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The utilization of 3D printing in medicine at point of care: the benefits, the challenges, and the future

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BOSTON UNIVERSITY

ARAM V. CHOBANIAN & EDWARD AVEDISIAN SCHOOL OF MEDICINE

Thesis

**THE UTILIZATION OF 3D PRINTING IN MEDICINE AT POINT OF CARE:
THE BENEFITS, THE CHALLENGES, AND THE FUTURE**

by

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Master of Science

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JOSEPH FARES

ABSTRACT

The application of 3D printing in medicine is a relatively new idea. However, as technology advances, more healthcare systems are adopting this technology. The use of 3D printing has been shown to benefit both the hospital provider and the patient. For the provider, 3D printing is utilized for a variety of purposes, including preoperative planning with anatomic models, creating surgical guides, and creating custom implants and prosthetics. These advantages benefit the patient by reducing time in the operating room and thus the amount of time the patient is under anesthesia. This situation lessens patient complications and saves money for the hospital. However, many issues with 3D printing remain unresolved, including ethical concerns, patient privacy, equity, regulation, and sustainability, and more research is needed to address these concerns. Despite these challenges, 3D printing is growing in popularity in healthcare systems across the country and is proving to play a significant role in the future of modern medicine.

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LIST OF ABBREVIATIONS

AMA	American Medical Association
API	active pharmaceutical ingredient
CAD	Computer Aided Design
CBCT	Cone Beam Computed Tomography
CDRH	Center for Devices and Radiological Health
CPT	Current Procedural Terminology
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DMLS	Direct Metal Laser Sintering
EBM	Electron Beam Melting
FDA	Food and Drug Administration
FDM	Fused Deposition Melting
FFDCA	Federal Food Drug and Cosmetic Act
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act
IDE	Integrated Development Environment
IND	Investigational New Drug
IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging
OR	Operating Room
PEEK	Polyetheretherketone

PHI	Protected Health Information
PMA	Pre-Market Approval
PMN	Pre-Market Notification
PPE.....	Personal Protective Equipment
PVA	Polyvinyl Alcohol
RUC	Realtime Value Update Committee
SLA.....	Stereolithography
SLS.....	Selective Laser Sintering
STL	Stereolithography

INTRODUCTION

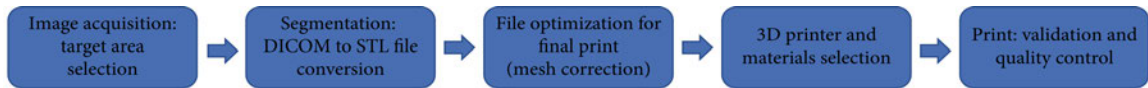
One of the many emerging technologies in medicine is the only one that has the ability to create a physical operational object from a computer-generated model which can be used directly in patient care. This technology is known as additive manufacturing, or 3D printing. Once upon a time, the idea of using 3D printing in the medical field was considered to be ridiculously far-fetched and futuristic. However, in more recent years, the medical field has begun to realize how helpful and advantageous this technology can be in the delivery of medical care. With 3D printing, surgeons can plan and prepare for an operation, take a more in-depth look at a patient's anatomy, and actually feel a patient's anatomy in their hands without opening up the patient, something that was virtually impossible before the advent of this technology.

This presents a tremendous opportunity for 3D printing in the field of healthcare. Printing custom devices that can be implanted into a patient using 3D printing offers a more tailored, accurate, and individualized method of treating patients, and it is one of the ways that physicians can utilize this technology. The use of 3D printing also offers significant advantages to educational pursuits in the medical field. Students and physicians-in-training have the opportunity to examine, hold in their hands, and otherwise interact with individualized anatomic models that can assist in providing a better understanding of the pathology of a patient. In addition, the use of 3D printing can be a good investment for hospitals because it can cut down on the amount of time spent in the operating room. As a result, hospitals can save money and improve patient outcomes by minimizing the amount of time that a patient is required to be sedated.

However, 3D printing at the point of care does not come without its own set of obstacles to overcome. Before 3D printing can be implemented as a routine standard of care practice across the country, there are still a great many questions and worries that need to be addressed. One of these concerns is the actual process itself. As shown in Figure 1, the process of obtaining a 3D-printed model is extremely complicated, but it can be broken down into five steps: selecting an anatomic area, creating a 3D digital image using medical imaging devices, preparing the file for printing, selecting the appropriate material and printer, and finally printing the model itself.

Figure 1

3D Printing Workflow



Note. This figure illustrates the five steps in the normal workflow of obtaining a 3D-printed model. DICOM = file format for 3D printers; STL = file format for medical imaging devices. From (Aimar et al., 2019).

The Fundamentals of 3D Printing

Types of 3D-Printed Devices Used in Medicine

There are three primary categories of items with three dimensions that can be utilized in a healthcare setting by a hospital. These categories are: anatomical models, cutting guides, and implantable devices. These items can be utilized at various points throughout the process of patient care by either the healthcare provider, the patient, or both of them.

One of the most common applications of 3D printers in the medical field at the moment is the creation of printed anatomic models. The reason for this is that it is beneficial for a variety of users, including the healthcare provider, the patient, and the student. When it comes to preoperative planning, 3D-printed anatomic models can be of tremendous assistance to surgeons in particular. It was found that if preoperative planning included the utilization of anatomic models, a safer surgical pathway could be found. This was accomplished by providing the surgeon with a three-dimensional view of the patient's anatomy (Perica & Sun, 2017). However, what distinguishes 3D-printed anatomic models from other models is the ability of these 3D models to be patient-specific and to mimic the pathology of the patient. Other models do not have this capability. This has significant applications not only in surgical education but also in preoperative care.

With regard to the training of surgeons, the 3D model presents the opportunity for trainee surgeons to experience pathologies that they may not have been exposed to yet in their training. It also has the potential to solve the issues that come with using cadavers.

Cadavers require a significant financial investment to preserve, and they are not always accessible to those who are undergoing training. In addition, cadavers pose a potential biohazard, which restricts the types of places where they can be used. Moreover, there are ethical considerations that should be taken into account when working with cadavers (Shui et al., 2017). Because of 3D-printed anatomic models, trainees are able to freely interact with the anatomy in a variety of settings. These models can also be used for many years without incurring high maintenance costs or raising ethical concerns. The 3D model has the potential to be beneficial to medical students as well, particularly those who have only encountered a particular pathology in a textbook or online. Before beginning their training, medical students may be able to acquire a more in-depth and comprehensive understanding of pathologic anatomy because of this opportunity.

Preoperative, intraoperative, and postoperative care can all benefit from the utilization of 3D-printed anatomic models by surgeons themselves. The preoperative planning phase presents surgeons with the greatest opportunities to benefit from preoperative care. The imaging of a patient can be used to print anatomic models that mimic a patient's pathology. This enables surgeons to get a more comprehensive view of the patient's condition and to test out a variety of treatment strategies. These benefits have enormous applications in a variety of fields, including orthopedic surgery. The production of bone using 3D printing is the most straightforward and uncomplicated aspect of human anatomy. The structures of soft tissues are significantly more complicated and display a degree of variation. Because different parts of the body are

made of different materials, they need to be printed using different kinds of printers.

Bone models, however, can be quite accurate.

Both the healthcare provider and the patient stand to benefit tremendously from the application of 3D printing technology to the process of creating bone. Patients who have bone deformities, fractures, or injuries can have their pathology reproduced by a 3D printer. This type of printing is typically used during the planning stages of complex surgical procedures or for patients who have difficult anatomy. This gives surgeons the opportunity to practice and improve the specific technique that they intend to use, as well as modify their approach in accordance with the results of those efforts. This has a lot of benefits, but the most important one is cutting down on the amount of time spent in the operating room and possibly lowering the risk of complications during the procedure.

These bone models are also helpful in the classroom as a teaching tool, and students are able to hold and feel bone deformities that they have never seen or felt previously. When applied to patients who have spine deformities, an imaging-based 3D model can detect and manifest deformities that may not have been obvious or identified from the imaging alone. Surgeons are able to see exactly where tumors may be encroaching on surrounding tissues from these models, and this allows the surgeons to adjust their surgical plans accordingly. Furthermore, these bone models help in reducing complications and time spent in the operating room, both of which are to the patient's great benefit (Guenette et al., 2016).

Another important application of 3D printing in the medical field is the creation of cutting guides and individualized surgical instruments. The conventional surgical

equipment that surgeons employ is in desperate need of a cutting-edge redesign accomplished with the help of 3D printing. In particular, traditional surgical tools require an innovative upgrade as the use of implantables manufactured with 3D printing technology becomes more widespread. It is possible to see significant benefits from using cutting guides printed using 3D printing when performing bone replacement surgeries. These benefits can be observed in a number of different ways. During these kinds of operations, the process of fixation is iterative, and any failure to achieve the desired outcome results in the requirement for revisions. This situation places the patient at a greater risk of experiencing additional complications and remaining in the hospital for an increased length of time.

Utilizing individualized surgical guides that have been printed with 3D printing technology enables the process of fixation to be carried out with increased accuracy and stabilization. This in turn leads to improved patient outcomes. Because of this, the number of possible edits may be cut down significantly. With the assistance of preoperative magnetic resonance imaging (MRI) and computed tomography (CT) scans, it is possible to generate a three-dimensional model of the bone. Subsequent to this, specialized cutting jigs can be fabricated utilizing the model. The use of these customized jigs offers a number of benefits, including an improvement in alignment, a reduction in the amount of time that is required in the operating room (OR), and a more direct method that is simple enough to be easily learned and taught. Among the other benefits offered by the use of these jigs is the ability to save time overall.

