake N, Rude T, Kang S, et al. 3D Printed renal cancer models derived from MRI data: application in pre-surgical planning. *Abdom Radiol* 2017; 42: 1501–1509.
18. Meyer-Szary J, Luis M, Mikulski S, et al. The role of 3D printing in planning complex medical procedures and training of medical professionals—cross-sectional multispecialty review. *Int J Environ Res Public Health* 2022; 19.
19. Moore R, Wallen W, Riggs K, et al. Three-dimensional printing in surgical planning: a case of aortopulmonary window with interrupted aortic arch. *Ann Pediatr Cardiol* 2018; 11: 201–203.
20. Inserra A, Borro L, Spada M, et al. Advanced 3D "Modeling" and "Printing" for the surgical planning of a successful case of thoraco-omphalopagus conjoined twins separation. *Front Physiol* 2020; 11.
21. Pratt E, Skubal M, McLarney B, et al. Prospective testing of clinical Cerenkov luminescence imaging against standard-of-care nuclear imaging for tumour location. *Nat Biomed Eng* 2022; 6: 559–568.
22. Agueda J, Chen Q, Maalihan R, et al. 3D Printing of biomedically relevant polymer materials and biocompatibility. *MRS Commun* 2021; 11: 197–212.
23. Food and Drug Administration. Discussion paper: 3D printing medical devices at the point of care. 2022.
24. Rahman Z, Barakh Ali S, Ozkan T, et al. Additive manufacturing with 3D printing: progress from bench to bedside. *AAPS J* 2018; 20.
25. Bernatikova S, Dudacek A, Prichystalova R, et al. Characterization of ultrafine particles and VOCs emitted from a 3D printer. *Int J Environ Res Public Health* 2021; 18: 929.
26. Gumperlein I, Fischer E, Dietrich-Gumperlein G, et al. Acute health effects of desktop 3D printing (fused deposition modeling) using acrylonitrile butadiene styrene and polylactic acid materials: an experimental exposure study in human volunteers. *Indoor Air* 2018; 28: 611–623.