Spine surgery is yet another field that stands to benefit tremendously from the application of individualized cutting guides printed from 3D printers. In spine surgery, the placement of screws is common; however, their insertion comes with certain risks, including the possibility of causing damage to nerves, vessels, and other organs that are in close proximity. Because of this issue, it is absolutely necessary to achieve pinpoint accuracy in the positioning of the spinal screws while performing a sutureless fusion of the vertebrae procedure. Even though there have been advancements in technology, such as image-guided navigation and robot-assisted technology, which have contributed to an improvement in accuracy, there is still room for even further development. It has been demonstrated that cutting guides that are printed using a 3D printer provide a high level of accuracy when compared with other methods. The use of these cutting guides has a number of advantages associated with the method, including increased precision, less time spent in the operating room (and consequently fewer blood losses), and an ease of application.

Despite the many benefits that can be gained from utilizing customized cutting guides, there is still the issue of an increase in both the cost and the amount of time required for the manufacturing of these guides. With the clinical benefits and the decreased time in the operating room, it is possible that these disadvantages could be justified; however, additional study is required to determine whether or not this is an acceptable trade-off (Yilmaz et al., 2019).

The fabrication of devices that can be implanted into patients using 3D printing technology is the third major application of 3D printing in medicine. Anatomy of a

human patient can be quite complicated and can differ slightly from patient to patient, particularly if the patient suffers from a deformity. One of the advantages of utilizing 3D-printed implantables is the ability to precisely tailor the implant to the patient's unique geometry and anatomy. This allows for a more natural and comfortable fit. Previously, commercial implants were used that might have been adequate for the patients. However, with 3D printing, surgeons are now able to provide patients with individualized implants that are tailored to the specific anatomical characteristics of each patient.

Types of 3D Printers

Medical imaging is required to formulate accurate models that can be 3D printed. Producing and manufacturing an implant can be accomplished through the utilization of a wide variety of different methods and technologies. In addition to fused deposition modeling (FDM), other additive manufacturing processes that are available include selective laser sintering (SLS), stereolithography (SLA), electron beam melting (EBM), and direct metal laser sintering (DMLS). Each of these processes has a unique set of benefits, and the one that works best for a given product is the one that takes the most advantage of those benefits.

Lasers are utilized in the creation of physical objects by SLS 3D printers. They accomplish this task by reshaping a powdered material into a particular configuration. These kinds of printers are able to produce a wide variety of complicated objects and find applications in various industries. The powdered bed that serves as the foundation of the printer is capable of being melted and fused by the high-energy lasers. The lasers proceed to work in a layered fashion in an ongoing manner until the desired object has been

completed. It is possible for SLS printers to use a wide variety of materials, such as nylon or polycarbonate, and this enables them to be extremely versatile and produce objects with a high level of strength. Because of its accuracy and durability, the SLS printer is an excellent printer for use in industries that demand extremely precise objects (Fina et al., 2017).

The 3D printers that use SLA technology also employ a laser. However, rather than starting with a powder base, they begin with a liquid resin and transform it into a solid object. The layers of liquid resin are used to create the three-dimensional object that is the product of stereolithography additive manufacturing, or SLA printing. These printers are wonderful for creating objects that are smooth and have an abundance of detail in them. The dental industry utilizes printers with these characteristics because they are considered to be advantageous. A variety of different types of resin can be used depending not only on the final product but also on the specific physical characteristics that are desired. The SLA printer has a very fine laser that enables it to produce objects with a great deal of detail and complex geometries (Szykiedans & Credo, 2016).

Electron beam melting (EBM) 3D printers construct objects from metal using electron beams. This is accomplished by beginning with a powdered metal as the foundation and directing electron beams at it to slice and melt away layers until the final product is the desired shape. It is advantageous to use this type of printer when seeking a product that is both strong and durable. Because of the electron beam that is utilized, these printers are also capable of producing objects with a high level of precision. A computer controls the electron beam, and the computer is programmed to direct the

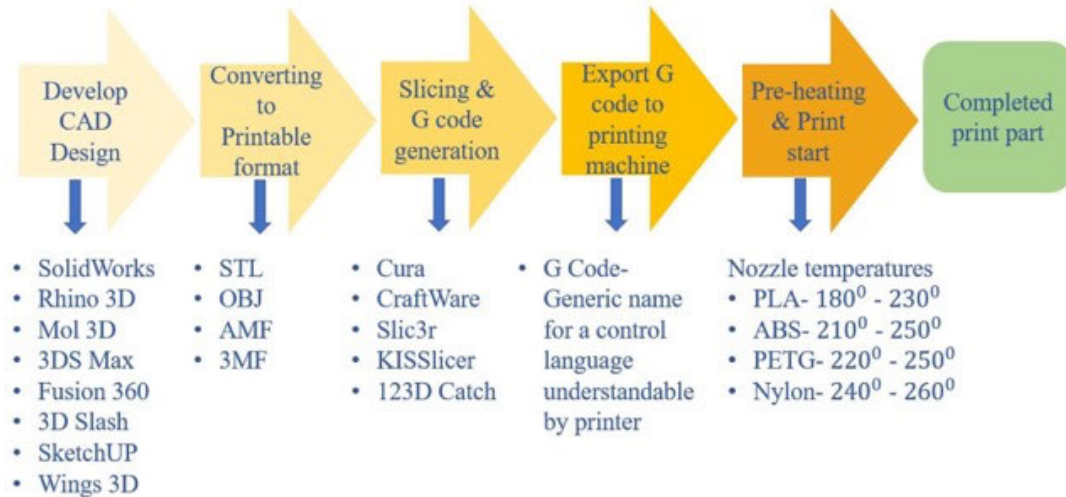
electron beam to produce an object with very precise dimensions. The products that come from EBM printers are made of metal, and as a result, they are able to withstand high temperatures as well as a great deal of stress. According to Popov et al. (2018), EBM printers can be utilized in the medical industry when something like an implant that needs to withstand the internal environment of the body is being fabricated.

In a manner analogous to EBM 3D printers, DMLS printers begin with a base composed of metal powder. The DMLS printer is distinct from other printing methods because it employs lasers rather than electron beams. It functions in a comparable fashion by slicing and fusing the metal powder in successive layers in order to construct the desired three-dimensional object. The fact that it can rapidly produce objects that are both robust and long-lasting is one of its primary advantages. DMLS printers are capable of using a wide variety of metals, which gives users the ability to create objects with the specific physical properties required for the object to function correctly in the environment in which it is intended to be used. In the field of medicine, DMLS printers are utilized to produce items such as implants and patient-specific prosthetics that are customized to the patient's specific anatomical characteristics (Bhaskaran et al., 2013).

Finally, the fused deposition modeling (FDM) printer is a type of 3D printer that works by building a physical object by successively laying down melted layers of material that comes in the form of filaments. The FDM printer requires computer-aided design (CAD) software that can plan the layers of the desired object before it is printed. There are many different kinds of software that are available for FDM 3D printers (Figure 2).

Figure 2

Flow Chart of Various Software for FDM 3D Printers



Note. This figure shows a graphic flow chart of the various software that can be used with FDM 3D printers. CAD = computer-aided design; FDM = fused deposition modeling.

From (Wickramasinghe et al., 2020).

When compared with other types of 3D printers, the fact that the FDM printer is both easily accessible and inexpensive contributes to the most significant advantages for using this printer in the field of medicine. The operation of these printers does not require a significant amount of space, and the setting in which they are used is not only inexpensive but also recyclable. FDM printers continue to have a high degree of accuracy and are able to produce complex objects such as models tailored to a specific patient, implants, and prosthetic devices (Wickramasinghe et al., 2020).

The type of implant that is desired determines not only the 3D printer but also the material. There are many different types of 3D printers using many different types of materials; for example, polymers, ceramics, metals, and composites (Honigmann et al., 2018). The material known as polyetheretherketone stands out among the others because it is distinguished by its name (PEEK). This material is a popular and advantageous choice for implantables that are intended for patients. Because of its high strength and rigidity, PEEK is an excellent material for the production of parts that are long-lasting. In addition, PEEK possesses a high level of chemical resistance, which enables it to thrive even in hostile environments. PEEK also has a high resistance to temperature and is able to withstand temperatures of over 200 °C without suffering any damage to its structure. Furthermore, PEEK is biocompatible, making it safe for use in and around the human body.

Because of these characteristics, PEEK-based 3D-printed objects can be an excellent choice for implants that are surgically inserted into the body of a patient. The human body is a hostile environment, and very few substances are able to remain intact and continue to thrive there. PEEK is a material that is highly useful and desirable when it comes to 3D printing in the field of medicine because of all these qualities as well as the ease with which it can be manufactured. Figure 3 shows an image of a PEEK filament that is medical grade.

Figure 3*Medical-Grade PEEK Filament*

Note. This image shows two rolls of high-performance polyetheretherketone (PEEK) filament used by FDM 3D printers to fabricate medical devices. FDM = fused deposition modeling. From (Honigmann et al., 2018).

The FDM printer is the one 3D printer that functions most effectively when used to print on PEEK filament (Figure 3). Like any other method of 3D printing, the FDM printer begins with a three-dimensional computer-aided design (CAD). A specialized piece of software slices this design into a number of horizontal layers. Material in the form of a filament is fed through a tube into the printer, and the melted material is then deposited layer by layer according to the software slices. There are many advantages to using an FDM printer, but two of the most notable are its low cost and its relative ease of operation. As a result, hospitals have the opportunity to potentially house and use FDM printers for 3D printing of medical supplies. Figure 4 shows a depiction of the workflow that provides a summary of the necessary steps to produce an implantable model.

Figure 4

Workflow to Generate a 3D Implantable Model

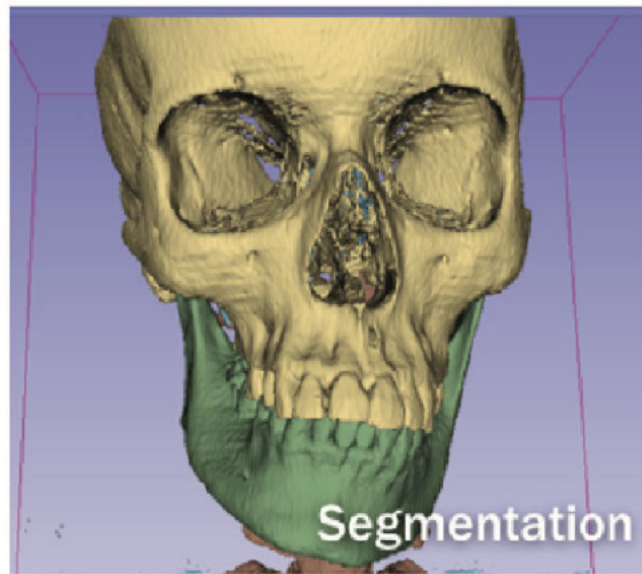
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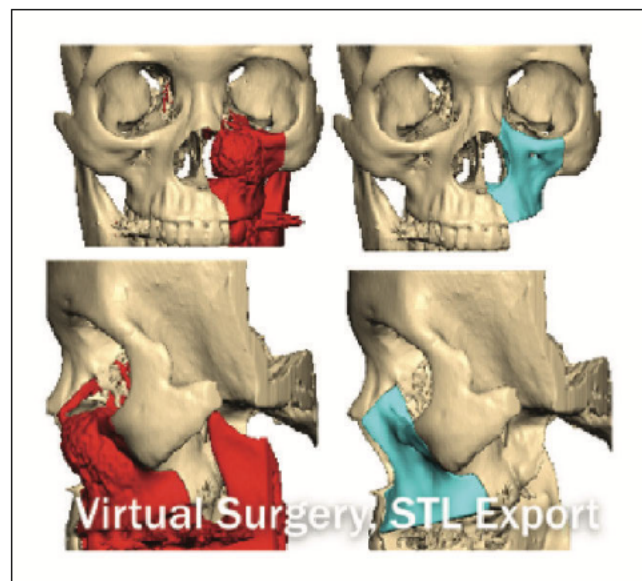
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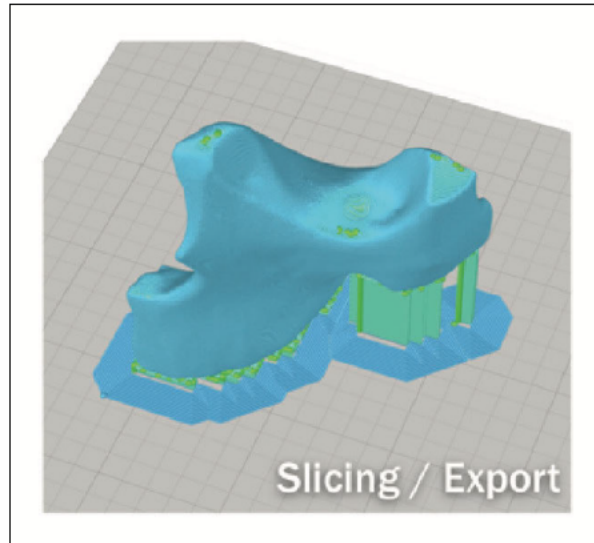


C



D



E**F**

Note. This sequence of images represents the workflow for creating a 3D model. The steps are as follows: (A) Obtain raw data of patient's anatomy from CT/CBCT/MRI scan. (B) Store scan data in DICOM format. (C) Special software segments the imaging (D) Segmented images are then exported to software (E) CAD software slices the images and exports them to printer (F) Product is printed. CBCT = cone-beam computed tomography; CT = computed tomography; DICOM = Digital Imaging and Communications in Medicine; MRI = magnetic resonance imaging; STL = Stereolithography. From (Honigmann et al., 2018).

Regulation of 3D Printing in Healthcare

CPT Codes for 3D Printing Services

There are still a number of unanswered questions and problems that need to be addressed before 3D printing can become a standard for hospital systems across the country. This is despite the fact that the use of 3D printers in medicine is becoming increasingly popular. One of these problems is the difficulty of billing and getting reimbursed for devices and services related to 3D printing. The universal standard language that is used to code medical services and procedures is known as the Current Procedural Terminology codes, or more commonly referred to as CPT codes. This system brings standardization to medical billing, allowing hospitals all over the country to categorize services and bill patients in a manner that is both accurate and efficient.

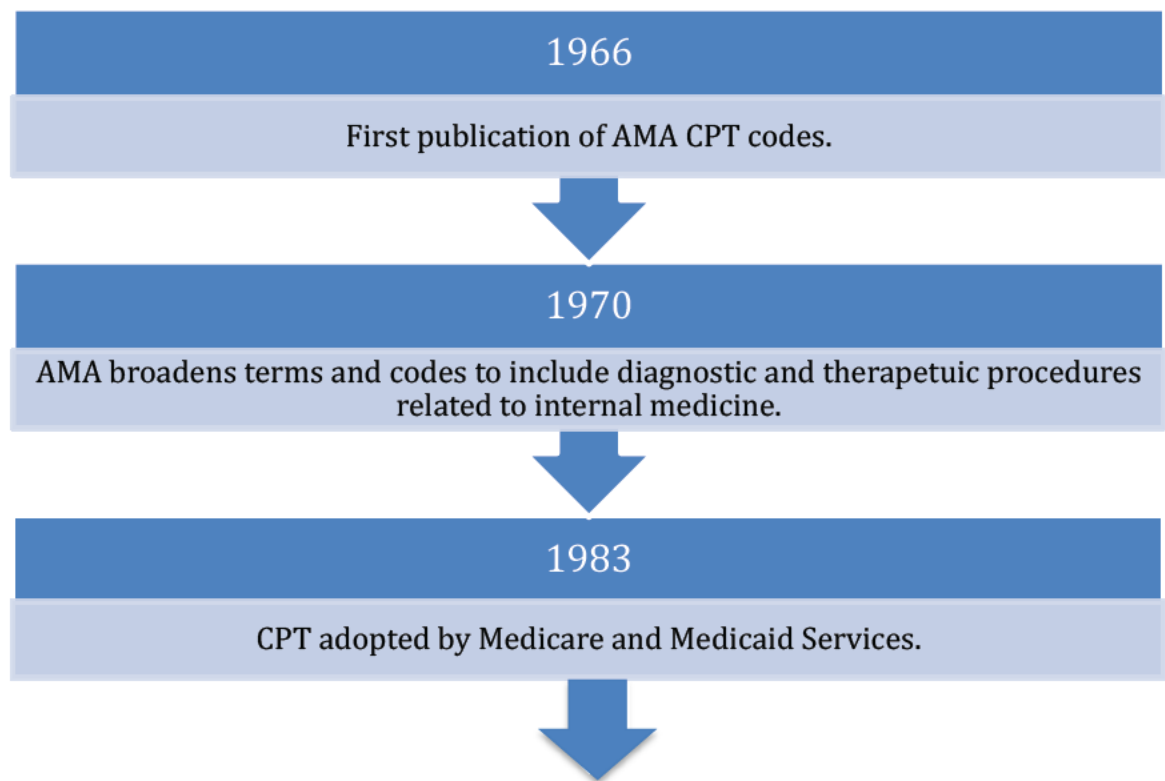
The CPT makes use of three primary classifications for its codes: Categories I, II, and III. Category I codes refer to particular medical services and procedures that are carried out by providers. These codes are typically identified by a numerical code (five digits in length) and are used in the medical industry. Codes assigned to Categories I and II of the CPT manual are typically presented in an alphabetic format and are utilized for quality of care and performance measurement. Last but not least, Category III CPT codes are used to determine the efficacy of newly developed techniques in the field of patient care. This could be a brand-new product, method, service, or anything else.

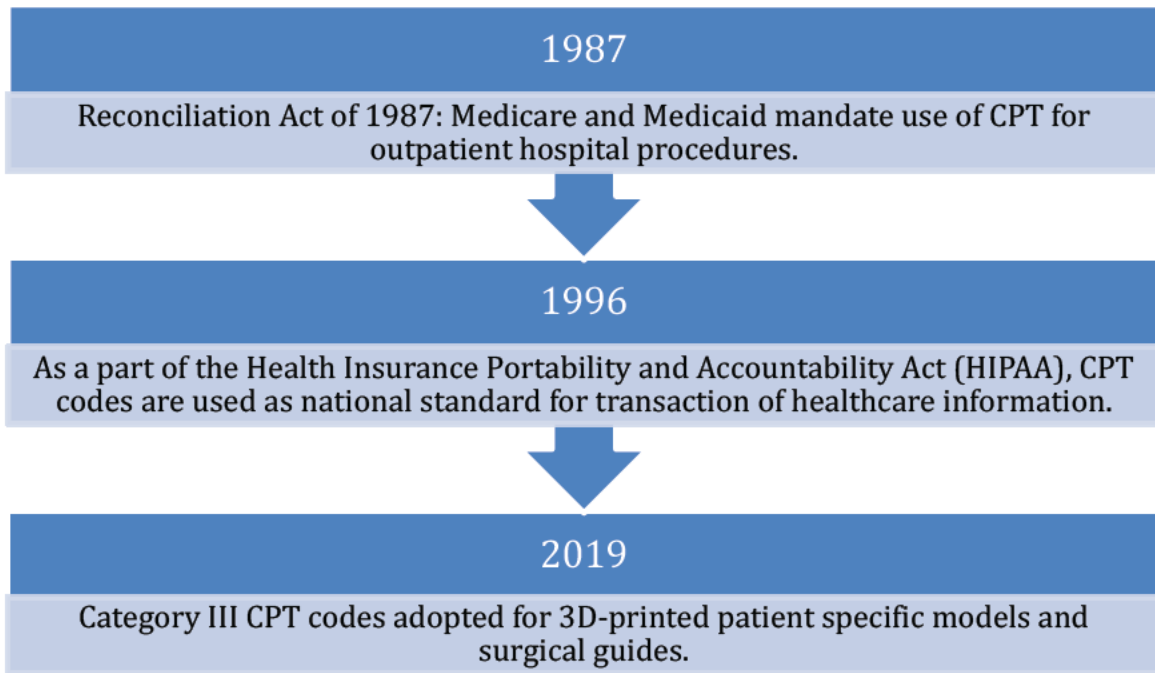
The American Medical Association (AMA) is the organization responsible for developing the CPT system. Throughout the course of the year, the AMA makes changes to the codes and adds and removes codes. The AMA is also in charge of assigning and

creating code descriptions (Dotson, 2013). The following timeline provides a concise summary of the history of CPT codes in the United States and includes how they came to be the gold standard for medical billing in hospitals all over the country.

Figure 5

Timeline of CPT Codes in the United States





Note. This diagram illustrates the timeline of CPT codes in the United States from 1966 to 2019. AMA = American Medical Association; CPT = Current Procedural Terminology. From (Dotson, 2013).

The question that arises in connection with 3D printers is how the processes and services that involve 3D printers should be coded. To have a meaningful conversation about this topic, it is important to be aware of the process by which new codes are developed in the first place. In order for the AMA to issue a new set of CPT codes, a provider, medical society, or any other interest group, society, or individual must first complete a series of steps in making the request.

In step 1, the first action of the AMA is to check if the request is a new one and has not been previously made by any other person or organization. In the event that a

previous request was made, the AMA notifies the current entity that made the request that this matter has already been examined and provides guidance on a CPT code. If the request is new, the AMA proceeds to the second step. In step 2, the request is sent to an advisory committee. At this stage, the AMA may take up to three months to collect all of the information and documents that are required. Following the completion of this task, step 3 takes place. The third step involves transferring the application to an editorial CPT group. Because the editorial panel only meets three times a year and discusses a wide variety of subjects, it is essential to keep the deadlines in mind when submitting a CPT request. Before the meeting, the panel is given all of the relevant documents and requests to ensure that there is sufficient time for review and feedback. In step 4, the panel votes on the proposal and gives its preliminary approval. The panel determines which category the codes are assigned to, and one of the following four outcomes is possible:

- (1) The request has the potential to be completely declined.
- (2) The request may be put on hold pending further investigation.
- (3) The request is tabled until the next meeting if there is not enough time to make a decision.
- (4) The request can be granted, and a new code can be included in the subsequent publication of the CPT booklet.

Following the particular outcome of the request, step 5 occurs in which the AMA informs the applicant of the decision. There is a provision for the applicant to request a re-evaluation of the decision in the event that the applicant is dissatisfied with the outcome. Step 6 involves the new code that was generated by the CPT editorial committee being

sent to the Relative Value Update Committee (RUC). In the process of surveying various providers in the field(s) associated with the new CPT code, the RUC performs a very important task. Based on the responses, the RUC attempts to quantify the value of the aforementioned service/product/procedure. The actual application of the new CPT code comes in step 7, which is the final step. The entire procedure, beginning with step 1 and continuing through step 7, can take from a few months to two years (Dotson, 2013).

In light of what has been covered, it is possible to conclude that 3D printing would be assigned a CPT code from either Category I or Category III, depending on the specifics of the process. Although there are currently CPT III codes for 3D printing, there are no CPT I codes. Until there are CPT I codes for 3D printing services and procedures, they will not be covered by either Medicare or Medicaid. However, private health insurance companies may still cover the costs of 3D printing services and procedures.

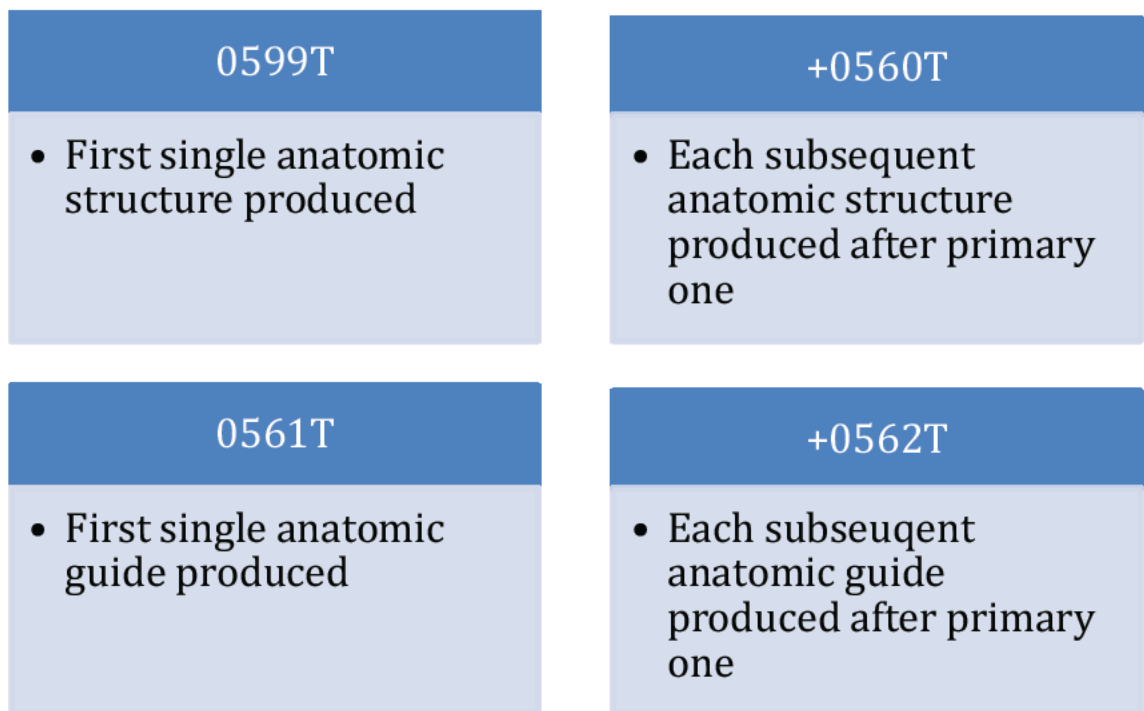
There have been recorded instances of hospital reimbursements as of the year 2019. There are two CPT III codes referred to as 0559T and 0560T, and both of these codes are utilized in the process of creating patient-specific 3D models for preoperative planning. In addition, there are two CPT III codes designated for 3D-printed surgical guides. These codes are 0561T and 0562T. Figure 6 shows a graphical representation of the existing CPT codes for 3D printing that are currently in use.

Given that these codes are two of the primary ways for hospitals to currently make use of 3D printers, this is encouraging news and a significant step forward (3DHeals, n.d.). It is possible that more specific CPT codes will be provided or updated as this technology becomes more commonplace in hospitals across the country. To

establish Category I CPT codes, there is still a great deal of work that needs to be done toward the goal of receiving coverage from Medicare and Medicaid (Wesley, 2019).

Figure 6

Current CPT III Codes for 3D Printing



Note. This diagram shows a graphic representation of the current CPT III codes that exist for 3D printing in the United States. CPT = Current Procedural Terminology. From (3DHeals, n.d.)

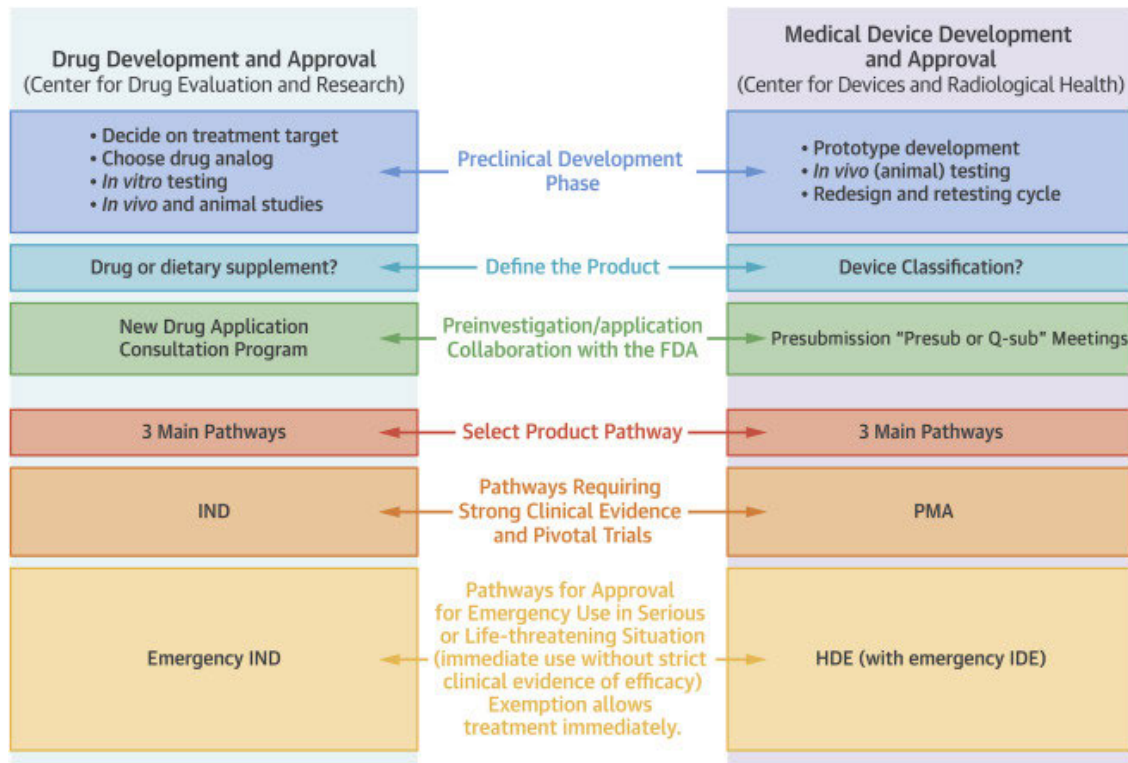
Regulatory Process

Another obstacle that many people face is the question of how the regulatory process works for 3D-printed medical devices. Fortunately, the Food and Drug

Administration (FDA) already has some regulations and guidance in place for 3D printing at the point of care. Within the FDA, there is a particular division known as the Center for Devices and Radiological Health (CDRH). This FDA division is in charge of ensuring that medical devices that are used in the treatment of patients are safe and effective and that providers have adequate access to these devices. Both the process of approving new drug development and the process of approving new medical device development follow very similar paths. These pathways are diagrammed in Figure 7.

Figure 7

Comparison of Drug and Medical Device Approval Pathways



Note. This diagram shows the similar approval pathways for drug development and medical device development. HDE = human device exemption; IND = investigational new drug; IDE = investigational device exemption; PMA = premarket approval. From (Van Norman, 2016).

The CDRH plays a significant part in the process of identifying new and developing technologies that have the potential to improve the delivery of medical care. There are many advantages to using 3D printing, and the CDRH is aware of these advantages. As a result, the CDRH sees 3D printing as having a tremendous potential for enhancing the quality of care.

For something like 3D-printed devices to be approved by the FDA, there are some main aspects that require evaluation. The FDA is responsible, first and foremost, for ensuring the safety of these devices and guaranteeing that they do not result in any adverse effects. This is in conjunction with the fact that the devices are efficient. If a tool is guaranteed to be risk-free but fails to deliver the desired results, there is no point in putting the tool to use. The FDA needs to make sure that this product is safe and effective everywhere, not just at one particular manufacturer or hospital. Moreover, the FDA must determine whether or not they will be able to control the newly developed technologies that come from 3D printing. This includes every step of the process from the conception and production of the device to its application at the point of care. It is also necessary to decide whether the medical facilities and providers located throughout the country are equipped with the necessary skills and infrastructure to make use of these devices. In addition to the ability of various healthcare systems to have a system and infrastructure in place to produce, house, and test these devices, it is necessary to take into consideration whether or not the providers require particular specialized training to use or operate the devices.

The United States Federal Food, Drug, and Cosmetic Act (FFDCA) regulates the industry as a whole and applies to every device, regardless of its intended use. Because 3D printing at the point of care is still a relatively novel idea, there is still some debate and uncertainty regarding the precise manner in which the FDA will regulate these devices and the level of control they will have over the manufacturing of these devices. The precise method by which the FDA will regulate these devices also depends on whether or not healthcare systems manufacture these devices in-house or instead work with an outside manufacturer. In spite of the fact that both have their advantages and disadvantages, the primary issue of liability is one that has to be resolved in either scenario. The critical question is: Who is liable and responsible for medical devices that are produced by a hospital as opposed to medical devices that are simply used by a hospital and produced by another manufacturer?

In answering this question, a distinction needs to be made between the person who uses the product and the person who manufactures the product. At the point of care, hospitals have traditionally been both the users and the providers of manufactured medical devices. There is a distinct line that can be drawn between the user and the manufacturer, and both parties are held accountable to the same standards of liability. However, in the following scenarios in which the 3D-printed devices are created either within the hospital or by the hospital, the distinction may not be as easy to make.

The first possible scenario involves a healthcare facility having 3D-printed medical devices made by a third-party manufacturer. When it comes to producing 3D-printed devices that will be used at the point of care, the manufacturer is the one who

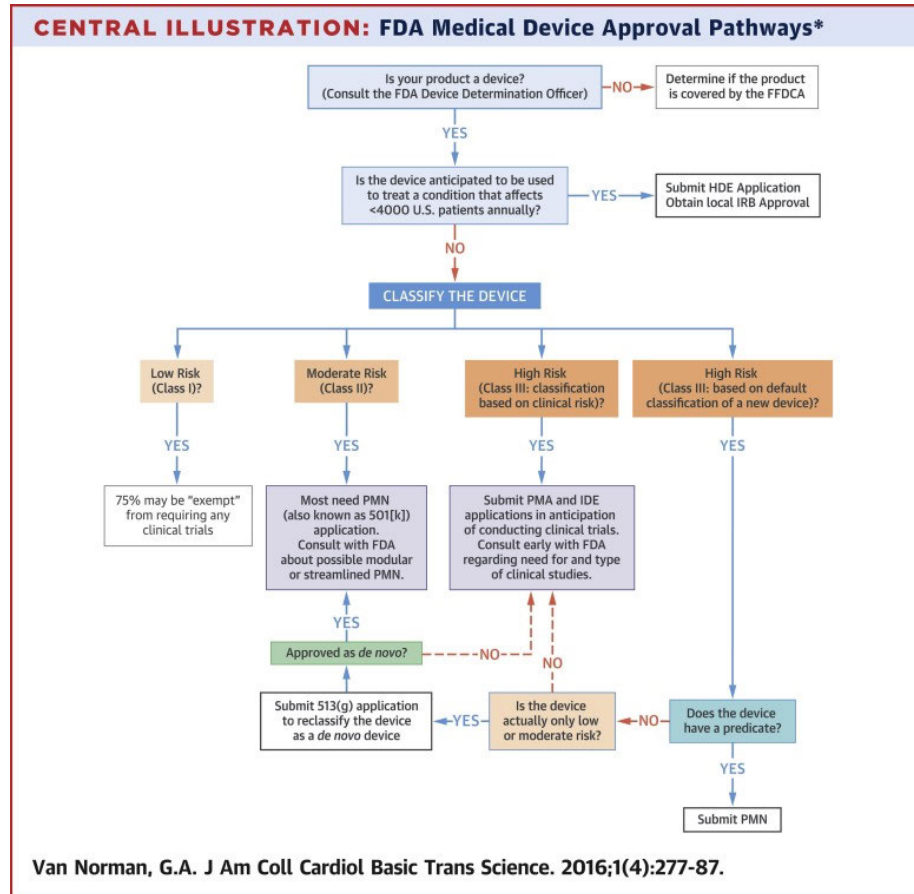
needs to have approval from the FDA. Therefore, liability in this scenario would rest with the manufacturing organization, and it would be that organization's duty to ensure compliance with all of the FDA's regulations. Similar to any other piece of medical equipment or technology that is manufactured outside of the hospital as a separate entity, the provider or operator, if they were to make use of the device, would assume the same responsibility as for other FDA devices approved for use at the point of care.

The second possible scenario is one in which a manufacturer is located within or in close proximity to a hospital for the sole purpose of supplying the hospital with various types of medical equipment. There are a number of obvious benefits to this situation; however, the question remains as to how this affects liability. This would not, in the vast majority of instances, affect who is legally responsible for something. Even if the manufacturing facility is physically located within the hospital or is co-located next to it, the manufacturer must continue to ensure that their products are in compliance with FDA regulations because they are the ones actually producing the devices.

The third possibility is that the hospital is responsible for the production of their own medical equipment. A hospital may choose to do this for a variety of reasons; nevertheless, because the hospital would not be using a conventional manufacturer, the hospital would be responsible for ensuring that the item complies with FDA regulations and would assume all responsibility associated with the decision.

Figure 8

FDA Medical Device Approval Process



Note. This diagram shows the FDA approval pathway for a medical device. FDA = Food and Drug Administration; FFDCAs = Federal Food, Drug, and Cosmetics Act; HDE = human device exemption; IDE = investigational device exemption; IRB = Institutional Review Board; PMA = premarket approval; PMN = premarket notification. From (Van Norman, 2016).

In-House Versus Outsource Manufacturing

Considering the various options for producing 3D-printed devices at the point of care and the associated liabilities, an important next step is to discuss the benefits and drawbacks of producing these devices in-house as opposed to contracting them out to a manufacturer. Whether or not a hospital chooses to manufacture its own products in-house rather than outsource the work depends on the existence of an in-house laboratory. It is necessary for the hospital to possess the necessary facilities, financial resources, and personnel to house and properly operate such a laboratory. If a hospital is too small or located in a rural area, it may not have the infrastructure necessary to run an in-house laboratory. Therefore, if the hospital wants to take advantage of the benefits of 3D printing, it will need to choose to outsource the work. At this time, there are only a handful of businesses that will manufacture medically-related 3D devices. Larger hospital networks, on the other hand, typically have the equipment and resources necessary to operate their own in-house labs, so they are faced with a decision: Which would be more beneficial for them, having a lab in-house or contracting it out?

When it comes to making a decision like this, there are many questions to think about. To begin with, how much money will the hospital need to invest in order to acquire the necessary technology for 3D printing? This includes a wide range of technologies, such as imaging and scanning machines as well as highly developed software. Will the addition of these technologies be prohibitively expensive if they are not already present in the medical facility? Furthermore, there needs to be a specific group of people and staff members dedicated to operating the technology and making use

of it. If the hospital system decides to use this technology, will they train their current staff to operate it, or will they hire specialized technicians? Both options may have a high price tag, but it is not yet clear whether or not this expenditure will be recouped at some point in the foreseeable future.

Other questions that a hospital needs to think about are: Which method is quicker and uses less time overall? How long does it take to complete the turnaround? An in-house lab may be more convenient, and it may be able to offer a faster turnaround and better communication between providers and the needs of patients. On the other hand, an outsource manufacturer is likely to have more advanced equipment that can produce more devices and offer quicker printing times.

The question that arises next is whether or not the delivery of these instruments to the hospitals would take a sufficient amount of time for outsourcing to be more efficient than an in-house laboratory within the hospital. Another factor that still plays a role in determining whether a hospital would want to do 3D printing in-house or outsource the work is whether or not the hospital is willing to assume liability and be concerned with complying with FDA rules and regulations. When it comes to doing things in-house, there can be a significant amount of red tape and bureaucratic challenges. As a result, a hospital may decide to outsource in order to surrender liability for the devices themselves.

However, one thing to keep in mind when developing patient-specific models is protected health information (PHI). There must be Health Insurance Portability and Accountability Act (HIPAA) compliance in all of the procedures and data transfer,

regardless of who is producing the devices. Is there a way for a hospital to be certain that an outsource manufacturer will comply with HIPAA regulations? The concept of HIPAA compliance is just one of a wide variety of ethical conundrums that can be brought about by patient-specific 3D models. The protection of the patient's privacy is an essential component of medical care. It is the means by which patients maintain and ensure trust with their providers. Consequently, it is essential to maintain this privacy when collecting patient data and information required to produce 3D models.

Informed consent is yet another issue that needs to be addressed. Consent that is given after being fully educated is essential to the practice of ethical medicine. It gives patients the right to be able to make informed decisions regarding the medical care of themselves or a loved one, as well as the ability to ensure that everything pertaining to their care is brought to their attention. If the providers want to print 3D models that are specific to the patient, do the patients need to give their permission and be informed? Because this is a patient-specific model, patients need to be informed of the process of producing a 3D-printed model. This is true even if the purpose of the model is to help the patient and provide a basis for preoperative planning. The reasoning is that 3D-printed, patient-specific models carry sensitive confidential information regarding a patient's anatomy and health status.

Within the context of the patient's care and treatment plan, if a model of the patient's anatomy is being created, the patient has the right to be informed of this process and to give permission for the process to proceed. Whether this is something that is incorporated into the general treatment consent or a consent of its own depends on the

hospital, how developed the 3D printing program is, and how often it is actually used by the providers. Some patients may also prefer a separate consent given the novelty of the technology or the fact that they have a different point of view. Consequently, this situation may call for a more in-depth conversation between the patient and the healthcare provider. In addition, patients should be informed of how their data will be used and stored and whether it will be de-identified in a database. It is of utmost importance that all this information is communicated to patients, especially when a hospital outsources 3D printing and data to a third party.

The manner in which the utilization of 3D printing contributes to health disparities is yet another important ethical concern that needs to be addressed. Will patients living in rural areas or areas with low incomes have access to innovative hospitals that are using 3D printing? If not, will this increase the gap between them and be another barrier to achieving health equity? It is highly likely that for the time being, 3D printing technology will only be available in large academic hospitals because of the cost of the equipment as well as the expertise required to use the equipment at the point of care. These innovative hospitals have the funds to put toward investing in new technologies. Although it will be a significant challenge, these hospitals must ensure that everyone has equal access to this technology. It is something that absolutely must be prioritized by healthcare systems in order to eliminate any potential for further aggravation of existing health disparities.

Cost and Sustainability

In the discussion of 3D printing, the issue of cost is a very important factor to take into consideration. Because there has been no reimbursement for the novel use of 3D printers in hospitals, the question naturally arises as to whether or not 3D-printed anatomic models and surgical guides are capable of paying for themselves. Do these products have the potential to reduce costs for hospitals?

One possible benefit of these models is that they decrease the amount of time spent in operating rooms, which results in cost savings for hospitals. This obviously has many financial benefits. However, it also has benefits for the patient because it reduces the amount of time that the patient spends in the operating room and under anesthesia, which may decrease the risk of complications.

Shippert (2005) conducted a study to investigate the feasibility of saving hundreds of thousands of dollars through the reduction of operating room (OR) time by the utilization of products that save time. The research investigated operating rooms located all over the United States and collected data on all of the hospital fees connected with booking an OR, including professional fees. Although no 3D-printed tools were examined, Shippert (2005) did evaluate a number of products to determine the degree to which those products that were more time efficient could save money in comparison with those that were less time efficient. According to the results of the investigation, the operating room had an average cost of \$66 dollars per minute. The study concluded that any instrument or product that required less staff or simply saved a few minutes in the

operating room could potentially and easily pay for itself over the course of its lifetime (Shippert, 2005).

Because this work by Shippert (2005) established that spending less time in the operating room is directly proportional to saving money, the logical next step is to examine how much time using 3D-printed models and surgical guides is actually saved in the operating room. In 2016, Tack and colleagues conducted a systematic literature review with the goal of analyzing the impact that using 3D-printed tools has on operating room time.

Based on all of the papers that were reviewed by Tack et al. (2016), there were four primary categories that were analyzed for their potential OR time saving. In the first category were custom implants that were printed using 3D technology. The procedures of maxillofacial surgery and cranial surgery frequently make use of these custom implants. Seventeen of the 28 papers that were examined discovered that the use of these individualized implants did, in fact, reduce the amount of time spent in the operating room. In the second category of anatomical models, 48 of the 89 studies that were reviewed found a decreased OR time. Tack et al. (2016) also analyzed 3D-printed molds for prosthetics, the third category. From the three available studies, these molds were discovered to be more cost effective than other molds while simultaneously reducing costs and, in one case, OR time. Last but not least, the fourth category contained surgical guides, one of the most common applications for 3D printing. The analysis of the relevant studies showed that using these surgical guides not only improved clinical outcomes but also reduced the amount of operating time in 28 of the 53 papers.

Table 1 illustrates the amount of time, measured in minutes, that can be saved by making use of a variety of products that have been created by 3D printers. It is clear that every device helped save time in the operating room, but the most notable examples of this are the individualized implants and the specialized surgical guides (Tack et al., 2016).

Table 1

Impact of Various 3D-Printed Products on Operating Room Time

		Count	Average (in min)	Standard deviation
Cranial surgery	Custom implant	4	-69.16	92.62
<i>Cranial surgery</i>	<i>Custom implant</i>	3	<i>-15.81</i>	<i>7.74</i>
Maxillofacial surgery	Model for implant shaping	1	-42	
Cerebrovascular	Model for surgery planning	1	-30	
Maxillofacial surgery	Model for surgery planning	5	-5.8	78.52
<i>Maxillofacial surgery</i>	<i>Model for surgery planning</i>	4	<i>-43.5</i>	<i>24.52</i>
Orthopedics hip	Model for surgery planning	2	0.75	6.75
Spinal surgery	Model for surgery planning	2	-45.5	17.5
Maxillofacial surgery	Surgical guide	6	-60.33	61.85
Orthopedics ankle	Surgical guide	1	-12	
Orthopedics hip	Surgical guide	4	-0.025	5.72
Orthopedics knee	Surgical guide	20	-6.73	13.68

Note. This table summarizes the number of studies and the average time saved (negative value) in the operating room by using various 3D-printed products. Italicized categories represent categories with an outlier study removed, resulting in an improved standard deviation. From (Tack et al., 2016).

Even though there are numerous advantages to utilizing 3D-printed devices, if a hospital does not have the financial means to purchase the necessary materials to manufacture these devices, then the hospital will not be able to reap the benefits of using them. Because of this, it is essential for hospitals to conduct their own cost analyses and determine whether or not these 3D-printed devices can actually reduce the amount of time spent in the operating room. Even though this was demonstrated in the work by Tack et al. (2016), the results may vary from one hospital to the next.

In this continuing discussion about 3D-printed devices, sustainability is another important topic that needs to be brought up and discussed. The material that is utilized in fabricating these different devices is almost always a relevant factor to consider in their longevity. PEEK is a common and advantageous material that is used when 3D printing a variety of medical devices that are used in and around the human body. This is because PEEK can withstand high temperatures and is biocompatible. As a result, PEEK is a material that is in high demand for 3D printing, and this demand contributes to its high cost. The high cost of PEEK could be a deterrent for some hospitals and could reduce the useful life of the material.

Although PEEK is also environmentally friendly, it is produced from fossil fuels which are nonrenewable; thus it cannot be considered a source that will be sustainable over the long term. However, for the purposes of 3D printing at the point of care, PEEK still proves to be the best option, even though it may not be the most sustainable one. There are other materials that offer much more sustainability such as bioplastics, recycled filaments, natural fibers, and bio-based polymers.

On the topic of sustainability, there is a further factor to take into consideration, and that factor is the expected life span of the 3D printer. With technology continuing to advance and new materials being developed to use specifically for medical purposes, 3D printers may have a more temporary life as updates and new equipment are required. However, this will depend on the use and the type of 3D printer, and some 3D printers may outlast others.

In spite of this, the fact that 3D printing can be used to create patient models, implants, and prosthetics that last for years at a time means that it has the potential to contribute to the overall reduction of waste. Because of its high level of accuracy and production, three-dimensional printing can significantly cut down on the amount of waste produced during the manufacturing process. As a result of the precise measurements and imaging that go into the production of these devices, there is no surplus or unused material that is left over.

At the beginning of the COVID-19 pandemic, there was an enormous spike in the demand for personal protective equipment (PPE), and manufacturers were unable to keep up with the demand. An academic facility utilized FDM 3D printers to meet this demand while simultaneously reducing the amount of waste produced as a result of the process. The facility was able to recycle discarded plastic and turn it into 3D printing filaments, which allowed them to supply production of 3D printing. Because of this, the production cycle ended up producing no waste (Kantaros et al., 2021).

Regardless of the fact that there are undoubtedly a great number of benefits and opportunities offered by 3D printing, there are still some concerns that need to be

addressed. For instance, the process of 3D printing can vary greatly from one hospital to the next, and it may be challenging to standardize the process to maintain a high level of quality and efficiency. In addition, there are some worries about the security of these devices because the regulatory process is not as complete or robust as the regulatory process in place for traditionally manufactured medical devices. Whether 3D printers will have a similar regulation and approval process is unknown, particularly because there is already a regulatory process in place for all new devices that could potentially be used on patients. Although there remains some unanswered questions about the use of 3D printers, it is still early, and their application is not as widespread as that of other medical devices.

3D Printing Challenges

Ownership

On the topic of patient-specific 3D models, one of the most important questions is: Who owns these models—the patient, the provider, the hospital, or someone else entirely? It is helpful to begin by examining patient data in general and determining who owns the information. Within the realm of contemporary medicine, maintaining patient care is now impossible without the utilization of electronic medical records and data collected from patients. As the digital age widens in scope, an increasing number of hospitals are moving away from keeping paper records and are instead relying solely on electronic records. Although this has many benefits, some of the most important include increased productivity, simplified accessibility, and lower impact on the environment.

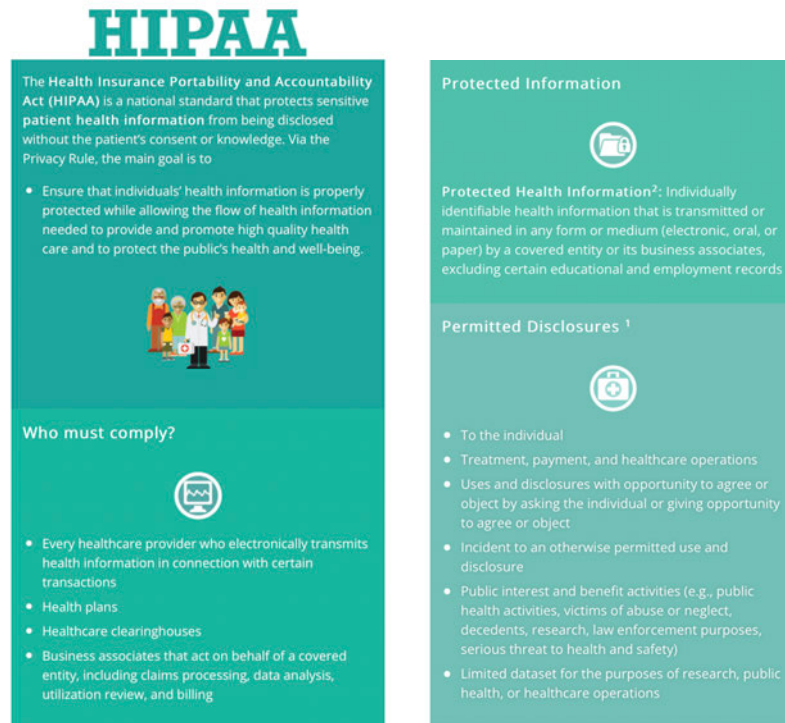
The issue of who owns the information collected on patients is one that is fraught with complexities and is occasionally contentious. The term "patient data" refers to any information that is gathered while a patient is receiving medical services in a healthcare system. This information is extremely important and includes everything from a person's name and address to medical history and demographic information. The patient's medical record is the repository for all of this information and serves as a record of the patient's entire healthcare journey, including the past, the present, and the future.

The fact that hospitals and providers are the ones who are responsible for collecting and storing these data is cited as a primary reason for support of hospitals and providers claiming ownership. According to this line of reasoning, they should be at liberty to make whatever use of the information that they deem appropriate. This could be for the purposes of research, the analysis of data, the enhancement of patient care, the assessment of trends, and even more.

On the other hand, there are those who contend that patients have a legitimate right to their own data. The logic behind this is that these data regarding the patient are inherently about the patient and not about anyone else. Patients have the right and should have the expectation that they will be informed of what data are being collected about them, how these data are being used, who has access to these data, and how these data are being stored.

The Health Insurance Portability and Accountability Act, also known as HIPAA, is a collection of laws that safeguards the privacy of patients and grants them control over the information that pertains to them. These laws ensure that hospitals and providers are

handling patient data in a confidential manner and that they regulate who has access to the information. In addition, these laws regulate the disclosure of patient data as well as its collection and use. HIPAA is a very detailed set of laws that applies not only to healthcare providers but also to insurance companies, businesses, and anyone else who might have access to patient data. These laws apply to everyone who might have access to patient information. HIPAA lays out in very specific terms the circumstances under which patient health information may be disclosed and to whom (Figure 9). There are also some extreme exceptions that may allow a provider to release a patient's protected health information (PHI) without the patient's consent; however, these instances are extremely uncommon.

Figure 9*Infographic Summarizing HIPAA Privacy Rule*

Note. This figure displays the infographic summarizing HIPAA rules on protecting sensitive patient health information. HIPAA = Health Insurance Portability and Accountability Act. From (Centers for Disease Control and Prevention, 2022).

Trust lies at the heart of providing quality care to patients. Patients have faith in their healthcare providers and hospitals to maintain the privacy of their medical records and to keep them confidential. It is the responsibility of healthcare providers to act in the patients' best interests, and this obligation includes safeguarding their patients' right to personal autonomy and confidentiality. Therefore, even though hospitals and providers are the ones who collect, use, and store patient data, in the end, it is the patient who is the owner of the personal data, and the patient has the right to know who has access to it and how it is being used.

With the application of current knowledge, this patient information can be used in the creation of patient-specific 3D models or implants. These models, along with any other data that have been gathered, need to be safeguarded and archived in an appropriate manner. The patient should be informed of how hospitals use and store these models, and steps should be taken to de-identify models so that only those individuals who have a legitimate need to know are aware of the identities. These models should be hidden away in a safe location, and access to them should be strictly regulated in order that only those individuals who are required to use them can do so and those who do not have authorization are prevented from doing so.

The question of whether or not a hospital outsources these models plays an enormous part in determining how the patient's privacy should be handled within the medical facility. For instance, if a hospital decides to outsource the 3D printing of its models, the third-party company that handles the printing must have access to the patient's medical records in order for the device to be printed accurately. As long as the

hospital and the manufacturer continue to comply with HIPAA regulations, there should not be any problems. However, maintaining patient confidentiality may be somewhat more challenging given the circumstances of this situation. Even though hospitals that have their own in-house 3D printing laboratories may have an easier time protecting patient data related to models, personnel at these hospitals should still handle these data with the utmost caution (Chiruvella & Guddati, 2021).

Prosthetics

Another area in which patients can significantly benefit from the utilization of 3D printing is the field of prosthetics. The advent of 3D printing has made it possible to produce prosthetics that are not only easily customizable but also relatively inexpensive. The conventional prosthetic is premade for a large number of patients and then modified to fit each individual patient's remaining limb. It is abundantly clear that the residual limbs of different patients are not the same, and as a consequence, the fit of a widely manufactured prosthetic may not be ideal for a patient who has particular requirements. If the patient is not completely satisfied with the fit, it may reduce the functionality of the device and cause the patient discomfort.

This issue is addressed by the technology of 3D printing, which makes it possible to create prosthetics that are extremely precise and specific to the patient's anatomy as well as individual requirements. This capability, in turn, allows the patient to have maximum functionality, support, and comfort while increasing the possibility of living a higher quality life. Not only are prosthetics made with a 3D printer better for patients, but they are also better for the hospitals that use them.

Traditional prosthetics are made from expensive materials and require manual labor to create, whereas 3D-printed prosthetics can use low-cost, high-quality materials in an automated process to produce a better and more functional prosthetic. Because 3D-printed prosthetics can be produced more quickly and at a lower cost than traditional prosthetics, the potential exists for these prosthetics to be available to a greater number of people who require them.

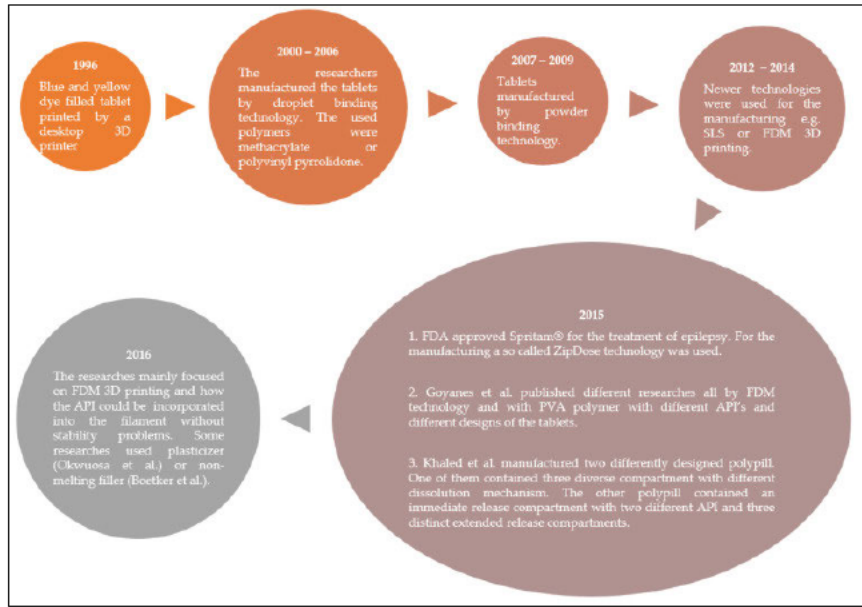
The speed of production is yet another advantage that comes with using a prosthetic that is printed using 3D printing. The production of traditional prosthetics can take from a few weeks to several months; however, the equivalent 3D-printed prosthetic can be made in a matter of days or even hours, depending on the complexity of the prosthetic. Patients who are in urgent need of prosthetics can now obtain them more quickly, which enables them to get back to their regular lives. As the use of prosthetics made with 3D printing becomes more widespread, prototypes can be created for patients and further refined to meet their needs. When compared with traditional prosthetics, these new designs can be easily tested and adapted in a much shorter amount of time.

Furthermore, a prosthetic limb that is printed using 3D printing technology is more environmentally friendly than traditional prosthetics. The production of traditional prosthetics requires a significant amount of resources and makes recycling them difficult or impossible. Prosthetics that are printed with a 3D printer make use of more environmentally friendly materials and are designed to be easily recycled once they are no longer required.

In comparison to conventional devices, 3D-printed ones offer a wide variety of benefits, each of which demonstrates an additional advantage that users may find useful. As the technology behind additive manufacturing becomes more widely accessible, an increasing number of people will have the opportunity to reap the benefits that come with using 3D prosthetics (Attaran, 2017).

Drug Delivery

There are currently a great number of applications for 3D printing in the medical field. However, as technology develops, there are more and more ways in which 3D printing is being used to make improvements in patient care. The administration of drugs is one of these ways. On the surface, it may appear that the two have no connection. Nevertheless, recent developments in 3D printing have opened up new doors for the creation of individualized drug delivery systems that can be tailored to meet the requirements of a particular patient. The production of tablets is outlined in the flow chart of Figure 10, which covers the years from 1996 to 2016 and also includes a brief history of the processes involved. From about 2016, there have not been any significant advances in the development of drug delivery systems.

Figure 10*Drug Delivery Breakthroughs Over the Years*

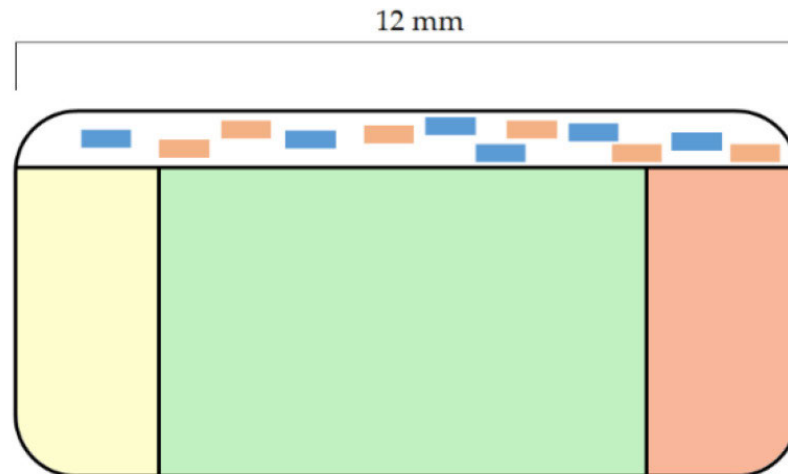
Note. This figure shows a flow chart of the most important research results for tablet manufacturing methods and breakthroughs between 1996 and 2016. API = active pharmaceutical ingredient; FDA = Food and Drug Administration; FDM = fused deposition modeling; PVA = polyvinyl alcohol; SLS = selective layer sintering. From (Bácskay et al., 2022).

Drug delivery systems, much like most other aspects of the medical industry, are manufactured in large quantities using mass production methods and are not something that have traditionally been conceived of as being personalized to the individual patient. The ability to potentially target a specific part of the body and improve delivery of a drug to that part of the body is one of the advantages that could be gained from the process of

creating a personalized drug delivery system for a patient. Personalization of the form and dimensions of the delivery system is one of the methods that can be utilized to accomplish this goal. In addition, 3D printing may be able to combine multiple medications into a single dose by using a combination of their active ingredients. This would minimize the number of pills that a patient would need to take each day, which could improve patient compliance. This type of pill is known as a polypill, and research has shown that it is very effective (Figure 11).

Figure 11

Cross-Section of Polypill With Medication-Release Compartments



Note. This figure shows a diagram of the polypill with various compartments for release of five different medications. The rapid-release compartment on top contains two medications (blue and orange rectangles), and the extended-release compartments on bottom contain three medications (yellow, green, and dark orange). From (Bácskay et al., 2022).

The use of 3D printing enables the creation of one-of-a-kind polypills that can be highly tailored to the individual patient. Within the polypill, it is possible to make various compartments that can house different medications, and these medications can be arranged in such a way that some of them have an immediate release and others have an extended release (Figure 11).

Another advantage of using 3D printing is that it can create new drug delivery systems much more quickly than traditional methods. The production of a new system by conventional manufacturers can take several months; however, using 3D printing allows for the production of more customized systems in a shorter amount of time, which can increase the rate at which a patient receives a particular drug.

Despite all of these positives, there are still some obstacles that need to be overcome before progress can be made. Most important, it is essential to ensure that the drug delivery systems that are created by the 3D printer are risk-free for patients to consume. Even though it was established earlier that many of the implants that are created by 3D printers can be used risk-free in patients, it is imperative that additional consideration be given to devices that are ingested. The regulatory pathway for these types of delivery systems is unclear, and it must be established before they have the potential for routine use.

This situation is similar to the circumstances of many other novel devices. The utilization of these innovative systems has as its primary objective the improvement of patient outcomes, the reduction of adverse effects, and the enhancement of efficacy. As more research is conducted on these drug delivery systems, it is possible that they will

play a tremendous role in reshaping the way in which patients take their medications in the future (Bácksay, 2022).

Conclusion

In conclusion, additive manufacturing, or 3D printing, is a technology that is advancing rapidly and is causing significant shifts in the medical field. It enables healthcare professionals to provide better and more personalized care in a shorter amount of time and at a lower cost. This is made possible by the ability of 3D printing to produce very precise and individualized devices.

There appears to be an almost infinite number of applications for 3D printing in the medical field, ranging from anatomic models to prosthetics, surgical guides, and implantables. In particular, the advent of 3D printing has made it possible for surgeons to better understand the patient's anatomy and pathology before the operation by providing novel solutions for the creation of personalized models and guides. These models and guides can be printed on a 3D printer.

This strategy of using 3D printing has many benefits, one of which is that it reduces the amount of time spent in the operating room, which in turn lowers the costs incurred by the hospital. The ability to personalize medical equipment to meet the specific anatomical requirements of individual patients has resulted in higher levels of patient satisfaction and improved clinical outcomes. Furthermore, 3D printing is a valuable asset for medical education and those who are in the process of training to become medical professionals. Students and trainees are given the opportunity to witness

pathologies firsthand, an experience they would not have otherwise. In addition, 3D printing enables them to practice on realistic models while simulating various surgical procedures. The benefits of 3D printing, when applied to prosthetics, directly lead to an improved quality of life for patients who have residual limbs, and it enables patients to have more comfort and flexibility so that they can meet their day-to-day requirements.

Despite the fact that 3D printing has enormous potential, there are still many obstacles and worries that need to be resolved before 3D printing can become a standard practice in medicine everywhere. First, making sure that 3D printing is safe and effective while also having a clear path to regulatory approval is absolutely necessary for its use in commercial settings. More in-depth research is required before concerns about liability can be addressed when an outside manufacturer is involved, and proper patient confidentiality must be maintained at all times. Furthermore, the ethical concerns that are intrinsic with 3D printing patient-specific devices must be addressed and answered before providers can feel confident using and recommending them and before patients can feel comfortable with the process. This will allow the technology to become a viable option for both parties. Finally, cost and accessibility are two major considerations that differ from one hospital to the next and are essential to the development of this technology.

In general, the advent of 3D printing has brought about the emergence of new opportunities in the field of medical care and treatment. If research and development are continued, the technology of 3D printing has the potential to revolutionize medicine, make significant contributions to the healthcare industry, and improve the lives of countless patients.

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